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# Appendix A. Exact search strategy

Search Strategy for MEDLINE, CENTRAL, CDSR (each in OVID starting in 1996), and Web of Science (limited to meeting abstracts only)

1. myocardial infarction.mp. or Myocardial Infarction/
2. acute myocardial infarction.mp.
3. AMI.mp.
4. MI.mp.
5. STEMI.mp.
6. ST-segment elevation.mp.
7. ACS.mp.
8. NSTEMI.mp.
9. acute coronary syndrome.mp. or Acute Coronary Syndrome/
10. ST-segment resolution.mp.
11. unstable angina.mp. or Angina, Unstable/
12. Q-wave.mp.
13. no-reflow.mp.
14. distal embolization.mp.
15. Angioplasty, Transluminal, Percutaneous Coronary/ or percutaneous coronary intervention.mp.
16. PCI.mp.
17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. thrombectomy.mp. or Thrombectomy/
19. embolic protection.mp.
20. distal protection.mp.
21. proximal protection.mp.
22. thrombus aspiration.mp.
23. aspiration catheter.mp.
24. rescue catheter.mp.
25. diver CE.mp.
26. Export catheter.mp.
27. transvascular aspiration catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
28. TVAC.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
29. Pronto.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
30. x-sizer.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
31. angiojet.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
32. filterwire.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
33. spiderx.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

34. spiderfx.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
35. angioguard.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
36. proxis.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
37. interceptor plus.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
38. rinspirator.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
39. microvena trap.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
40. percusurge.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
41. triactiv.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
42. cardioshield.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
43. thrombobuster.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
44. rio catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
45. fetch catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
46. quickcat.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
47. rubicon catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
48. parodi anti-embolisation.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
49. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48
50. 17 and 49
51. 50 not carotid.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
52. limit 51 to humans

# Appendix B. Data abstraction form

**Study Identification**

| First Author:<br>Study Name: | Year: |
|---|---|
| Language (if not English):<br>Geographic location: | Single or Multi-center: |
| Funding Source Specify:<br>❑ Industry<br>❑ Government/Foundation<br>❑ Academia<br>❑ Other/Unknown | Publication form:<br>❑ Full-text<br>❑ Abstract<br>❑ Other (specify): |

**Design Characteristics**

Study Design
❑ RCT ❑ Observational

Random Allocation Concealment? Y N Blinded Outcome Assessment? Y N Intention to treat principle used? Y N

**Study Population**

Inclusion Criteria:

| | |
|---|---|
| ❑ Native vessel | ❑ TIMI 0/1 |
| ❑ Acute MI within ___ hrs | ❑ Time from symptom onset: |
| ❑ Angiographically visible thrombus | ❑ Age ≥ 18 years |
| ❑ Chest pain associated with ACS >___min | ❑ ST-segment elevation ≥ 0.1mV (1mm) in 2 or more ECG leads |

Exclusion Criteria:

- ❑ Saphenous vein grafts
- ❑ Contraindication to GP 2B3A Inhibitor
- ❑ Cardiogenic shock
- ❑ Left- BBB
- ❑ Ventricular pacing at baseline
- ❑ Previous MI in past____days
- ❑ Inability to obtain informed consent
- ❑ Previous Coronary Bypass surgery
- ❑ Killip class IV
- ❑ Ventricular Tachycardia
- ❑ Cardiac tamponade
- ❑ Aortic dissection
- ❑ Myocarditis
- ❑ Renal Failure
- ❑ Pregnancy
- ❑ Fibrinolytic treatment

Device name:

Device category:

❑Catheter Aspiration (Export, TVAC, Rescue, Pronto, Diver CE)

❑Mechanical Thrombectomy (Angiojet, X-Sizer)

❑Balloon Distal Embolic Protection (Guardwire)

❑Filter Distal Embolic Protection (Filterwire, SpiderX, Angioguard)

❑Proximal Embolic Balloon Protection

❑Proximal Embolic Filter Protection

Follow-Up Months (study) :

| Follow-Up for primary outcome, n/N (%):<br>Define primary outcome: | **Device Group** | **Control Group** |
|---|---|---|
| | | |

**Baseline Characteristics**

| | **Device Group** | **Control Group** | | | **Device Group** | **Control Group** |
|---|---|---|---|---|---|---|
| N | | | | Dyslipidemia, n/N (%) | | |
| Age, years (mean± SD) | | | | Hypertension n/N (%) | | |
| Males, n/N (%) | | | | Baseline TIMI 0-1 Flow, n/N (%) or mean ± SD, specify | | |
| Anterior MI n/N (%) | | | | DM n/N (%) | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Family history of CAD n/N (%) | | | | Smoker n/N (%) | | | |
| Prior Myocardial Infarction n/N (%) | | | | Failed TL n/N (%) | | | |
| Mean Ischemic Time, min (mean± SD or median±IQR, specify) Definition: | | | | Killip Class n/N (%) Definition: | | | |
| Definition: | | | | Thrombus Score n/N (%) Definition: | | | |
| | | **Device Group** | **Control Group** | | | **Device Group** | **Control Group** |
| ACS n/N (%) | STEMI | | | Infarct Related Artery n/N (%) | LAD Lesion | | |
| | N-STEMI | | | | LCX Lesion | | |
| | Unstable Angina | | | | RCA Lesion | | |
| | | | | | Other: | | |
| Multi-vessel Disease n/N (%) Definition: | | | | Visible lesion on angiography n/N (%) Definition: | | | |
| Pre-cTFC (mean± SD) | | | | Pre-LVEF (mean± SD) | | | |
| Ethnicity reported? | | | | | | | |

**Concurrent Drugs Used**

***Anti-platelet Therapy***

❑Aspirin Regimen:
❑Ticlopidine: Regimen:
❑Clopidogrel Regimen:
❑GP2B3A Regimen:
❑Other Regimen:

***Antithrombotic Therapy***

❑Heparin Regimen:
❑Others Regimen:
ACT (or other monitoring parameter, please specify):

***Vasodilators***

❑ Nitrates Regimen:
❑ Nitroglycerine Regimen:
❑ Others Regimen:

**Procedural Characteristics**

| | | **Device Group** | **Control Group** |
|---|---|---|---|
| Procedural Time (min) mean± SD or median±IQR, specify | Definition: | | |
| | | | |
| Stent n/N (%) | | | |
| Direct Stent n/N (%) | | | |
| Need of IABP n/N (%) | | | |
| Need of pacing n/N (%) | | | |
| Emergency CABG n/N (%) | | | |
| GP2B3A use n/N (%) Define use: | | | |
| Lesion debris removed from filter n/N (%) | | | |

**Surrogate Outcomes**

| | Device Group | Control Group |
|---|---|---|
| MBG n/N (%)<br>Definition: | | |
| Post-PCI TIMI 3 n/N (%) | | |
| Post cTFC (mean % ±SD) | | |
| LVEF (mean % ±SD) | | |
| Distal embolization n/N (%) | | |
| Infarct size (mean % ± SD) | | |
| Procedural Success Rate n/N (%) | | |
| No Reflow n/N (%) | | |
| Slow Reflow n/N (%) | | |
| CK-MB n/N (%) or mean ± SD<br>Definition: | | |

**Safety Outcomes**

| | Device Group | Control Group |
|---|---|---|
| Coronary Dissection n/N (%) | | |
| Perforation n/N (%) | | |
| Prolonged Procedure n/N (%) | | |
| Other (please specify): | | |
| Other (please specify): | | |

**ST-Segment Resolution**

| Post Procedure/immediate | | | | | 60 Minutes | | | |
|---|---|---|---|---|---|---|---|---|
| **STSR %** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| **Device Group n/N (%)** | | | | | | | | |
| **Control Group n/N (%)** | | | | | | | | |

| 90 Minutes | | | | | Others | | | |
|---|---|---|---|---|---|---|---|---|
| **STSR %** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| **Device Group n/N (%)** | | | | | | | | |
| **Control Group n/N (%)** | | | | | | | | |

**Other measures of ST resolution:**

**Final Health Outcomes**

| Composite MACE or MACCE n/N (%) | Definition | Time Period | Device Group | Control Group |
|---|---|---|---|---|
| | | | | |
| | | | | |
| Other individual endpoints included in MACE or MACCE not listed below | Endpoint: | | | |
| | | | | |
| | | | | |
| Mortality n/N (%) | Definition | | | |
| | | | | |
| | | | | |
| TVR n/N (%) | | | | |
| | | | | |
| Reinfarction n/N (%) | | | | |
| | | | | |
| Stroke n/N (%) | | | | |
| | | | | |

# Appendix C. Excluded studies from full-text review

| Reference | Reason for Exclusion |
|---|---|
| Adlbrecht C, Bonderman D, Plass C, et al. Thrombus bound endothelin and leukocytes extracted by thrombectomy in acute myocardial infarction correlate with ST-segment resolution [abstract]. *Circulation* 2006;114:458 | Uncontrolled study |
| Ali A, Afzal A, Kazmouz G, et al. Rheolytic thrombectomy facilitates restoration of coronary flow in patients with acute myocardial infarction [abstract]. *Am J Cardiol* 2001;88:TCT63 | Not an RCT or an observational study enrolling more than 500 patients |
| Ali A, LaLond T, Schreiber T, et al. Reduction in no-flow, slow flow, and distal embolization with Angiojet thrombectomy-facilitated catheter-based reperfusion therapy for acute myocardial infarction [abstract]. *Am J Cardiol* 2002;90:TCT268 | Not an RCT or an observational study enrolling more than 500 patients |
| Ali A., Malik FS, Collins T, et al. Reduction in QT dispersion with rheolytic thrombectomy in acute myocardial infarction: Evidence of electrical stability with reperfusion therapy [abstract]. *Am J Cardiol* 1997;80:TCT261 | Uncontrolled study |
| Ali A, Rehan A, Rahbar M, et al. Rheolytic thrombectomy in acute myocardial infarction results in a higher degree of ST-segment resolution [abstract]. *Am J Cardiol* 2002;90:TCT39 | Not an RCT or an observational study enrolling more than 500 patients |
| Ali A, Schreiber TL. The role of percutaneous thrombectomy in the contemporary treatment of acute myocardial infarction. *J Invasive Cardiol* 2004;16:546-8 | A narrative review, editorial or letter to the editor |
| Alidjan FMF, Koch KT, Henriques JP, et al. Combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the Proxis (R) device [abstract]. *Eur Heart J* 2006;27:771 | Uncontrolled study |
| Alidjan F. Combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the Proxis (R)-device [abstract]. *Circulation* 2006;114:739 | Uncontrolled study |
| Amabile N, Cochet A, Lorgis L, et al. Impact of thrombectomy devices for reperfusion of STEMI in the real world: insights from cardiac magnetic resonance imaging [abstract]. *Circulation* 2009;120:S337 | Not an RCT or an observational study enrolling more than 500 patients |
| Amato JL, Shamoon FE, Haft JI. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2640 | A narrative review, editorial or letter to the editor |
| An Y, Kaji S, Yamamuro A, et al. Thrombus aspiration during primary percutaneous coronary intervention improves myocardial viability and infarct transmurality: a magnetic resonance imaging study [abstract]. *J Am Coll Cardiol* 2009;53:A282 | Not an RCT or an observational study enrolling more than 500 patients |
| Antoniucci D. Rheolytic thrombectomy in acute myocardial infarction: the Florence experience and objectives of the multicenter randomized JETSTENT trial. *J Invasive Cardiol* 2006;18:32C-34C | A narrative review, editorial or letter to the editor |
| Antoniucci D. Rheolytic thrombectomy in acute myocardial infarction: the Florence experience and objectives of the multicenter randomized JETSTENT trial. *J Invasive Cardiol* 2006;18:32C-34C | A narrative review, editorial or letter to the editor |
| Bartorelli AL. Acute thrombosis of a coronary artery aneurysm: toughing it out with the poor man's thrombectomy catheter technique. *Catheter Cardiovasc Interv* 2006;68:403-5 | A narrative review, editorial or letter to the editor |
| Bartorelli AL, Koh TH, Di Pede F, et al. The RUBY registry: assessment of distal embolic protection during coronary angioplasty in patients with acute | Uncontrolled study |

| Reference | Reason for Exclusion |
|---|---|
| coronary syndrome [abstract]. *Circulation* 2004;110:3403 | |
| Bass TA. Mechanical thrombectomy to the RESCUE. *Catheter Cardiovasc Interv* 2002;55:244 | A narrative review, editorial or letter to the editor |
| Bates ER. Aspirating and filtering atherothrombotic debris during percutaneous coronary intervention. *JACC: Cardiovasc Interv* 2008;1:265-7 | A narrative review, editorial or letter to the editor |
| Belardi J. Beyond the limit on percutaneous intervention of saphenous vein graft. *Catheter Cardiovasc Interv* 2005;64:387-8 | A narrative review, editorial or letter to the editor |
| Belli G, Silva P, Pezzano A, et al. Primary protected percutaneous intervention for acute myocardial infarction with the PercuSurge system in native coronary arteries [abstract]. *Am J Cardiol* 2000;86:79 | Uncontrolled study |
| Berger-Kucza A, Lelek M, Wita K, et al. Thrombus aspiration for microvascular protection in patients with acute MI undergoing early primary PCI [abstract]. *Circulation* 2008;118:E311 | Not an RCT or an observational study enrolling more than 500 patients |
| Bilge AK, Nisanci Y, Yilmaz E, et al. Effects of percutaneous coronary thrombectomy with the X-sizer catheter on epicardial flow and microvascular function in acute coronary syndrome. *Clin Appl Thromb Hemost* 2005;11:461-6 | Not an RCT or an observational study enrolling more than 500 patients |
| Blackman DJ, Channon KM. Prevention of embolisation during percutaneous vein graft intervention using a Filter Wire distal protection device. *Heart* 2003;89:376 | A narrative review, editorial or letter to the editor |
| Bonello L, De Labriolle A, Steinberg D, et al.Thrombus aspiration during percutaneous coronary intervention. *Lancet* 2008;372:1034 | A narrative review, editorial or letter to the editor |
| Buellesfeld L, Gerckens U, Grube E. [Background and indications for distal protection devices in percutaneous coronary interventions]. *Dtsch Med Wochenschr* 2006;131:2160-4 | A narrative review, editorial or letter to the editor |
| Burzotta F, Crea F. Thrombus-aspiration: a victory in the war against no reflow. *Lancet* 2008;371:1889-90 | A narrative review, editorial or letter to the editor |
| Burzotta F, Romagnoli E, Manzoli A, et al. The outcome of PCI for stent-ThrombosIs MultIcentre Study (OPTIMIST): rationale and design of a multicenter registry. *Am Heart J* 2007;153:377e1-e5 | Uncontrolled study |
| Carter AJ, Gregory K. Thrombo-atherectomy: hope for pesky thrombus-containing lesions? *Catheter Cardiovasc Interv* 2002;55:140-1 | A narrative review, editorial or letter to the editor |
| Carter LI, Golzar JA, Cavendish JJ, et al. Embolic protection of saphenous vein graft percutaneous interventions. *J Interv Cardiol* 2007;20:351-8 | A narrative review, editorial or letter to the editor |
| Chaliha BHK, Singh RS, Bahl A, et al. A study of abciximab versus distal protection device during percuteneous coronary stenting in acute coronary syndrome [abstract]. *Indian Heart J* 2004;56:417 | |
| Choi YS, Chung WS, Park CS, et al. Angiographic improvement after thrombus aspiration concomitant with glycoprotein IIb/IIIa inhibitor therapy does not affect long-term mortality during primary PCI [abstract]. *Am J Cardiol* 2009;103:AS8 | Not an RCT or an observational study enrolling more than 500 patients |
| Choudhury RP, Pillay P, Porto I, et al. Quantification of embolic material captured by the filterwire distal protection device during percutaneous intervention in native coronary arteries (NCA) and comparison with saphenous vein grafts (SVG) [abstract]. *Heart* 2004;90:51 | Uncontrolled study |
| Choudhury RP, Porto I, Banning AP. Images in cardiovascular medicine. Debris trapped by a distal protection device may mimic no-reflow during percutaneous coronary intervention. *Circulation* 2004;109:803-4 | Uncontrolled study |
| Chung WY, Cho YS, Chae IH, et al. The efficacy of distal protection device on ventricular remodeling and microvascular obstruction in ST elevation acute | Incomplete data and no response from author |

| Reference | Reason for Exclusion |
|---|---|
| myocardial infarction [abstract]. *Am J Cardiol* 2006;98:M | |
| Cohen DJ, Ramee S, Baim DS, et al. Economic assessment of rheolytic thrombectomy versus intracoronary urokinase for treatment of extensive intracoronary thrombus: Results from a randomized clinical trial. *Am Heart J* 2001;142:648-56 | Outside of ACS patients |
| Cohen R, Faucher R, Domniez T, et al. Predictive factors of successful intracoronary thrombectomy with the export aspiration catheter before angioplasty in patients with ST-segment elevation myocardial infarction [abstract]. *Am Heart J* 2006;98:59M | Not an RCT or an observational study enrolling more than 500 patients |
| Costa JR, Costa R, Feres F, et al. Preliminary experience with the Novel MGuard (TM) Stent System containing a protection net to prevent distal embolization - results from a prospective, non-randomized, single center study [abstract]. *Circulation* 2008;118:S745 | Uncontrolled study |
| Cox DA, Stuckey T, Babb J, et al. Early and late results of thrombectomy prior to stenting in acute myocardial infarction: Principal report of the EndiCOR X-SIZER AMI registry [abstract]. *J Am Coll Cardiol* 2002;39:308A | Uncontrolled study |
| Cox DA, Stuckey T, Babb J, et al. The EndiCOR X-SIZER AMI registry: Improvement in myocardial blush scores with adjunctive thrombectomy combined with stenting for AMI [abstract].*Circulation* 2001;104:2387 | Uncontrolled study |
| Cox DA, Stuckey T, Low R, et al. Adjunctive thrombectomy combined with stenting for AMI: The Endicor X-SIZER AMI registry [abstract]. *J Am Coll Cardiol* 2001;37:306S | Uncontrolled study |
| Cox DA, Turco M, Stuckey T, et al. Stent placement combined with thrombectomy improves outcomes in thrombotic lesions: Results from the X-SIZER acute myocardial infarction registry [abstract]. *Am J Cardiol* 2002;90:TCT124 | Uncontrolled study |
| Cox D, Lui H, Caputo R, et al. Lower MACE can be achieved in SVG PCI: Stenting in saphenous vein grafts with distal protection using a second generation filter-based catheter - The combined BLAZE I and BLAZE II registries [abstract]. *Am J Cardiol* 2005;96:5H | Uncontrolled study |
| Cox D, Stuckey T, Babb J, et al. The EndiCOR X-SIZER acute myocardial infarction (AMI) registry: Adjunctive thrombectomy combined with stenting for AMI [abstract]. *Am J Cardiol* 2001;88:TCT62 | Uncontrolled study |
| Cox D, Stuckey T, Babb J, et al. The X-SIZER acute myocardial infarction (AMI) registry: Improvement in myocardial blush scores and ST-segment resolution with the use of thrombectomy before stenting in AMI [abstract]. *Am J Cardiol* 2002;90:TCT38 | Uncontrolled study |
| Dangas,G. Interventional therapy for acute myocardial infarction: respect the microvasculature. *J Am Coll Cardiol* 2003;42:1403-5 | A narrative review, editorial or letter to the editor |
| De Carlo M, Cortese B, Borelli G, et al. Successful treatment of acute myocardial infarction due to subocclusive thrombosis over a small atherosclerotic plaque with the "Rinspiration" device, a novel thrombectomy catheter. *Int J Cardiol* 2007;115:95-6 | Uncontrolled study |
| De Carlo M, Webb JG, Grube E, et al. International Rinspiration Registry (100 patients treated with fluidic thrombectomy in the AMI setting) [abstract]. *Am J Cardiol* 2005; 96:76H-77H | Uncontrolled study |
| De Luca G, Suryapranata H, Chiariello M. Aspiration thrombectomy and primary percutaneous coronary intervention. *Heart* 2006;92:867-9 | A narrative review, editorial or letter to the editor |
| De Luca L, Sardella G. Tirofiban plus sirolimus-eluting stent vs abciximab plus bare-metal stent. *JAMA* 2005;294:1617 | A narrative review, editorial or letter to the editor |
| De Rosa S, Cirillo P, De Luca G, et al. Rheolytic thrombectomy during | Not an RCT or an |

| Reference | Reason for Exclusion |
|---|---|
| percutaneous coronary intervention improves long-term outcome in high-risk patients with acute myocardial infarction. *J Interv Cardiol* 2007;20:292-8 | observational study enrolling more than 500 patients |
| De Vita M, Burzotta F, Trani C, et al. Urgent PCI in patients with stent thrombosis: an observational single-center study comparing thrombus aspiration and standard PCI. *J Invasive Cardiol* 2008;20:161-5 | Uncontrolled study |
| De Young MB, Kazziha S. Use of a thrombus extraction catheter (Pronto) in the treatment of acute myocardial infarction after coronary embolism post mitral valve replacement. *J Invasive Cardiol* 2006;18:E273-5 | Uncontrolled study |
| DeLago A, Papaleo R, Macina A. Initial experience with Angiojet (R) mechanical thrombectomy in the treatment of acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2000;35:19A | Uncontrolled study |
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| Okamura A, Ito H, Iwakura K, et al. Detection of embolic particles with the Doppler guide wire during coronary intervention in patients with acute myocardial infarction: efficacy of distal protection device. *J Am Coll Cardiol* 2005;45:212-5 | Does not report outcomes of interest |
| Orrego PS, Delgado A, Piccalo G, et al. Distal protection in native coronary arteries during primary angioplasty in acute myocardial infarction: single-center experience. *Catheter Cardiovasc Interv* 2003;60:152-8 | Not an RCT or an observational study enrolling more than 500 patients |
| Oyama N, Urasawa K, Sakai H, et al. PCI for totally occluded site consisting of huge thrombus. *J Invasive Cardiol* 2003;15:604-6 | Uncontrolled study |
| Pan W, Wang LF, Yang SS, et al. [Efficacy of the thrombectomy on no-reflow in patients with acute myocardial infarction.] *Zhongguo Wei Zhong Bing Ji Jiu Yi Xue* 2007;19:687-90 | |
| Park CH, Salem M, Jauhar R, et al. Effect of distal protection or thrombectomy on corrected thrombolysis in myocardial infarction frame counts in stenting for acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2003;41:356A-357A | Not an RCT or an observational study enrolling more than 500 |
| Parodi G, Memisha G, Bellandi B, et al. Effectiveness of primary percutaneous coronary interventions for stent thrombosis. *Am J Cardiol* 2009;103:913-6 | Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI |
| Porto I, Choudhury RP, Pillay P, et al. Filter no-reflow during percutaneous coronary interventions using the filtewire distal protection device [abstract]. *Eur Heart J* 2004;25:312 | Uncontrolled study |
| Porto I, Greco F, Buffon A. Coronary arteriovenous fistula following X-sizer thrombectomy. *J Cardiovasc Med* 2007;8:973-4 | Uncontrolled study |
| Porto I, De Maria GL, Biasucci LM, et al. Levels of platelet microparticles are increased in thrombectomy-aspirated blood of ST-elevation myocardial infarction patients and correlate with thrombus burden of the culprit lesion [abstract]. *Am J Cardiol* 2009;104:76D | Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI |
| Porto I, De Maria GL, Biasucci LM, et al. Levels of endothelial progenitor cells are increased in thrombectomy-aspirated blood of ST-elevation myocardial infarction patients and correlate with microvascular damage [abstract]. *Am J Cardiol* 2009;104:79D | Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI |
| Porto L, Choudhury RP, Pillay P, et al. Filter no-reflow during percutaneous coronary intervention using the FilterWire distal protection device [abstract]. *Am J Cardiol* 2004;94:153E | Uncontrolled study |
| Reho I, Gruner C, Roffi M. Coronary thrombectomy by retrieval of an open emboli-protection filter device. *Heart* 2008;94:274 | Uncontrolled study |
| Remondino A, Seiler C, Rakhit R, et al. Distal embolisation protection during percutaneous coronary intervention in acute myocardial infarction protects coronary collateral flow [abstract]. *Eur Heart J* 2003;24:713 | Not an RCT or an observational study enrolling more than 500 |
| Richartz BM. [Randomized comparison of the effect of distal protection and drug eluting stent versus bare metal stent implantation during percutaneous coronary | A narrative review, editorial or letter to the editor |

| Reference | Reason for Exclusion |
|---|---|
| intervention for ST-elevation myocardial infarction.] *Herz* 2007;32:249 | |
| Rigatelli G, Giordan M, Cardaioli P, et al. Peripheral devices for recanalizing a giant thrombosed aneurysmal coronary artery. *Cardiovasc Revasc Med* 2006;7:199-200 | Uncontrolled study |
| Rittersma SZ, van der Wal AC, Koch KT, et al. Plaque disruption frequently occurs days or weeks before occlusive coronary thrombosis: A pathologic thrombectomy study in primary PCI [abstract]. *Circulation* 2004;110:1941 | Uncontrolled study |
| Sakai T, Inoue S, Takei M, et al. Role of Inflammatory Cells Activation In Growing Thrombus: Immunohistochemical Analysis of Aspiration Samples in Acute Coronary Syndrome [abstract]. *Circulation* 2008;118:S581 | Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI |
| Sakuma T, Okada T, Hayashi Y, et al. Myocardial tissue protection with distal coronary protection and thrombus aspiration, or pharmacological intervention during reperfusion, which is better in patients with acute myocardial infarction? [abstract] *Eur Heart J* 2004;25:421 | Uncontrolled study |
| Sakuma T, Okada T, Ishibashi K, et al. Myocardial tissue protection with distal coronary protection and adenosine triphosphate disodium infusion can further reduce no-reflow in acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2005;45:302A | Uncontrolled study |
| Sarmento-Leite R, Machado PR, Garcia,SL, et al. [Intracoronary thrombectomy. An alternative in the management of the acute ischemic syndromes.] *Arq Bras Cardiol* 2002;79:428 | Uncontrolled study |
| Satler L. Feasibility of primary clot extraction prior to percutaneous coronary intervention in acute myocardial infarction. *Catheter Cardiovasc Interv* 2008;71:877-8 | A narrative review, editorial or letter to the editor |
| Satler L. Improving outcomes for primary PCI. *Catheter Cardiovasc Interv* 2007;69:497-9 | A narrative review, editorial or letter to the editor |
| Satler L. Importance of creativity: new applications of the Proxis catheter. *Catheter Cardiovasc Interv* 2009;74:446-7 | A narrative review, editorial or letter to the editor |
| Schneider H, Ince H, Casale PN, et al. Efficacy And Safety Of A Thrombectomy Aspiration Device In Patients With High Thrombus Burden Acute Coronary Syndrome [abstract]. *Am J Cardiol* 2008;102:1201 | Uncontrolled study |
| Schomig A, Kastrati A. Distal embolic protection in patients with acute myocardial infarction: attractive concept but no evidence of benefit. *JAMA* 2005;293:1116-8 | A narrative review, editorial or letter to the editor |
| Sena MA., Peixoto RTS, Tedeschi AL. Thrombectomy with the X-Sizer catheter in thrombus-containing lesions during acute coronary syndrome. outcomes in-hospital and at 1year [abstract]. *Am J Cardiol* 2003;92:233L | Uncontrolled study |
| Seth A. Another "nail in the coffin" for protection devices in acute MI? *Catheter Cardiovasc Interv* 2008;71:E3-4 | A narrative review, editorial or letter to the editor |
| Shah PB, Lilly CM. Interventional therapy for coronary artery disease. *Am J Respir Crit Care Med* 2002;166:791-6 | A narrative review, editorial or letter to the editor |
| Sharma M, Yeghiazarians Y. Stent thrombosis--a complication best avoided. *J Invasive Cardiol* 2008;20:166-7 | A narrative review, editorial or letter to the editor |
| Sharma SK, Tamburrino F, Mares AM, et al. Improved outcome with AngioJet thrombectomy during primary stenting in acute myocardial infarction patients with high-grade thrombus. *J Invasive Cardiol* 2006;18:8-11 | Not an RCT or an observational study enrolling more than 500 |
| Sheiban I, Moretti C, Prathap K, et al. Thrombus aspiration for the treatment of no-reflow phenomenon complicating primary angioplasty for acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2004;43:248A | Uncontrolled study |

| Reference | Reason for Exclusion |
|---|---|
| Shiba M, Nakamura M, Wada M. The distal protection during primary PCI is associated with delayed recovery of myocardial perfusion in AMI patients [abstract]. *Am J Cardiol* 2005;95:28A-29A | Not an RCT or an observational study enrolling more than 500 |
| Sievert H, Schuler G, Diederich K, et al. Preclinical and clinical experience with the proxis device: A novel proximal occlusion system for prevention of distal embolization during percutaneous coronary intervention [abstract]. *Am J Cardiol* 2002;90:TCT57 | Conducted outside of humans |
| Silva JA. Percutaneous coronary intervention of thrombotic lesions: still challenging! *Catheter Cardiovasc Interv* 2002;56:8-9 | A narrative review, editorial or letter to the editor |
| Silva JA, Ramee SR, Cohen D, et al. Rheolytic thrombectomy for the treatment of acute myocardial infarction in patients with angiographic large thrombus burden: One-year results of the VeGAS 2 acute myocardial infarction registry [abstract]. *J Am Coll Cardiol* 2004;43:248A | Uncontrolled study |
| Silva JA, Ramee SR, Kuntz R, et al. Mechanical thrombectomy using the angiojet catheter in the treatment of acute myocardial infarction [abstract]. *J Am Coll Cardiol* 1998;31:410A-411A | Uncontrolled study |
| Silva JA., Saucedo JF, Lanoue AS, et al. Rheolytic thrombectomy using the POSSIS AngioJet -> catheter in patients with acute myocardial infarction presenting within eight hours of symptom onset [abstract]. *Circulation* 1998;98:762 | Uncontrolled study |
| Sison EOD, Tan HC, Lee R, et al. Thrombectomy using the thrombus vacuum catheter (Nipro (R)) in primary angioplasty for acute myocardial infarction [abstract]. *Am J Cardiol* 2005;96:75H-76H | Uncontrolled study |
| Skowasch M, Schofer J, Diedrich K, et al. Initial experiences with the Proxis System: A proximal occlusion device for embolic protection during percutaneous coronary intervention [abstract]. *Am J Cardiol* 2005;95:64A | Uncontrolled study |
| Stoel MG, von Birgelen C, Zijlstra F. Aspiration of embolized thrombus during primary percutaneous coronary intervention. *Catheter Cardiovasc Interv* 2009;73:781-6 | Uncontrolled study |
| Stone GW, Cox DA, Babb J, et al. Prospective, randomized evaluation of thrombectomy prior to percutaneous intervention in diseased saphenous vein grafts and thrombus-containing coronary arteries. *J Am Coll Cardiol* 2003;42:2007-13 | Outside of ACS patients |
| Stone, GW, Cox, DA, Low, R, et al. Safety and efficacy of a novel device for treatment of thrombotic and atherosclerotic lesions in native coronary arteries and saphenous vein grafts: results from the multicenter X-Sizer for treatment of thrombus and atherosclerosis in coronary applications trial (X-TRACT) study. *Catheter Cardiovasc Interv* 2003;58:419-27. | Not in native vessel |
| Sutsch G, Metzler C, Murphy S, et al. Distal protection accelerates ST-segment resolution and improves epicardial flow in percutaneous coronary intervention for acute myocardial infarction [abstract]. *Am J Cardiol* 2002;90:TCT43 | Uncontrolled study |
| Sutsch G, Eberli FR, Serruys PW. Evaluation of proximal embolic protection during percutaneous coronary intervention in acute myocardial infarction with Proxis.(TM) [abstract]. *Am J Cardiol* 2004;94:36E | Uncontrolled study |
| Sutsch G, Kiowski W, Amann W. The new reduced profile GuardWire (028) embolic protection device is feasible for percutaneous coronary intervention in native coronary arteries [abstract]. *Am J Cardiol* 2002;90:TCT90 | Uncontrolled study |
| Sutsch G, Kiowski W, Bossard A, et al. Recanalisation in acute myocardial infarction: preliminary experiences with the PercuSurge (R)-Protection device in native coronary arteries [abstract]. *Eur Heart J* 2000;21:P1003 | Uncontrolled study |
| Sutsch G, Murphy S, Kiowski W, et al. Does embolic protection in native | Not an RCT or an |

| Reference | Reason for Exclusion |
|---|---|
| coronary arteries acutely affect the outcome of percutaneous coronary intervention in acute myocardial infarction? [abstract] *Am J Cardiol* 2002;90:TCT110 | observational study enrolling more than 500 |
| Sutsch G, Puippe G, Kessel M., et al. No angiographic evidence of harm, to native coronary arteries using the GuardWire distal embolization protection device [abstract]. *Am J Cardiol* 2001;88:TCT83 | Uncontrolled study |
| Tamburrino F, Kini AS, Gupta S, et al. The improved outcome with AngioJet (TM) thrombectomy catheter during primary stenting in acute myocardial infarction patients with high-grade thrombus [abstract]. *Am J Cardiol* 2005;96:76H | Not an RCT or an observational study enrolling more than 500 |
| Tarsia G;Polosa D, Biondi-Zoccai G, et al. Passive Versus Active Thrombectomy In Primary And Rescue Percutaneous Coronary Intervention For ST-elevation Acute Myocardial Infarction [abstract]. *Am J Cardiol* 2008;102:481 | Not an RCT or an observational study enrolling more than 500 |
| Testa L, Bedogni F, Biondi Zoccai GG. Letter by Testa et al regarding article, "presence of older thrombus is an independent predictor of long-term mortality in patients with ST-elevation myocardial infarction treated with thrombus aspiration during primary percutaneous coronary intervention". *Circulation* 2009;120:e3 | A narrative review, editorial or letter to the editor |
| Tomoda H, Izumi N, Aoki N. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2540 | A narrative review, editorial or letter to the editor |
| Tsubotan T, Muramatsu T, Tsukahara R, et al. Clinical results of intravascular ultrasound-guided distal protection therapy for acute myocardial infarction [abstract]. *Am J Cardiol* 2005;95:9A | Not an RCT or an observational study enrolling more than 500 |
| Turco MA, Cox DA, Stuckey T, et al. Impact of glycoprotein IIb/IIIa inhibitors in conjunction with the X-SIZER thrombectomy catheter system during acute myocardial infarction (AMI) intervention: Results from the X-SIZER AMI registry [abstract]. *Am J Cardiol* 2002;90:TCT121 | Uncontrolled study |
| Upadhyay S, Sawar A. Device failure and acute vessel thrombosis with PercuSurge. *J Invasive Cardiol* 2008;20:E256 | Uncontrolled study |
| Uretsky BF. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2639 | A narrative review, editorial or letter to the editor |
| van Ommen V, Michels R, Heymen E, van Asseldonk J, et al. Usefulness of the rescue PT catheter to remove fresh thrombus from coronary arteries and bypass grafts in acute myocardial infarction. *Am J Cardiol* 2001;88:306-8 | Uncontrolled study |
| Vink MA, Dirksen MT, Tijsserr JGP, et al. Thrombus Aspiration During Primary Percutaneous Coronary Intervention: Post-hoc Analysis of the PASSION Trial [abstract]. *Am J Cardiol* 2009;104:197D | Uncontrolled study |
| Vink MA., Patterson MS, Van Etten J, et al. Thrombus Removal by Extraction or Aspiration in Primary PCI in the Treatment of ST-elevation Myocardial Infarction (TREAT-MI). A follow-up study [abstract].. *Am J Cardiol* 2009;104 :197D-198D | Uncontrolled study |
| Vlaar PJ, Diercks G, Svilaas T, et al. One-year follow-up of the Thrombus Aspiration during Primary percutaneous coronary intervention in Acute non-ST-elevation myocardial infarction Study (TAPAS-II) - pilot – trial [abstract]. *J Am Coll Cardiol* 2009;53:A64 | Not an RCT or an observational study enrolling more than 500 |
| von Korn H, Yu JT, Ohlow M, et al. The export aspiration system in patients with acute coronary syndrome and visible thrombus demonstrates no remarkable benefit [abstract]. *J Am Coll Cardiol* 2006;47:38B | Not an RCT or an observational study enrolling more than 500 |
| Wang FW, Osman A, Otero J, et al. Distal myocardial protection with intracoronary propranolol during percutaneous coronary intervention is widely applicable [abstract]. *J Am Coll Cardiol* 2003;41:17A | Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in |

| Reference | Reason for Exclusion |
|---|---|
| | PCI |
| Wang L, Nguyen T, Yang X, et al. Distal protection with AngioGuard during PCI for acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:38L | Not an RCT or an observational study enrolling more than 500 |
| Weisz G, Rogers C, Herrmiller J, et al. Predilatation before distal protection device placement is associated with increased procedure-related myocardial infarction: Analysis from the FIRE trial [abstract]. *J Am Coll Cardiol* 2004;43:52A | Not a PCI in native vessel |
| Wong A, Nait D, Phay C, et al. Rate of distal embolization in primary angioplasty in acute myocardial infarction without distal embolization prevention and thrombectomy devices [abstract]. *Am J Cardiol* 2005;95:12A | Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI |
| Worthley MI, Traboulsi M. Thrombectomy and acute myocardial infarction. *Intern Med J* 2006;36:470-1 | Uncontrolled study |
| Yamaguchi K, Hiasa Y, Nada T, et al. Rescue percutaneous thrombectomy catheter is less beneficial in acute myocardial infarction with large vessel diameter [abstract]. *Eur Heart J* 2002;23:350 | Uncontrolled study |
| Yamasaki T, Koizumi T, Iida S, et al. Benefit of thrombus aspiration for myocardial infarction with ST-segment elevation: analysis by biomarkers of thrombosis and inflammation [abstract]. *Circulation* 2009;120:S926 | Uncontrolled study |
| Yang SS, Li WM, Zhou LJ, et al. [The efficacy of percutaneous coronary intervention combined percutaneous thrombectomy on coronary thrombotic lesions in patients with acute myocardial infarction]. *Zhonghua Xin Xue Guan Bing Za Zhi* 2007;35:1136-40 | Does not report outcomes of interest |
| Yip HK, Wu CJ, Chang HW, et al. Effect of the PercuSurge GuardWire device on the integrity of microvasculature and clinical outcomes during primary transradial coronary intervention in acute myocardial infarction. *Am J Cardiol* 2003;92:1331-5 | Not an RCT or an observational study enrolling more than 500 |
| Yoon MH, Tahk SJ, Choi SY, et al. The effect of distal protection device on the protection of microvascular integrity during primary stenting in AMI [abstract]. *Circulation* 2003;108:1877 | Not an RCT or an observational study enrolling more than 500 |
| Yoon MH, Tahk SJ, Choi SY, et al. The effect of a distal protection device on the protection of microvascular integrity during primary stenting in acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:37L | Not an RCT or an observational study enrolling more than 500 |
| Yoshida K, Oku K, Uchida Y, et al. The effect for chronic phase left ventricular ejection fraction using adjunctive distal protection during percutaneous coronary intervention in patients with acute coronary syndrome [abstract]. *Am J Cardiol* 2005;95:28A | Not an RCT or an observational study enrolling more than 500 |
| Zalewski D, Zajdel W, El-Massri N, et al. The immediate and long-term results of successful thrombectomy during primary coronary angioplasty in acute myocardial infarction [abstract]. *Am J Cardiol* 2005;96:74H | Uncontrolled study |

# Appendix D. Characteristics and quality assessment of included trials, studies and meta-analyses

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Liistro, 2009 | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Computer generated random assignment number 1:1 in blocks of 10<br><br>**Outcome assessment:**<br>Evaluated by 2 readers without the knowledge of clinical status, treatment modality, angiographic and echocardiographic data<br><br>**Number of participants enrolled:**<br>111 | **Inclusion criteria:**<br>Symptoms associated with ACS > 30 min, < 12 h symptom onset, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads<br><br>**Exclusion criteria:**<br>Contraindication to GP2BAi, previous MI, inability to obtain informed consent, rescue PCI after failed lysis, absence of optimal ECHO apical view, existence of disease with life expectancy < 6 m<br><br>**Intervention:**<br>PCI with thrombus aspiration by Export Aspiration Catheter<br><br>**Comparator:**<br>Standard PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG ≥ 2, TIMI-3, DE, no reflow (post-procedure); EF (post-procedure and 180 d); STSR ≥ 70% (90 min)<br><br>**Final:**<br>MACE, TLR, reinfarction (180 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Lipiecki, 2009 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>France<br><br>**Funding:**<br>Regional Project of Clinical Research grant and Medtronic Company<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomized 1:1<br><br>**Outcome assessment:**<br>Coronary flow assessment offline by 2 experienced interventional cardiologist<br><br>**Number of participants enrolled:**<br>44 | **Inclusion criteria:**<br>Chest pain associated with ACS > 30 min, TIMI 0/1 of proximal segment of LAD, LCX, or RCA, ST-segment elevation ≥ 2 mm in 2 or more ECG lead, PCI scheduled within 48 h of symptom onset, success of guidewire to cross culprit lesion, first STEMI<br><br>**Exclusion criteria:**<br>LBBB, ventricular pacing at baseline, previous MI or CABG, Killip Class > II, contraindication to SPECT or MRI<br><br>**Intervention:**<br>PCI with Export catheter<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>7<br><br>**Followup:**<br>NR | **Intermediate:**<br>MBG-2, TIMI-3, DE (post-procedure); EF (7 d); STSR > 70% (90 min, 24 h)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partial<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Moura, 2009 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Brazil<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>152 | **Inclusion criteria:**<br>Acute STEMI within 6 h<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>Thrombectomy aspiration catheter<br><br>**Comparator:**<br>Conventional PCI with stent<br><br>**Duration of followup (d):**<br>270<br><br>**Followup:**<br>NR | **Intermediate:**<br>MBG ≥ 2 (post-procedure); STSR > 70% (NR)<br><br>**Final:**<br>MACE (mortality, new MI, stent thrombosis, TVR) (in-hospital, 30 d, 270 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Sardella, 2009<br><br>EXPIRA | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>NR<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Random assignment 1:1<br><br>**Outcome assessment:**<br>Blinded operators using an off-line dedicated workstation<br><br>**Number of participants enrolled:**<br>175 | **Inclusion criteria:**<br>First STEMI, ≤ 9 h symptom onset, IRA ≥ 2.5 mm, TS ≥ 3, TIMI ≤ 1, > 18 y<br><br>**Exclusion criteria:**<br>Previous PCI on IRA, MI or CABG, cardiogenic shock, 3-vessel or left main disease, severe valvular heart disease, thrombolysis, contraindication to GP2B3Ai<br><br>**Intervention:**<br>Primary PCI with Export Medtronic<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>720<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG ≥ 2, TIMI ≥ 2, (post-procedure); EF (3-5 d post-procedure); STSR > 70% (90 min)<br><br>**Final:**<br>MACE (cardiac mortality, nonfatal reinfarction, TVR) (30 d, 270, 720 d); MACCE (MACE + stroke) (30 d); mortality (in-hospital, 30 d, 180 d); TVR, reinfarction (in-hospital; 30 d, 720 d); stroke (in-hospital)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Chao, 2008 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Taiwan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Coronary angiograms reviewed offline by 2I interventional cardiologists who were blinded to the clinical data<br><br>**Number of participants enrolled:**<br>74 | **Inclusion criteria:**<br>STEMI with chest pain > 30 min and ST-segment elevation ≥ 0.1 mV in 2 or more ECG leads within 12 h of symptom onset, eligible for primary PCI<br><br>**Exclusion criteria:**<br>Previous CABG, Killip IV, ventricular tachycardia, significant left main disease, culprit vessel diameter < 2mm, existing TIMI-3 flow without visible thrombus in IRA<br><br>**Intervention:**<br>Primary PCI with Export aspiration catheter<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG, TIMI blood flow (post-procedure); EF (30 d)<br><br>**Final:**<br>MACE (mortality, stroke, nonfatal reinfarction), mortality, TVR (180 d)<br><br>**Safety:**<br>Coronary dissection, procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Chevalier, 2008<br><br>EXPORT | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>Europe and India<br><br>**Funding:**<br>Medtronic Vascular<br><br>**Number of centers:**<br>24<br><br>**Randomization:**<br>Computerized telephone system on a 1:1 basis<br><br>**Outcome assessment:**<br>Three independent interventional cardiologist reviewed MACE and serious adverse device events, ECG and angiographic results analyzed by an independent core laboratory<br><br>**Number of participants enrolled:**<br>249 | **Inclusion criteria:**<br>Acute MI within 12 h of symptom onset, TIMI 0/1 before placing wire, age ≥ 18 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads, vessel diameter ≥ 2.5 mm<br><br>**Exclusion criteria:**<br>Cardiogenic shock, pacemaker, fibrinolytic treatment, cardiac arrest, treatment with GP2B3Ai, medical condition with expected survival < 1 y, participation in other investigations<br><br>**Intervention:**<br>Primary PCI with Export aspiration catheter followed by stenting<br><br>**Comparator:**<br>Conventional stenting<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 50% (60 min)<br><br>**Final:**<br>MACCE (mortality, reinfarction, emergent bypass surgery, TLR or TVR, cerebrovascular accident), mortality, TVR, TLR, reinfarction, cerebrovascular accident (30 d)<br><br>**Safety:**<br>Procedure time, side branch occlusion | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Ciszewski, 2008 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Poland<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>135 | **Inclusion criteria:**<br>TIMI < 2, ≤ 12 h from symptom onset, first anterior or inferior STEMI, LAD or RCA lesion<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>Thrombectomy with Rescue or Diver followed by stent implantation<br><br>**Comparator:**<br>Standard primary PCI with stenting<br><br>**Duration of followup (d):**<br>5-8<br><br>**Followup:**<br>96.92% in device group, 91.43% in control group | **Intermediate:**<br>EF (5-8 d)<br><br>**Final:**<br>Mortality (3-7 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)?Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Dudek, 2008<br><br>PHIRATE | **Publication type:**<br>Slide presentation<br><br>**Geographical location:**<br>Poland, Italy, Hungary<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>196 | **Inclusion criteria:**<br>TIMI 0/1 in occluded IRA, STEMI < 6 h from symptom onset, ST-segment elevation ≥ 3 mm in one ECG lead<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>Primary PCI with Diver CE thrombectomy system followed by direct stenting<br><br>**Comparator:**<br>Standard balloon predilation followed by stenting<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3,TIMI-3, DE (post-procedure); STSR > 70% (Immediately post-procedure, 60 min)<br><br>**Final:**<br>MACE (mortality, reinfarction, re-PCI or re-CABG) (in-hospital); mortality, reinfarction (in-hospital, 180 d); TVR (in-hospital)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Ikari, 2008<br><br>VAMPIRE | **Publication type:**<br>Full text, slide presentation, abstract<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>Nipro<br><br>**Number of centers:**<br>23<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Data analysis by an independent clinical research organization, clinical events adjudicated by an independent committee<br><br>**Number of participants enrolled:**<br>355 | **Inclusion criteria:**<br>AMI ≤ 24 h and > 30 min from symptom onset, age ≥ 21 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads or new LBBB<br><br>**Exclusion criteria:**<br>Cardiogenic shock, fibrinolytic treatment, previous CABG, chronic renal failure (Cr > 2.0 mg/dL or HD), presence of primary thrombolysis prior to randomization, history of cardiac arrest, left main disease, target vessel < 2.5 or > 5 mm in diameter<br><br>**Intervention:**<br>Primary PCI with TVAC<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Duration of followup (d):**<br>240<br><br>**Followup:**<br>98.89% in device group, 97.71% in control group | **Intermediate:**<br>MBG-3, TIMI-3, EF (post-procedure, 180 d); DE, no reflow (post-procedure); STSR > 70% (immediately post-procedure, 3-6 h)<br><br>**Final:**<br>MACE (mortality, recurrence of MI, TLR) (in-hospital, 240 d, 720 d), mortality, recurrence of MI, TLR, (in-hospital, 240 d)<br><br>**Safety:**<br>Coronary dissection, perforation, procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)?Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Svilaas, 2008<br><br>TAPAS | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>Netherlands<br><br>**Funding:**<br>Medtronic, Thorax Center of university Medical Center<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Computerized voice-response system to select randomly permuted blocks of 3-6 stratified by the interventional cardiologist<br><br>**Outcome assessment:**<br>Coronary angiogram data analyzed at an independent core laboratory<br><br>**Number of participants enrolled:**<br>1071 | **Inclusion criteria:**<br>AMI ≤ 12 h and > 30 min from symptom onset, ST-segment elevation ≥ 0.1 mV in 2 or more ECG leads<br><br>**Exclusion criteria:**<br>Fibrinolytic therapy, inability to obtain informed consent, known existence of disease with life expectancy < 6 m<br><br>**Intervention:**<br>Primary PCI with thrombus aspiration by 6-French Export Aspiration Catheter<br><br>**Comparator:**<br>Conventional PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>91.59% in device group, 91.42% in control group | **Intermediate:**<br>MBG-3, TIMI-3 (post-procedure); STSR > 70% (30-60 min)<br><br>**Final:**<br>MACE (mortality, reinfarction, TVR), mortality, reinfarction, TVR (30 d, 365 d)<br><br>**Safety:**<br>Coronary dissection, procedure time, side branch occlusion | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| DeLuca, 2006 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomized on a 1:1 basis<br><br>**Outcome assessment:**<br>TIMI flow and MBG were analyzed offline<br><br>**Number of participants enrolled:**<br>76 | **Inclusion criteria:**<br>Anterior STEMI with chest pain > 30 min and new persistent ST-segment elevation ≥ 0.1mV in 2 or more ECG leads, identified thrombus on IRA at coronary angiography, age ≥ 18 y<br><br>**Exclusion criteria:**<br>Previous MI or CABG, 3 vessel CAD, severe valvular heart disease, TIMI-2 or 3 flow at initial angiography, unsuccessful PCI (no antegrade flow or > 50% residual stenosis in the IRA)<br><br>**Intervention:**<br>Primary PCI with Diver CE aspiration thrombectomy catheter<br><br>**Comparator:**<br>Conventional PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup**:<br>92.11% in device group, 94.74% in control group | **Intermediate:**<br>MBG-3, TIMI-3 (post-procedure); EF (post-procedure, 180 d); STSR > 70% (90 min)<br><br>**Final:**<br>MACE (mortality, reinfarction, hospitalization for CHF), mortality, reinfarction (180 d)<br><br>**Safety:**<br>Coronary dissection | • Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No<br>• Were outcomes assessed using a valid methodology and criteria? Yes<br>• Were outcome assessors blind to exposure/intervention status? Partially<br>• Were incomplete outcome data adequately addressed? Yes<br>• Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>• Was the overall loss to followup low (< 30%)? Yes<br>• Conflict of interest reported and insignificant? Yes<br>• Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Kaltoft, 2006 | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>Denmark<br><br>**Funding:**<br>Partially by Boston Scientific<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Telephone line-accessible computer based block randomization using varying block sizes (6/4/2) stratified by sex and diabetes compliant with international criteria for proper concealment<br><br>**Outcome assessment:**<br>Angiographic measurements made by 4 experienced observers blinded to randomization<br><br>**Number of participants enrolled:**<br>215 | **Inclusion criteria:**<br>Symptom onset > 30 min and < 12 h; ST-segment elevation ≥ 2 mm in 2 or more ECG leads, PCI indicated upon angiography, IRA suitable for thrombectomy<br><br>**Exclusion criteria:**<br>LBBB, previous MI within 30 d, previous CABG, fibrinolytic treatment, inability to obtain informed consent, left main disease, need for mechanical ventilation, severe heart failure treated with IABP<br><br>**Intervention:**<br>Primary PCI with Rescue catheter<br><br>**Comparator:**<br>Standard PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>73.15% in device group, 83.18% in control group | **Intermediate:**<br>TIMI-3, DE (post-procedure); EF (30 d); STSR > 70% (immediately post-procedure, 90 min, 6 h)<br><br>**Final:**<br>MACE (mortality, reinfarction, disabling stroke), mortality, reinfarction, disabling stroke (30 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Lee, 2006<br><br>TSUNAMI | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Korea<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>133 | **Inclusion criteria:**<br>STEMI scheduled for primary PCI<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>Primary PCI with Export aspiration catheter<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>In-hospital<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, STSR, DE, no reflow (post-procedure)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Silva-Orrego, 2006<br><br>DEAR-MI | **Publication type:**<br>Full text, abstract, slide presentation<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>Niguarda Hospital, Milan<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomly assigned on a 1:1 basis<br><br>**Outcome assessment:**<br>Angiographic and ECG data analysis by 2 blinded observers<br><br>**Number of participants enrolled:**<br>148 | **Inclusion criteria:**<br>Continuous chest pain > 30 min and < 12 h, ST-segment elevation ≥ 0.1 mV (≥ 0.2 mV in case of anterior leads) in ≥ 3 ECG leads, technical feasibility for primary angioplasty independent of initial TIMI flow or angiographic evidence of intraluminal thrombus in culprit artery<br><br>**Exclusion criteria:**<br>Contraindication to GP2B3Ai, cardiogenic shock, LBBB, ventricular pacing, previous MI or CABG, fibrinolytic treatment<br><br>**Intervention:**<br>Primary PCI with Pronto extractor catheter<br><br>**Comparator:**<br>Standard angioplasty with stenting<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, STSR, DE, no reflow (post-procedure)<br><br>**Final:**<br>Mortality, TVR, reinfarction, stroke (in-hospital, 180 d)<br><br>**Safety:**<br>Coronary dissection, procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Burzotta, 2005<br><br>REMEDIA | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>1:1 by computer generated random series of numbers<br><br>**Outcome assessment:**<br>ECG analyzed by blinded cardiologist, angiographic data analyzed offline by two expert interventional cardiologists<br><br>**Number of participants enrolled:**<br>99 | **Inclusion criteria:**<br>Acute STEMI within 12 h, eligible for primary or rescue PCI<br><br>**Exclusion criteria:**<br>No angiographic exclusion criteria were applied<br><br>**Intervention:**<br>Primary or rescue PCI with Diver CE<br><br>**Comparator:**<br>Standard PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure), EF(24 h); STSR > 70% (post-procedure)<br><br>**Final:**<br>MACE (major adverse events), mortality, TLR, reinfarction, stroke (30 d);<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Noel, 2005 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>France<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>50 | **Inclusion criteria:**<br>Acute STEMI within 12 h, initial TIMI flow < 3<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with Export<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>1 h<br><br>**Followup:**<br>In-hospital | **Intermediate:**<br>TIMI < 3, no reflow, (post-procedure); STSR > 50%, STSR > 70% (60 min)<br><br>**Final:**<br>MACE, mortality (NR)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Dudek, 2004 | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Poland<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>Randomized using a computer system<br><br>**Outcome assessment**:<br>ECG data analyzed by 2 blinded investigators<br><br>**Number of participants enrolled:**<br>72 | **Inclusion criteria:**<br>AMI, TIMI 0/1 or 2/3 with large thrombus in IRA documented by angiogram, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads<br><br>**Exclusion criteria:**<br>Cardiogenic shock, previous fibrinolytic treatment, previous GP2B3Ai, IRA reference diameter < 2.5 mm<br><br>**Intervention:**<br>Primary PCI with Rescue system<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>90<br><br>**Followup:**<br>NR | **Intermediate:**<br>MBG-3, TIMI-3 (post-procedure); EF (in-hospital, 90 d); STSR > 70% (60 min)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Fair |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: ACS=acute coronary syndrome; AMI=acute myocardial infarction; CABG=coronary artery bypass graft; CAD=coronary artery disease; CHF=congestive heart failure; CHF=congestive heart failure; Cr=creatinine; d=days; DE=distal embolization; ECG=electrocardiogram; ECHO=echocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; HD=hemodialysis; IABP=intra-aortic balloon pump; IRA=infarct related artery; LAD=left anterior descending artery; LBBB=left bundle branch block; LCX=left circumflex; m=months; MACE=major adverse cardiac events; MACCE=major adverse cardiac and cerebrovascular events; MBG=myocardial blush grade; mg/dL= milligrams/deciliter; MI=myocardial infarction; min=minutes; mm=millimeters; MRI=magnetic resonance imaging; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; RCA=right coronary artery; SPECT=single-photon emission computerized tomography; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TS=thrombus score; TVAC=Transvascular aspiration catheter; TVR=target vessel revascularization; y=years

Table 2. Characteristics and quality assessment of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Migliorini, 2010<br><br>JETSTENT | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>International<br><br>**Funding:**<br>Medrad Interventional/ Possis<br><br>**Number of centers:**<br>Multiple<br><br>**Randomization:**<br>Computer generated sequence of number and assignments were provided by a centralized telephone system<br><br>**Outcome assessment:**<br>STSR assessed by physicians blinded to treatment assignment at a central core laboratory, all angiographic markers of reperfusion and quantitative coronary angiography analysis performed at central core laboratory by physicians not involved in study, clinical events by independent committee blinded to treatment allocation<br><br>**Number of participants enrolled:**<br>501 | **Inclusion criteria:**<br>STEMI with chest pain > 30 min and < 12 h, ST-segment elevation > 1 mm in 2 or more ECG leads or a new LBBB, TIMI thrombus grade 3-5 after infarct artery wiring, IRA > 2.5 mm on visual assessment<br><br>**Exclusion criteria:**<br>Fribrinolytic treatment for current AMI, history of stroke in the last 30 d or any history of haemorrhagic stroke, major surgery in last 6 wk, comorbidities with expected survival < 1 y, participation in another study, TIMI thrombus grade < 3, IRA diameter < 2.5 mm, previous stenting of IRA, inability to identify IRA<br><br>**Intervention:**<br>Rheolytic thrombectomy with AngioJet followed by direct stenting<br><br>**Comparator:**<br>Direct stenting<br><br>**Duration of followup (d):**<br>365<br><br>**Followup:**<br>96.09% in device group, 97.90% in control group | **Intermediate:**<br>MBG-3,TIMI-3 post-procedure); STSR > 50% (30 min)<br><br>**Final:**<br>MACCE (mortality, MI, TVR, stroke), mortality, TVR, reinfarction, stroke (30 d, 180 d, 365 d)<br><br>**Safety:**<br>Perforation, procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 2. Characteristics and quality assessment of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Ali, 2006<br><br>AIMI | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>USA, Canada<br><br>**Funding:**<br>Possis Medical, Millenium Incorporation<br><br>**Number of centers:**<br>Multiple<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Independent adjudication committee for clinical events, infarct size and angiographic data, analyzed by core laboratory. ECG analyzed by reviewers blinded to the treatment assignment<br><br>**Number of participants enrolled:**<br>480 | **Inclusion criteria:**<br>< 12 h from symptom onset, age ≥ 18 y, anterior or large inferior myocardial infarction (new ST-segment elevation > 1 mm in 2 or more ECG leads in $V_1$ to $V_6$ or II, II and aVF), reference coronary artery > 2 mm in diameter<br><br>**Exclusion criteria:**<br>Contraindication to GP2B3Ai, cardiogenic shock (SBP < 80 mmHg requiring inotrope), inability to obtain informed consent, known prior EF < 35%, major surgery within last 6 w, history of stroke within 30 d, history of haemorrhagic stroke<br><br>**Intervention:**<br>Conventional PCI with AngioJet catheter<br><br>**Comparator:**<br>Conventional PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>82.08% in device group, 85.42% in control group | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure), EF (14-28 d); STSR > 70% (90 min)<br><br>**Final:**<br>MACCE (mortality, reinfarction, emergent CABG, TLR, stroke, stent thrombosis), reinfarction, stroke, TLR (30 d); mortality (30 d, 180 d)<br><br>**Safety:**<br>Coronary dissection, perforation, procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 2. Characteristics and quality assessment of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Lefèvre, 2005 | **Publication type:**<br>Full text, abstract, slide presentation<br><br>**Geographical location:**<br>France, Germany, Italy, Austria, UK, and Spain<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>14<br><br>**Randomization:**<br>Randomly assigned on a 1:1 basis<br><br>**Outcome assessment:**<br>Coronary angiogram, MBG, and ECG analyzed by blinded independent core laboratory<br><br>**Number of participants enrolled:**<br>201 | **Inclusion criteria:**<br>AMI < 12 h, chest pain > 30 min, ST elevation ≥ 2 mm in 2 or more ECG leads, de novo lesion, single vessel treatment in a native vessel ≥ 2.5 mm in diameter, thrombus containing lesion, TIMI 0/1 in IRA, patients amenable to PCI<br><br>**Exclusion criteria:**<br>Saphenous vein graft, LBBB, fibrinolytic treatment, Killip ≥ III, previous PCI in IRA, rescue PCI, IRA with excessive proximal tortuousity or severe calcification, osital lesion, LVEF < 30%, contraindication to emergency CABG, current participation in any other study<br><br>**Intervention:**<br>PCI with X-Sizer catheter system and stenting<br><br>**Comparator:**<br>PCI with balloon angioplasty and/or stenting<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>90% in device group, 94.06% in control group | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 50% (60 min)<br><br>**Final:**<br>MACCE (major adverse cardiac and cerebral events), mortality, TVR, reinfarction, stroke (30 d,180 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 2. Characteristics and quality assessment of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Antoniucci, 2004 | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Computer generated sequence and assignment using a closed envelope system<br><br>**Outcome assessment:**<br>Independent analysis of ECG, scintigrams, and angiograms by investigators unaware of patients' treatment assignments<br><br>**Number of participants enrolled:**<br>100 | **Inclusion criteria:**<br>Chest pain > 30 min, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads<br><br>**Exclusion criteria:**<br>BBB or pacing at baseline, previous MI, fibrinolytic treatment, IRA < 2.5 mm on visual angiography, inability to obtain informed consent<br><br>**Intervention:**<br>PCI with AngioJet<br><br>**Comparator**:<br>Direct IRA stenting only<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>STSR ≥ 50% (30 min)<br><br>**Final:**<br>MACE, mortality, TVR, stroke (30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 2. Characteristics and quality assessment of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Napodano, 2003<br><br>MIRANO | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomly assigned on 1:1 basis<br><br>**Outcome assessment:**<br>Angiographic data analyzed offline by 2 experienced operators blinded to clinical data<br><br>**Number of participants enrolled:**<br>92 | **Inclusion criteria:**<br>AMI within 12 h, chest pain > 30 min, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads, ST-segment depression in right pre-cordial leads, angiographic evidence of intramural thrombus in IRA, TIMI ≤ 2 and /or ≥ 70% diameter stenosis, TS ≥ 2, vessel accessible to X-Sizer<br><br>**Exclusion criteria:**<br>Contraindication to GP2B3Ai and antiplatelets, LBBB, ventricular pacing at baseline, pregnancy, left main stem lesions, IRA diameter < 2.5 mm<br><br>**Intervention:**<br>Thrombectomy with X-Sizer catheter system followed by stenting<br><br>**Comparator:**<br>Conventional stenting<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (at discharge); STSR ≥ 50% (60 min)<br><br>**Final:**<br>Mortality, TVR, reinfarction, stroke (in-hospital, 30 d)<br><br>**Safety:**<br>Side branch occlusion | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; BBB=bundle branch block; CABG=coronary artery bypass graft; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; IRA=infarct related artery; LBBB=left bundle branch block; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MACCE=major adverse cardiac and cerebrovascular events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mm=millimeters; mmHg=millimeters of mercury; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; SBP=systolic blood pressure; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TS=thrombus score; TVR=target vessel revascularization; w=weeks; y=years

Table 3. Characteristics and quality assessment of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Kelbæk, 2008<br><br>DEDICATION | **Publication type:**<br>Full text, abstract, slide presentation<br><br>**Geographical location:**<br>Denmark<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>2<br><br>**Randomization:**<br>Centralized telephone randomization performed by computerized assignment stratified with regard to gender and presence of diabetes<br><br>**Outcome assessment:**<br>Angiographic lesion characteristics were evaluated by independent core laboratory technicians unaware of treatment, commercial software was used to analyze ST-segment data, ECG were analyzed manually<br><br>**Number of participants enrolled:**<br>626 | **Inclusion criteria:**<br>Chest pain > 30 min presenting within 12 h, age ≥18 y, total ST-segment elevation > 4 mm in 2 or more ECG leads, high grade stenosis or occlusion of native coronary artery without excess tortuousity or calcification prohibiting advancement of of filterwire to the distal vascular bed of the vessel<br><br>**Exclusion criteria:**<br>Previous MI in target vessel area, culprit lesion in unprotected left main coronary arteries or saphenous vein grafts, GI bleed in the last month, childbearing potential or pregnancy, known renal failure, life expectancy <1 y, linguistic problems<br><br>**Intervention:**<br>Primary PCI with FilterWire EZ or SpiderX<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>96.79% in device group, 95.86% in control group | **Intermediate:**<br>TIMI-3 (post-procedure) STSR > 70% (90 min)<br><br>**Final:**<br>MACE (mortality, TLR, reinfarction, stroke) (30 d, 240 d); mortality, TLR, reinfarction, stroke (30 d),<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 3. Characteristics and quality assessment of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Cura, 2007<br><br>PREMAIR | **Publication type:**<br>Full text, abstract, slide presentation<br><br>**Geographical location:**<br>Argentina, Chile, Israel<br><br>**Funding:**<br>Partial funding from ev3<br><br>**Number of centers:**<br>20<br><br>**Randomization:**<br>Randomized in a 1:1 ratio according to IRA and physician's intention to use GP2B3Ai<br><br>**Outcome assessment:**<br>ST-segment resolution, reperfusion, EF and angiographic data analyzed in a blinded manner by a core laboratory, clinical events adjudicated by a blinded committee<br><br>**Number of participants enrolled:**<br>140 | **Inclusion criteria:**<br>Continuous chest pain ≥ 30 min and within 12 h of onset , ST-segment elevation ≥ 2 mm in 2 or more ECG leads consistent with AMI, age 21-80 y, referred for primary or rescue PCI, absence of conditions precluding evaluation of ST-segment changes on the admission ECG such as sustained idioventricular rhythm, Wolff-Parkinson-White syndrome, LBBB, ventricular pacemaker, or technically inadequate ECG<br>**Exclusion criteria:**<br>SVG, cardiogenic shock, previous CABG or PCI within 6 m, cardiac tamponade, aortic dissection, myocarditis, known renal failure (Cr > 2 mg/dL), pregnancy, oral anticoagulation, allergy to nitinol, stainless steel, aspirin, or thienopyridibe, TIMI-3 at baseline, culprit lesion < 50% stenosis, vessel ≤ 2.5 mm, left main disease, bifurfication lesion, excessive proximal tortuousity, need for treatment of > 1 vessel during index procedure<br>**Intervention:**<br>PCI with SpiderX<br>**Comparator:**<br>PCI<br>**Duration of followup (d):**<br>180<br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, EF, DE, no reflow (post-procedure); STSR > 70% (60 min)<br><br>**Final:**<br>MACE (mortality, reinfarction, heart failure), mortality, TVR, reinfarction, (30 d,180 d)<br><br>**Safety:**<br>Coronary dissection, perforation, procedure time, side branch occlusion | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 3. Characteristics and quality assessment of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Guetta, 2007<br><br>UPFLOW MI | **Publication type:**<br>Full text, slide presentation<br><br>**Geographical location:**<br>Israel<br><br>**Funding:**<br>Partial funding from Boston Scientific<br><br>**Number of centers:**<br>5<br><br>**Randomization:**<br>Computer-generated, permuted blocks, random sequence by a statistician unknown to the investigators and attending medical team, Patient were given opaque, sealed envelope by statistician who was not involved in the performing the study<br><br>**Outcome assessment:**<br>Angiographic data and ST-segment resolution analyzed offline by an independent angiographic core laboratory<br><br>**Number of participants enrolled:**<br>100 | **Inclusion criteria:**<br>< 24 h of chest pain with ≥ 1 episode of atypical pain lasting > 30 min, ST-segment elevation ≥ 1 mm in 2 ECG leads, age > 21 y, IRA 2.5 - 5.0 mm, coronary artery lesion suitable for PCI and filter device application, coronary artery occlusion or angiographic appearance of fresh thrombus<br><br>**Exclusion criteria:**<br>Culprit lesion in a saphenous vein graft, contradiction to GP2B3Ai, aspirin, clopidogrel, or heparin, cardiogenic shock, inability to obtain informed consent, presumed distal vessel < 2.5 mm, relevant coronary left main involvement, vessel anatomy interfering with safe placement of filter device<br><br>**Intervention:**<br>PCI with FilterWire EZ<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>96.08% in device group, 97.96% in control group | **Intermediate:**<br>MBG-3, TIMI-3, EF (post procedure); STSR > 70% (60 min)<br><br>**Final:**<br>MACE (mortality, nonfatal MI, CHF), mortality, reinfarction (30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 3. Characteristics and quality assessment of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Lefèvre, 2004<br><br>DIPLOMAT | **Publication type:**<br>Abstract, slide presentation<br><br>**Geographical location:**<br>France, Italy<br><br>**Funding:**<br>CORDIS<br><br>**Number of centers:**<br>5<br><br>**Randomization:**<br>Randomized on a 1:1 basis<br><br>**Outcome assessment:**<br>ECG and echocardiography analyzed at a central core laboratory<br><br>**Number of participants enrolled:**<br>60 | **Inclusion criteria:**<br>AMI within 12 h with ST-segment elevation > 2 mm in 2 or more ECG leads, clinical indication for primary PTCA, de novo or restenotic lesions in single native coronary vessel, vessel diameter ≥ 3 and < 5.5 mm, target lesion stenosis > 80%<br><br>**Exclusion criteria:**<br>RBBB or LBBB, fibrinolytic treatment, Killip class IV, unprotected left main with > 50% stenosis in case left coronary artery is treated, ostial target lesion, contraindication to aspirin, heparin, stainless steel or contrast media<br><br>**Intervention:**<br>PCI with Angioguard XP<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>93.75% in device group, 92.86% in control group | **Intermediate:**<br>TIMI-3, DE, no reflow (post-procedure); STSR > 70% (NR)<br><br>**Final:**<br>MACE (mortality + MI), mortality, AMI (30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Partial<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; CABG=coronary artery bypass graft; CHF=congestive heart failure; Cr=creatinine; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GI=gastrointestinal; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; IRA=infarct related artery; LBBB=left bundle branch block; MACE=major adverse cardiac events; MBG=myocardial blush grade; mg/dL= milligrams/deciliter; MI=myocardial infarction; min=minutes; mm=millimeters; NR=not reported; PCI=percutaneous coronary intervention; PTCA= percutaneous transluminal coronary angioplasty; RBBB=right bundle branch block; STSR=ST-segment resolution; SVG=saphenous vein graft; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVR=target vessel revasclarization; y=years

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Tahk, 2008 | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Korea<br><br>**Funding:**<br>Supported in part by Medtronic Inc.<br><br>**Number of centers:**<br>7<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>116 | **Inclusion criteria:**<br>First-time STEMI, chest pain > 30 min, presentation within 12 h after symptom onset, ST-segment elevation > 2 mV in 2 or more ECG leads, reference vessel diameter of target lesion 2.75 - 4.5 mm, diameter stenosis > 70%, lesion length short enough to be covered by a single stent deployment<br><br>**Exclusion criteria:**<br>Saphenous vein or arterial graft lesion, contraindication to GP2B3Ai, cardiogenic shock, pregnancy, LVEF ≤ 25%, left main disease, bifurcation lesion, history of bleeding tendency or coagulopathy, allergy to radiocontrast dye, aspirin, clopidogrel or heparin, co-morbidity with expected survival < 1 y<br><br>**Intervention:**<br>Primary PCI with PercuSurge GuardWire system<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>TMP-3; TIMI-3 (post-procedure); EF (post-procedure, 180 d)<br><br>**Final:**<br>MACE (mortality, reinfarction, ischemia-driven TVR), mortality, TVR, reinfarction (30 d,180 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Hahn, 2007 | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>South Korea<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Coronary angiograms analyzed by 2 blinded observers, MRI analyzed independently by 2 experienced radiologists blinded to the clinical information<br><br>**Number of participants enrolled:**<br>39 | **Inclusion criteria:**<br>Chest pain > 30 min but < 12 h after symptom onset, ST-segment elevation > 1 mm in 2 or more ECG leads or presumably new LBBB, IRA lesion eligible for primary PCI with stenting, distal vessel > 2.5 mm in diameter and suitable for balloon occlusion and aspiration device<br><br>**Exclusion criteria:**<br>Previous MI, hemodynamic instability, requirement for multivessel intervention during index PCI, contraindication to aspirin, clopidogrel or heparin<br><br>**Intervention:**<br>Primary PCI with GuardWire<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (3 d,180 d); STSR > 50% (90 min)<br><br>**Final:**<br>MACE (mortality, MI, TLR), mortality, TLR, reinfarction (180 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Matsuo, 2007<br><br>MICADO | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>14<br><br>**Randomization:**<br>Randomized using envelope method<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>154 | **Inclusion criteria:**<br>STEMI within 24 h after onset with chest pain > 30 min, age ≥ 18 y, ST-segment elevation in 2 or more ECG leads, vascular diameter 3 cm distal to culprit lesion was 3 mm or more, no severe tortuosity or kinks<br><br>**Exclusion criteria:**<br>Severe blood, hepatic, or renal disease with history of internal organ bleeding within the past month, allergy to antiplatelets or anticoagulants, chronic renal failure (Cr 2.6 mg/dL or greater)<br><br>**Intervention:**<br>PCI with GuardWire Plus<br><br>**Comparator:**<br>Conventional PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post procedure); EF (post procedure,180 d); STSR > 70% (30 min)<br><br>**Final:**<br>MACE (mortality, non-lethal MI, heart failure, ischemic-driven revascularization), mortality, TVR, reinfarction (30 d,180 d)<br><br>**Safety:**<br>Procedure time, side branch occlusion | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Muramatsu, 2007<br><br>ASPARAGUS | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>Medtronic Japan Co. Ltd<br><br>**Number of centers:**<br>22<br><br>**Randomization:**<br>Randomized according to envelope method<br><br>**Outcome assessment:**<br>Clinical and basic angiographic data collected and case report forms sent to and reviewed by reviewed by core laboratory<br><br>**Number of participants enrolled:**<br>341 | **Inclusion criteria:**<br>Native vessel, AMI within 12 h of chest pain onset, age ≥ 18 y, ST-segment elevation, patients considered treatable by stenting<br><br>**Exclusion criteria:**<br>SVG, left main trunk disease, reference vessel diameter < 2.5 mm, cardio-pulmonary arrest<br><br>**Intervention:**<br>Primary PCI with GuardWire Plus<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post- procedure); EF (post-procedure, 30 d, 180 d); STSR > 70% (90 min)<br><br>**Final:**<br>MACE (mortality, myocardial infarction or TVR) (30 d, 180 d); mortality, TVR, reinfarction (in-hospital, 30 d, 180 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Zhou, 2007 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>NR<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>Randomized using sealed envelopes<br><br>**Outcome assessment:**<br>TIMI flow grade and MBG evaluated by 2 experienced investigators who were blinded to all clinical data<br><br>**Number of participants enrolled:**<br>112 | **Inclusion criteria:**<br>Continuous chest pain > 30 min, < 12 h from symptom onset, ST-segment elevation ≥ 0.1 mV in 2 or more contiguous ECG leads, culprit lesion with diameter stenosis ≥ 70% and TIMI flow grade ≤ 2<br><br>**Exclusion criteria:**<br>Thrombolytic treatment before PCI, GP2B3Ai before PCI, reference vessel diameter < 3.0 mm, Killip IV or cardiogenic shock, left main coronary artery lesion<br><br>**Intervention:**<br>Primary stenting with PercuSurge GuardWire<br><br>**Comparator:**<br>Primary stenting<br><br>**Duration of followup (d):**<br>In-hospital<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3 (post-procedure)<br><br>**Final:**<br>MACE (in-hospital)<br><br>**Safety:**<br>Coronary dissection, perforation | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Okamura, 2005 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Data assessed using an offline personal computer<br><br>**Number of participants enrolled:**<br>16 | **Inclusion criteria:**<br>Chest pain > 30 min, and presentation ≤ 24 h after symptom onset, ST-segment elevation ≥ 2 mm in 2 or more ECG leads, TIMI 0,1 or 2 on initial angiogram, reference luminal diameter ≥ 3 mm in IRA<br><br>**Exclusion criteria:**<br>Cardiogenic shock, previous CABG, atrial fribrillation<br><br>**Intervention:**<br>PCI with PercuSurge Guidewire<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>In-hospital until discharge, 22 ± 4<br><br>**Followup:**<br>100% | **Intermediate:**<br>TIMI-3 (post-procedure); EF (discharge)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Stone, 2005<br><br>EMERALD | **Publication type:**<br>Full text, abstract, slide presentation<br><br>**Geographical location:**<br>USA, Canada, France, Italy, Germany, Switzerland, Japan<br><br>**Funding:**<br>Medtronic<br><br>**Number of centers:**<br>38<br><br>**Randomization:**<br>Telephone randomization in random blocks of 4 or 6 patients stratified by intention to use GP2B3Ai and by primary versus rescue PCI | **Inclusion criteria:**<br>AMI > 30 min but < 6 h from symptom onset, age ≥ 18 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads or presumably new LBBB, primary or rescue PCI, vessel diameter at the infarct lesion 2.5 - 5.0 mm without excess tortuosity or lesion/vessel calcification with 3 cm or more of distal vessel available<br><br>**Exclusion criteria:**<br>Cardiogenic shock, CABG within 30 d, unprotected left main disease, renal insufficiency (SCr > 2.5 mg/dL), hepatic dysfunction, multivessel intervention required during index PCI, cardiogenic shock, major surgery or active bleeding within 6 wk, allergy to aspirin, thienopyridine or heparin, neutropenia (< 1000 neutrophils/mm$^3$), thrombocytopenia (< 100,000 platelets/mm$^3$), non-cardiac condition with expected survival < 1 y, current participation in another study | **Intermediate:**<br>MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 70% (30 min)<br><br>**Final:**<br>MACE related to ischemic complications, mortality, TVR, reinfarction, stroke (30 d, 180 d);<br><br>**Safety:**<br>Perforation, procedure time, side branch occlusion | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Yes<br>Overall quality rating: Good |

Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| | **Outcome assessment:**<br>STSR by core laboratory, infarct size by a staff blinded to treatment assignment at a central core laboratory and all primary and secondary clinical endpoints adjudicated by a clinical events committee blinded to treatment allocation<br><br>**Number of participants enrolled:**<br>501 | **Intervention:**<br>PCI GuardWire Plus<br><br>**Comparator:**<br>PCI<br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>93.06% in device group and 89.76% in control group | | |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; CABG=coronary artery bypass graft; cm=centimeters; Cr=creatinine; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; IRA=infarct related artery; LBBB=left bundle branch block; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MBG=myocardial blush grade; mg/dL=milligrams/deciliter; MI=myocardial infarction; min=minutes; mm=millimeters; mV=millivolts; MRI=magnetic resonance imaging; NR=not reported; PCI=percutaneous coronary intervention; SCr= serum creatinine; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TMP=TIMI myocardial perfusion; TVR=target vessel revascularization; wk=weeks; y=years

Table 5. Characteristics and quality assessment of randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Haeck, 2009<br><br>PREPARE | **Publication type:**<br>Full text, abstract, slide presentation<br><br>**Geographical location:**<br>Netherlands and Canada<br><br>**Funding:**<br>St. Jude Medical, University of Amsterdam<br><br>**Number of centers:**<br>2<br><br>**Randomization:**<br>Randomized on a 1:1 basis<br><br>**Outcome assessment:**<br>STSR analysis performed by a central core laboratory, coronary angiograms assessed by 2 experienced investigators blinded to all other data, clinical event data obtained from hospital records and telephone interviews<br><br>**Number of participants enrolled:**<br>284 | **Inclusion criteria:**<br>Symptoms of MI < 6 h after onset, persistent ST-segment elevation of ≥ 200 µV in 2 or more contiguous leads, TIMI 0/1 after first angiogram, coronary anatomy suitable for treatment with the Proxis system<br><br>**Exclusion criteria:**<br>Age < 18 y, contraindication to use of GP2B3Ai, co-existent condition with limited life expectancy, prior CABG or lytics, recurrent MI in the same myocardial area, ECG unsuitable for STSR evaluation (LBBB, ventricular pacemaker, atrial fibrillation), left main occlusion, left main stenosis > 30%, heavy proximal calcification, small infarct related artery (< 2.5 mm in diameter), proximal location of lesion with insufficient landing zone for Proxis system (generally < 10-12 mm)<br><br>**Intervention:**<br>Primary PCI with Proxis device<br><br>**Comparator:**<br>Primary PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>89.36% in device group,<br>90.21% in control group | **Intermediate:**<br>MBG-3, TIMI-3, DE (post-procedure); STSR ≥ 70% (60 min)<br><br>**Final:**<br>MACE (death, spontaneous or procedural MI, stroke, percutaneous or surgical TVR), mortality, reinfarction, TVR, stroke (30 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

* Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: CABG=coronary artery bypass graft; d=days; DE=distal embolization; ECG=electrocardiogram; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; LBBB=left bundle branch block; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; mm=millimeters; NR=not reported; PCI=percutaneous coronary intervention; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization; y=years; μV=microvolts

Table 6. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Webster, 2008<br><br>A-F Trial | **Publication type:**<br>Slide presentation<br><br>**Geographical location:**<br>Canada, Australia, New Zealand<br><br>**Funding:**<br>Boston Scientific<br><br>**Number of centers:**<br>14<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Unblinded design, core laboratories for ECG and angiographic data<br><br>**Number of participants enrolled:**<br>151 | **Inclusion criteria:**<br>NSTEMI ACS with high risk features during 24 h prior to angiography (elevated troponin, angina at rest, dynamic ST or T-wave changes, not ST-segment elevation MI), culprit lesion with 2 or more high risk angiographic features (intra-coronary filling deficit consistent with thrombus, lesion ulceration, eccentric shape, irregular or scalloped border, abrupt edges to lesion, lesion length > 20 mm)<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with distal filter embolic protection using BSC FilterWire EZ<br><br>**Comparator:**<br>Standard PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>TIMI-3 (post-procedure)<br><br>**Final:**<br>MACE (mortality, recurrent MI, emergency CABG, repeat TVR) (in-hospital, 30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Cant' tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

Table 6. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Dudek, 2003 | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Poland<br><br>**Funding:**<br>Paper sponsored by Komitet Badan Naukowych (Scientific Research Committee)<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>31 | **Inclusion criteria:**<br>Consent to participate, unstable angina, patient qualified to single vessel coronary angioplasty with the use of stent in the vessel > 3 mm in diameter, no contraindications to GP2B3Ai<br><br>**Exclusion criteria:**<br>Recent STEMI, LVEF< 30%, complete closing of the vessel, cancer, impaired liver and kidney function, increased transferases (> 3 times the max normal values), muscle diseases, CK-MB level above normal at baseline, age > 75 y, alcohol abuse, hypersensitivity to used medication, continuation of treatment to cyclosporine and other immunosuppressant drugs, pregnancy and breast feeding<br><br>**Intervention:**<br>PCI with distal filter embolic protection using Angioguard<br><br>**Comparator:**<br>Angioplasty supported by pharmacotherapy<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>TIMI-3, no reflow (post-procedure)<br><br>**Final:**<br>Mortality, TVR, reinfarction (30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: ACS=Acute coronary syndrome; CABG=coronary artery bypass graft; CK-MB=creatinine kinase MB-isoenzyme; d=days; ECG=electrocardiogram; GP2B3Ai=glycoprotein IIb IIIa inhibitor; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MI=myocardial infarction; mm=millimeters; NR=not reported; NSTEMI=non-ST-segment elevation myocardial infarction; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; TIMI=Thrombolysis myocardial infarction; TVR=target vessel revascularization; y=years

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Parikh, 2008<br><br>RAPID | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>India<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization**:<br>Randomly divided into 2 groups depending on whether PercuSurge was used or not<br><br>**Outcome assessment**:<br>Coronary angiograms reviewed by 2 independent cardiologists unaware of the patients' medical histories and details<br><br>**Number of participants enrolled:**<br>67 | **Inclusion criteria:**<br>AMI patients with angiographically detected thrombotic lesions who were to undergo primary/rescue PCI within 24 h of onset of chest pain<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with distal balloon embolic protection using PercuSurge GuardWire Plus Temporary Occlusion and Aspiration System<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>720<br><br>**Followup:**<br>100% | **Intermediate:**<br>TMP-3, TIMI-3, DE, no reflow (post-procedure)<br><br>**Final:**<br>Mortality (730 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Fair |

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Gick, 2005<br><br>PROMISE | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Germany<br><br>**Funding:**<br>Boston Scientific<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomization sequence set in blocks of 20 by statistician, unknown to the investigators and medical staff | **Inclusion criteria:**<br>Both at least 1 episode of typical angina pain > 30 min within the preceding 48 h and coronary artery lesion deemed suitable for stent placement and application of filter wire plus at least one of the following: ST-segment elevation ≥ 1 mm in 2 or more ECG leads, elevation of creatinine kinase ≥ 3 times the upper limit with concomitant rise of MB isoenzyme, coronary artery occlusion with angiographic appearance of fresh thrombus<br><br>**Exclusion criteria:**<br>Presumed distal vessel diameter < 3 mm, relevant coronary left main involvement, vessel anatomy interfering with safe placement of filterwire, culprit lesion in saphenous vein graft, contraindication to abxicimab, aspirin, clopidogrel, or heparin, mechanical ventilation or inotropic support, inability to give informed consent | **Intermediate:**<br>MBG > 1, TIMI-3, DE (post-procedure); EF (3 d,180 d)<br><br>**Final:**<br>MACE (180 d); mortality, reinfarction (30 d,180 d); TVR, stroke (30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| | **Outcome assessment:**<br>MRI images examined by 2 experienced observers who were unaware of the patients' group assignment, angiographic images analyzed offline by independent core laboratory<br><br>**Number of participants enrolled:**<br>200 | **Intervention:**<br>PCI with distal filter embolic protection using FilterWire EX<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | | |
| Sardella, 2005 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>NR<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>62 | **Inclusion criteria:**<br>Anterior MI undergoing primary PCI of de novo coronary lesions with angiographic presence of intracoronary thrombus<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with catheter aspiration using Diver-Invatec plus stenting<br><br>**Comparator:**<br>Conventional coronary stenting<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>NR | **Intermediate:**<br>MBG-3, TIMI-3 (post procedure)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Kunii, 2004<br><br>NONSTOP | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>258 | **Inclusion criteria:**<br>< 24 h of symptom onset, lesion diameter > 2.5 mm, no severe calcification at or proximal to the lesion, no proximal tortuosity preventing Rescue use or stent delivery, no cardiogenic shock, no left main disease<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with catheter aspiration using Rescue PT catheter<br><br>**Comparator:**<br>Primary stenting<br><br>**Duration of followup (d):**<br>In-hospital<br><br>**Followup:**<br>NR | **Intermediate:**<br>TIMI-3 (post-procedure)<br><br>**Final:**<br>Mortality (in-hospital)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Nanasato, 2004 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>64 | **Inclusion criteria:**<br>AMI within 12 h of onset<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with distal balloon embolic protection using GuardWire Plus<br><br>**Comparator:**<br>Conventional PCI<br><br>**Duration of followup (d):**<br>In-hospital<br><br>**Followup:**<br>NR | **Intermediate:**<br>MBG-3, TIMI-3, EF, (post procedure)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Can't tell<br>6. Was the overall loss to followup low (< 30%)? Can't tell<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Matsushita, 2003 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>80 | **Inclusion criteria:**<br>First anteroseptal MI undergoing coronary intervention and stenting within 12 h from onset of MI and who had coronary blood flow measurements immediately after the procedure<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with balloon distal embolic protection using Guard Wire PercuSurge system<br><br>**Comparator:**<br>PCI<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% for MACE and mortality | **Intermediate:**<br>NR<br><br>**Final:**<br>MACE (180 d); mortality (in-hospital)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Can't tell<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Can't tell<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Beran, 2002 | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Austria<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomized on a 1:1 basis<br><br>**Outcome assessment:**<br>Angiographic measurements were performed by 2 experienced observers who were blinded to randomization, ECG recording were analyzed by 2 observers blinded to randomization and angiographic findings<br><br>**Number of participants enrolled:**<br>61 | **Inclusion criteria:**<br>STEMI with chest pain > 30 min and ST-segment elevation > 1 mm 2 or more ECG leads, patients with UA were allowed if presented with recurrent chest pain at rest associated with ST-segment or T-wave changes, native vessel occlusion or intraluminal filling defect<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>Mechanical thrombectomy with X-Sizer followed by stenting or PTCA<br><br>**Comparator:**<br>PTCA or stenting<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>90.19% in device group and 93.94% in control group | **Intermediate:**<br>TIMI-3, STSR > 50% (post-procedure)<br><br>**Final:**<br>MACE, mortality, TVR (30 d)<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)?Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIb IIIa inhibitor; h=hours; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mm=millimeters; MRI=magnetic resonance imaging; NR=not reported; PCI=percutaneous coronary intervention; PTCA=percutaneous transluminal coronary angioplasty; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TMP=TIMI myocardial perfusion; TVR=target vessel revascularization; UA=unstable angina

Table 8. Characteristics and quality assessment of direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Sardella, 2008<br><br>RETAMI | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Italy<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomly assigned in a 1:1 basis<br><br>**Outcome assessment:**<br>Coronary angiograms analyzed offline by 2 expert interventional cardiologists in a blinded manner<br><br>**Number of participants enrolled:**<br>103 | **Inclusion criteria:**<br>STEMI (chest pain > 30 min and new ST-segment elevation ≥ 2 mm in 2 or more contiguous ECG leads) within 12 h of symptom onset, de novo coronary lesion, occluded single native vessel ≥ 2.5 mm in diameter, angiographically identifiable thrombus (filling defect within the coronary lumen surrounded by contrast medium observed in multiple projections, without calcium within the filling defect or persistence of contrast medium within the coronary lumen), TIMI flow grade 0-1 and age > 18 y<br><br>**Exclusion criteria:**<br>Previous PCI on IRA, rescue PCI, previous MI or CABG and current participation in another study<br><br>**Intervention:**<br>Primary PCI with catheter aspiration using Diver-Invatec<br><br>**Comparator:**<br>Primary PCI with catheter aspiration using Export-Medtronic<br><br>**Duration of followup (d):**<br>365<br><br>**Followup:**<br>100% | **Intermediate:**<br>MGB-3, TIMI-3 (post-procedure); STSR > 70% (90 min)<br><br>**Final:**<br>MACE (cardiac death, Q and non-Q-wave MI, TVR), TVR, reinfarction (30 d, 365 d)<br><br>**Safety:**<br>Coronary dissection, perforation | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table8. Characteristics and quality assessment of direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Yan, 2007 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>China<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomly assigned on a 1:1 basis according to a computer generated random series of number<br><br>**Outcome assessment:**<br>Coronary angiograms reviewed offline by 2 experienced observers who were blinded to randomization<br><br>**Number of participants enrolled:**<br>122 | **Inclusion criteria**:<br>Symptoms > 30 min but < 12 h, ST segment elevation ≥ 2 mV in 2 or more contiguous inferior ECG leads and total occlusion of the left coronary artery<br><br>**Exclusion criteria:**<br>LBBB, previous MI within last 30 d, fibrinolytic treatment , previous CABG, left main stenosis, need for mechanical ventilation, severe heart failure treated with IABP and tortuous IRA unsuitable for thrombectomy<br><br>**Intervention:**<br>PCI with catheter aspiration using Diver CE<br><br>**Comparator:**<br>PCI with distal balloon embolic protection using Guardwire Plus<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG > 2, TIMI-3, no reflow/slow flow (post-procedure); STSR > 70% (90 min); EF (30 d)<br><br>**Final:**<br>MACE (mortality, MI, TVR, stroke), mortality, TVR, reinfarction, stroke (30 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: CABG=coronary artery bypass graft; d=days; ECG=electrocardiogram; EF=ejection fraction; h=hours; IABP=intra-aortic balloon pump; IRA=infarct related artery; LBBB=left bundle branch block; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization; y=years

Table 9. Characteristics and quality assessment of randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Wita, 2009 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Poland<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomized on a 1:1 basis<br><br>**Outcome assessment:**<br>Quantitative analysis of all images by 1 investigator blinded to the type of procedure, using a quantitative analysis tool<br><br>**Number of participants enrolled:**<br>42 | **Inclusion criteria:**<br>Age > 18 y, chest pain > 20 min in conjunction with persistent ST-segment elevation in the precordial leads, LAD closure (TIMI-0), restored blood flow after PCI (TIMI-3) within 12 h from MI onset<br><br>**Exclusion criteria:**<br>Cardiogenic shock, history of previous MI, hypertrophic cardiomyopathy, significant valvular disease, lack of IRA identification, residual stenosis after PCI > 50%, electrical instability, ICD or pacemaker , or females of child bearing potential<br><br>**Intervention:**<br>Catheter aspiration using Diver CE flowed by stenting<br><br>**Comparator:**<br>Stenting<br><br>**Duration of followup (d):**<br>30<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG 2-3 (post-procedure); EF (7 d, 30 d)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Yes<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 9. Characteristics and quality assessment of randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Ozaki, 2006 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomized using envelope method<br><br>**Outcome assessment:**<br>3 or more cardiologists evaluated the success or failure of acute stage coronary angiography, a data processing super computer was used for analysis of SPECT data<br><br>**Number of participants enrolled:**<br>77 | **Inclusion criteria:**<br>Chest pain ≥ 30 min, ST-segment elevation ≥ 1 mm on 2 or more contiguous ECG leads, plasma creatinine level ≥ 2 times higher than normal value, abnormalities in the left ventricular wall motion on ECHO, ≤ 6 h of symptom onset<br><br>**Exclusion criteria:**<br>Fibrinolytic treatment with tissue plasminogen activator or urokinase before admission, cardiogenic shock, contraindication to aspirin or ticlopidine, coronary no-reflow/slow flow and chronic stage restenosis<br><br>**Intervention A:**<br>Stent insertion after catheter aspiration using Rescue system or Thrombuster system<br><br>**Intervention B:**<br>Stent insertion after distal balloon embolic protection using PercuSurge GuardWire catheter<br><br>**Comparator:**<br>Direct stent<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>80% in Rescue/Thrombuster group, 83.3% in the PercuSurge GuardWire group, 71.43% in the direct stenting group | **Intermediate:**<br>EF (180 d)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? No<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? No<br>6. Was the overall loss to followup low (< 30%)? No<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Fair |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: d=days; ECG=electrocardiogram; ECHO=echocardiogram; EF=ejection fraction; h=hours; ICD=implantable cardioverter-defibrillator; IRA=infarct related artery; LAD=left anterior descending artery; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mm=millimeters; NR=not reported; PCI=percutaneous coronary intervention; SPECT=single-photon emission computerized tomography; TIMI=thrombolysis in myocardial infarction; y=years

Table 10. Characteristics and quality assessment of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Yamamoto, 2006 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>Randomly assigned using the envelope method<br><br>**Outcome assessment:**<br>TMP grade assessed by single observer who was blinded to the treatment assignment and clinical outcome<br><br>**Number of participants enrolled:**<br>44 | **Inclusion criteria:**<br>First onset STEMI, no contraindication to mutant plasminogen activator<br><br>**Exclusion criteria:**<br>Age > 75 y, presence of active bleeding (intracranium, GI or urinary tract), intracranial lesion (tumor, aneurysm, AV malformation), intracranial/spinal surgery or injury within 2 m, persistent BP > 180 mmHg systolic or > 100 mmHg diastolic, post cardiopulmonary resuscitation<br><br>**Intervention:**<br>PCI with catheter aspiration using Thrombuster and mutant tissue plasminogen activator<br><br>**Comparator:**<br>PCI with catheter aspiration using Thrombuster<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>TMP-3, TIMI-3 (post-procedure); EF (1-3 d, 180 d)<br><br>**Final:**<br>Mortality, TVR reinfarction, stroke (180 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Yes<br><br>Overall quality rating: Good |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; AV=arteriovenous; BP=blood pressure; CK-MB=creatinine kinase MB-isoenzyme; d=days; EF=ejection fraction; GI=gastrointestinal; h=hours; IRA=infarct related artery; m=months; MBG=myocardial blush grade; MI=myocardial infarction; mm=millimeters; mmHg=millimeters of mercury; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; TIMI=thrombolysis in myocardial infarction; TMP=TIMI myocardial perfusion; TVR=target vessel revascularization; y=years

Table 11. Characteristics and quality assessment of randomized controlled trials with unique comparisons in patients with mixed acute coronary syndrome

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Ochala, 2007 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>Poland<br><br>**Funding:**<br>KBN Grant<br><br>**Number of centers:**<br>NR<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>Angiographic data analysis by independent investigator<br><br>**Number of participants enrolled:**<br>120 | **Inclusion criteria:**<br>AMI < 12 h referred for primary PCI, ≥ 2 or 3 signs/symptoms of AMI (typical clinical symptom, new ST-segment elevation in at least 2 adjacent leads ≥ 0.2 mV in $V_1$-$V_2$ and 0.1mV in other leads, elevation of troponin / CK-MB levels above MI cut-off values), critical stenosis or total occlusion of IRA and reference diameter of IRA distally to occlusion between 3.0 - 4.5 mm<br><br>**Exclusion criteria:**<br>Lack of patients' informed consent, critical stenosis of left main artery, complex occlusive lesion (> 20 mm length or in the segment bent at $90^0$ or incorporating ostium of a large side branch > 2 mm in diameter), cardiogenic shock, respiratory distress requiring intubation, previous PCI in the culprit artery, previous surgical myocardial revascularization, contraindication to abxicimab, aspirn, clopidogrel or heparin, critical lesions in other segments of coronary arteries requiring revascularization within 6 m,, valvular disease requiring surgical intervention<br><br>**Intervention:**<br>Primary PCI with distal balloon embolic protection using PercuSurge device<br><br>**Comparator:**<br>Primary PCI with abciximab<br><br>**Duration of followup (d):**<br>180<br><br>**Followup:**<br>100% | **Intermediate:**<br>MBG-3, TIMI-3 (post-procedure); EF (180 d)<br><br>**Final:**<br>Mortality (death /cardiovascular death), TVR, reinfarction (180 d)<br><br>**Safety:**<br>Procedure time | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Yes<br>3. Were outcome assessors blind to exposure/intervention status? Partially<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? Yes<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Good |

Table 11. Characteristics and quality assessment of randomized controlled trials with unique comparisons in patients with mixed acute coronary syndrome

| Study, Year | Trial Characteristics | Population, Interventions and Followup* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Kanaya, 2003 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Japan<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Randomization:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>60 | **Inclusion criteria:**<br>AMI within 12 h of symptom onset<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>Thrombectomy and stenting with distal protection method<br><br>**Comparator:**<br>Thrombectomy and stenting<br><br>**Duration of followup (d):**<br>In-hospital<br><br>**Followup:**<br>100% | **Intermediate:**<br>TIMI-3 (post-procedure)<br><br>**Final:**<br>NR<br><br>**Safety:**<br>NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes<br>2. Were outcomes assessed using a valid methodology and criteria? Can't tell<br>3. Were outcome assessors blind to exposure/intervention status? Can't tell<br>4. Were incomplete outcome data adequately addressed? Yes<br>5. Was the differential loss to followup between the compared groups low (< 10%)? Yes<br>6. Was the overall loss to followup low (< 30%)? Yes<br>7. Conflict of interest reported and insignificant? No<br>8. Were the methods used for randomization adequate? Can't tell<br><br>Overall quality rating: Poor |

*Duration of followup is reported as the original study's longest reported followup and followup is reported for the study's pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; d=days; h=hours; NR=not reported; TIMI=thrombolysis in myocardial infarction

Table 12. Characteristics and quality assessment of controlled observational studies

| Study, Year | Study Characteristics | Population, Intervention, and Followup | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Ko, 2009<br><br>KAMIR | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>Korea<br><br>**Study design:**<br>Registry<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>NR<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>1050 | **Inclusion criteria:**<br>Acute STEMI, PCI within 3 h of symptom onset<br><br>**Exclusion criteria:**<br>NR<br><br>**Intervention:**<br>PCI with distal protection device (device name NR)<br><br>**Comparator:**<br>PCI without distal protection device<br><br>**Duration of followup (d):**<br>365<br><br>**Covariates/potential confounders adjusted for:**<br>NR, subgroup analyses based on LV dysfunction and use of GP2B3Ai | **Intermediate:**<br>NR<br><br>**Final:**<br>MACE (365 d)<br><br>**Safety:**<br>NR | 1. Unbiased selection of the cohort? Partially<br>2. Selection minimizes baseline differences in prognostic factors? Yes<br>3. Sample size calculated? No<br>4. Adequate description of the cohort? No<br>5. Validated method to ascertain exposure? Yes<br>6. Validated method for ascertaining clinical outcomes? Can't tell<br>7. Outcome assessment blinded to exposure? Can't tell<br>8. Adequate followup period? Yes<br>9. Completeness of followup? Yes<br>10. Analysis controls for confounding? Yes<br>11. Analytic methods appropriate? Yes<br><br>Overall quality rating: Poor |

Table 12. Characteristics and quality assessment of controlled observational studies (continued)

| Study, Year | Study Characteristics | Population, Intervention, and Followup | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Nilsen, 2009 | **Publication type:**<br>Abstract<br><br>**Geographical location:**<br>NR<br><br>**Study design:**<br>Retrospective cohort<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>123<br><br>**Outcome assessment:**<br>Core lab analysis[1]<br><br>**Number of participants enrolled:**<br>3298, 3233[1] | **Inclusion criteria:**<br>See table 2 of original study[2]<br><br>**Exclusion criteria:**<br>See table 2 of original study[2]<br><br>**Intervention:**<br>PCI with catheter aspiration (Device name NR)<br><br>**Comparator:**<br>PCI without catheter aspiration<br><br>**Duration of followup (d):**<br>30<br><br>**Covariates/potential confounders adjusted for:**<br>NR | **Intermediate:**<br>DE[1], (post-procedure); STSR > 70%[1](60 min)<br><br>**Final:**<br>MACE (mortality, reinfarction, ischemic TVR, stroke), mortality, reinfarction, ischemic TVR, stroke (30 d)<br><br>**Safety:**<br>Dissection[1] | 1. Unbiased selection of the cohort? Yes<br>2. Selection minimizes baseline differences in prognostic factors? Yes<br>3. Sample size calculated? No<br>4. Adequate description of the cohort? No<br>5. Validated method to ascertain exposure? Yes<br>6. Validated method for ascertaining clinical outcomes? Can't tell<br>7. Outcome assessment blinded to exposure? Yes<br>8. Adequate followup period? Yes<br>9. Completeness of followup? Yes<br>10. Analysis controls for confounding? Yes<br>11. Analytic methods appropriate? Yes<br><br>Overall quality rating: Fair |

Table 12. Characteristics and quality assessment of controlled observational studies (continued)

| Study, Year | Study Characteristics | Population, Intervention, and Followup | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Nakatani, 2007<br><br>OACIS | **Publication type:**<br>Full text, abstract<br><br>**Geographical location:**<br>Japan<br><br>**Study design:**<br>Prospective registry<br><br>**Funding:**<br>Government (Japanese Ministry of Education, Culture, Sports, Sciences, and Technology); Foundation (Japan Arteriosclerosis Prevention Fund)<br><br>**Number of centers:**<br>25<br><br>**Outcome assessment:**<br>NR<br><br>**Number of participants enrolled:**<br>3913 | **Inclusion criteria:**<br>Undergoing PCI, AMI/symptoms within 24 h<br><br>**Exclusion criteria:**<br>Admittance > 24 h (or time unknown) after onset of AMI, treated conservatively, with thrombolytic therapy, emergent CABG, or with distal protection<br><br>**Intervention:**<br>PCI with catheter aspiration (RESCUE catheter, Thrombuster catheter, TVAC catheter, Export PercuSurge System)<br><br>**Comparator:**<br>PCI without catheter aspiration<br><br>**Duration of followup (d):**<br>30<br><br>**Covariates/potential confounders adjusted for:**<br>Mortality adjusted for hospital volume, age, male gender, diabetes mellitus, hypertension, hyperlipidemia, smoking, body mass index ≥ 25 kg/m$^2$, a history of myocardial infarction, preangina, Killip class ≥ II, ST-segment elevation myocardial infarction, onset to admission < 12 h, angiographic findings (including multivessel disease, collateral circulation, and initial TIMI grade flow), use of stenting | **Intermediate:**<br>NR<br><br>**Final:**<br>Mortality (cardiac and non-cardiac) (30 d)<br><br>**Safety:**<br>NR | • Unbiased selection of the cohort? Yes<br>• Selection minimizes baseline differences in prognostic factors? Yes<br>• Sample size calculated? No<br>• Adequate description of the cohort? Yes<br>• Validated method to ascertain exposure? Yes<br>• Validated method for ascertaining clinical outcomes? Yes<br>• Outcome assessment blinded to exposure? Can't tell<br>• Adequate followup period? Yes<br>• Completeness of followup? Yes<br>• Analysis controls for confounding? Yes<br>• Analytic methods appropriate? Yes<br><br>Overall quality rating: Fair |

Table 12. Characteristics and quality assessment of controlled observational studies (continued)

| Study, Year | Study Characteristics | Population, Intervention, and Followup | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Chinnaiyan, 2006 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>NR<br><br>**Study design:**<br>Retrospective cohort<br><br>**Funding:**<br>NR<br><br>**Number of centers:**<br>1<br><br>**Outcome assessment:**<br>Examined according to whether patient received mechanical thrombectomy or not<br><br>**Number of participants enrolled:**<br>1260 | **Inclusion criteria:**<br>Undergoing primary or rescue PCI, symptoms consistent with AMI lasting < 24 h, ST-segment elevation ≥ 1 mm in two contiguous leads<br><br>**Exclusion criteria:**<br>SVG culprit, stent thrombosis<br><br>**Intervention:**<br>PCI with mechanical thrombectomy (AngioJet XMI or XVG catheter)<br><br>**Comparator:**<br>PCI without mechanical thrombectomy<br><br>**Duration of followup (d):**<br>In-hospital<br><br>**Covariates/potential confounders adjusted for:**<br>MACE and mortality adjusted for baseline clinical and angiographic characteristics | **Intermediate:**<br>TIMI-3 (post-procedure)<br><br>**Final:**<br>MACE (mortality, reinfarction, TVR, stroke), mortality, TVR, stroke, reinfarction (in-hospital)<br><br>**Safety:**<br>Coronary artery perforation | 1. Unbiased selection of the cohort? Yes<br>2. Selection minimizes baseline differences in prognostic factors? Yes<br>3. Sample size calculated? No<br>4. Adequate description of the cohort? Yes<br>5. Validated method to ascertain exposure? Yes<br>6. Validated method for ascertaining clinical outcomes? Yes<br>7. Outcome assessment blinded to exposure? No<br>8. Adequate followup period? Yes<br>9. Completeness of followup? Yes<br>10. Analysis controls for confounding? Yes<br>11. Analytic methods appropriate? Yes<br><br>Overall quality rating: Fair |

Table 12. Characteristics and quality assessment of controlled observational studies (continued)

| Study, Year | Study Characteristics | Population, Intervention, and Followup | Outcomes of Interest (Timing) | Quality Assessment / Comments |
|---|---|---|---|---|
| Simonton, 2006 | **Publication type:**<br>Full text<br><br>**Geographical location:**<br>United States<br><br>**Study design:**<br>Prospective registry<br><br>**Funding:**<br>Unknown<br><br>**Number of centers:**<br>9<br><br>**Outcome assessment:**<br>Patient contact by phone for clinical outcome assessment, physician adjudicated MACE events, routine data audits<br><br>**Number of participants enrolled:**<br>1368 | **Inclusion criteria:**<br>Undergoing PCI, TIMI thrombus grade ≥ 3, 9 m followup available, no use of distal protection device<br><br>**Exclusion criteria:**<br>Inability to provide informed consent<br><br>**Intervention:**<br>PCI with mechanical thrombectomy (AngioJet)<br><br>**Comparator:**<br>PCI without mechanical thrombectomy or distal protection<br><br>**Duration of followup (d):**<br>270<br><br>**Covariates/potential confounders adjusted for:**<br>Unadjusted | **Intermediate:**<br>TIMI-3 (post-procedure)<br><br>**Final:**<br>MACE (mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event), mortality, TVR, MI (270 d)<br><br>**Safety:**<br>NR | 1. Unbiased selection of the cohort? Yes<br>2. Selection minimizes baseline differences in prognostic factors? Yes<br>3. Sample size calculated? No<br>4. Adequate description of the cohort? No<br>5. Validated method to ascertain exposure? Yes<br>6. Validated method for ascertaining clinical outcomes? Yes<br>7. Outcome assessment blinded to exposure? Can't tell<br>8. Adequate followup period? Yes<br>9. Completeness of followup? Yes<br>10. Analysis controls for confounding? No<br>11. Analytic methods appropriate? No<br><br>Overall quality rating: Poor |

Abbreviations: AMI=acute myocardial infarction; CABG=coronary artery bypass graft; d=days; DE=distal embolization; h=hours; GP2B3Ai=glycoprotein IIb IIIa inhibitor; Kg/m2=kilogram-meter squared; LV=left ventricular; m=months; MACE=major adverse cardiac events; MI=myocardial infarction; min=minutes; mm=millimeter; NR=not reported; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft ; TVAC=transvacular aspiration catheter; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization

Table 13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Mongeon, 2010 | **Number of studies (participants):**<br>Overall analysis: 21 (4299)<br>Aspiration-only analysis: 16 (3365)<br><br>**Study design(s) included:**<br>RCTs only (full text and abstracts)<br><br>**Literature search:**<br>Undefined electronic databases; reference review; international meeting program review; updated thru October 2009<br><br>**Languages:**<br>English, French<br><br>**Statistical methods:**<br>Bayesian random-effects model | **Population:**<br>Primary and rescue PCI in STEMI only<br><br>**Intervention:**<br>PCI with catheter aspiration or mechanical thrombectomy<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality, MACE (mortality, MI or stroke) (30 d); TIMI-3, TMPG 3, no reflow, DE, and STSR ≥ 50% (post-procedure); procedure time, STBT | **Overall analysis**<br>**Intermediate:**<br>TIMI-3: OR 1.38 (0.97 to 2.01)<br>TMPG-3: OR 2.50 (1.48 to 4.41)<br>No reflow: OR 0.39 (0.18 to 0.69)<br>DE: OR 0.46 (0.28 to 0.70)<br>STSR ≥ 50%: OR 2.22 (1.60 to 3.23)<br><br>**Final:**<br>Mortality : OR 0.94 (0.47 to 1.80)<br>MACE: OR 1.07 (0.63 to 1.92)<br><br>**Safety:**<br>PT (min): 5.8 (-29.2 to 40.6)<br>STBT (min): -12.8 (-116.4 to 91.4)<br><br>**Aspiration-only analysis**<br>**Intermediate:**<br>TIMI-3: OR 1.49 (1.14 to 1.99)<br>TMPG-3: OR 3.04 (1.74 to 5.78)<br>No-reflow: OR 0.36 (0.11 to 0.88)<br>DE: OR 0.47 (0.25 to 0.87)<br>STSR ≥ 50%: OR 2.24 (1.53 to 3.46)<br><br>**Final:**<br>Mortality: OR 0.58 (0.28 to 1.22)<br>MACE: OR 0.75 (0.42 to 1.52)<br><br>**Safety:**<br>PT (min): 2.2 (-75.6 to 80.2)<br>STBT (min): -13.2 (-166.3 to 138.0) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Can't answer<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? No<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? No<br>11. Was the conflict of interest stated? No<br><br>Total 'Yes' responses (out of 11): 6 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Tamhane, 2010 | **Number of studies (participants):**<br>Overall analysis: 17 (3909)<br>Manual Aspiration-only analysis*: 9 (2114)<br>Vacuum Aspiration-only analysis*: 4 (911)<br>Mechanical Aspiration-only analysis*: 5 (934)<br>**Study design included:**<br>RCTs only (full-text, abstracts, and expert slide presentations)<br>**Literature search:**<br>MEDLINE, Google Scholar, Embase, ISI Web of Knowledge, Current Contents, International Pharmaceutical Abstracts databases and the Cochrane Central Register of Randomized controlled trial from 1996 through December 2009. Abstracts from 2005 through 2009 scientific meetings of the AHA, the ACC, the ESC, published review articles, editorials, and internet-based sources (www.cardiosource.com, www.tctmd.com, www.crtonline.com, www.theherat.org, www.medscape.com)<br>**Languages:**<br>Not specified<br>**Statistical methods:**<br>Used both fixed- and random-effects models to produce across-study summary odds ratios with 95% confidence intervals however random-effect models were preferentially reported due to significant heterogeneity, although fixed-effects models gave similar results | **Population:**<br>STEMI only<br><br>**Intervention:**<br>PCI with catheter aspiration or mechanical thrombectomy<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality, stroke, TVR, reinfarction (30 d); STSR > 70%; TIMI-3, MBG-0/1, MBG-3 (post-procedure) | **Overall Analysis**<br>**Intermediate:**<br>TIMI-3: OR 1.41 (1.10 to 1.81)<br>MBG-0/1: OR 0.51 (0.32 to 0.82)<br>MBG-3: OR 2.42 (1.63 to 3.61)<br>STSR > 70%: OR 2.30 (1.64 to 3.23)<br>**Final:**<br>Mortality : OR 0.84 (0.54 to 1.29)<br>Stroke: OR 2.88 (1.06 to 7.85)<br>TVR: OR 0.92 (0.57 to 1.49)<br>Reinfarction: OR 0.59 (0.29 to 1.22)<br>**Manual Aspiration-only analysis***<br>**Intermediate:**<br>MBG-3: OR 2.30 (1.90 to 2.79)<br>TIMI-3: OR 1.50 (1.17 to 1.92)<br>STSR > 70%: OR 1.95 (1.62 to 2.34)<br>**Final:**<br>Mortality : OR 0.59 (0.35 to 1.01)<br>Stroke: OR 2.84 (0.51 to 15.65)<br>**Vacuum Aspiration -only analysis***<br>**Intermediate:**<br>MBG-3: OR 3.01 (1.98 to 4.60)<br>TIMI-3: OR 1.49 (0.99 to 2.23)<br>STSR > 70%: OR 1.80 (1.01 to 3.18)<br>**Final:**<br>Mortality : OR 0.75 (0.18 to 3.05)<br>Stroke: OR 5.05 (0.24 to 106.37)<br>**Mechanical-only analysis***<br>**Intermediate:**<br>MBG-3: OR 1.06 (0.78 to 1.45)<br>TIMI-3: OR 0.79 (0.43 to 1.45)<br>STSR > 70%: OR 1.40 (1.02 to 1.91)<br>**Final:**<br>Mortality : OR 2.07 (0.95 to 4.48)<br>Stroke: OR 2.61 (0.68 to 10.09) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? Yes<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? Yes<br><br>Total 'Yes' responses (out of 11): 11 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Burzotta, 2009 and De Vita, 2009 | **Number of studies (participants):**<br>Overall analysis:11 (2686)<br><br>**Study design(s) included:**<br>RCTs only (full-text, abstracts, and expert slide presentations)<br><br>**Literature search:**<br>Systematic MEDLINE database search (www.ncbi.nlm.nih.gov) according to a modified Robinson and Dickersin strategy. TCT (http://www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (http://www.americaheart.org), and ESC (www.escardio.org) websites searched for pertinent abstracts and expert slides presentations between October 2003 and February 2008<br><br>**Languages:**<br>No restrictions<br><br>**Statistical methods:**<br>Individual patient-data meta-analysis. Peto fixed effects method for patient-level analysis (according to event counts reported at the longest available followup) as well as a random effect method with generic inverse variance weighting (according to risk estimates obtained with Cox proportional hazard analysis). Peto fixed effects method results reported. | **Population:**<br>STEMI only<br><br>**Intervention:**<br>PCI with catheter aspiration or mechanical thrombectomy<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>TLR/TVR, MI, mortality, MACE (all-cause mortality, TLR/TVR, MI) and mortality + MI (longest available clinical outcome) | **Final:**<br>TLR/TVR: OR 0.87 (0.67 to 1.12)<br>MI: OR 0.72 (0.47 to 1.10)<br>Mortality : OR 0.71 (0.49 to 1.00)<br>Mortality + MI: OR 0.70 (0.52 to 0.93)<br>MACE: OR 0.80 (0.65 to 0.98) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? No<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? No<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? Yes<br><br>Total 'Yes' responses (out of 11): 9 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Inaba, 2009 | **Number of studies (participants):**<br>Overall analysis: 25 (5919)<br>Aspiration-only analysis: 10 (2656)<br>Mechanical-only analysis: 5 (934)<br>Embolic Protection-only analysis: 10 (2329)<br>**Study design(s) included:**<br>RCTs only (full-text, oral presentations, and expert slide presentations)<br>**Literature search:**<br>Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process & other Non-Indexed Citations, Cochrane Central Register of Randomized controlled trial, and Cochrane Database of Systematic Reviews through March 2009. Relevant reviews and conference proceedings from major international cardiology meetings including AHA, ACC, and ESC. Oral presentations and expert slide presentations from TCT (http://www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (http://www.americaheart.org), and ESC (www.escardio.org) from January 2006 and December 2008. Search limited to human studies and filter for RCT applied.<br>**Languages:**<br>No restrictions<br>**Statistical methods:**<br>Dersimonian and Laird random effects model with RR and 95% CI for dichotomous variables and WMD and 95% CI for continuous variables | **Population:**<br>AMI only<br><br>**Intervention:**<br>PCI with catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, or distal filter embolic protection<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>MBG < 3, STSR < 70% (< 50% < 70% not available) (post-procedure); mortality (NR) | **Overall Analysis**<br>**Intermediate:**<br>MBG < 3: RR 0.75 (0.66 to 0.84)<br>STSR < 70% :RR 0.77 (0.68 to 0.87)<br><br>**Final:**<br>Mortality: RR 0.78 (0.57 to 1.05)<br><br>**Aspiration-only analysis**<br>**Intermediate:**<br>MBG < 3: RR 0.56 (0.36 to 0.87)<br>STSR < 70%: RR 0.69 (0.58 to 0.83)<br><br>**Final:**<br>Mortality: RR 0.56 (0.36 to 0.87)<br><br>**Mechanical-only analysis**<br>**Intermediate:**<br>MBG < 3: RR 1.98 (0.92 to 4.27)<br>STSR < 70%: RR 0.61 (0.37 to 1.02)<br><br>**Final:**<br>Mortality: RR 1.98 (0.92 to 4.27)<br><br>**Embolic Protection-only analysis**<br>**Intermediate:**<br>MBG < 3: RR 0.79 (0.48 to 1.31)<br>STSR < 70%: RR 0.94 (0.84 to 1.04)<br><br>**Final:**<br>Mortality: RR 0.79 (0.48 to 1.31) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? No<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? Yes<br><br>Total 'Yes' responses (out of 11): 10 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Amin, 2009 | **Number of studies (participants):**<br>Overall analysis: 23 (5728)<br>Thrombectomy-only analysis‡: 16 (3848)<br>Distal Protection-only analysis‡: 7 (1880)<br><br>**Study design(s) included:**<br>RCTs (full-text, abstracts, and expert talks and slides)<br><br>**Literature search:**<br>RCTs from pervious meta-analyses. Searched MEDLINE database and expert talks, slides, and abstracts that were not included in earlier meta-analyses<br><br>**Languages:**<br>NR<br><br>**Statistical methods:**<br>DerSimonian and Laird random effects models | **Population:**<br>STEMI only<br><br>**Intervention:**<br>PCI with thrombectomy (catheter aspiration, or mechanical thrombectomy) or embolic protection device (distal balloon or distal filter embolic protection)<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>MBG < 3, TIMI < 3 (post-procedure); failed STSR (< 50% or < 70%) | **Overall Analysis**<br>**Intermediate:**<br>TIMI < 3: OR 0.68 (0.58 to 0.79)<br>MBG < 3: OR 0.66 (0.58 to 0.75)<br>Failed STSR: OR 0.65 (0.58 to 0.73)<br><br>**Thrombectomy-only Analysis‡**<br>**Intermediate:**<br>TIMI < 3: OR 0.66 (0.55 to 0.80)<br>MBG < 3: OR 0.61 (0.52 to 0.71)<br>Failed STSR: OR 0.57 (0.50 to 0.65)<br><br>**Distal Protection-only Analysis‡**<br>**Intermediate:**<br>TIMI < 3: OR 0.71 (0.53 to 0.93)<br>MBG < 3: OR 0.83 (0.65 to 1.05)<br>Failed STSR: OR 0.88 (0.72 to 1.08) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? No<br>2. Was there duplicate study selection and data extraction? No<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? Yes<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? No<br>11. Was the conflict of interest stated? No<br><br>Total 'Yes' responses (out of 11): 7 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes [“X”R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Bavry, 2008 | **Number of studies (participants):**<br>Overall analysis: 30 (6415)<br>Aspiration-only analysis: 13 (3026)<br>Mechanical-only analysis: 5 (934)<br>Embolic Protection-only analysis: 12 (2442)<br><br>**Study design(s) included:**<br>RCTs only (full-text, abstracts, and oral/expert slide presentations)<br><br>**Literature search:**<br>Cochrane and MEDLINE (R) databases from January 1996 to June 2008; Manual search of supplements from the Journal of the American College of Cardiology, Circulation, European Heart Journal, and American Journal of Cardiology; Review of prior meta-analyses; Search of http://clincialtrials.gov and www.tctmd.com websites.<br><br>**Languages:**<br>No restrictions | **Population:**<br>AMI within 12 hours<br><br>**Intervention:**<br>PCI with catheter aspiration, mechanical thrombectomy, or embolic protection device<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality, MI, TVR, stroke, MACE (mortality, MI, TVR) (maximal extent of clinical followup); mortality (hospital discharge to 30 d); TBG-3, complete STSR (60 min) | **Overall Analysis**<br>**Intermediate:**<br>TBG-3: RR 1.38 (1.20 to 1.58)<br>Complete STSR: RR 1.27 (1.15 to 1.41)<br><br>**Final:**<br>Mortality (WMF 5 m): RR 0.87 (0.67 to 1.13)<br>MI: RR 0.71 (0.48 to 1.05)<br>TVR: RR 0.92 (0.75 to 1.13)<br>Stroke: RR 1.92 (0.96 to 3.83)<br>MACE: RR 0.88 (0.74 to 1.04)<br><br>**Aspiration-only analysis**<br>**Intermediate:**<br>TBG-3: RR 1.69 (1.26 to 2.28)<br>Complete STSR: RR 1.41 (1.21 to 1.64)<br>**Final:**<br>Mortality (WMF 6.2 m): RR 0.63 (0.43 to 0.93)<br>Mortality (WMF 0.6 m): RR 0.65 (0.40 to 1.06)<br>MI (WMF 6.2 m): RR 0.65 (0.37 to 1.12)<br>TVR (WMF 6.2 m): RR 0.83 (0.64 to 1.08)<br>Stroke (WMF 6.2 m): RR 3.43 (0.85 to 14)<br>MACE (WMF 6.2 m): RR 0.76 (0.62 to 0.95)<br><br>**Mechanical-only analysis**<br>**Intermediate:**<br>TBG-3: RR 1.16 (0.71 to 1.90)<br>Complete STSR: RR 1.25 (0.99 to 1.58) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? No<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? Yes<br><br>Total ‘Yes’ responses (out of 11): 10 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| | **Statistical methods:**<br>Mantel-Haenszel fixed effects model used to construct fixed effects summary risk rations (RR) and risk differences, whereas a DerSimonian Laird random effects model used for random effects summary estimates. Outcomes were reported using fixed-effects model unless there was significant heterogeneity, where random-effects model was used | | **Final:**<br>Mortality (WMF 4.6 m): RR 1.93 (1.00 to 3.72)<br>Mortality (WMF 1.0 m): RR 2.01 (0.95 to 4.23)<br>MI (WMF 2.1 m): RR 0.67 (0.19 to 2.33)<br>TVR (WMF 2.1 m): RR 1.14 (0.43 to 3.01)<br>Stroke (WMF 2.1 m): RR 2.67 (0.71 to 10.0)<br>MACE (WMF 2.1m): RR 1.64 (0.60 to 4.44)<br><br>**Embolic Protection-only analysis**<br>**Intermediate:**<br>TBG-3: RR 1.18 (1.02 to 1.38)<br>Complete STSR: RR 1.07 (0.98 to 1.16)<br><br>**Final:**<br>Mortality (WMF 3.7m): RR 0.92 (0.60 to 1.40)<br>Mortality (WMF 0.8m): RR 0.79 (0.49 to 1.29)<br>MI (WMF 3.7m): RR 0.82 (0.44 to 1.51)<br>TVR (WMF 3.7): RR 1.04 (0.74 to 1.47)<br>Stroke (WMF): RR 0.99 (0.34 to 2.92)<br>MACE (WMF 3.7m): RR 0.95 (0.69 to 1.30) | |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Burzotta, 2008 | **Number of studies (participants):**<br>Overall analysis: 18 (3180)<br>Thrombectomy-only analysis†: 12 (1934)<br>Distal Protection-only analysis†: 6 (1246)<br><br>**Study design(s) included:**<br>RCTs (full-texts, abstracts, and expert slides presentations)<br><br>**Literature search:**<br>MEDLINE database search according to a modified Robinson and Dickersin strategy. TCT (http://www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (http://www.americaheart.org), and ESC (www.escardio.org) websites searched<br><br>**Languages:**<br>No restrictions<br><br>**Statistical methods:**<br>Both Mantel-Haenszel fixed effects and Der Simonian and Laird random effects models were used however, as significant heterogeneity was present, the data are presented according to the random effects model. | **Population:**<br>STEMI only<br><br>**Intervention:**<br>PCI with thrombectomy (catheter aspiration, or mechanical thrombectomy) or embolic protection device (distal balloon or distal filter embolic protection)<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality or MI, MACCE (mortality, MI, TVR, stroke) (up to 30 d); DE, Absence of STSR > 70% (within 90 min); TIMI < 3, MBG < 3 (post-procedure) | **Overall Analysis**<br>**Intermediate:**<br>TIMI < 3: OR 0.76 (0.51 to 1.12)<br>MBG < 3: OR 0.53 (0.37 to 0.76)<br>DE: OR 0.54 (0.37 to 0.81)<br>Absence of STSR > 70%: OR 0.60 (0.45 to 0.78)<br><br>**Final:**<br>Mortality or MI: OR 0.85 (0.54 to 1.33)<br>MACCE: OR 1.01 (0.63 to 1.60)<br><br>**Thrombectomy-only Analysis†**<br>**Intermediate:**<br>TIMI < 3: OR 0.68 (0.42 to 1.09)<br>MBG < 3: OR 0.42 (0.23 to 0.75)<br>DE: OR 0.51 (0.28 to 0.92)<br>Absence of STSR > 70%: OR 0.46 (0.32 to 0.66)<br><br>**Final:**<br>Mortality or MI: OR 1.07 (0.50 to 2.32)<br>MACCE: OR 1.09 (0.60 to 1.96)<br><br>**Distal Protection-only Analysis†**<br>**Intermediate:**<br>TIMI < 3: OR 0.95 (0.43 to 2.12)<br>MBG < 3: OR 0.72 (0.55 to 0.96)<br>DE: OR 0.55 (0.28 to 1.08)<br>Absence of STSR > 70%: OR 1.01 (0.79 to 1.29)<br><br>**Final:**<br>Mortality or MI: OR 0.68 (0.39 to 1.19)<br>MACCE: OR 0.81 (0.40 to 1.65) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? Yes<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? No<br><br>Total 'Yes' responses (out of 11): 10 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| De Luca, 2008 | **Number of studies (participants):**<br>Overall analysis: 9 (2417)<br><br>**Study design(s) included:**<br>RCTs only (full-text, abstracts, and oral/expert slide presentations)<br><br>**Literature search:**<br>Electronic databases (MEDLINE, CENTRAL, EMBASE, and The Cochrane Central Register of Randomized controlled trial from January 1990 to May 2008. Scientific session abstracts (from January 1990 to May 2008) and oral presentation and/or expert slide presentations (from January 2002 to May 2008) on TCT, AHA, ESC, ACC, and EuroPCR websites. Reference list of relevant studies scanned<br><br>**Languages:**<br>No restrictions<br><br>**Statistical methods:**<br>DerSimonian and Laird random effects model | **Population:**<br>STEMI only<br><br>**Intervention:**<br>PCI with catheter aspiration<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality (30 d); TIMI-3, MBG-3, DE (post-procedure) | **Intermediate:**<br>TIMI-3: OR 1.59 (1.26 to 2.0)<br>TMPG-3: OR 2.44 (2.04 to 2.92)<br>DE: OR 0.30 (0.20 to 0.44)<br><br>**Final:**<br>Mortality : OR 0.58 (0.34 to 0.98) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? Yes<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? Yes<br><br>Total 'Yes' responses (out of 11): 11 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Grines, 2008 | **Number of studies (participants):**<br>Overall analysis: 90 (25094)<br><br>**Study design(s) included:**<br>RCTs and non-RCTs<br><br>**Literature search:**<br>Published (U.S. National Library of Medicine Database) and FDA sources for AngioJet experience and on published sources only for the PCI reference experience from January 1, 1999, to March 1, 2007.<br><br>**Languages:**<br>English<br><br>**Statistical methods:**<br>Bayesian random-effects model. Bayesian hierarchical model used to compare short-term mortality estimates from RCTs and non-RCTs and to provide a pooled meta-analytic estimate across study designs | **Population:**<br>STEMI with chest pain more than 30 min and less than 24 hours treated with primary or rescue PCI<br><br>**Intervention:**<br>PCI with mechanical thrombectomy (Angiojet)<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality, MACE (mortality, recurrent MI, stroke, TVR) (short-term ≤ 42 d); TIMI-3 (post-procedure) | **Intermediate:**<br>TIMI-3: OR 1.12 (0.70 to 2.27)<br><br>**Final:**<br>Mortality : OR 0.98 (0.53 to 1.50)<br>MACE: OR 1.25 (0.54 to 2.40) | **AMSTAR assessment:**<br>• Was an 'a priori' design provided? Yes<br>• Was there duplicate study selection and data extraction? Yes<br>• Was a comprehensive literature search performed? Yes<br>• Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>• Was a list of studies (included and excluded) provided? No<br>• Were the characteristics of the included studies provided? Yes<br>• Was the scientific quality of the included studies assessed and documented? No<br>• Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>• Were the methods used to combine the findings of studies appropriate? Yes<br>• Was the likelihood of publication bias assessed? Yes<br>• Was the conflict of interest stated? Yes<br><br>Total 'Yes' responses (out of 11): 9 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| De Luca, 2007 | **Number of studies (participants):**<br>Overall analysis: 21 (3721)<br>Thrombectomy-only analysis[§]: 13 (2219)<br>Distal Protection-only analysis[§]: 8 (1502)<br><br>**Study design(s) included:**<br>RCTs (full-text, abstracts, oral presentations, and expert slide presentations)<br><br>**Literature search:**<br>electronic databases (MEDLINE and CENTRAL) from January 1990 to October 2006) and the scientific session abstracts in Circulation, Journal of American College of Cardiology, European Heart Journal, and American Journal of Caridology from January 1990 to October 2006. Oral presentations and or expert slide presentation (searched on the TCT (www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (www.aha.org), and ESC (www.escardio.org) websites) from January 2002 to October 2005.<br><br>**Languages:**<br>No restrictions<br><br>**Statistical methods:**<br>DerSimonian and Laird random-effects models | **Population:**<br>AMI<br><br>**Intervention:**<br>PCI with thrombectomy (catheter aspiration or mechanical thrombectomy) or embolic protection device (distal balloon or distal filter embolic protection)<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality (30 d); TIMI-3, MBG-3, DE (post-procedure); coronary perforation (NR) | **Overall Analysis**<br>**Intermediate:**<br>TIMI-3: OR 1.34 (1.02 to 1.76)<br>MBG-3: OR 2.21 (1.48 to 3.32)<br>DE: OR 0.58 (0.39 to 0.87)<br><br>**Final:**<br>Mortality : OR 0.97 (0.64 to 1.46)<br><br>**Safety:**<br>Coronary perforation: OR 3.05 (0.48 to 19.40)<br><br>**Thrombectomy-only Analysis[§]**<br>TIMI-3: OR 1.43 (0.99 to 2.06)<br>MBG-3: OR 2.64 (1.35 to 5.16)<br>DE: OR 0.52 (0.32 to 0.85)<br><br>**Final:**<br>Mortality : OR 1.32 (0.76 to 2.31)<br><br>**Safety:**<br>Coronary perforation: OR 2.1 (0.18 to 22.30)<br><br>**Distal Protection-only Analysis[§]**<br>**Intermediate:**<br>TIMI-3: OR 1.22 (0.79 to 1.86)<br>MBG-3: OR 1.73 (1.09 to 2.75)<br>DE: OR 0.7 (0.35 to 1.39)<br><br>**Final:**<br>Mortality : OR 0.66 (0.35 to 1.23)<br><br>**Safety:**<br>Coronary perforation: OR 5.15 (0.25 to 107.9) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? No<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? Yes<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? Yes<br>11. Was the conflict of interest stated? Yes<br><br>Total 'Yes' responses (out of 11): 10 |

Table13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text (continued)

| Study, Year | Review Characteristics | Population, Intervention, Comparator, Outcomes of Interest (Timing) | Outcomes ["X"R (95%CI)] | Quality Scoring/Comments |
|---|---|---|---|---|
| Kunadian, 2007 | **Number of studies (participants):**<br>Overall analysis: 14 (2630)<br><br>**Study design(s) included:**<br>RCTs (full-texts and abstracts)<br><br>**Literature search:**<br>PubMed, OVID, the Cochrane databases, references of articles, and abstracts of conference proceedings from September 2000 to October 2005. Hand-searched relevant journals and used the Science Citation Index to cross reference any articles that met the inclusion criteria. Searched www.tctmd.com and www.theheart.org websites<br><br>**Languages:**<br>NR<br><br>**Statistical methods:**<br>Both Mantel-Haenzel fixed effects model and the DerSimonian and Laird random effects model were used, however results are reported from the random effects model. | **Population:**<br>AMI only<br><br>**Intervention:**<br>PCI with thrombectomy (catheter aspiration or mechanical thrombectomy) or embolic protection (distal balloon or distal filter embolic protection) device<br><br>**Comparator:**<br>PCI without thrombectomy<br><br>**Outcomes (Timing):**<br>Mortality or reinfarction, mortality, reinfarction, MACE (nonfatal reinfarction, stroke, repeat TVR) (30 d) | **Overall Analysis**<br>**Final:**<br>Mortality or reinfarction : OR 0.82 (0.55 to 1.24)<br>Mortality: OR 0.92 (0.56 to 1.51)<br>Reinfarction: OR 0.78 (0.40 to 1.52)<br>MACE: OR 1.00 (0.71 to 1.42)<br><br>**Thrombectomy-only Analysis**[‖]<br>**Final:**<br>Mortality or reinfarction: OR 0.98 (0.53 to 1.83)<br>Mortality: OR 1.10 (0.49 to 2.43)<br>Reinfarction: OR 0.88 (0.37 to 2.11)<br>MACE: OR 1.25 (0.78 to 1.99)<br><br>**Distal Protection-only Analysis**[‖]**:**<br>**Final:**<br>Mortality or reinfarction: OR 0.68 (0.37 to 1.23)<br>Mortality: OR 0.70 (0.34 to 1.44)<br>Reinfarction: OR 0.67 (0.24 to 1.85)<br>MACE: OR 0.75 (0.44 to 1.28) | **AMSTAR assessment:**<br>1. Was an 'a priori' design provided? Yes<br>2. Was there duplicate study selection and data extraction? Yes<br>3. Was a comprehensive literature search performed? Yes<br>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes<br>5. Was a list of studies (included and excluded) provided? No<br>6. Were the characteristics of the included studies provided? Yes<br>7. Was the scientific quality of the included studies assessed and documented? Yes<br>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes<br>9. Were the methods used to combine the findings of studies appropriate? Yes<br>10. Was the likelihood of publication bias assessed? No<br>11. Was the conflict of interest stated? No<br><br>Total 'Yes' responses (out of 11): 6 |

*Names of devices along with category are in Table 1 of original text. More information in reference ID # 9; [†]Names of devices along with category are in Table 1 of original text; [‡]Names of devices along with category are in Table 1 of original text; [§]Names of devices along with category are in Table 1 of original text; [‖]Names of devices along with category are on pages 489-490 of original text

Abbreviations: ACC=American College of Cardiology; AHA=American Heart Association; AMI=acute myocardial infarction; CI=confidence interval; d=days; DE=distal embolization; ESC=European Society of Cardiology; FDA=Food and Drug Administration; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; m=months; NR=not reported; OR=odds ratio; PCI=percutaneous coronary intervention; PT=procedure time; RCT=randomized control trial; RR=relative risk; STBT=symptom onset to balloon time; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment

resolution; TBG=Timi blush grade; TCT=Transcatheter Cardiovascular Therapeutics; TIMI=thrombolysis in myocardial infarction; TMPG=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVR=target vessel revascularization; U.S.=United States; WMF=weighted mean followup; WMD=weighted mean difference

Table 14. Characteristics and quality assessment of meta-analyses published in abstract form

| Study, Year | Total Studies (Participants) | Inclusion Criteria | Outcomes (Timing) | Overall Outcomes ["X"R (95%CI)] | Outcomes of Device Subtypes ["X"R (95%CI)] |
|---|---|---|---|---|---|
| Masotti 2008 and Salazar, 2008 | 7 (1456) | STEMI; RCT evaluating thrombectomy, distal protection and aspiration devices | Mortality, reinfarction, mortality + reinfarction (6 m) | Mortality: OR 0.75 (0.41 to 1.36)<br>Reinfarction: OR 0.5 (0.23 to 1.1)<br>Mortality + reinfarction: OR 0.62 (0.38 to 1.01) | Thrombectomy + aspiration<br>Mortality: OR 0.69 (0.2 to 2.34)<br>Reinfarction: OR 0.71 (0.14 to 3.68)<br>Mortality+reinfarction: OR 0.66 (0.23 to 1.9)<br><br>Distal protection devices<br>Mortality: OR 0.77 (0.38 to 1.53)<br>Reinfarction: OR 0.45 (0.18 to 1.1)<br>Mortality+reinfarction: OR 0.61 (0.35 to 1.06) |
| Masotti 2008 | 8 (2527) | RCT using embolic protection devices in patients with STEMI | Mortality (6 m) | Mortality: OR 0.60 (0.40 to 0.89) | Aspiration<br>Mortality: OR 0.49 (0.29 to 0.82)<br><br>Thrombectomy<br>Mortality: OR 1.01 (0.25 to 4.16)<br><br>Filters<br>Mortality: OR 0.77 (0.38 to 1.53) |
| Mongeon 2008 | 16 (2944) | STEMI; RCT comparing primary PCI with and without thrombectomy | No reflow, STSR > 50%, TMPG-3, TIMI-3, DE (post-procedure) | No-reflow: OR 0.35 (0.10 to 0.95)<br>STSR > 50%: OR 2.24 (1.40 to 3.82)<br>TMPG-3: OR 2.45 (1.11 to 5.81)<br>TIMI-3: OR 1.32 (0.84 to 2.28)<br>DE: OR 0.58 (0.19 to 1.45) | N/A |
| Masotti 2007 | 10 (2275) | RCT using thrombectomy or distal protection devices in conjunction with PCI | Mortality, reinfarction, mortality + reinfarction (1m) | Mortality: OR 0.77 (0.5 to 1.20)<br>Reinfarction: OR 0.66 (0.30 to 1.46)<br>Mortality + reinfarction: OR 0.73 (0.49 to 1.09) | Thrombectomy<br>Mortality: OR 0.69 (0.39 – 1.22)<br>Reinfarction: OR 0.59 (0.18 – 1.94)<br>Mortality + reinfarction: OR 0.66 (0.39 – 1.11)<br><br>Distal protection<br>Mortality: OR 0.91 (0.43 – 1.90)<br>Reinfarction: OR 0.72 (0.25 – 2.12)<br>Mortality+reinfarction: OR 0.84 (0.46 – 1.56) |
| Brahmbhatt 2006 | 11 (NR) | Thrombectomy in the setting of STEMI, RCT in full text or abstracts from TCT, AHA, ACC | MACE (30d); MBG≥2, MBG-3, TIMI-3, STSR > 50% (post-procedure) | MBG-3: OR 2.73 (2.07 to 3.6)<br>MBG ≥ 2: OR 1.87 (1.21 to 1.89)<br>TIMI-3: 1.56 (1.07 to 2.28)<br>STSR > 50%: 3.5 (2.17 to 5.65)<br>MACE: 0.94 (0.6 to 1.47) | N/A |

Table14. Characteristics and quality assessment of meta-analyses published in abstract form (continued)

| Study, Year | Total Studies (Participants) | Inclusion Criteria | Outcomes (Timing) | Overall Outcomes ["X"R (95%CI)] | Outcomes of Device Subtypes ["X"R (95%CI)] |
|---|---|---|---|---|---|
| Salazar 2006 and Salazar 2006 | 9 (2060) | RCT using thrombectomy or distal protection devices in conjunction with PCI | Mortality, reinfarction, mortality + reinfarction (1 m) | Mortality: OR 0.78 (0.5 to 1.23)<br>Reinfarction: OR 0.70 (0.31 to 1.59)<br>Mortality+reinfarction: OR 0.76 (0.51 to 1.13) | Thrombectomy<br>Mortality: OR 0.7 (0.4 to 1.27)<br>Reinfarction: OR 0.67 (0.19 to 2.37)<br>Mortality+reinfarction: OR 0.7 (0.41 to 1.19)<br><br>Distal protection<br>Mortality: OR 0.9 (0.44 to 1.91)<br>Reinfarction: OR 0.73 (0.25 to 2.12)<br>Mortality + reinfarction: OR 0.85 (0.46 to 1.06) |
| Qayyum 2006 | 7 (2447)<br><br>Native vessel AMI population 4 (551) | Trials that examined effects on mortality or recurrent AMI of distal protection devices within 30 days of SVG without AMI and PCI for native vessel AMI<br><br>Note: For this meta-analysis, only results for PCI for native vessel AMI are included in this table) | Mortality(30 d) | Mortality: OR 0.69 (0.39 to 1.22) | N/A |

Abbreviations: ACC=American College of Cardiology; AHA=American heart Association; AMI=acute myocardial infarction; d=days; m=months; MACE=major adverse cardiac events; MBG=myocardial blush grade; N/A: not applicable; OR=odds ratio; PCI=percutaneous coronary intervention; RCT=randomized controlled trial; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft; TCT=Transcatheter Cardiovascular Therapeutics; TIMI=thrombolysis in myocardial infarction; TMPG=TIMI myocardial perfusion grade

# Appendix E. Baseline and procedural characteristics of included trials and studies

Table 15. Baseline characteristics of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | 55 | 64 (11) | 78 | 69 | 189 (105) | 0 | --- | 0 | 38 | --- | 20 | 60 | 34 | 63 | 38 |
| | Control | 56 | 65 (11) | 77 | 76 | 209 (147) | 0 | --- | 0 | 46 | --- | 12 | 53 | 30 | 64 | 23 |
| Lipiecki, 2009 | Export Catheter | 20 | 59 (13) | 60 | 100 | 426 (294) | 0 | --- | 15 | 35 | --- | 5 | 25 | 30 | 35 | --- |
| | Control | 24 | 59 (13) | 75 | 95.83 | 444 (408) | 0 | --- | 8 | 46 | --- | 8 | 33 | 21 | 38 | --- |
| Moura, 2009 | TAC | 76 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 76 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | 88 | 66.7 (14.1) | 64.7 | 100 | 372 (54) | 0 | 43.18 | 0 | 43.2 | 100 | 23.8 | 67.0 | --- | 48.8 | 29.5 |
| | Control | 87 | 64.6 (12.5) | 55.1 | 100 | 366 (108) | 0 | 42.53 | 0 | 43.7 | 100 | 18.4 | 49.4 | --- | 26.4 | 36.8 |
| Chao, 2008 | Export Aspiration Catheter | 37 | 60 (13) | 83.78 | --- | 312 (183) | 11 | 60 | 0 | 56.76 | 81 | 32 | 57 | 60 | 41 | --- |
| | Control | 37 | 62 (11) | 86.49 | --- | 331 (175) | 3 | 65 | 0 | 59.46 | 73 | 22 | 57 | 57 | 46 | --- |
| Chevalier, 2008 | Export Aspiration Catheter | 120 | 59.2 (12.8) | 80.8 | 99.2 | 321.7 (413.5) | 10.83 | --- | 0 | 47.5 | --- | 16.7 | 41.4 | 36.7 | 42.5 | 32.5 |
| | Control | 129 | 61.2 (12.9) | 81.4 | 100 | 271.4 (197.6) | 10.85 | --- | 0 | 51.9 | --- | 13.2 | 44.2 | 41.9 | 35.7 | 25.6 |
| Ciszewski, 2008 | Rescue/Diver | 65 | 64.3(12.4) † | 65.19 † | --- | --- | --- | 32.28 † | 0 | --- | --- | --- | --- | --- | --- | --- |
| | Control | 70 | | | --- | --- | --- | | 0 | --- | --- | --- | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | 100 | 61 (10) | 79 | 100 | --- | 2 | --- | 0 | 38.2 | --- | 12 | 58 | 42 | 63 | 33 |
| | Control | 96 | 58 (10) | 81 | 100 | --- | 0 | --- | 0 | 40.9 | --- | 10 | 54 | 50 | 63 | 26 |
| Ikari, 2008 | TVAC | 180 | 63.2 (10.6) | 80.6 | 74.6 | 270 (300) | --- | --- | 0 | 50.3 | 81.11 | 23.3 | 54.8 | 50.0 | 56.6 | 13.9 |
| | Control | 175 | 63.5 (9.9) | 77.7 | 75.3 | 312 (330) | --- | --- | 0 | 52.0 | 82.29 | 29.9 | 59.0 | 48.5 | 50.9 | 14.4 |
| Svilaas, 2008 | 6F Export Aspiration Catheter | 535 | 63 (13) | 67.9 | 54.8 | 190 (110-270)‡ | 9.5 | --- | 0 | 42.9 | 48.6§ | 10.6 | 33.1 | 23.7 | 46.0 | 46.2 |
| | Control | 536 | 63 (13) | 73.1 | 59.5 | 185 (107-263)‡ | 10.7 | --- | 0 | 43.1 | 44.0§ | 12.6 | 37.1 | 27.1 | 48.0 | 44.6 |
| DeLuca, 2006 | Diver CE | 38 | 66.7 (14.1) | 71 | 100 | 432 (114) | 0 | --- | 0 | 97.4 | 100 | 23.7 | 39.5 | --- | 18.4 | 13.1 |
| | Control | 38 | 64.6 (12.5) | 55.3 | 100 | 456 (108) | 0 | --- | 0 | 100 | 100 | 18.4 | 50 | --- | 26.3 | 36.8 |
| Kaltoft, 2006 | Rescue Catheter | 108 | 65 (11) | 76 | 68 | 242 (171-321)‡ | 13 | 46.30 | 0 | 46 | 69 | 8 | 31 | 9 | 55 | --- |
| | Control | 107 | 63 (13) | 80 | 69 | 208 (155-329)‡ | 10 | 42.99 | 0 | 43 | 79 | 6 | 21 | 9 | 64 | --- |

Table 15. Baseline characteristics of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lee, 2006 | Export Aspiration Catheter | 67 | 60.8(1.05)[†] | 69.9[†] | --- | --- | --- | --- | 0 | 42.9[†] | --- | --- | --- | --- | --- | --- |
| | Control | 66 | | | --- | --- | --- | --- | 0 | | --- | --- | --- | --- | --- | --- |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | 74 | 57.3 (13) | 84 | 81 | 206 (115) | 0 | 42 | 0 | 43 | --- | 21 | 37 | 34 | 54 | --- |
| | Control | 74 | 58.9 (14) | 76 | 73 | 199 (124) | 0 | 51 | 0 | 51 | --- | 15 | 46 | 25 | 60 | --- |
| Burzotta, 2005 | Diver CE | 50 | 61 (13) | 90.0 | 86 | 274 (137) | --- | 40.0 | 32.0 | 40.0 | --- | 22.0 | 62.0 | 54.0 | 62.0 | 30.0 |
| | Control | 49 | 60 (13) | 77.6 | 89.8 | 300 (202) | --- | 51.0 | 24.5 | 51.0 | --- | 18.4 | 57.1 | 34.7 | 53.1 | 22.4 |
| Noel, 2005 | Export | 24 | 61.2(11.3)[†] | --- | 100[‖] | 282 (186)[†] | --- | 44[†] | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 26 | | --- | 100[‖] | | --- | | --- | --- | --- | --- | --- | --- | --- | --- |
| Dudek, 2004 | Rescue System | 40 | 56.7 (8.1) | 80 | 79 | 258 (198) | 15 | 40 | 0 | --- | --- | 10 | 75 | --- | 45 | 40 |
| | Control | 32 | 59.1 (7.8) | 69 | 66 | 236 (162) | 25 | 56 | 0 | --- | --- | 19 | 81 | --- | 31 | 50 |

*Symptom onset to balloon, ischemic time, symptom to randomization,symptom onset to hospital, symptom onset to laboratory, symptom onset to angiography, symptom onset to admission, symptom onset to procedure; [†]Mean for the total study population; [‡]Median (interquartile range); [§]% of visible thrombi out of all thrombi; [‖]TIMI<3

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TAC=thrombectomy aspiration catheter; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis; TVAC = transvascular aspiration catheter

Table 16. Procedural characteristics of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | 55 | 75.7 (30.0) | 55/55 (100) | 12/55 (21) | 55/55 (100) | Aspirin 500 mg and clopidogrel 600 mg load pre-PCI | Heparin 70 IU/kg pre-PCI |
| | Control | 56 | 75.9 (38.7) | 56/56 (100) | 5/56 (9) | 56/56 (100) | | |
| Lipiecki, 2009 | Export Catheter | 20 | --- | 19/20 (95) | 10/20 (55) | 5/20 (25) | Aspirin and clopidogrel 300 mg load pre-PCI | Heparin pre-PCI |
| | Control | 24 | --- | 22/24 (92) | 6/24 (33) | 15/24 (62) | | |
| Moura, 2009 | TAC | 76 | --- | --- | --- | 45/76 (59) | --- | --- |
| | Control | 76 | --- | --- | --- | 62/76 (82) | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | 88 | --- --- | 88/88 (100) | 67/88 (76.2) | 88/88 (100) | Aspirin 300 mg and clopidogrel 300 mg pre-PCI | Heparin 7.5 UI pre-PCI |
| | Control | 87 | | 87/87 (100) | 2/87 (2.3) | 87/87 (100) | Aspirin and clopidogrel (for 12 m) post-PCI | |
| Chao, 2008 | Export Aspiration Catheter | 37 | 49 (18)† | 35/37 (95) | 19/37 (51) | 7/37 (19) | Aspirin 300 mg and clopidogrel 300 mg load pre-PCI | Heparin 70-100 IU/kg IV (ACT >200 s) pre-PCI and for at least 24 hours |
| | Control | 37 | 53 (23)† | 34/37 (92) | 4/37 (11) | 12/37 (32 | Aspirin 100 mg/d indefinitely and clopidogrel 75 mg/d for 3 m post-PCI | |
| Chevalier, 2008 | Export Aspiration Catheter | 120 | 36.7 (18.0) | 120/120 (100) | --- | --- | Aspirin and clopidogrel used at investigator's discretion | Heparin used at investigator's discretion |
| | Control | 129 | 34.5 (21.5) | 129/129 (100) | --- | --- | | |
| Ciszewski, 2008 | Rescue/Diver | 65 | --- | 65/65 (100) | --- | --- | --- | --- |
| | Control | 70 | --- | 70/70 (100) | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | 100 | --- | 99/100 (99) | 75/100 (75) | 62/100 (62) | --- | --- |
| | Control | 96 | --- | 93/96 (97) | 5/96 (5) | 60/96 (63) | --- | --- |
| Ikari, 2008 | TVAC | 178 | 87.0 (32.4) | 167/178 (94.1) | --- | 0/178 (0) | Aspirin pre-PCI | Heparin (ACT≥300 s) pre-PCI |
| | Control | 180 | 93.6 (78.6) | 160/171 (93.4) | --- | 0/180 (0) | Ticlopidine (cilostizol if intolerant to ticlopidine) and aspirin post-PCI | |
| Svilaas, 2008 | 6F Export Aspiration Catheter | 535 | 28 (14-42)* | 442/279 (92.3) | 295/535 (55.1) | 469/502 (93.4) | Aspirin 500 mg bolus and clopidogrel 600mg pre-PCI and standard aspirin and clopidogrel therapy post-PCI | Heparin 5000 IU pre-PCI plus additional doses based on ACT |
| | Control | 536 | 26 (12-40)* | 438/476 (92.0) | --- | 452/503 (89.9) | | |
| DeLuca, 2006 | Diver CE | 38 | --- | 38/38 (100) | 35/38 (92.1) | --- | Aspirin 300 mg pre-PCI and 100 mg/d post-PCI and ticlopidine 250 mg BID for at least 4 weeks or clopidogrel 300 mg followed by 75 mg/d for at least 4 weeks | Heparin 8000 IU IV pre-PCI continued for 48 hours post-PCI |
| | Control | 38 | --- | 38/38 (100) | 2/38 (5.3) | --- | | |
| Kaltoft, 2006 | Rescue Catheter | 108 | 39 (29-48)* | 103/108 (95) | --- | 104/108 (96) | Aspirin 300 mg and clopidogrel 300 mg pre-PCI | Heparin 10,000 IE IV pre-PCI |
| | Control | 107 | 29 (23-38)* | 104/107 (97) | --- | 100/107 (93) | Aspirin 75 mg/d and clopidogrel 75 mg/d for 12 m post-PCI | |
| Lee, 2006 | Export Aspiration Catheter | 67 | --- | --- | --- | --- | --- | --- |
| | Control | 66 | --- | --- | --- | --- | --- | --- |

Table 16. Procedural characteristics of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (conintued)

| Study, Year | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|
| Silva-Orrego, 2006 | Pronto Extraction Catheter | 74 | 57 (19) | 73/74 (99) | 52/74 (70) | 74/74 (100) | Aspirin pre-PCI | Heparin 60 U/kg pre-PCI |
| | Control | 74 | 54 (21) | 72/74 (97) | 18/74 (24) | 74/74 (100) | | |
| Burzotta, 2005 | Diver CE | 50 | 81 (43) | --- | 33/50 (66.0) | 34/50 (68.0) | Aspirin and clopidogrel (300 mg load followed by 75 mg/d) for at least 4 weeks | Heparin (ACT 250-300 s) |
| | Control | 49 | 72 (34) | --- | 12/49 (24.4) | 31/49 (63.3) | | |
| Noel, 2005 | Export | 24 | --- | --- | --- | --- | --- | --- |
| | Control | 26 | --- | --- | --- | --- | --- | --- |
| Dudek, 2004 | Rescue System | 40 | --- | --- | --- | --- | Aspirin 75 mg/d, clopidogrel (initially 300 mg, followed by 75 mg/d) or ticlopidine (500 mg/d) for 1 m | --- |
| | Control | 32 | --- | --- | --- | --- | | --- |

*Median (interquartile range); †Lab to TIMI-3

Abbreivations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=international units; IV=intravenous; kg=kilogram; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; TAC=thrombectomy aspiration catheter; TVAC=transvascular aspiration catheter; U=units

Table 17. Baseline characteristics of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Age (SD) | Male (%) | TIMI -0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Migliorini 2010 | AngioJet Rheolytic Thrombectmy | 256 | 63.0 (12.3) | 76 | 83.5 | 125 (85-221.5)† | 3.9 | 39 | 0 | 42 | --- | 14 | 47 | 30 | --- | --- |
| | Control | 245 | 64.3 (11.5) | 81 | 83.9 | 135 (86-227)† | 4.9 | 37 | 0 | 37 | --- | 15 | 47 | 35 | --- | --- |
| Ali, 2006 | AngioJet Catheter | 240 | 60 (51.0-69.0)† | 75.8 | 68.4 | 144 (198) | --- | --- | 14.2 | 38.9 | 20.83 | 16.7 | 42.9 | 22.1 | 44.2 | --- |
| | Control | 240 | 59.9 (49.0 -70.0)† | 74.2 | 63.2 | 150 (192) | --- | --- | 13.3 | 37.4 | 19.19 | 15.8 | 42.1 | 25.4 | 45.0 | --- |
| Lefèvre 2005 | X-Sizer Catheter | 100 | 61 (13) | 76 | 100 | 251 (151) | 10 | 54 | 0 | 55 | --- | 25 | 54 | 58 | 52 | --- |
| | Control | 101 | 62 (11) | 73 | 100 | 264 (194) | 6 | 50 | 0 | 48 | --- | 18 | 50 | 61 | 51 | --- |
| Antoniucci 2004 | AngioJet | 50 | 63 (13) | 82 | 76 | 234 (120) | --- | 34 | 0 | 34 | --- | 18 | 36 | 46 | 38 | --- |
| | Control | 50 | 66 (12) | 78 | 80 | 264 (168) | --- | 46 | 0 | 46 | --- | 16 | 38 | 48 | 28 | --- |
| Napodano 2003 | X-Sizer Catheter | 46 | 61.3 (10.8) | 82.6 | 73.9 | 202.9 (204.9) | 17.4 | 39.1 | --- | --- | 100 | 13.0 | 60.9 | 50.0 | 45.6 | --- |
| | Control | 46 | 63.6 (11.7) | 71.7 | 84.7 | 165.7 (134.7) | 6.5 | 43.5 | --- | --- | 100 | 13.0 | 65.2 | 52.1 | 34.8 | --- |

*Symptom onset to emergency room, symptom onset to angiogram, time to treatment, symptom onset to hospital; †Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 18. Procedural characteristics of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy<br>Control | 256<br>245 | 59.5 (44.7-70)*<br>46 (35-60)* | 256/256 (100)<br>245/245 (100) | 256/256 (100)<br>245/245 (100) | 249/256 (97)<br>239/245 (98) | Aspirin 325 mg po or 500 mg IV and clopidogrel 600 mg load pre-PCI or immediately post-PCI<br>Aspirin 100 to 325 mg/d indefinitely and clopidogrel 75 mg/d for 6 m post-PCI | Heparin 70 U/kg bolus with additional doses (ACT 200-250 s) |
| Ali, 2006 | AngioJet Catheter<br>Control | 240<br>240 | 75.4 (30.9)<br>59.2 (26.8) | 224/240 (93.7)<br>227/240 (94.5) | ---<br>--- | 228/240 (95.0)<br>226/240 (94.2) | Aspirin 325 mg and clopidogrel 300 mg load then 75 mg/d for at least 4 weeks (ticlopidine 500mg load then 250 BID if intolerant to clopidogrel) | Heparin during PCI (ACT >250 s) |
| Lefèvre, 2005 | X-Sizer Catheter<br>Control | 100<br>101 | 54 (28)<br>45 (25) | 100/100 (100)<br>100/101 (99) | 60/100 (60)<br>34/101 (34) | 55/100 (55)<br>66/101 (65) | Aspirin pre-PCI | Heparin 70 U/kg (ACT >250 s) |
| Antoniucci, 2004 | AngioJet<br>Control | 50<br>50 | ---<br>--- | 49/50 (98)<br>49/50 (98) | 47/50 (94)<br>41/50 (82) | 49/50 (98)<br>49/50 (98) | Aspirin 325 mg/d indefinitely and ticlopidine (500 mg/d for 1 m) or clopidogrel (75 mg/d for 1 m) | Heparin 70 U/kg bolus and additional doses (ACT 200-300 s) |
| Napodano, 2003 | X-Sizer Catheter<br>Control | 46<br>46 | ---<br>--- | 43/46 (93.5)<br>42/46 (91.3) | 28/46 (60.8)<br>13/46 (28.3) | 20/46 (43.4)<br>19/46 (41.3) | Aspirin 250-500 mg IV pre-PCI/during PCI and 100-375 mg/d indefinitely post-PCI<br>Ticlopidine 250 mg twice/d pre-PCI/during PCI and post-PCI<br>Clopidogrel 75 mg/d pre-PCI/during PCI and post-PCI for 1 m | Heparin 70 U/kg IV pre-PCI/ during PCI and 7-12 IU/kg/hour for 48 hours (ACT >250 s) |

*Median (interquartile range)

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=international units; IV=intravenous; kg=kilogram; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; po=by mouth; s=seconds; SD=standard deviation; U=units

Table 19. Baseline characteristics of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | 312 | 62 (12.3) | 74.4 | 67 | 200 (26-1350)† | 6.4 | --- | 0 | 44 | 68 | 9.0 | 32.1 | 18.6 | 56.7 | 36.5 |
| | Control | 314 | 63 (12.1) | 72.0 | 68 | 199 (40-996)† | 6.4 | --- | 0 | 38 | 75 | 11.8 | 34.1 | 20.4 | 50.3 | 37.6 |
| Cura, 2007 | SpideRX | 70 | 60.2 (9.9) | 86 | 85 | 150 (80-270)† | 21 | --- | 3 | 53 | 90 | 19 | 56 | --- | 33 | --- |
| | Control | 70 | 60.4 (10.4) | 77 | 83 | 146 (75-236)† | 13 | --- | 4 | 56 | 97 | 20 | 49 | --- | 47 | --- |
| Guetta, 2007 | FilterWire EZ | 51 | 60 (12) | 82 | 78 | 180 (90-420)† | 12 | --- | --- | 51 | --- | 22 | 44 | 48 | 43 | --- |
| | Control | 49 | 57 (10) | 82 | 92 | 120 (66-180)† | 11 | --- | --- | 53 | --- | 23 | 51 | 50 | 44 | --- |
| Lefèvre, 2004 | AngioGuardXP | 32 | 61 (15) | 81 | 71.88 | --- | --- | --- | --- | 41 | 100 | 19 | 50 | 62 | --- | --- |
| | Control | 28 | 62 (12) | 83 | 67.86 | --- | --- | --- | --- | 53 | 100 | 14 | 43 | 61 | --- | --- |

*Symptom onset to hospital, symptom onset to angiography, symptom onset to emergency room; †Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 20. Procedural characteristics of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | 312 | --- | 307/312 (98) | --- | 301/312 (97) | Aspirin 300-500 mg and clopidogrel 300-600 mg pre-PCI<br>Clopidogrel continued for 1 year and aspirin continued indefinitely | Heparin 10,000 IU pre-PCI |
| | Control | 314 | --- | 312/314 (99) | --- | 302/314 (96) | | |
| Cura, 2007 | SpideRX | 70 | 52 (43-70)* | 69/70 (99) | --- | 18/70 (26) | Aspirin 325 mg and clopidogrel 300-600 mg load pre- or immediately after PCI<br>Clopidogrel recommended for 12 m and aspirin indefinitely post-PCI | Heparin IV during PCI (ACT>250 s) |
| | Control | 70 | 43.5 (30-54)* | 68/70 (97) | --- | 18/70 (26) | | |
| Guetta, 2007 | FilterWire EZ | 51 | --- | --- | --- | 38/51 (74) | Aspirin 500 mg IV or 200 mg orally and clopidogrel 300 mg load pre-PCI | Heparin 70 U/kg pre-PCI |
| | Control | 49 | --- | --- | --- | 38/49 (77) | | |
| Lefèvre, 2004 | AngioGuardXP | 32 | --- | 32/32 (100) | --- | --- | --- | --- |
| | Control | 28 | --- | 28/28 (100) | --- | --- | --- | --- |

*Median (interquartile range)

Abbreivations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=international units; IV=intravenous; kg=kilogram; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; TAC=thrombectomy aspiration catheter; TVAC=transvascular aspiration catheter; U=units

Table 21. Baseline characteristics of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | 60 | 55.9 (13.9) | 85 | 67 | 339.3 (189.2) | 0 | 53 | 0 | 53 | --- | 20 | 36 | --- | 68 | --- |
| | Control | 56 | 58.8 (14.5) | 71 | 76 | 327.8 (209.5) | 0 | 56 | 0 | 56 | --- | 21 | 54 | --- | 57 | --- |
| Hahn, 2007 | GuardWire | 19 | 55 (45-62)† | 79 | 95 | 212 (160-325)† | --- | 58 | 0 | 58 | --- | 32 | 47 | 26 | 63 | --- |
| | Control | 20 | 56 (45-65)† | 95 | 75 | 248 (185-480)† | --- | 55 | 0 | 55 | --- | 15 | 25 | 20 | 65 | --- |
| Matsuo, 2007 | GuardWire Distal Protection System | 80 | 65 (12) | 86 | 78 | 312 (252) | 5 | --- | --- | 57 | --- | 20 | 51 | 35 | 47 | 12 |
| | Control | 74 | 65 (13) | 76 | 71 | 264 (174) | 8 | --- | --- | 40 | --- | 25 | 49 | 39 | 50 | 7 |
| Muramatsu, 2007 | GuardWire Plus System | 173 | 63.5 (12.3) | 78.6 | 69 | 252 (168) | 1.7 | --- | 0 | 50 | --- | 31.8 | 42.2 | 32.9 | 51.4 | 4.6 |
| | Control | 168 | 64.7 (11.1) | 72.9 | 68 | 264 (204) | 2.9 | --- | 0 | 48 | --- | 32.3 | 44.1 | 32.9 | 49.4 | 4.1 |
| Zhou, 2007 | PercuSurge GuardWire | 52 | 55 (14) | 62 | 100 | 310 (145) | --- | --- | 0 | 54 | --- | 23 | 37 | --- | 67 | --- |
| | Control | 60 | 57 (15) | 67 | 100 | 315 (176) | --- | --- | 0 | 48 | --- | 22 | 35 | --- | 60 | --- |
| Okamura, 2005 | PercuSurge GuardWire | 8 | 59 (13) | 75 | 75 | 450 (348) | --- | --- | --- | 25 | --- | 25 | 38 | 38 | 75 | --- |
| | Control | 8 | 59 (8) | 88 | 38 | 510 (492 | --- | --- | --- | 75 | --- | 25 | 63 | 38 | 63 | --- |
| Stone, 2005 | GuardWire Plus | 252 | 58.5(51.1-69.3)† | 76.2 | 64.0 | 233 (178-296)† | 9.5 | --- | 18.3 | 40.2 | 72.1 | 7.5 | 35.9 | 20.2 | 40.5 | --- |
| | Control | 249 | 59.8 (52.1-69.3)† | 80.7 | 67.8 | 211 (158-273)† | 12.4 | --- | 18.9 | 38.5 | 72.1 | 17.3 | 38.2 | 28.5 | 44.6 | --- |

*Symptom onset to stenting, symptom onset to balloon, symptom onset to hospital arrival, symptom onset to reperfusion, elapsed time before reperfusion; †Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 22. Procedural characteristics of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | 60 | --- | 60/60 (100) | 0/60 (0) | --- | Aspirin 300 mg and clopidogrel 300-600 mg pre-PCI | Heparin IV during PCI (ACT 300 s) |
| | Control | 56 | --- | 56/56 (100) | 1/56 (1.8) | --- | | |
| Hahn, 2007 | GuardWire | 19 | --- | 19/19 (100) | --- | 1/19 (5.3) | Appropriate antiplatelet therapy | Heparin |
| | Control | 20 | --- | 29/20 (100) | --- | 1/20 (5.0) | | |
| Matsuo, 2007 | GuardWire Distal Protection System | 80 | 75.8 (30) | --- | --- | 9/80 (11) | Aspirin 100 mg and ticlopidine 200 mg pre-PCI | Heaparin 5000 U (ACT >250 s) |
| | Control | 74 | 53 (25) | --- | --- | 5/74 (7) | | |
| Muramatsu, 2007 | GuardWire Plus System | 173 | 29.7 (18.3)* | 173/173 (100) | --- | --- | Aspirin 81-100 mg/d and ticlopidine 200 mg/d for at least 2 weeks | --- |
| | Control | 168 | 29.5 (18.2)* | 168/168 (100) | --- | --- | | --- |
| Zhou, 2007 | PercuSurge GuardWire | 52 | --- | 52/52 (100) | --- | 0/52 (0) | Aspirin 300 mg and clopidogrel 300 mg pre-PCI then aspirin 100 mg/d and clopidogrel 75 mg/d post-PCI | Heparin IV during PCI (ACT ≥300 s) |
| | Control | 60 | --- | 60/60 (100) | --- | 0/60 (0) | | |
| Okamura, 2005 | PercuSurge GuardWire | 8 | --- | 8/8 (100) | --- | --- | Aspirin 243 mg at least 30 min pre-PCI | Heparin 100 U/kg IV |
| | Control | 8 | --- | 8/8 (100) | --- | --- | | |
| Stone, 2005 | GuardWire Plus | 252 | 53 (42-69)† | 244/252 (96.8) | --- | 210/252 (83.3) | Aspirin 324 mg and clopidogrel 300 mg pre-PCI | Heparin IV 70 U/kg bolus (ACT >300 s pre-PCI or 200-300 s if GP2B3Ai used) |
| | Control | 249 | 39 (29-51)† | 241/249 (96.8) | --- | 208/249 (83.5) | | |

*Operation time; †Median (interquartile range)

Abbreivations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IV=intravenous; kg=kilogram; mg=milligram; min=minutes; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units

Table 23. Baseline characteristics of randomized controlled trials evaluating proximal balloon embolic protection versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | 141 | 62 (11) | 80 | 98.58 | 170 (132-234)† | 6 | --- | 0 | 29 | 76 | 12 | 31 | 21 | 50 | 35 |
| | Control | 143 | 59 (11) | 80 | 96.50 | 153 (126-212)† | 9 | --- | 0 | 29 | 66 | 6 | 23 | 13 | 65 | 38 |

*Symptom onset to balloon; †Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 24. Procedural characteristics of randomized controlled trials evaluating proximal balloon embolic protection versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | 141 | 45 (36-58)* | --- | 15/141 (11) | 61/141(43) | Aspirin 300 mg pre-PCI and at least 80 mg/d post-PCI and clopidogrel 600 mg load pre-PCI followed by 75 mg/d post-PCI | Heparin 70 U/kg pre-PCI |
| | Control | 143 | 31 (25-40)* | --- | 27 /143 (19) | 50/143 (35) | | |

*Median (interquartile range)

Abbreviations: d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; kg=kilogram; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; SD=standard deviation; U=units

Table 25. Baseline characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus cotnrol in patients with mixed acute coronary syndrome

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Parikh 2008 | Distal Balloon Embolic Protection | GuardWire | 30 | 55.17 (12) | 90 | --- | --- | --- | --- | --- | 53 | 100 | 20 | 20 | 3 | 17 | 23 |
| | | Control | 37 | 56.16 (11.31) | 95 | --- | --- | --- | --- | --- | 62 | 100 | 41 | 28 | 8 | 19 | 27 |
| Gick 2005 | Distal Filter Embolic Protection | FilterWire | 100 | 62.9 (11.3) | 86 | 65 | 372 (210-726)† | 12 | --- | --- | 45 | --- | 21 | 65 | --- | 35 | --- |
| | | Control | 100 | 60.2 (13.0) | 80 | 57 | 474 (266-936)† | 17 | --- | --- | 39 | --- | 26 | 69 | --- | 35 | --- |
| Sardella 2005 | Catheter Aspiration | Diver CE | 28 | 65.3 (11.2)‡ | 77.42‡ | --- | 408 (138)‡ | --- | 100 | 0 | --- | 100 | --- | 78 | --- | --- | --- |
| | | Control | 34 | | | --- | | --- | 100 | 0 | --- | 100 | --- | 55 | --- | --- | --- |
| Kunii 2004 | Catheter Aspiration | Rescue PT | 129 | 64 (11.8) | 79.84 | --- | --- | --- | --- | 0 | 34.1 | --- | --- | --- | --- | --- | --- |
| | | Control | 129 | 65.9 (11.1) | 79.84 | --- | --- | --- | --- | 0 | 45.8 | --- | --- | --- | --- | --- | --- |
| Nanasato 2004 | Distal Balloon Embolic Protection | GuardWire | 34 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 30 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Matsushita 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire | 24 | 63 (13) | 83.33 | --- | --- | 0 | 100 | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 56 | 63 (10) | 76.79 | --- | --- | 0 | 100 | --- | --- | --- | --- | --- | --- | --- | --- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer | 30 | 55.9 (9.9) | 73 | 80.00 | 291 (177) | 10 | 35 | 23 | 30 | --- | 17 | 53 | 60 | 57 | --- |
| | | Control | 31 | 53.9 (10.0) | 77 | 74.19 | 279 (185) | 10 | 35 | 10 | 32 | --- | 13 | 36 | 58 | 55 | --- |

*Symptom onset to balloon, symptom onset to percutaneous coronary intervention; †Median (interquartile range); ‡Mean for the total study population

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 26. Procedural characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndrome

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire<br>Control | 30<br>37 | 25.01 (11.89)<br>31.98 (15.33) | ---<br>--- | 10/30 (33)<br>3/37 (8) | 13/30 (43)<br>26/37 (70) | ---<br>--- | ---<br>--- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire<br>Control | 100<br>100 | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | Aspirin 500 mg IV and clopidogrel 600 mg load pre-PCI | Heparin 100 U/kg pre-PCI |
| Sardella, 2005 | Catheter Aspiration | Diver CE<br>Control | 28<br>34 | ---<br>--- | 28/28 (100)<br>34/34 (100) | ---<br>--- | 28/28 (100)<br>34/34 (100) | ---<br>--- | Heparin |
| Kunii, 2004 | Catheter Aspiration | Rescue PT<br>Control | 129129 | ---<br>--- | 129/129 (100)<br>129/129 (100) | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire<br>Control | 34<br>32 | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire<br>Control | 24<br>56 | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer<br>Control | 30<br>31 | ---<br>--- | ---<br>--- | 14/30 (46.67)<br>2/31 (6.45) | 22/30 (73)<br>21/31 (68) | STEMI or UA: Aspirin pre-PCI and 100 mg post-PCI and clopidogrel 600 mg immediately after stenting and then 75 mg/d for 30 d | STEMI: Heparin (ACT >300 s) pre-PCI and during intervention<br><br>UA: low-molecular weight heparin pre-PCI and heparin during intervention (ACT >300 s) |

*Median (interquartile range)

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IV=intravenous; kg=kilogram; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; STEMI=ST-segment elevation myocardial infarction; U=units; UA=unstable angina

Table 27. Baseline characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD) | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Webster 2008 | Distal Filter Embolic Protection | FilterWire EZ | 77 | 58 (11) | 83 | --- | --- | --- | --- | --- | 39 | --- | 16 | 39 | 69 | 71 | --- |
| | | Control | 74 | 60 (13) | 89 | --- | --- | --- | --- | --- | 32 | --- | 26 | 46 | 62 | 66 | --- |
| Dudek 2003 | Distal Filter Embolic Protection | AngioGuard | 15 | 59.4 (66.6) | 66.6 | --- | --- | 60 | --- | --- | --- | --- | 0 | 40 | 26.0 | --- | --- |
| | | Control | 16 | 49.3 (8.4) | 62.5 | --- | --- | 50 | --- | --- | --- | --- | 0 | 62.5 | 31.0 | --- | --- |

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 28. Procedural characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ | 77 | --- | --- | --- | --- | --- | --- |
| | | Control | 74 | --- | --- | --- | --- | --- | --- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard | 15 | 63 (17) | 15/15 (100) | --- | --- | Aspirin 75 mg and ticlopidine 500 mg/d | Heparin 60 U/kg (ACT 200-300 s) |
| | | Control | 16 | --- | 16/16 (100) | --- | --- | | |

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; kg=kilogram; mg=milligram; n=number; N=number of participants in the group; s=seconds; SD=standard deviation; U=units

Table 29. Baseline characteristics of direct comparative randomized controlled trials in ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sardella 2008 | Catheter Aspiration | Diver Invatec catheter | 52 | 64.6 (12.5) | 78.8 | 100 | 414 (60) | 0 | --- | 0 | 46.1 | 100 | 26.9 | 63.4 | --- | 42.3 | 23.0 |
| | Catheter Aspiration | Export Medtronic | 51 | 66.7 (14.1) | 78.4 | 100 | 408 (54) | 0 | --- | 0 | 41.2 | 100 | 23.5 | 66.6 | --- | 49.0 | 29.4 |
| Yan 2007 | Catheter Aspiration | Diver CE catheter | 61 | 60 (14) | 82 | 100 | 350 (185) | --- | 0 | 0 | 0 | --- | 31 | 62 | 54 | 62 | 30 |
| | Distal Balloon Embolic Protection | GuardWire Plus | 61 | 60 (13) | 84 | 100 | 345 (180) | --- | 0 | 0 | 0 | --- | 28 | 57 | 56 | 61 | 23 |

*Symptom onset to balloon, Symptom onset to angiogram

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 30. Procedural characteristics of direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | 52 | --- | 52/52 (100) | 32/52 (65.3) | 52/52 (100) | Aspirin 300 mg and clopidogrel 300 mg load pre-PCI and aspirin 100 mg/d and clopidogrel 75 mg/d (for 6 m) post-PCI | Heparin (ACT >250 s) and continued for 48 hours post-PCI |
| | Catheter Aspiration | Export Medtronic | 51 | --- | 51/51 (100) | 39/51 (76.4) | 51/51 (100) | | |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | 61 | 60 (24) | --- | 39/61 (64) | 7/61 (11) | Aspirin 300 mg and clopidogrel 300-600 mg pre-PCI<br>Aspirin 300 mg/d for 4 weeks then 100 mg/d and clopidogrel 75 mg/d for greater than 9-12 m | Heparin 8000-10000 U IV during PCI and low-molecular weight heparin for 1 week if needed post-PCI |
| | Distal Balloon Embolic Protection | GuardWire Plus | 61 | 65 (28) | --- | 41/61 (67) | 8/61 (13) | | |

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIb IIIa inhibitor; IV=intravenous; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units

Table 31. Baseline characteristics of randomized controlled trials with selective inclusion/exclusion criteria in patient with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | 19 | 56.6 (10.9) | 79 | 100 | 268 (197) | 0 | 100 | --- | 100 | --- | 5.3 | 42.1 | 10.5 | 68.4 | --- |
| | | Control | 23 | 58.1 (10.8) | 70.9 | 100 | 323 (183) | 0 | 100 | --- | 100 | --- | 16.7 | 39.1 | 8.3 | 83.3 | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | 25 | 68 (9) | 100 | --- | --- | 0 | 0 | 0 | --- | --- | 45 | 45 | 55 | 50 | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | 24 | 60 (18) | 100 | --- | --- | 0 | 0 | 0 | --- | --- | 45 | 50 | 65 | 55 | --- |
| | | Control | 28 | 66 (13) | 100 | --- | --- | 0 | 0 | 0 | --- | --- | 40 | 50 | 65 | 65 | --- |

*Time to reperfusion

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 32. Procedural characteristics of randomized controlled trials with selective inclusion / exclusion criteria in patient with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | 19 | 39.5 (10.1) | 19/19 (100) | --- | 19/19 (100) | Aspirin and clopidogrel load pre-PCI | Heparin (ACT >200 s) |
| | | Control | 23 | 32.3 (18.6) | 23/23 (100) | --- | 23/23 (100) | | |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | 25 | --- | 25/25 (100) | --- | --- | Aspirin 162 mg and ticlopidine 200 mg pre-PCI and post-PCI | Heparin 10,000 U intra-arterial pre-PCI and 20,000 U/d IV post-PCI |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | 24 | --- | 24/24 (100) | --- | --- | | |
| | | Control | 28 | --- | 28/28 (100) | --- | --- | | |

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IV=intravenous; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units

Table 33. Baseline characteristics of controlled observational studies

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | 1050† | 58(12)‡ | 72.5‡ | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | | | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | 381 | --- | --- | --- | --- | --- | --- | 0 | --- | 25.6 | --- | --- | --- | --- | --- |
| | | Control | 2917 | --- | --- | --- | --- | --- | --- | 0 | --- | 14.3 | --- | --- | --- | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices§ | 990 | 63.3 (11.7) | 79.8 | 6.4 | 252 (288) | 13.9 | --- | 0 | 40.0 | --- | 31.3 | 53.0 | 47.2 | 66.0 | --- |
| | | Control | 2923 | 64.9 (11.4) | 76.7 | 14.6 | 282 (330) | 13.6 | --- | 0 | 47.0 | --- | 34.2 | 53.8 | 43.5 | 66.5 | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | 239 | 62 (13) | 60 | --- | --- | 13 | 30.1 | 16 | 30.5 | --- | 15 | 49 | 56 | 47 | --- |
| | | Control | 1021 | 61 (13) | 50 | --- | --- | 11 | 49.8 | 15 | 50.2 | --- | 16 | 53 | 53 | 38 | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | 200 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 1168 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Symptom onset to admission; †Total study population; ‡Mean for the total study population; §Multiple devices including Rescue catheter, Thrombuster catheter, Transvascular aspiration catheter and Export

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 34. Procedural characteristics of controlled observational studies

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Ko, 2009 | Catheter Aspiration | Aspiration Catheter | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- |
| Nilsen, 2009 | Distal Embolic Protection | Distal Protection Device | 381 | --- | --- | 155/381 (40.7) | --- | --- | --- |
| | | Control | 2917 | --- | --- | 855/2917(29.3) | --- | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | 990 | --- | 784/990 (79.2) | --- | --- | --- | --- |
| | | Control | 2923 | --- | 1789/2923 (61.2) | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | 239 | --- | 215/239 (90) | --- | 132/239 (55) | --- | Heparin (ACT>250 s) |
| | | Control | 1021 | --- | 878/1021 (86) | --- | 639/1021 (63) | --- | |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | 200 | --- | --- | --- | --- | --- | --- |
| | | Control | 1168 | --- | --- | --- | --- | --- | --- |

*Multiple devices including Rescue catheter, Thrombuster catheter, Transvascular aspiration catheter and Export

Abbreviations: ACT=activated clotting time; GP2B3Ai=glycoprotein IIbIIIa inhibitor; n=number; N=number of participants in the group; s=seconds; SD=standard deviation

Table 35. Baseline characteristics of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD)* | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | 23 | 58 (10) | 82.61 | 34.78 | 186 (186) | 0 | --- | --- | 43 | --- | 61 | 48 | 65 | 74 | --- |
| | | Thrombuster | 21 | 62 (8) | 80.95 | 90.48 | 126 (78) | 0 | --- | --- | 48 | --- | 19 | 52 | 90 | 81 | --- |

*Symptom onset to arrival

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; MtPA=mutant plasminogen activator; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 36. Procedural characteristics of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | 23 | 57 (22) | 23/23 (100) | --- | --- | Aspirin 100 mg and ticlopidine 100 mg pre-PCI and both for 6 m post-PCI | Heparin 60 U/kg |
| | | Thrombuster | 21 | 64 (21) | 21/21 (100) | --- | --- | | |

Abbreviations: ACT=activated clotting time; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=International Units; kg=kilogram; m=months; mg=milligram; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units

Table 37. Baseline characteristics of randomized controlled trials with unique comparisons in patients with mixed acute coronary syndrome

| Study, Year | Device Category | Group | N | Mean Age (SD) | Male (%) | TIMI-0/1 (%) | Mean Ischemic Time in Minutes (SD) | Prior MI (%) | Anterior MI (%) | Failed TL (%) | IRA LAD (%) | Visible Lesion (%) | DM (%) | HTN (%) | HCL (%) | Smoker (%) | FHx (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | 57 | 57.75 (6.78) | 52.63 | 84.2 | 360 (240-540)† | 22.81 | 43.86 | 0 | --- | 57.89 | 26.32 | 63.16 | 49.12 | 49.12 | --- |
| | | Abciximab | 63 | 58.71 (7.41) | 71.43 | 77.8 | 360 (300-720)† | 20.63 | 41.27 | 0 | --- | 71.43 | 30.16 | 61.90 | 50.79 | 49.21 | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | 30 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Thrombectomy + Stenting | 30 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=total number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 38. Procedural characteristics of randomized controlled trials with unique comparison in patients with mixed acute coronary syndrome

| Study, Year | Device Category | Group | N | Mean Procedure Time in Minutes (SD) | Stenting n/N (%) | Direct Stenting n/N (%) | Procedural GP2B3Ai Use n/N (%) | Anti-platelet Drugs Used | Anti-thrombotic Drugs Used |
|---|---|---|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | 57 | 58 (35-88)* | 57/57 (100) | 40/57 (57) | --- | Aspirin 300 mg and clopidogrel 300 mg pre-PCI | Device group: heparin 100 IU/kg (ACT >300 s) |
| | | Abciximab | 63 | 43 (25-87)* | 63/63 (100) | 41/63 (65.7) | 63/63 (100) | | Abciximab group: heparin 70 IU/kg (ACT >250 s) |
| Kanaya, 2003 | Thrombectomy + Distal protection device | Thrombectomy + stenting + distal protection device | 30 | --- | 30/30 (100) | --- | --- | --- | --- |
| | | Thrombectomy + stenting | 30 | --- | 30/30 (100) | --- | --- | --- | --- |

Abbreviations: GP2B3Ai=glycoprotein IIbIIIa inhibitor; n=number; N=number of participants in the group; SD=standard deviation

# Appendix F. Additional evidence tables and reference list

Table 39. Mortality in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | Cardiac death | --- | --- | 1/55 | --- |
| | Control | | --- | --- | 0/56 | --- |
| Lipiecki, 2009 | Export Catheter | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Moura, 2009 | TAC | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | Death | 0/88 | 0/88 | 0/88* | 0/88# |
| | Control | 720-day data = cardiac death | 1/87 | 1/87 | 1/87* | 6/87# |
| Chao, 2008 | Export Aspiration Catheter | Death | --- | --- | 1/37 | --- |
| | Control | | --- | --- | 0/34 | --- |
| Chevalier, 2008 | Export Aspiration Catheter | Cardiac+ non-cardiac death | --- | 4/120 | --- | --- |
| | Control | | --- | 5/129 | --- | --- |
| Ciszewski, 2008 | Rescue/Diver | Death | 5/135† | --- | --- | --- |
| | Control | | | --- | --- | --- |
| Dudek, 2008 | Diver CE | Death | 3/100 | --- | 4/100 | --- |
| | Control | | 3/96 | --- | 3/96 | --- |
| Ikari, 2008 | TVAC | Death | 1/178 | --- | 2/170‡ | --- |
| | Control | | 1/171 | --- | 1/158‡ | --- |
| Svilaas, 2008 | 6F Export Aspiration Catheter | Death | --- | 11/529 | --- | 25/535** |
| | Control | | --- | 21/531 | --- | 41/536** |
| DeLuca, 2006 | Diver CE | Death | --- | --- | 0/35 | 2/20* |
| | Control | | --- | --- | 2/38 | 4/28* |
| Kaltoft, 2006 | Rescue Catheter | Death | --- | 0/108 | --- | --- |
| | Control | | --- | 1/107 | --- | --- |
| Lee, 2006 | Export Aspiration Catheter | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | Death | 0/74 | --- | 0/74 | --- |
| | Control | | 0/74 | --- | 0/70 | --- |

Table 40. Mortality in randomized controlled trials evaluating catheter aspiration devices in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|
| Burzotta, 2005 | Diver CE | Death | 1/48[§] | 3/48 | --- | --- |
| | Control | | 2/48[§] | 3/48 | --- | --- |
| Noel, 2005 | Export | Death | 1/48[‖] | --- | --- | --- |
| | Control | | 2/48[‖] | --- | --- | --- |
| Dudek, 2004 | Rescue System | Death | 0/24[¶] | --- | --- | --- |
| | Control | | 1/26[¶] | --- | --- | --- |

*270-day data; [†]3-7 days post PCI in the both the groups together; [‡]240-day data; [§]In the catheterization lab; [‖]Post-PCI; [¶]Time period not specified; [#]730-day data; **365-day data

Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 41. Mortality in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectomy | Death | --- | 4/256 | 7/251 | 7/221* |
| | Control | | --- | 7/245 | 11/242 | 14/220* |
| Ali, 2006 | AngioJet Catheter | Death independent of MACE at 30 days Death at 6 months | --- | 11/240 | 14/24 | --- |
| | Control | | --- | 2/240 | 5/240 | --- |
| Lefèvre, 2005 | X-Sizer Catheter | Death | --- | 4/100 | 6/100 | --- |
| | Control | | --- | 4/101 | 4/101 | --- |
| Antoniucci, 2004 | AngioJet | Death | --- | 0/50 | --- | --- |
| | Control | | --- | 0/50 | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | Death | 3/46 | 3/46 | --- | --- |
| | Control | | 3/46 | 3/46 | --- | --- |

*365-day data

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

Table 42. Mortality in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | Death | --- | 8/312 | --- | --- |
| | Control | | --- | 8/314 | --- | --- |
| Cura, 2007 | SpideRX | Death | --- | 4/70 | 5/70 | --- |
| | Control | | --- | 4/70 | 4/70 | --- |
| Guetta, 2007 | FilterWire EZ | Death | --- | 2/51 | --- | --- |
| | Control | | --- | 0/49 | --- | --- |
| Lefèvre, 2004 | AngioGuard XP | Death | --- | 1/32 | --- | --- |
| | Control | | --- | 1/28 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 43. Mortality in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | Death | --- | 0/54 | 0/54 | --- |
| | Control | | --- | 2/52 | 2/52 | --- |
| Hahn, 2007 | GuardWire | Death | --- | --- | 0/19 | --- |
| | Control | | --- | --- | 1/20 | --- |
| Matsuo, 2007 | GuardWire Distal Protection System | Cardiac death | --- | 1/80 | 1/80 | --- |
| | Control | | --- | 2/74 | 3/74 | --- |
| Muramatsu, 2007 | GuardWire Plus System | Death | 5/173 | 5/173 | 11/173 | --- |
| | Control | | 7/168 | 7/168 | 11/168 | --- |
| Zhou, 2007 | PercuSurge GuardWire | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Stone, 2005 | GuardWire Plus | Death | --- | 5/246 | 8/243 | --- |
| | Control | | --- | 7/244 | 8/233 | --- |

Abbreviations: n=number; N=number of participants in the group

Table 44. Mortality in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | Death | --- | 2/141 | --- | --- |
| | Control | | --- | 2/143 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 45. Mortality in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire<br>Control | Death | 1/30<br>--- | ---<br>1/37 | ---<br>--- | 1/30*<br>4/37* |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire<br>Control | Death | ---<br>--- | 2/100<br>3/100 | 3/100<br>3/100 | ---<br>--- |
| Sardella, 2005 | Catheter Aspiration | Diver CE<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT<br>Control | Death | 2/129<br>2/129 | ---<br>--- | ---<br>--- | ---<br>--- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire<br>Control | Death | 0/24<br>3/56 | ---<br>--- | ---<br>--- | ---<br>--- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer<br>Control | Death | ---<br>--- | 2/33<br>1/33 | ---<br>--- | ---<br>--- |

*730-day data

Abbreviations: n=number; N=number of participants in the group

Table 46. Mortality in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard<br>Control | --- | ---<br>--- | 0/15<br>0/16 | ---<br>--- | ---<br>--- |

Abbreviations: n=number; N=number of participants in the group

Table 47. Mortality in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | Cardiac death | --- | 2/52 | --- | 2/50* |
| | Catheter Aspiration | Export Medtronic | | --- | 3/51 | --- | 0/48* |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | Death | --- | 2/61 | --- | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | | --- | 2/61 | --- | --- |

*365-day data

Abbreviations: n=number; N=number of participants in the group

Table 48. Mortality in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | --- | --- | --- | --- | --- |
| | | Control | | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | --- | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | | | | | |
| | | Control | | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 49. Mortality in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | Death | --- | --- | 0/19 | --- |
| | | Thrombuster | | --- | --- | 0/14 | --- |

Abbreviations: MtPA=mutant plasminogen activator; n=number; N=number of participants in the group

Table 50. Mortality in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | Death | --- | --- | 0/57 | --- |
| | | Abciximab | | --- | --- | 0/63 | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | --- | --- | --- | --- |
| | | Thrombectomy+ Stenting | | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 51. Mortality in observational studies

| Study, Year | Device Category | Group | Mortality definition | In-hospital Mortality n/N | 30-day Mortality n/N | 180-day Mortality n/N | 365-day Mortality n/N |
|---|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- | --- |
| | | Control | | --- | --- | --- | --- |
| Nilsen, 2009* | Catheter Aspiration | Aspiration Catheter | Death | --- | 10/381 | --- | --- |
| | | Control | | --- | 70/2917 | --- | --- |
| Nilsen, 2009* | Catheter Aspiration | Aspiration Catheter | Cardiac death | --- | 10/381 | --- | --- |
| | | Control | | --- | 64/2917 | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices[†] | Death | --- | 37/990 | --- | --- |
| | | Control | | --- | 180/2923 | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | Death | 7/239 | --- | --- | --- |
| | | Control | | 55/1021 | --- | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | Death | --- | --- | 10/200[‡] | --- |
| | | Control | | --- | --- | 76/1168[‡] | --- |

*Data from a single study; [†]Rescue Catheter, Thrombuster Catheter, Transvascular Aspiration Catheter, Export Catheter; [‡]270-day data;

Abbreviations: n=number; N=number of participants in the group

Table 52. Myocardial infarction in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | --- | --- | 3/55 | --- |
| | Control | --- | --- | 3/56 | -- |
| Lipiecki, 2009 | Export Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Moura, 2009 | TAC | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | 0/88 | 0/88 | 0/88 | 0/88* |
| | Control | 0/87 | 0/87 | 0/87 | 1/87* |
| Chao, 2008 | Export Aspiration Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Chevalier, 2008 | Export Aspiration Catheter | --- | 2/120 | --- | --- |
| | Control | --- | 1/129 | --- | --- |
| Ciszewski, 2008 | Rescue/Diver | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | 0/100 | --- | 1/100 | --- |
| | Control | 1/96 | --- | 3/96 | --- |
| Ikari, 2008 | TVAC | 0/178 | --- | 0/170† | --- |
| | Control | 1/171 | --- | 1/158† | --- |
| Svilaas, 2008 | 6F Export Aspiration Catheter | --- | 4/529 | --- | 12/535‡ |
| | Control | --- | 10/531 | --- | 23/536‡ |
| DeLuca, 2006 | Diver CE | --- | --- | 1/35 | --- |
| | Control | --- | --- | 0/38 | --- |
| Kaltoft, 2006 | Rescue Catheter | --- | 0/108 | --- | --- |
| | Control | --- | 1/107 | --- | --- |
| Lee, 2006 | Export Aspiration Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | 0/74 | --- | 0/74 | --- |
| | Control | 074 | --- | 1/7 | --- |
| Burzotta, 2005 | Diver CE | --- | 2/48 | --- | --- |
| | Control | --- | 2/48 | --- | --- |
| Noel, 2005 | Export | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Dudek, 2004 | Rescue System | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

*730-day data; †240-day data; ‡365-day data;
Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 53. Myocardial infarction in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | --- | 2/256 | 2/251 | 2/22* |
| | Control | --- | 3/245 | 3/242 | 3/220* |
| Ali, 2006 | AngioJet Catheter | --- | 0/240 | --- | --- |
| | Control | --- | 0/240 | --- | --- |
| Lefèvre, 2005 | X-Sizer Catheter | --- | 1/100 | 2/100 | --- |
| | Control | --- | 3/101 | 4/101 | --- |
| Antoniucci, 2004 | AngioJet | --- | 0/50 | --- | --- |
| | Control | --- | 0/50 | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | 0/46 | 2/46 | --- | --- |
| | Control | 0/46 | 2/46 | --- | --- |

*365-day data

Abbreviations: n=number; N=number of participants in the group

Table 54. Myocardial infarction in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | --- | 5/312 | --- | --- |
| | Control | --- | 1/314 | --- | --- |
| Cura, 2007 | SpideRX | --- | 0/70 | 0/70 | --- |
| | Control | --- | 5/70 | 5/70 | --- |
| Guetta, 2007 | FilterWire EZ | --- | 0/51 | --- | --- |
| | Control | --- | 1/49 | --- | --- |
| Lefèvre, 2004 | AngioGuardXP | --- | 1/32 | --- | --- |
| | Control | --- | 1/28 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 55. Myocardial infarction in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | --- | 1/54 | 1/54 | --- |
| | Control | --- | 0/52 | 1/52 | --- |
| Hahn, 2007 | GuardWire | --- | --- | 0/19 | --- |
| | Control | --- | --- | 1/20 | --- |
| Matsuo, 2007 | GuardWire Distal Protection System | --- | 1/80 | 1/80 | --- |
| | Control | --- | 0/74 | 0/74 | --- |
| Muramatsu, 2007 | GuardWire Plus System | 0/173 | 0/173 | 0/173 | --- |
| | Control | 1/168 | 1/168 | 1/168 | --- |
| Zhou, 2007 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Stone, 2005 | GuardWire Plus | --- | 5/246 | 6/243 | --- |
| | Control | --- | 7/244 | 9/233 | --- |

Abbreviations: n=number; N=number of participants in the group

Table 56. Myocardial infarction in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | --- | 2/141 | --- | --- |
| | Control | --- | 3/143 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 57. Myocardial infarction in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire | 1/30 | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | --- | --- | 3/57 | --- |
| | | Abciximab | --- | --- | 2/63 | --- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire | --- | 0/100 | 0/100 | --- |
| | | Control | --- | 0/100 | 0/100 | --- |
| Sardella, 2005 | Catheter Aspiration | Diver CE | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 58. Myocardial infarction in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard | --- | 0/15 | --- | --- |
| | | Control | --- | 0/16 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 59. Myocardial infarction in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | --- | 0/52 | --- | 1/50* |
| | Catheter Aspiration | Export Medtronic | --- | 0/51 | --- | 1/48* |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | --- | 1/61 | --- | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | --- | 0/61 | --- | --- |

*730-day data

Abbreviations: n=number; N=number of participants in the group

Table 60. Myocardial infarction in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | | | | |
| | | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 61. Myocardial infarction in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | --- | --- | 1/19 | --- |
| | | Thrombuster | --- | --- | 0/14 | --- |

Abbreviations: MtPA= mutant plasminogen activator; n=number; N=number of participants in the group

Table 62. Myocardial infarction in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | --- | --- | 3/57 | --- |
| | | Abciximab | --- | --- | 2/63 | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | --- | --- | --- |
| | | Thrombectomy+ Stenting | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 63. Myocardial infarction in observational studies

| Study, Year | Device Category | Group | In-hospital Myocardial infarction n/N | 30-day Myocardial infarction n/N | 180-day Myocardial infarction n/N | 365-day Myocardial infarction n/N |
|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | --- | 5/381 | --- | --- |
| | | Control | --- | 55/2917 | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | 6/239 | --- | --- | --- |
| | | Control | 10/1021 | --- | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | --- | --- | 8/200 | --- |
| | | Control | --- | --- | 25/1168 | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group

Table 64. Stroke in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Lipiecki, 2009 | Export Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Moura, 2009 | TAC | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | 2/88 | --- | --- | --- |
| | Control | 0/87 | --- | --- | --- |
| Chao, 2008 | Export Aspiration Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Chevalier, 2008 | Export Aspiration Catheter | --- | 2/120 | --- | --- |
| | Control | --- | 0/129 | --- | --- |
| Ciszewski, 2008 | Rescue/Diver | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Ikari, 2008 | TVAC | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Svilaas, 2008 | 6F Export Aspiration Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| DeLuca, 2006 | Diver CE | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Kaltoft, 2006 | Rescue Catheter | --- | 2/108 | --- | --- |
| | Control | --- | 0/107 | --- | --- |
| Lee, 2006 | Export Aspiration Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | --- | --- | 0/74 | --- |
| | Control | --- | --- | 0/70 | --- |
| Burzotta, 2005 | Diver CE | --- | 1/48 | --- | --- |
| | Control | --- | 1/48 | --- | --- |
| Noel, 2005 | Export | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Dudek, 2004 | Rescue System | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 65. Stroke in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | --- | 0/256 | 1/251 | 2/221* |
| | Control | --- | 1/245 | 1/242 | 1/220* |
| Ali, 2006 | AngioJet Catheter | --- | 4/240 | --- | --- |
| | Control | --- | 2/240 | --- | --- |
| Lefèvre, 2005 | X-Sizer Catheter | --- | 2/100 | 2/100 | --- |
| | Control | --- | 0/101 | 0/101 | --- |
| Antoniucci, 2004 | AngioJet | --- | 1/50 | --- | --- |
| | Control | --- | 0/50 | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | 0/46 | 0/46 | --- | --- |
| | Control | 0/46 | 0/46 | --- | --- |

*365-day data

Abbreviations: n=number; N=number of participants in the group

Table 66. Stroke in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | --- | 3/312 | --- | --- |
| | Control | --- | 2/314 | --- | --- |
| Cura, 2007 | SpideRX | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Guetta, 2007 | FilterWire EZ | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Lefèvre, 2004 | AngioGuardXP | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 67. Stroke in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Hahn, 2007 | GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Matsuo, 2007 | GuardWire Distal Protection System | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Muramatsu, 2007 | GuardWire Plus System | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Zhou, 2007 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Stone, 2005 | GuardWire Plus | --- | 0/246 | 2/243 | --- |
| | Control | --- | 4/244 | 4/233 | --- |

Abbreviations: n=number; N=number of participants in the group

Table 68. Stroke in randomized controlled trials evaluating proximal balloon embolic protection versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | --- | 0/141 | --- | --- |
| | Control | --- | 1/143 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 69. Stroke in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire<br>Control | ---<br>--- | 0/100<br>0/100 | ---<br>--- | ---<br>--- |
| Sardella, 2005 | Catheter Aspiration | Diver CE<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |

Abbreviations: n=number; N=number of participants in the group

Table 70. Stroke in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |

Abbreviations: n=number; N=number of participants in the group

Table 71. Stroke in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | --- | --- | --- | --- |
| | Catheter Aspiration | Export Medtronic | --- | --- | --- | --- |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | --- | 0/61 | --- | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | --- | 0/61 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 72. Stroke in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | | | | |
| | | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 73. Stroke in studies with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | --- | --- | 0/19 | --- |
| | | Thrombuster | --- | --- | 0/14 | --- |

Abbreviations: MtPA=mutant plasminogen activator; n=number; N=number of participants in the group

Table 74. Stroke in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | --- | --- | --- | --- |
| | | Abciximab | --- | --- | --- | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | --- | --- | --- |
| | | Thrombectomy+ Stenting | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 75. Stroke in observational studies

| Study, Year | Device Category | Group | In-hospital Stroke n/N | 30-day Stroke n/N | 180-day Stroke n/N | 365-day Stroke n/N |
|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | --- | 5/381 | --- | --- |
| | | Control | --- | 12/2917 | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | 1/239 | --- | --- | --- |
| | | Control | 5/1021 | --- | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group

Table 76. Target revascularization in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | TLR | --- | --- | 4/55 | --- |
| | Control | | --- | --- | 4/56 | --- |
| Lipiecki, 2009 | Export Catheter | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Moura, 2009 | TAC | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | TVR | --- | 0/88 | 5/87* | 4/88[†] |
| | Control | | --- | 0/87 | 0/88* | 5/87[†] |
| Chao, 2008 | Export Aspiration Catheter | TVR | --- | --- | 3/37 | --- |
| | Control | | --- | --- | 4/37 | --- |
| Chevalier, 2008 | Export Aspiration Catheter | TLR+TVR | --- | 2/120 | --- | --- |
| | Control | | --- | 1/129 | --- | --- |
| Ciszewski, 2008 | Rescue/Diver | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | Re-PCI (TVR, TLR, non-infarct involved vessel or CABG) | 2/100 | --- | --- | --- |
| | Control | | 1/96 | --- | --- | --- |
| Ikari, 2008 | TVAC | TLR | 0/178 | --- | 20/170[‡] | --- |
| | Control | | 1/171 | --- | 31/158[‡] | --- |
| Svilaas, 2008 | 6F Export Aspiration Catheter | TVR | --- | 24/529 | --- | 60/535[§] |
| | Control | | --- | 31/531 | --- | 69/536[§] |
| DeLuca, 2006 | Diver CE | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Kaltoft, 2006 | Rescue Catheter | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Lee, 2006 | Export Aspiration Catheter | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |

Table76. Target revascularization in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (coninued)

| Study, Year | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|
| Silva-Orrego, 2006 | Pronto Extraction Catheter | TVR | 1/74 | --- | 1/74 | --- |
| | Control | | 0/74 | --- | 2/70 | --- |
| Burzotta, 2005 | Diver CE | TLR | --- | 1/48 | --- | --- |
| | Control | | --- | 1/48 | --- | --- |
| Noel, 2005 | Export | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Dudek, 2004 | Rescue System | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |

*270-day data; †730-day data; ‡240-day data; §365-day data;

Abbreviations: CABG=coronary artery bypass graft; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TAC=Thrombectomy Aspiration Catheter; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVAC=Transvascular aspiration catheter; TVR=target vessel revascularization

Table 77. Target revascularization in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | TVR | --- | 2/256 | 18/251 | 22/221* |
| | Control | | --- | 6/245 | 32/242 | 32/220* |
| Ali, 2006 | AngioJet Catheter | TLR or sub-acute thrombosis | --- | 5/240 | --- | --- |
| | Control | | --- | 1/240 | --- | --- |
| Lefèvre, 2005 | X-Sizer Catheter | TVR | --- | 2/100 | 3/100 | --- |
| | Control | | --- | 0/101 | 5/101 | --- |
| Antoniucci, 2004 | AngioJet | TVR | --- | 0/50 | --- | --- |
| | Control | | --- | 0/50 | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | TVR | 0/46 | 0/46 | --- | --- |
| | Control | | 0/46 | 0/46 | --- | --- |

*365-day data

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 78. Target revascularization in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | TLR | --- | 6/312 | --- | --- |
| | Control | | --- | 2/314 | --- | --- |
| Cura, 2007 | SpideRX | Revascularization | --- | --- | 6/70 | --- |
| | Control | | --- | --- | 6/70 | --- |
| Guetta, 2007 | FilterWire EZ | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Lefèvre, 2004 | AngioGuardXP | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization

Table 79. Target revascularization in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | TVR | --- | 1/54 | 3/54 | --- |
| | Control | | --- | 1/52 | 2/52 | --- |
| Hahn, 2007 | GuardWire | TLR | --- | --- | 0/19 | --- |
| | Control | | --- | --- | 2/20 | --- |
| Matsuo, 2007 | GuardWire Distal Protection System | TVR | --- | --- | 5/80 | --- |
| | Control | | --- | --- | 9/74 | --- |
| Muramatsu, 2007 | GuardWire Plus System | TLR | 0/173 | 0/173 | 17/173 | --- |
| | Control | | 1/168 | 1/168 | 16/168 | --- |
| Zhou, 2007 | PercuSurge GuardWire | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- |
| Stone, 2005 | GuardWire Plus | TVR | --- | 9/246 | 15/243 | --- |
| | Control | | --- | 6/244 | 13/233 | --- |

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 80. Target revascularization in randomized controlled trials evaluating proximal balloon embolic protection device versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|
| Haeck, 2009* | Proxis<br>Control | Urgent percutaneous TVR | ---<br>--- | 2/141<br>4/143 | ---<br>--- | ---<br>--- |
| Haeck, 2009* | Proxis<br>Control | Urgent percutaneous TLR | ---<br>--- | 2/141<br>3/143 | ---<br>--- | ---<br>--- |
| Haeck, 2009* | Proxis<br>Control | Surgical TVR | ---<br>--- | 1/141<br>2/143 | ---<br>--- | ---<br>--- |

*Data from the same study

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 81. Target revascularization in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire<br>Control | TVR | 0/30*<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire<br>Control | Revascularization | ---<br>--- | 0/100<br>0/100 | ---<br>--- | ---<br>--- |
| Sardella, 2005 | Catheter Aspiration | Diver CE<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer<br>Control | ---<br>--- | 0/33<br>1/33 | ---<br>--- | ---<br>--- | ---<br>--- |

*Within 3 days of index procedure

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TVR=target vessel revascularization

Table 82. Target revascularization in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard | Revascularization | --- | 0/15 | --- | --- |
| | | Control | | --- | 0/16 | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 83. Target revascularization in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | TVR | --- | 0/52 | --- | 3/50* |
| | Catheter Aspiration | Export Medtronic | | --- | 0/51 | --- | 2/48* |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | TVR | --- | 1/61 | --- | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | | --- | 1/61 | --- | --- |

*365-day data

Abbreviations: n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 84. Target revascularization in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration Distal Balloon Embolic Protection | Rescue or Thrombuster systems PercuSurge GuardWire | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 85. Target revascularization in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+Mt PA | Re-intervention of IRA | --- | --- | 4/19 | --- |
| | | Thrombuster | | --- | --- | 4/14 | --- |

Abbreviations: IRA=infarct related artery; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention

Table 86. Target revascularization in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | Re-PCI | --- | --- | 8/57 | --- |
| | | Abciximab | | --- | --- | 8/63 | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | --- | --- | --- | --- |
| | | Thrombectomy+ Stenting | --- | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 87. Target revascularization in observational studies

| Study, Year | Device Category | Group | Target Revascularization Definition | In-hospital Target Revascularization n/N | 30-day Target Revascularization n/N | 180-day Target Revascularization n/N | 365-day Target Revascularization n/N |
|---|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | TVR | --- | 7/381 | --- | --- |
| | | Control | | --- | 73/2917 | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical thrombectomy | AngioJet XMI or XVG Catheter | TVR | 5/239 | --- | --- | --- |
| | | Control | | 28/1021 | --- | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | TVR | --- | --- | 11/200† | --- |
| | | Control | | --- | --- | 56/1168† | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter; †270-day data

Abbreviations: n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 88. Major adverse cardiac events in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | --- | --- | --- | 8/55 | --- |
| | Control | | --- | --- | 7/56 | --- |
| Lipiecki, 2009 | Export Catheter | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Moura, 2009 | TAC | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | Cardiac mortality, nonfatal reinfarction and TVR | 2/88* | 0/88 | 4/88† | 4/88‡ |
| | Control | | 1/87* | 1/87 | 9/87† | 12/87‡ |
| Chevalier, 2008 | Export Aspiration Catheter | Mortality, reinfarction, emergent bypass surgery, TLR or CVA | --- | 7/120 | --- | --- |
| | Control | | --- | 6/129 | --- | --- |

Table 88. Major adverse cardiac events in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|
| Chao, 2008 | Export Aspiration Catheter | Mortality, stroke, non fatal reinfarction, TVR | --- | --- | 5/37 | --- |
| | Control | | --- | --- | 10/37 | --- |
| Ciszewski, 2008 | Rescue/Diver | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | Mortality, reinfarction, rePCI | 5/100 | --- | 5/100[§] | --- |
| | Control | | 5/96 | --- | 6/96[§] | --- |
| Ikari, 2008 | TVAC | Mortality, recurrence of MI and TLR | 1/178 | --- | 22/170[‖] | 36/180[#] |
| | Control | | 2/171 | --- | 33/158[‖] | 62/175[#] |
| Svilaas, 2008 | 6F Export Aspiration Catheter | Mortality, reinfarction or TVR | --- | 36/529 | --- | 89/535[**] |
| | Control | | | 50/531 | --- | 109/536[**] |
| DeLuca, 2006 | Diver CE | Mortality, new onset MI, and hospitalization for CHF | --- | --- | 3/35 | --- |
| | Control | | --- | --- | 4/38 | --- |
| Kaltoft, 2006 | Rescue Catheter | Mortality, reinfarction, disabling stroke | --- | 2/108 | --- | --- |
| | Control | | --- | 2/107 | --- | --- |
| Lee, 2006 | Export Aspiration Catheter | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Burzotta, 2005 | Diver CE | Major adverse events | --- | 5/48 | --- | --- |
| | Control | | --- | 5/48 | --- | --- |
| Noel, 2005 | Export | --- | 1/24[††] | --- | --- | --- |
| | Control | | 2/26[††] | --- | --- | --- |
| Dudek, 2004 | Rescue System | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |

*Cardiac Mortality, non fatal reinfarction, TVR and stroke; [†]270-day data; [‡]730-day data; [§]Reinfarction and mortality; [‖] 240-day data; [#]1095-day data; [**]365-day data; [††]no time period specified

Abbreviations: CHF=congestive heart failure; CVA=cerebrovascular accident; n=number; MACE=major adverse cardiac events; MI=myocardial infarction; N=number of participants in the group; PCI=percutaneous coronary intervention; TAC=Thrombectomy Aspiration Catheter; TLR=target lesion revascularization; TVAC=Transvascular aspiration catheter; TVR=target vessel revascularization

Table 89. Major adverse cardiac events in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | Mortality, MI, TVR, stroke | --- | 8/256 | 28/251 | 33/22* |
| | Control | | --- | 17/245 | 47/242 | 50/220* |
| Ali, 2006 | AngioJet Catheter | Mortality, new Q wave MI , emergent CABG, TLR, stroke, stent thrombosis | --- | 16/240 | --- | --- |
| | Control | | --- | 4/240 | --- | --- |
| Lefèvre, 2005 | X-Sizer Catheter | Major adverse cardiac and cerebral events | --- | 9/100 | 13/100 | --- |
| | Control | | --- | 7/101 | 13/101 | --- |
| Antoniucci, 2004 | AngioJet | --- | --- | 0/50 | --- | --- |
| | Control | | --- | 0/50 | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |

*365-day data

Abbreviations: CABG=coronary artery bypass graft; n=number; MACE=major adverse cardiac events; MI=myocardial infarction; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 90. Major adverse cardiac events in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | Mortality, TLR, reinfarction, stroke | --- | 17/312 | 22/312* | --- |
| | Control | | --- | 10/314 | 18/314* | --- |
| Cura, 2007 | SpideRX | Mortality, reinfarction, HF | --- | 10/70 | 10/70 | --- |
| | Control | | --- | 10/70 | 11/70 | --- |
| Guetta, 2007 | FilterWire EZ | Mortality, non fatal MI, CHF | --- | 3/51 | --- | --- |
| | Control | | --- | 1/49 | --- | --- |
| Lefèvre, 2004 | AngioGuardXP | Mortality and MI | --- | 2/32 | --- | --- |
| | Control | | --- | 2/28 | --- | --- |

*240-day data

Abbreviations: CHF=congestive heart failure; HF=heart failure; MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TLR=target lesion revascularization

Table 91. Major adverse cardiac events in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | Mortality, reinfarction and ischemia driven TVR | --- | 2/54 | 4/54 | --- |
| | Control | | --- | 2/52 | 5/52 | --- |
| Hahn, 2007 | GuardWire | Mortality, MI and TLR | --- | --- | 0/19 | --- |
| | Control | | --- | --- | 4/20 | --- |
| Matsuo, 2007 | GuardWire Distal Protection System | Mortality, non lethal MI, heart failure, ischemia-driven revascularization | --- | 3/80 | 10/80 | --- |
| | Control | | --- | 3/74 | 12/74 | --- |
| Muramatsu, 2007 | GuardWire Plus System | Mortality, myocardial infarction or TLR | 5/173 | 5/173 | 28/173 | --- |
| | Control | | 9/168 | 9/168 | 28/168 | --- |
| Zhou, 2007 | PercuSurge GuardWire | --- | 0/52 | --- | --- | --- |
| | Control | | 0/60 | --- | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- | --- |
| | Control | | --- | --- | --- | --- |
| Stone, 2005* | GuardWire Plus | MACE related to ischemic complications | --- | 14/246 | 24/243 | --- |
| | Control | | --- | 18/244 | 26/233 | --- |
| Stone, 2005* | GuardWire Plus | MACE related to LV dysfunction | --- | 36/246 | 40/243 | --- |
| | Control | | --- | 32/244 | 35/233 | --- |

*Data from a single study

Abbreviations: LV=left ventricular; MACE=major adverse cardiac events; MI=Myocardial infarction; n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 92. Major adverse cardiac events in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with St-segment elevation myocardial infarction

| Study, Year | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | Mortality, spontaneous or procedural MI, stroke, percutaneous or surgical TVR | --- | 6/141 | --- | --- |
| | Control | | --- | 10/143 | --- | --- |

Abbreviations: MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 93. Major adverse cardiac events in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire<br>Control | --- | ---<br>--- | ---<br>--- | 13/100<br>12/100 | ---<br>--- |
| Sardella, 2005 | Catheter Aspiration | Diver CE<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire<br>Control | --- | ---<br>--- | ---<br>--- | 1/24<br>7/56 | ---<br>--- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer<br>Control | --- | ---<br>--- | 2/33<br>2/33 | ---<br>--- | ---<br>--- |

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

Table 94. Major adverse cardiac events in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ<br>Control | Mortality, recurrent MI, emergent CABG, repeat TVR | 9/77<br>7/74 | 9/77<br>8/74 | ---<br>--- | ---<br>--- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard<br>Control | --- | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |

Abbreviations: CABG=coronary artery bypass graft; MACE=Major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 95. Major adverse cardiac events in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | Cardiac mortality, Q and non Q wave MI, TVR | --- | 2/52 | --- | 5/50* |
| | Catheter Aspiration | Export Medtronic | | --- | 3/51 | --- | 2/48* |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | Mortality, MI,TVR, stroke | --- | 4/61 | --- | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | | --- | 3/61 | --- | --- |

*365-day data

Abbreviation: MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 96. Major adverse cardiac events in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | --- | --- | --- | --- | --- |
| | | Control | | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | --- | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | | --- | --- | --- | --- |
| | | Control | | --- | --- | --- | --- |

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

Table 97. Major adverse cardiac events in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | --- | --- | --- | --- | --- |
| | | Thrombuster | | --- | --- | --- | --- |

Abbreviations: MACE=major adverse cardiac events; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group

Table 98. Major adverse cardiac events in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | --- | --- | --- | --- | --- |
| | | Abciximab | | --- | --- | --- | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | --- | --- | --- | --- |
| | | Thrombectomy+ Stenting | | --- | --- | --- | --- |

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

Table 99. Major adverse cardiac events in observational studies

| Study, Year | Device Category | Group | MACE definition | In-hospital MACE n/N | 30-day MACE n/N | 180-day MACE n/N | 365-day MACE n/N |
|---|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- | --- |
| | | Control | | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | Mortality, re-infarction, TVR for ischemia, stroke | --- | 21/381 | --- | --- |
| | | Control | | --- | 155/2917 | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | --- | --- | --- | --- | --- |
| | | Control | | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | Mortality, re-infarction, TVR, stroke | 18/239 | --- | --- | --- |
| | | Control | | 92/1021 | --- | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | Mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event | --- | --- | 28/200† | --- |
| | | Control | | --- | --- | 136/1168† | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter; †270-day data

Abbreviations: MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 100. ST-segment resolution in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Liistro, 2009 | Export Thrombectomy Catheter | 39/55 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 39/55 | --- | --- | --- | --- | --- |
| | Control | 22/56 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 22/56 | --- | --- | --- | --- | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Lipiecki, 2009 | Export Catheter | 11/19 | --- | --- | --- | --- | --- | --- | --- | --- | 3/19 | 5/19 | 11/19 | --- | 2/19[†] | 2/19[†] | 15/19[†] | --- |
| | Control | 11/24 | --- | --- | --- | --- | --- | --- | --- | --- | 6/21 | 4/21 | 11/21 | --- | 3/21[†] | 7/21[†] | 12/21[†] | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Moura, 2009 | TAC | 67/76 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 67/76[‡] | --- |
| | Control | 33/76 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 33/76[‡] | --- |
| | Export | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Sardella, 2009 | Medtronic (EM) | 70/88 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 70/88 | --- | --- | --- | --- | --- |
| | Control | 34/87 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 34/87 | --- | --- | --- | --- | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Chao, 2008 | Export Aspiration Catheter | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Chevalier, 2008 | Export Aspiration Catheter | 88/120 | --- | --- | --- | --- | --- | --- | --- | 88/120[§] | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 84/129 | --- | --- | --- | --- | --- | --- | --- | 88/129[§] | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Ciszewski, 2008 | Rescue/Diver | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Dudek, 2008 | Diver CE | 50/100 | --- | --- | 41/100 | --- | --- | --- | 50/100 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 39/96 | --- | --- | 26/96 | --- | --- | --- | 39/96 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Ikari, 2008 | TVAC | 37/115 | 39/115 | 39/115 | 37/115 | --- | --- | --- | --- | --- | --- | --- | --- | --- | 31/113[‖] | 36/113[‖] | 46/113[‖] | --- |
| | Control | 28/105 | 43/105 | 34/105 | 28/105 | --- | --- | --- | --- | --- | --- | --- | --- | --- | 25/105[‖] | 39/105[‖] | 41/105[‖] | --- |
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Svilaas, 2008 | 6F Export Aspiration Catheter | 275/486 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 61/486[¶] | 150/486[¶] | 275/486[¶] | --- |
| | Control | 219/496 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 89/496[¶] | 188/496[¶] | 219/496[¶] | --- |

Table100. ST-segment resolution in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| DeLuca, 2006 | Diver CE | 31/38 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 31/38 | --- | --- | --- | --- | --- |
| | Control | 21/38 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 21/38 | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Kaltoft, 2006 | Rescue Catheter | 37/93 | 43/97 | 32/97 | 22/97 | --- | --- | --- | --- | --- | 22/93 | 34/93 | 37/93 | --- | 16/80[#] | 29/80[#] | 35/80[#] | --- |
| | Control | 34/89 | 48/91 | 23/91 | 20/91 | --- | --- | --- | --- | --- | 25/89 | 30/89 | 34/89 | --- | 26/79[#] | 24/79[#] | 29/79[#] | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Lee, 2006 | Export Aspiration Catheter | 40/67 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 40/67[‡§] |
| | Control | 24/66 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 24/66[‡§] |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | 50/74 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 3/74[‡] | 21/74[‡] | 50/74[‡] | --- |
| | Control | 37/74 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 10/74[‡] | 27/74[‡] | 37/74[‡] | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Burzotta, 2005 | Diver CE | 29/46 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 29/46[‡] | --- |
| | Control | 18/49 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 18/49[‡] | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Noel, 2005 | Export | 12/24 | --- | --- | --- | --- | --- | --- | 12/24 | 21/24[§] | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 3/26 | --- | --- | --- | --- | --- | --- | 3/26 | 16/26[§] | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Dudek, 2004 | Rescue System | 27/40 | --- | --- | --- | --- | 6/40 | 6/40 | 27/40 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 8/32 | --- | --- | --- | --- | 8/32 | 16/32 | 8/32 | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; [†]24 hours after PCI; [‡]Post procedure, time period not specified; [§]>50% Resolution; [||]3-6 hours after PCI; [¶]30-60 minutes after PCI; [#]6 hours after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 101. ST-segment resolution in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | 211/246 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 211/246[†‡] |
| | Control | 189/240 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 189/240[†‡] |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Ali, 2006 | AngioJet Catheter | 105/176 | --- | --- | --- | --- | --- | --- | --- | --- | 21/176[§] | 50/176[§] | 105/176[§] | 136/176[§‡] | --- | --- | --- | --- |
| | Control | 111/164 | --- | --- | --- | --- | --- | --- | --- | --- | 18/164[§] | 35/164[§] | 130/164[§] | 130/164[§‡] | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Lefèvre, 2005 | X-Sizer Catheter | 61/90 | --- | --- | --- | --- | --- | --- | --- | 61/90[‡] | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 50/95 | --- | --- | --- | --- | --- | --- | --- | 50/95[‡] | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Antoniucci, 2004 | AngioJet | 45/50 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 45/50[†‡] |
| | Control | 36/50 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 36/50[†‡] |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Napodano, 2003 | X-Sizer Catheter | 38/46 | --- | --- | --- | --- | --- | --- | --- | 38/46[‡] | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 24/46 | --- | --- | --- | --- | --- | --- | --- | 24/46[‡] | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; [†]30 minutes after PCI; [‡]>50% Resolution; [§]90 minutes (allowed up to 180 minutes) after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 102. ST-segment resolution in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | 230/302 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 230/302 | 211/302[†] | --- | --- | --- | --- |
| | Control | 218/301 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 218/301 | 198/301[†] | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Cura, 2007 | SpideRX | 43/70 | --- | --- | --- | --- | --- | --- | 43/70 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | 42/70 | --- | --- | --- | --- | --- | --- | 42/70 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Guetta, 2007 | FilterWire EZ | 33/51 | --- | --- | --- | --- | 5/51 | 13/51 | 33/51 | --- | 0/51 | 18/51 | 33/51 | --- | --- | --- | --- | --- |
| | Control | 32/49 | --- | --- | --- | --- | 5/49 | 12/49 | 32/49 | --- | 2/49 | 13/49 | 35/49 | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Lefèvre, 2004 | AngioGuardXP | 20/30 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 20/30[‡] | 24/30[‡§] |
| | Control | 14/26 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 14/26[‡] | 19/26[‡§] |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; [†]100% Resolution; [‡]Post procedure, time period not specified; [§]>50% Resolution

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 103. ST-segment resolution in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Tahk, 2008 | PercuSurge GuardWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Hahn, 2007 | GuardWire | 16/19 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 16/19[‡] | --- | --- | --- | 15/19[†‡] |
| | Control | 9/20 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 9/20[‡] | --- | --- | --- | 12/20[†‡] |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Matsuo, 2007 | GuardWire Distal Protection System | 41/80 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 41/80[§] | --- |
| | Control | 39/74 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 39/74[§] | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Muramatsu, 2007 | GuardWire Plus System | 66/173 | --- | --- | --- | --- | --- | --- | --- | --- | 52/173 | 55/173 | 66/173 | --- | 46/173 | 49/173 | 78/173 | --- |
| | Control | 60/168 | --- | --- | --- | --- | --- | --- | --- | --- | 56/168 | 52/168 | 60/168 | --- | 42/168 | 53/168 | 73/168 | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Zhou, 2007 | PercuSurge GuardWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** | **<30%** | **30-70%** | **>70%** | **Others** |
| Stone, 2005 | GuardWire Plus | 152/240 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 152/240 | --- |
| | Control | 148/239 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 148/239 | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; [†]180 minutes after PCI; [‡]>50% Resolution; [§]30 minutes after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 104. ST-segment resolution in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patient with ST-segment elevation myocardial infarction

| Study, Year | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Haeck, 2009 | Proxis | 101/126 | --- | --- | 85/129 | --- | --- | --- | 101/126 | --- | --- | --- | 100/124 | --- | --- | --- | 96/130[†] | 98/126[‡] |
| | Control | 93/129 | --- | --- | 97/131 | --- | --- | --- | 93/129 | --- | --- | --- | 97/131 | --- | --- | --- | 87/135[†] | 100/131[‡] |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; [†]30 minutes after PCI; [‡]≥70 % at 120 minutes after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 105. ST-segment resolution in randomized controlled trials evaluating thrombectomy or distal protection devices versus control in mixed acute coronary syndromes population

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sardella, 2005 | Catheter Aspiration | Diver CE | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire | 27/34† | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 15/30† | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer | 19/23 | --- | --- | --- | 19/23‡ | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 12/23 | --- | --- | --- | 12/23‡ | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †Early ST-segment resolution; ‡>50% Resolution

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 106. ST-segment resolution in randomized controlled trials evaluating thrombectomy or distal protection devices versus control in unstable angina or non- ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 107. ST-segment resolution in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Sardella, 2008 | Catheter Aspiration | Diver | 34/52 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 34/52 | --- | --- | --- | --- | --- |
| | Catheter Aspiration | Invatec catheter Export Medtronic | 42/51 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 42/51 | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | 35/61 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 35/61† | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | 36/61 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | 36/61† | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †Measured immediately, 90 minutes and 6 hours

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 108. ST-segment resolution in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Wita, 2009 | Catheter Aspiration | Diver CE | 10/19 | --- | --- | --- | --- | --- | --- | --- | 10/19† | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 13/19 | --- | --- | --- | --- | --- | --- | --- | 13/23† | --- | --- | --- | --- | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †>50% Resolution

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 109. ST-segment resolution in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+ MtPA | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Thrombuster | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes

Abbreviations: : MtPA=Mutant Plasminogen Activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

TAble 110. ST-segment resolution in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | 29/57 | --- | --- | --- | --- | 12/57 | 16/57 | 29/57 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Abciximab | 25/63 | --- | --- | --- | --- | 19/63 | 19/63 | 25/63 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy +Stenting +Distal Protection Device | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Thrombectomy + Stenting | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 111. ST-segment resolution in observational studies

| Study, Year | Device Category | Group | Composite STSR Definition* (n/N) | Immediately after PCI (n/N) | | | | 60 minutes after PCI | | | | 90 minutes after PCI | | | | Other Times after PCI | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | 153/318 | --- | --- | --- | --- | --- | --- | 153/318 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | 1466/2915 | --- | --- | --- | --- | --- | --- | 1466/2915 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices† | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others | <30% | 30-70% | >70% | Others |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 112. Ejection fraction of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction.

| Study, Year | Device Category | Group | n | Time EF Measured | Mean EF (SD) | P-value |
|---|---|---|---|---|---|---|
| Yamamoto, 2006* | Catheter Aspiration | Thrombuster+MtPA | 17 | 1-3d | 53 (12) | 0.31 |
| | | Thrombuster | 16 | | 48 (12) | |
| Yamamoto, 2006* | Catheter Aspiration | Thrombuster+MtPA | 18 | 180d | 59 (8) | 0.57 |
| | | Thrombuster | 12 | | 56 (10) | |

*Data from a single study; †Mutant Plasminogen Activator

Abbreviations: d=days; EF=ejection fraction; MtPA=mutant plasminogen activator; n=number of participants included in the analysis of ejection fraction; SD=standard deviation

Table 113. Ejection fraction in observational studies.

| Study, Year | Device Category | Group | n | Time EF Measured | Mean EF (SD) | P-value |
|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device<br>Control | ---<br>--- | --- | ---<br>--- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter<br>Control | ---<br>--- | --- | ---<br>--- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices*<br>Control | ---<br>--- | --- | ---<br>--- | --- |
| Chinnaiyan, 2006 | Mechanical thrombectomy | AngioJet XMI or XVG Catheter<br>Control | ---<br>--- | --- | ---<br>--- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet<br>Control | ---<br>--- | --- | ---<br>--- | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; PCI=percutaneous coronary intervention; SD=standard deviation

Table 114. Intermediate health outcomes in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter<br>Control | 51/55*<br>40/56* | 53/55<br>46/56 | 4/55<br>14/56 | 2/55<br>10/56 |
| Lipiecki, 2009 | Export Catheter<br>Control | 6/20*<br>7/20* | ---<br>--- | 2/20<br>3/24 | ---<br>--- |
| Moura, 2009 | TAC<br>Control | 68/75*<br>47/76* | ---<br>--- | ---<br>--- | ---<br>--- |
| Sardella, 2009 | Export Medtronic (EM)<br>Control | 62/88<br>25/87 | 88/88<br>86/87 | ---<br>--- | ---<br>--- |
| Chao, 2008 | Export Aspiration Catheter<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Chevalier, 2008 | Export Aspiration Catheter<br>Control | 43/120<br>33/129 | 98/120<br>99/129 | 11/120<br>22/129 | 4/120<br>13/129 |
| Ciszewski, 2008 | Rescue/Diver<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Dudek, 2008 | Diver CE<br>Control | 76/100<br>57/96 | 88/100<br>79/96 | ---<br>--- | ---<br>--- |
| Ikari, 2008 | TVAC<br>Control | 82/178<br>35/171 | 156/178<br>138/171 | 28/178<br>50/171 | 22/178†<br>33/171† |

Table114. Intermediate health outcomes in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|
| Svilaas, 2008 | 6F Export Aspiration Catheter | 224/490 | 431/501 | --- | --- |
| | Control | 158/490 | 409/496 | --- | --- |
| DeLuca, 2006 | Diver CE | 14/38 | 30/38 | --- | --- |
| | Control | 5/38 | 26/38 | --- | --- |
| Kaltoft, 2006 | Rescue Catheter | --- | 93/104 | 9/104 | --- |
| | Control | --- | 91/104 | 6/105 | --- |
| Lee, 2006 | Export Aspiration Catheter | 16/67 | --- | 6/67 | 5/67 |
| | Control | 8/66 | --- | 2/66 | 3/66 |
| Silva-Orrego, 2006 | Pronto Extraction Catheter | 65/74 | 66/74 | 4/74 | 2/74 |
| | Control | 32/74 | 58/74 | 14/74 | 11/74 |
| Burzotta, 2005 | Diver CE | 21/50 | 41/50 | 4/50 | 4/48 |
| | Control | 11/49 | 34/49 | 8/49 | 6/49 |
| Noel, 2005 | Export | --- | 23/24 | --- | 2/24[‡] |
| | Control | --- | 21/26 | --- | 7/26[‡] |
| Dudek, 2004 | Rescue System | 22/40 | 30/35 | --- | --- |
| | Control | 12/32 | 28/32 | --- | --- |

*MBG≥2; [†]TIMI<3; [‡] Slow flow/no reflow/distal embolization

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TAC=Thrombectomy Aspiration Catheter; TIMI=thrombolysis in myocardial infarction; TVAC=Transvascular aspiration catheter

Table 115. Intermediate health outcomes in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | 155/215 | 203/252 | --- | --- |
| | Control | 167/211 | 207/241 | --- | --- |
| Ali, 2006 | AngioJet Catheter | 63/234 | 213/234 | 10/234 | 6/234 |
| | Control | 75/235 | 228/235 | 12/235 | 5/235 |
| Lefèvre, 2005 | X-Sizer Catheter | 29/92 | 93/97 | 2/97 | 3/97 |
| | Control | 28/91 | 89/100 | 10/100 | 10/100 |
| Antoniucci, 2004 | AngioJet | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | 33/46 | 43/46 | 2/46 | 1/46 |
| | Control | 17/46 | 44/46 | 7/46 | 5/46 |

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 116. Intermediate health outcomes in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | --- | 295/312 | --- | --- |
| | Control | --- | 268/314 | --- | --- |
| Cura, 2007 | SpideRX | --- | 29/32 | --- | 1/32* |
| | Control | --- | 27/28 | --- | 3/28* |
| Guetta, 2007 | FilterWire EZ | 47/70 | 55/70 | 5/70 | 2/70 |
| | Control | 59/70 | 60/70 | 8/70 | 2/70 |
| Lefèvre, 2004 | AngioGuardXP | 33/49 | 43/49 | --- | --- |
| | Control | 32/48 | 45/48 | --- | --- |

*Slow flow/no reflow/distal embolization

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 117. Intermediate health outcomes in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | 39/60 | 58/60 | --- | --- |
| | Control | 20/56 | 43/56 | --- | --- |
| Hahn, 2007 | GuardWire | 6/19 | 18/19 | 4/19 | 1/19 |
| | Control | 5/20 | 19/20 | 6/20 | 1/20 |
| Matsuo, 2007 | GuardWire Distal Protection System | 46/80 | 64/80 | 5/80 | 3/80 |
| | Control | 32/74 | 56/74 | 4/74 | 2/74 |
| Muramatsu, 2007 | GuardWire Plus System | 42/167 | 133/173 | 4/173 | 2/173 |
| | Control | 32/158 | 131/168 | 7/168 | 6/168 |
| Zhou, 2007 | PercuSurge GuardWire | 34/52 | 50/52 | --- | --- |
| | Control | 20/60 | 48/60 | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | 8/8 | --- | --- |
| | Control | --- | 8/8 | --- | --- |
| Stone, 2005 | GuardWire Plus | 138/226 | 219/239 | 22/237 | 1/238 |
| | Control | 120/227 | 215/241 | 14/242 | 6/242 |

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 118. Intermediate health outcomes in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | 113/141 | 131/141 | 14/141 | --- |
| | Control | 117/143 | 125/143 | 20/143 | --- |

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 119. Intermediate health outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire<br>Control | 24/30<br>5/37 | 26/30<br>18/37 | 0/30<br>--- | 9/30<br>31/37 |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire<br>Control | 64/100*<br>67/100* | 93/100<br>93/100 | 3/100<br>8/100 | --- |
| Sardella, 2005 | Catheter Aspiration | Diver CE<br>Control | 11/28<br>3/34 | 24/28<br>21/34 | ---<br>--- | ---<br>--- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT<br>Control | ---<br>--- | 121/129<br>119/129 | ---<br>--- | ---<br>--- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire<br>Control | 24/34<br>11/30 | 34/34<br>28/30 | ---<br>--- | ---<br>--- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire<br>Control | ---<br>--- | ---<br>--- | ---<br>--- | ---<br>--- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer<br>Control | ---<br>--- | 27/30<br>26/31 | ---<br>--- | ---<br>--- |

*MBG>1

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 120. Intermediate health outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ<br>Control | ---<br>--- | 72/77<br>70/74 | ---<br>--- | ---<br>--- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard<br>Control | ---<br>--- | 15/15<br>16/16 | 3/15<br>--- | 0/15<br>0/16 |

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 121. Intermediate health outcomes in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | 16/52 | 38/52 | --- | --- |
| | Catheter Aspiration | Export Medtronic | 22/51 | 42/51 | --- | --- |
| Yan, 2007 | Catheter Aspiration Distal Balloon Embolic Protection | Diver CE catheter | 43/61 | 58/61 | --- | 5/61* |
| | | GuardWire Plus | 44/61 | 59/61 | --- | 4/61* |

*Slow flow/no reflow/distal embolization

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 122. Intermediate health outcomes in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | 12/19 | 19/19 | --- | --- |
| | | Control | 14/23 (MBG 2-3) | 23/23 | --- | --- |
| Ozaki, 2006 | Catheter Aspiration Distal Balloon Embolic Protection | Rescue or Thrombuster systems PercuSurge GuardWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 123. Intermediate health outcomes in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | 13/23 | 22/23 | --- | --- |
| | | Thrombuster | 3/21 | 18/21 | --- | --- |

Abbreviations: MBG=myocardial blush grade; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 124. Intermediate health outcomes in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | 34/55 | 51/57 | --- | --- |
| | | Abciximab | 38/58 | 56/63 | --- | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | 26/30 | --- | --- |
| | | Thrombectomy+ Stenting | --- | 20/30 | --- | --- |

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 125. Intermediate health outcomes in observational studies

| Study, Year | Device Category | Group | Post-PCI MBG-3 (n/N) | Post-PCI TIMI-3 (n/N) | Distal Embolization (n/N) | No reflow (n/N) |
|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | --- | --- | 29/318 | --- |
| | | Control | --- | --- | 93/2915 | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | --- | 205/239 | --- | --- |
| | | Control | --- | 922/1021 | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | --- | 170/200 | --- | --- |
| | | Control | --- | 1086/1168 | --- | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 126. Adverse outcomes in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|
| Liistro, 2009 | Export Thrombectomy Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Lipiecki, 2009 | Export Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Moura, 2009 | TAC | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Sardella, 2009 | Export Medtronic (EM) | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Chao, 2008 | Export Aspiration Catheter | 0/37 | --- | --- | --- |
| | Control | 1/37 | --- | --- | --- |
| Chevalier, 2008 | Export Aspiration Catheter | --- | --- | 1/120 | 2/120 |
| | Control | --- | --- | 0/129 | 2/129 |
| Ciszewski, 2008 | Rescue/Diver | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Dudek, 2008 | Diver CE | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Ikari, 2008 | TVAC | 4/178 | 0/178 | --- | --- |
| | Control | 15/171 | 0/171 | --- | --- |
| Svilaas, 2008 | 6F Export Aspiration Catheter | 0/502 | --- | --- | 5/502 |
| | Control | 0/503 | --- | --- | 4/503 |
| DeLuca, 2006 | Diver CE | 1/38 | --- | --- | --- |
| | Control | 0/38 | --- | --- | --- |
| Kaltoft, 2006 | Rescue Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Lee, 2006 | Export Aspiration Catheter | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

Table 126. Adverse outcomes in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|
| Silva-Orrego, 2006 | Pronto Extraction Catheter | 0/74 | --- | --- | --- |
| | Control | 4/74 | --- | --- | --- |
| Burzotta, 2005 | Diver CE | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Noel, 2005 | Export | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Dudek, 2004 | Rescue System | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 127. Adverse outcomes in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|
| Migliorini, 2010 | AngioJet Rheolytic Thrombectmy | --- | 0/256 | --- | --- |
| | Control | --- | 1/245 | --- | --- |
| Ali, 2006 | AngioJet Catheter | 9/234 | 2/234 | 1/234 | --- |
| | Control | 6/235 | 1/235 | 2/235 | |
| Lefèvre, 2005 | X-Sizer Catheter | --- | 0/100 | --- | --- |
| | Control | --- | --- | --- | --- |
| Antoniucci, 2004 | AngioJet | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Napodano, 2003 | X-Sizer Catheter | --- | --- | --- | 1/46 |
| | Control | --- | --- | --- | 1/46 |

Abbreviations: n=number; N=number of participants in the group

Table 128. Adverse outcomes in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|
| Kelbæk, 2008 | FilterWire-EZ or SpiderX protection device | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Cura, 2007 | SpideRX | 0/70 | 0/70 | 0/70 | 0/70 |
| | Control | 0/70 | 0/70 | 0/70 | 1/70 |
| Guetta, 2007 | FilterWire EZ | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Lefèvre, 2004 | AngioGuardXP | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 129. Adverse outcomes in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|
| Tahk, 2008 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Hahn, 2007 | GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Matsuo, 2007 | GuardWire | --- | --- | --- | 2/80 |
| | Control | --- | --- | --- | 1/74 |
| Muramatsu, 2007 | GuardWire Plus | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Zhou, 2007 | PercuSurge GuardWire | 0/52 | 0/52 | --- | --- |
| | Control | 0/60 | 0/60 | --- | --- |
| Okamura, 2005 | PercuSurge GuardWire | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |
| Stone, 2005 | GuardWire | --- | 2/229 | 11/238 | 34/238 |
| | Control | --- | 0/234 | 6/242 | 38/242 |

Abbreviations: n=number; N=number of participants in the group

Table 130. Adverse outcomes in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|
| Haeck, 2009 | Proxis | --- | --- | --- | --- |
| | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 131. Adverse outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Parikh, 2008 | Distal Balloon Embolic Protection | GuardWire | --- | --- | 0/30 | --- |
| | | Control | --- | --- | --- | --- |
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | --- | --- | --- | --- |
| | | Abciximab | --- | --- | --- | --- |
| Gick, 2005 | Distal Filter Embolic Protection | FilterWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Sardella, 2005 | Catheter Aspiration | Diver CE | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Kunii, 2004 | Catheter Aspiration | Rescue PT | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Nanasato, 2004 | Distal Balloon Embolic Protection | GuardWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Matsushita, 2003 | Distal Balloon Embolic Protection | PercuSurge GuardWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Beran, 2002 | Mechanical Thrombectomy | X-sizer | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 132. Adverse outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Webster, 2008 | Distal Filter Embolic Protection | FilterWire EZ | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Dudek, 2003 | Distal Filter Embolic Protection | AngioGuard | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 133. Adverse outcomes in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Sardella, 2008 | Catheter Aspiration | Diver Invatec catheter | 0/52 | 0/52 | --- | --- |
| | Catheter Aspiration | Export Medtronic | 1/51 | 0/51 | --- | --- |
| Yan, 2007 | Catheter Aspiration | Diver CE catheter | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | GuardWire Plus | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 134. Adverse outcomes in randomized controlled trials with selective inclusion/exclusion criteria in patient with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Wita, 2009 | Catheter Aspiration | Diver CE | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Ozaki, 2006 | Catheter Aspiration | Rescue or Thrombuster systems | --- | --- | --- | --- |
| | Distal Balloon Embolic Protection | PercuSurge GuardWire | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group

Table 135. Adverse outcomes in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Yamamoto, 2006 | Catheter Aspiration | Thrombuster+MtPA | --- | --- | --- | --- |
| | | Thrombuster | --- | --- | --- | --- |

Abbreviations: MtPA=mutant plasminogen activator; n=number; N=number of participants in the group

Table 136. Adverse outcomes in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Ochala, 2007 | Distal Balloon Embolic Protection | PercuSurge Guardwire | --- | --- | --- | --- |
| | | Abciximab | --- | --- | --- | --- |
| Kanaya, 2003 | Thrombectomy + Distal Protection Device | Thrombectomy + Stenting + Distal Protection Device | --- | --- | --- | --- |
| | | Thrombectomy+ Stenting | --- | --- | --- | --- |

Abbreviations: n=number; N=number of participants in the group; vs=versus

Table 137. Adverse outcomes in observational studies

| Study, Year | Device Category | Group | Coronary dissection (n/N) | Perforation (n/N) | Vessel spasm (n/N) | Side branch closure (n/N) |
|---|---|---|---|---|---|---|
| Ko, 2009 | Distal Embolic Protection | Distal Protection Device | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Nilsen, 2009 | Catheter Aspiration | Aspiration Catheter | 21/318 | --- | --- | --- |
| | | Control | 154/2915 | --- | --- | --- |
| Nakatani, 2007 | Catheter Aspiration | Multiple devices* | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |
| Chinnaiyan, 2006 | Mechanical Thrombectomy | AngioJet XMI or XVG Catheter | --- | 0/239 | --- | --- |
| | | Control | --- | 2/1021 | --- | --- |
| Simonton, 2006 | Mechanical Thrombectomy | AngioJet | --- | --- | --- | --- |
| | | Control | --- | --- | --- | --- |

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group

Table 138. Impact of catheter aspiration devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 8.08 | 0.66 (0.45 to 0.997) | 0% |
| Myocardial infarction | 9.02 | 0.64 (0.37 to 1.09) | 0% |
| Stroke | 0.79 | 3.18 (0.73 to 13.88) | 0% |
| Target revascularization | 9.78 | 0.80 (0.62 to 1.03) | 0% |
| MACE | 13.20 | 0.73 (0.61 to 0.88) | 0% |

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 139. Impact of mechanical thrombectomy devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 7.80 | 1.19 (0.51 to 2.76) | 54.9 |
| Myocardial infarction | 8.98 | 0.71 (0.27 to 1.85) | 0% |
| Stroke | 5.79 | 2.42 (0.75 to 7.78) | 0% |
| Target revascularization | 6.22 | 0.87 (0.36 to 2.10) | 39.2% |
| MACE | 6.22 | 1.23 (0.50 to 3.01) | 79.9% |

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 140. Impact of distal ffilter embolic protection devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1.81 | 1.19 (0.57 to 2.52) | 0% |
| Myocardial infarction | 1.81 | 0.62 (0.05 to 8.12) | 62.9% |
| Stroke | 1 | 1.51 (0.30 to 7.52)* | NA |
| Target revascularization | 1.91 | 1.48 (0.52 to 4.21) | NA |
| MACE | 6.87 | 1.15 (0.72 to 1.83) | 0% |

*Results based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 141. Impact of distal balloon embolic protection devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 6 | 0.82 (0.45 to 1.51) | 2.5% |
| Myocardial infarction | 6 | 0.67 (0.29 to 1.57) | 0% |
| Stroke | 6 | 0.48 (0.10 to 2.22)* | NA |
| Target revascularization | 6 | 0.93 (0.61 to 1.42) | 0% |
| MACE | 6 | 0.87 (0.64 to 1.19) | 0% |

*Result based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 142. Impact of proximal balloon embolic protection devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1 | 1.01 (0.18 to 5.69)* | NA |
| Myocardial infarction | 1 | 0.68 (0.14 to 3.34)* | NA |
| Stroke | 1 | 0.34 (0 to 3.87)* | NA |
| Target revascularization | 1 | 0.51 (0.14 to 1.81)* | NA |
| MACE | 1 | 0.61 (0.23 to 1.57)* | NA |

*Results based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 143. Impact of embolic protection devices combined on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 3.61 | 0.96 (0.61 to 1.50) | 0% |
| Myocardial infarction | 3.77 | 0.71 (0.36 to 1.41) | 0% |
| Stroke | 2.72 | 0.74 (0.23 to 2.31) | 0% |
| Target revascularization | 3.90 | 0.96 (0.66 to 1.38) | 0% |
| MACE | 5.71 | 0.92 (0.72 to 1.18) | 0% |

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 144. Impact of catheter aspiration devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 0.79 | 0.65 (0.39 to 1.10) | 0% |
| Myocardial infarction | 0.77 | 0.55 (0.24 to 1.25) | 0% |
| Stroke | 0.79 | 3.18 (0.73 to 13.88) | 0% |
| Target revascularization | 0.70 | 0.85 (0.53 to 1.38) | 0% |
| MACE | 0.79 | 0.80 (0.57 to 1.12) | 0% |

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 145. Impact of mechanical thrombectomy devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1 | 1.25 (0.47 to 3.32) | 48.7% |
| Myocardial infarction | 1 | 0.63 (0.21 to 1.96) | 0% |
| Stroke | 1 | 1.89 (0.55 to 6.48) | 0% |
| Target revascularization | 1 | 1.62 (0.21 to 12.55) | 62% |
| MACE | 1 | 1.28 (0.37 to 4.38) | 80.4% |

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 146. Impact of distal filter embolic protection devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1 | 1.09 (0.52 to 2.27) | 0% |
| Myocardial infarction | 1 | 0.73 (0.12 to 4.44) | 44.3% |
| Stroke | 1 | 1.51 (0.30 to 7.52)* | NA |
| Target revascularization | 1 | 3.01 (0.61 to 14.84)* | NA |
| MACE | 1 | 1.34 (0.80 to 2.26) | 0% |

*Results based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 147. Impact of distal balloon embolic protection devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1 | 0.64 (0.30 to 1.39) | 0% |
| Myocardial infarction | 1 | 0.85 (0.32 to 2.23) | 0% |
| Stroke | 1 | 0.11 (0 to 0.94)* | NA |
| Target revascularization | 1 | 1.38 (0.55 to 3.50) | 0% |
| MACE | 1 | 0.74 (0.44 to 1.23) | 0% |

*Results based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 148. Impact of proximal balloon embolic protection devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1 | 1.01 (0.14 to 7.10)* | NA |
| Myocardial infarction | 1 | 0.68 (0.11 to 3.99)* | NA |
| Stroke | 1 | 0.34 (0.01 to 8.23)* | NA |
| Target revascularization | 1 | 0.51 (0.13 to 1.99)* | NA |
| MACE | 1 | 0.61 (0.23 to 1.63)* | NA |

*Results based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 149. Impact of embolic protection devices combined versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

| Final Health Outcome | Weighted Mean Followup (months) | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|---|
| Mortality | 1 | 0.86 (0.52 to 1.44) | 0% |
| Myocardial infarction | 1 | 0.83 (0.41 to 1.69) | 0% |
| Stroke | 1 | 0.56 (0.11 to 2.84) | 22.1% |
| Target revascularization | 1 | 1.24 (0.62 to 2.48) | 0% |
| MACE | 1 | 0.94 (0.66 to 1.32) | 0% |

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 150. In-hospital mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.81 (0.23 to 2.86) | 0% |
| Mechanical Thrombectomy | 1.00 (0.24 to 4.16)* | NA |
| Distal Filter Embolic Protection Devices | ---† | ---† |
| Distal Balloon Embolic Protection Devices | 0.69 (0.24 to 2.03)* | NA |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | 0.69 (0.24 to 2.03)* | NA |

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 151. 30-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.61 (0.35 to 1.07) | 0% |
| Mechanical Thrombectomy | 1.25 (0.47 to 3.32) | 48.7% |
| Distal Filter Embolic Protection Devices | 1.09 (0.52 to 2.27) | 0% |
| Distal Balloon Embolic Protection Devices | 0.64 (0.30 to 1.39) | 0% |
| Proximal Balloon Embolic Protection Device | 1.01 (0.18 to 5.69)* | NA |
| Embolic Protection Devices Combined | 0.86 ( 0.52 to 1.44) | 0% |

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 152. 180-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.89 (0.31 to 2.51) | 2.8% |
| Mechanical Thrombectomy | 1.35 (0.53 to 3.44) | 58.4% |
| Distal Filter Embolic Protection Devices | 1.25 (0.38 to 4.16)* | NA |
| Distal Balloon Embolic Protection Devices | 0.86 (0.48 to 1.57) | 0% |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | 0.92 (0.54 to 1.58) | 0% |

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 153. 365-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.62 (0.39 to 0.98) | NA |
| Mechanical Thrombectomy | 0.50 (0.21 to 1.17) | NA |
| Distal Filter Embolic Protection Devices | ---* | ---* |
| Distal Balloon Embolic Protection Devices | ---* | ---* |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | ---* | ---* |

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 154. In-hospital myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.32 (0.03 to 3.06) | NA |
| Mechanical Thrombectomy | 1.00 (0.11 to 9.41)* | NA |
| Distal Filter Embolic Protection Devices | ---† | ---† |
| Distal Balloon Embolic Protection Devices | 0.32 (0.00 to 3.71)* | NA |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | 0.32 (0.00 to 3.71)* | NA |

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 155. 30-day myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.60 (0.25 to 1.45) | 0% |
| Mechanical Thrombectomy | 0.63 (0.21 to 1.96) | 0% |
| Distal Filter Embolic Protection Devices | 0.73 (0.12 to 4.44) | 44.3% |
| Distal Balloon Embolic Protection Devices | 0.85 (0.32 to 2.23) | 0% |
| Proximal Balloon Embolic Protection Devices | 0.68 (0.14 to 3.34)* | NA |
| Embolic Protection Devices Combined | 0.83 (0.41 to 1.69) | 0% |

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 156. 180-day myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.70 (0.24 to 1.99) | 0% |
| Mechanical Thrombectomy | 0.57 (0.17 to 1.92) | NA |
| Distal Filter Embolic Protection Devices | 0.09 (0 to 0.74)* | NA |
| Distal Balloon Embolic Protection Devices | 0.67 (0.29 to 1.57) | 0% |
| Proximal Balloon Embolic Protection Device | ---† | ---† |
| Embolic Protection Devices Combined | 0.57 (0.25 to 1.29) | 0% |

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 157. 365-day myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.51 (0.26 to 1.00) | NA |
| Mechanical Thrombectomy | 0.66 (0.13 to 3.29) | NA |
| Distal Filter Embolic Protection Devices | ---* | ---* |
| Distal Balloon Embolic Protection Devices | ---* | ---* |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | ---* | ---* |

* Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 158. In-hospital stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | 4.94 (0.52 to infinity) | NA |
| Mechanical Thrombectomy Devices | ---* | ---* |
| Distal Filter Embolic Protection Devices | ---† | ---† |
| Distal Balloon Embolic Protection Devices | ---† | ---† |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | ---† | ---† |

*Risk could not be calculated because one trial evaluated this outcome and no events occurred ; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 159. 30-day stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 2.77 (0.51 to 14.98) | 0% |
| Mechanical Thrombectomy | 1.89 (0.55 to 6.48) | 0% |
| Distal Filter Embolic Protection Devices | 1.51 (0.30 to 7.52)* | NA |
| Distal Balloon Embolic Protection Devices | 0.11 (0 to 0.94)* | NA |
| Proximal Balloon Embolic Protection Devices | 0.34 (0 to 3.87)* | NA |
| Embolic Protection Devices Combined | 0.56 (0.11 to 2.84) | 22.1% |

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 160. 180-day stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | ---* | ---* |
| Mechanical Thrombectomy Devices | 2.05 (0.27 to 15.78) | NA |
| Distal Filter Embolic Protection Devices | ---† | ---† |
| Distal Balloon Embolic Protection Devices | 0.48 (0.10 to 2.22)‡ | NA |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | 0.48 (0.10 to 2.22) | NA |

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Risk could not be calculated because no trials evaluated this outcome; ‡Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 161. 365-day stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | ---* | ---* |
| Mechanical Thrombectomy Devices | 1.99 (0.26 to 15.14) | NA |
| Distal Filter Embolic Protection Devices | ---* | ---* |
| Distal Balloon Embolic Protection Devices | ---* | ---* |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | ---* | ---* |

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 162. In-hospital target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | 1.35 (0.26 to 6.94) | 0% |
| Mechanical Thrombectomy Devices | ---* | ---* |
| Distal Filter Embolic Protection Devices | ---† | ---† |
| Distal Balloon Embolic Protection Devices | 0.32 (0.00 to 3.71)‡ | NA |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | 0.32 (0.00 to 3.71)‡ | NA |

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Risk could not be calculated because no trials evaluated this outcome; ‡Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 163. 30-day target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | 0.82 (0.50 to 1.35) | 0% |
| Mechanical Thrombectomy Devices | 1.62 (0.21 to 12.55) | 62% |
| Distal Filter Embolic Protection Devices | 3.02 (0.70 to 13.01)* | NA |
| Distal Balloon Embolic Protection Devices | 1.38 (0.55 to 3.50) | 0% |
| Proximal Balloon Embolic Protection Devices | 0.51 (0.14 to 1.81)* | NA |
| Embolic Protection Devices Combined | 1.24 (0.62 to 2.48) | 0% |

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 164. 180-day target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | 0.62 (0.40 to 0.96) | 0% |
| Mechanical Thrombectomy Devices | 0.55 (0.33 to 0.92) | NA |
| Distal Filter Embolic Protection Devices | 1.00 (0.35 to 2.82)* | NA |
| Distal Balloon Embolic Protection Devices | 0.93 (0.61 to 1.42) | 0% |
| Proximal Balloon Embolic Protection Devices | ---† | ---† |
| Embolic Protection Devices Combined | 0.94 (0.64 to 1.39) | 0% |

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 165. 365-day target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration Devices | 0.87 (0.63 to 1.19) | NA |
| Mechanical Thrombectomy Devices | 0.68 (0.41 to 1.13) | NA |
| Distal Filter Embolic Protection Devices | ---* | ---* |
| Distal Balloon Embolic Protection Devices | ---* | ---* |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | ---* | ---* |

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable

Table 166. In-hospital MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.97 (0.36 to 2.58) | 0% |
| Mechanical Thrombectomy | ---* | ---* |
| Distal Filter Embolic Protection Devices | ---* | ---* |
| Distal Balloon Embolic Protection Devices | ---† | ---† |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | ---† | ---† |

*Risk could not be calculated because no trials evaluated this outcome; †Risk could not be calculated because one trial evaluated this outcome and no events occurred

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 167. 30-day MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.79 (0.56 to 1.13) | 0% |
| Mechanical Thrombectomy | 1.28 (0.37 to 4.38) | 80.4% |
| Distal Filter Embolic Protection Devices | 1.34 (0.80 to 2.26) | 0% |
| Distal Balloon Embolic Protection Devices | 0.74 (0.44 to 1.23) | 0% |
| Proximal Balloon Embolic Protection Devices | 0.61 (0.23 to 1.57)* | NA |
| Embolic Protection Devices Combined | 0.94 (0.66 to 1.32) | 0% |

*Result is based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 168. 180-day MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.66 (0.47to 0.94) | 0% |
| Mechanical Thrombectomy | 0.71 (0.41 to 1.20) | NA |
| Distal Filter Embolic Protection Devices | 1.10 (0.68 to 1.78) | NA |
| Distal Balloon Embolic Protection Devices | 0.87 (0.64 to 1.19) | 0% |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | 0.93 (0.72 to 1.21) | 0% |

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 169. 365-day MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Device Category | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Catheter Aspiration | 0.61 (0.26 to 1.41) | NA |
| Mechanical Thrombectomy | 0.66 (0.44 to 0.97) | NA |
| Distal Filter Embolic Protection Devices | ---* | ---* |
| Distal Balloon Embolic Protection Devices | ---* | ---* |
| Proximal Balloon Embolic Protection Devices | ---* | ---* |
| Embolic Protection Devices Combined | ---* | ---* |

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 170. Impact of cathter aspiration devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Intermediate health outcomes | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| MBG-3 | 1.75 (1.44 to 2.14) | 69.2% |
| TIMI-3 | 1.07 (1.04 to 1.11) | 0% |
| Distal embolization | 0.48 (0.34 to 0.66) | 33.7% |
| No reflow | 0.45 (0.27 to 0.75) | 22.3% |
| ST-segment resolution | 1.39 (1.21 to 1.61) | 60.4% |

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Table 171. Impact of mechanical thrombectomy devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Intermediate health outcomes | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| MBG-3 | 1.07 (0.80 to 1.43) | 76.5% |
| TIMI-3 | 0.98 (0.92 to 1.04) | 67.5% |
| Distal embolization | 0.44 (0.17 to 1.12) | 41.6% |
| No reflow | 0.50 (0.17 to 1.48) | 41.7% |
| ST-segment resolution | 1.16 (0.99 to 1.36) | 75.1% |

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Table 172. Impact of distal filter embolic protection devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Intermediate health outcomes | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| MBG-3 | 0.97 (0.81 to 1.15) | NA |
| TIMI-3 | 0.996 (0.87 to 1.15) | 79.5% |
| Distal embolization | 0.63 (0.22 to 1.82) | NA |
| No reflow | 1.00 (0.18 to 5.55)* | NA |
| ST-segment resolution | 1.04 (0.96 to 1.14) | 0% |

*Result is based on a single trial

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; NA=not applicable; TIMI=thrombolysis in myocardial infarction

Table 173. Impact of distal balloon embolic protection devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Intermediate health outcomes | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| MBG-3 | 1.39 (1.15 to 1.69) | 43.5% |
| TIMI-3 | 1.07 (1.00 to 1.16) | 56.1% |
| Distal embolization | 1.10 (0.67 to 1.81) | 5.8% |
| No reflow | 0.51 (0.19 to 1.33) | 0% |
| ST-segment resolution | 1.08 (0.91 to 1.29) | 41.2% |

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Table 174. Impact of proximal balloon embolic protection devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Intermediate health outcomes | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| MBG-3 | 0.98 (0.88 to 1.10)* | NA |
| TIMI-3 | 1.06 (0.98 to 1.16)* | NA |
| Distal embolization | 0.71 (0.38 to 1.33)* | NA |
| No reflow | ---† | ---† |
| ST-segment resolution | 1.11 (0.97 to 1.28)* | NA |

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; NA=not applicable; TIMI=thrombolysis in myocardial infarction

Table 175. Impact of embolic protection devices combined versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Intermediate health outcomes | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| MBG-3 | 1.20 (1.02 to 1.40) | 68.2% |
| TIMI-3 | 1.05 (1.00 to 1.11) | 57.5% |
| Distal embolization | 0.91 (0.64 to 1.30) | 0.2% |
| No reflow | 0.58 (0.25 to 1.37) | 0% |
| ST-segment resolution | 1.06 (1.00 to 1.13) | 0% |

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Table 176. Impact of catheter aspiration devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Adverse event | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Coronary dissection | 0.30 (0.12 to 0.75) | 0% |
| Perforation | ---* | ---* |
| Side-branch occlusion | 1.19 (0.40 to 3.54) | NA |

*Risk could not be calculated because one trial evaluated the outcome and no events occurred

Abbreviations: CI=confidence interval; NA=not applicable

Table 177. Impact of mechanical trhombectomy devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Adverse event | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Coronary dissection | 1.51 (0.57 to 4.01)* | NA |
| Perforation | 1.04 (0.15 to 7.04) | NA |
| Side-branch occlusion | 1.00 (0.11 to 9.41)* | NA |

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 178. Impact of distal filter embolic protection devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Adverse event | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Coronary dissection | ---* | ---* |
| Perforation | ---* | ---* |
| Side-branch occlusion | 0.33 (0.00 to 3.80)† | NA |

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 179. Impact of distal balloon embolic protection devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Adverse event | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Coronary dissection | ---* | ---* |
| Perforation | 5.11 (0.53 to infinity)† | NA |
| Side-branch occlusion | 0.93 (0.61 to 1.42) | NA |

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 180. Impact of proximal balloon embolic protection devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Adverse event | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Coronary dissection | ---* | ---* |
| Perforation | ---* | ---* |
| Side-branch occlusion | ---* | ---* |

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval

Table 181. Impact of embolic protection devices combined versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

| Adverse event | Relative Risk (95% CI) | $I^2$ for Relative Risk |
|---|---|---|
| Coronary dissection | ---* | ---* |
| Perforation | 5.11 (0.53 to infinity)† | NA |
| Side-branch occlusion | 0.91 (0.60 to 1.39) | 0% |

*Risk could not be calculated because in the two trials that evaluated this outcome no events occurred; †Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

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# Appendix G. Strength of evidence for outcomes

Table 182. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus control in ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 11 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Myocardial infarction | 11 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Stroke | 4 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Target revascularization | 10 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Major adverse cardiac events | 12 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| ST-segment resolution | 16 | RCTs and Observational study | No serious limitation | Serious inconsistency | No serious indirectness | No serious imprecision | None | Moderate | Important |
| Ejection fraction | 10 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | No serious imprecision | None | Moderate | Important |
| Myocardial blush grade 3 | 13 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | No serious imprecision | None | Moderate | Important |
| Thrombolysis in myocardial infarction -3 | 13 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Distal embolization | 11 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| No reflow | 7 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |

Abbreviation: RCT=randomized controlled trials

Table 183. Strength of evidence for intermediate and final health outcomes for mechanical thrombectomy devices versus control in ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 5 | RCTs and Observational study | No serious limitation | Serious inconsistency | No serious indirectness | No serious imprecision | None | Moderate | Important |
| Myocardial infarction | 4 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Stroke | 5 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Target revascularization | 4 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Major adverse cardiac events | 4 | RCTs and Observational study | No serious limitation | Serious Inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| ST-segment resolution | 5 | RCTs | No serious limitation | Serious Inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Ejection fraction | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Myocardial blush grade 3 | 4 | RCTs | No serious limitation | Serious Inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Thrombolysis in myocardial infarction-3 | 5 | RCTs and Observational study | No serious limitation | Serious inconsistency | No serious indirectness | No serious imprecision | None | Moderate | Important |
| Distal embolization | 3 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| No reflow | 3 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |

Abbreviation: RCT=randomized controlled trials

Table 184. Strength of evidence for intermediate and final health outcomes for distal filter embolic protection devices versus control in ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summaryof Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Myocardial Infarction | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Stroke | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Target revascularization | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Major adverse cardiac events | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| ST-segment resolution | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Ejection fraction | 2 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Myocardial blush grade 3 | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Thrombolysis in myocardial infarction-3 | 4 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Distal Embolization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| No reflow | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |

Abbreviation: RCT=randomized controlled trials

Table 185. Strength of evidence for intermediate and final health outcomes for distal balloon embolic protection devices versus control in ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Myocardial infarction | 5 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Stroke | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Target revascularization | 5 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Major adverse cardiac events | 5 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| ST-segment resolution | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Ejection fraction | 5 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Myocardial blush grade 3 | 6 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| Thrombolysis in myocardial infarction-3 | 7 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Distal embolization | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| No reflow | 4 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |

Abbreviation: RCT=randomized controlled trials

Table 186. Strength of evidence for intermediate and final health outcomes for proximal balloon embolic protection devices versus control in ST-segment elevation myocardial infarction patients under key question 1

| | | | QualityAssessment | | | | | Summaryof Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Myocardial infarction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Stroke | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Target revascularization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Major adverse cardiac events | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| ST-segment resolution | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3 | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Thrombolysis in myocardial infarction-3 | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Distal Embolization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 187. Strength of evidence for intermediate and final health outcomes for embolic protection devices combined versus control in ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 10 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| Myocardial Infarction | 10 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Stroke | 3 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Target revascularization | 8 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| Major adverse cardiac events | 11 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| ST-segment resolution | 9 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Ejection fraction | 7 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Myocardial blush grade 3 | 9 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | No serious imprecision | None | Moderate | Important |
| Thrombolysis in myocardial infarction-3 | 11 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Distal Embolization | 6 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious inconsistency | None | Moderate | Important |
| No reflow | 6 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |

Abbreviation: RCT=randomized controlled trials

Table 188. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus control in patients with mixed acute coronary syndromes under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 2 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Myocardial infarction – Not reported | 0 | - | - | - | - | - | - | - | - |
| Stroke - Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization - Not reported | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events - Not reported | 0 | - | - | - | - | - | - | - | - |
| St-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3 | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Low | Important |
| Thrombolysis in myocardial infarction-3 | 2 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Distal embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 189. Strength of evidence for intermediate and final health outcomes for mechanical thrombectomy devices versus control in patients with mixed acute coronary syndromes under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 2 | RCT and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Myocardial infarction | 1 | Observational study | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization | 2 | RCT and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Major adverse cardiac events | 2 | RCT and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| ST-segment resolution | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3 – Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3 | 2 | RCT and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Distal embolization – Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 190. Strength of evidence for intermediate and final health outcomes for distal filter embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Myocardial infarction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Stroke | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Target revascularization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Major adverse cardiac events | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| ST-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Myocardial blush grade 3 - Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3 | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Distal embolization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 191. Strength of evidence for intermediate and final health outcomes for distal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Myocardial infarction – Not reported | 0 | - | - | - | - | - | - | - | - |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization - Not reported | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| ST-segment resolution | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Ejection fraction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Myocardial blush grade 3 | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Thrombolysis in myocardial infarction-3 | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Distal Embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | High | Important |

Abbreviation: RCT=randomized controlled trials

Table 192. Strength of evidence for intermediate and final health outcomes for proximal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 0 | - | - | - | - | - | - | - | - |
| Myocardial infarction | 0 | - | - | - | - | - | - | - | - |
| Stroke | 0 | - | - | - | - | - | - | - | - |
| Target revascularization | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events | 0 | - | - | - | - | - | - | - | - |
| ST-segment resolution | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3 | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3 | 0 | - | - | - | - | - | - | - | - |
| Distal Embolization | 0 | - | - | - | - | - | - | - | - |
| No reflow | 0 | - | - | - | - | - | - | - | - |

Table 193. Strength of evidence for intermediate and final health outcomes for combined embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 3 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Myocardial infarction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Stroke | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Target revascularization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Major adverse cardiac events | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| ST-segment resolution | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Ejection fraction | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Myocardial blush grade 3 | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Thrombolysis in myocardial infarction-3 | 3 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Distal Embolization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| No reflow | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | High | Important |

Abbreviation: RCT=randomized controlled trials

Table 194. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality- Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial infarction – Not reported | 0 | - | - | - | - | - | - | - | - |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization - Not reported | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events - Not reported | 0 | - | - | - | - | - | - | - | - |
| ST-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Distal embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 195. Strength of evidence for intermediate and final health outcomes for mechanical thrombectomy devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality- Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial infarction – Not reported | 0 | - | - | - | - | - | - | - | - |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization - Not reported | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events - Not reported | 0 | - | - | - | - | - | - | - | - |
| ST-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Distal embolization – Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 196. Strength of evidence for intermediate and final health outcomes for distal filter embolic protection devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Myocardial infarction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Major adverse cardiac events | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| ST-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3 – Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3 | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Distal embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |

Abbreviation: RCT=randomized controlled trials

Table 197. Strength of evidence for intermediate and final health outcomes for distal balloon embolic protection devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality- Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial infarction – Not reported | 0 | - | - | - | - | - | - | - | - |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization - Not reported | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events - Not reported | 0 | - | - | - | - | - | - | - | - |
| St-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Distal embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 198. Strength of evidence for intermediate and final health outcomes for proximal balloon embolic protection devices versus control in unstable angina/non-ST-elevation myocardial infarction patients under key question 1

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality- Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial infarction – Not reported | 0 | - | - | - | - | - | - | - | - |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization - Not reported | 0 | - | - | - | - | - | - | - | - |
| Major adverse cardiac events - Not reported | 0 | - | - | - | - | - | - | - | - |
| St-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3- Not reported | 0 | - | - | - | - | - | - | - | - |
| Distal embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 199. Strength of evidence for intermediate and final health outcomes for combined embolic protection devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Mortality | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Myocardial infarction | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Stroke – Not reported | 0 | - | - | - | - | - | - | - | - |
| Target revascularization | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |
| Major adverse cardiac events | 1 | RCT | No Serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| ST-segment resolution – Not reported | 0 | - | - | - | - | - | - | - | - |
| Ejection fraction - Not reported | 0 | - | - | - | - | - | - | - | - |
| Myocardial blush grade 3 – Not reported | 0 | - | - | - | - | - | - | - | - |
| Thrombolysis in myocardial infarction-3 | 1 | RCT | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Insufficient | Important |
| Distal embolization - Not reported | 0 | - | - | - | - | - | - | - | - |
| No reflow | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |

Abbreviation: RCT=randomized controlled trials

Table 200. Strength of evidence for adverse outcomes for catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection | 5 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| Perforation | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | - |
| Prolonged procedure time | 8 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| Side branch occlusion | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |

Abbreviation: RCT=randomized controlled trials

Table 201. Strength of evidence for adverse outcomes for mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Low | Important |
| Perforation | 3 | RCTs and Observational study | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Prolonged procedure time | 3 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | High | Important |
| Side branch occlusion | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Insufficient | Important |

Abbreviation: RCT=randomized controlled trials

Table 202. Strength of evidence for adverse outcomes for distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Perforation | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Prolonged procedure time | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Side branch occlusion | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Low | Important |

Abbreviation: RCT=randomized controlled trials

Table 203. Strength of evidence for adverse outcomes for distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection | 1 | RCT | No serious limitation | Not graded | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Perforation | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Very serious imprecision | None | Low | Important |
| Prolonged procedure time | 3 | RCTs | No serious limitation | Serious inconsistency | No serious indirectness | Serious imprecision | None | Low | Important |
| Side branch occlusion | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |

Abbreviation: RCT=randomized controlled trials

Table 204. Strength of evidence for adverse outcomes for proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation – Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 205. Strength of evidence for adverse outcomes for embolic protection devices combined versus control in patients with ST-segment elevation myocardial infarction under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | No serious imprecision | None | Insufficient | Important |
| Perforation | 2 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Very serious imprecision | None | Low | Important |
| Prolonged procedure time | 5 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Side branch occlusion | 3 | RCTs | No serious limitation | No serious inconsistency | No serious indirectness | Serious imprecision | None | Moderate | Important |

Abbreviation: RCT=randomized controlled trials

Table 206. Strength of evidence for adverse outcomes for catheter aspiration devices versus control in patients with mixed acute coronary syndromes under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 207. Strength of evidence for adverse outcomes for mechanical thrombectomy devices versus control in patients with mixed acute coronary syndromes under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 208. Strength of evidence for adverse outcomes for distal filter embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 209. Strength of evidence for adverse outcomes for distal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 2

| | | | Quality Assessment | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 210. Strength of evidence for adverse outcomes for proximal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection - Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 211. Strength of evidence for adverse outcomes for embolic protection devices combined versus control in patients with mixed acute coronary syndromes under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time | 1 | RCT | No serious limitation | Not graded | No serious indirectness | Serious imprecision | None | Moderate | Important |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Abbreviation: RCT=randomized controlled trials

Table 212. Strength of evidence for adverse outcomes for catheter aspiration devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| Outcome | Number of Studies | Design | Limitations | Inconsistency | Indirectness | Imprecision | Other Considerations | Quality | Importance |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 213. Strength of evidence for adverse outcomes for mechanical thrombectomy devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| Outcome | Number of Studies | Design | Limitations | Inconsistency | Indirectness | Imprecision | Other Considerations | Quality | Importance |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 214. Strength of evidence for adverse outcomes for distal filter embolic protection devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 215. Strength of evidence for adverse outcomes for distal balloon embolic protection devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

Table 216. Strength of evidence for adverse outcomes for embolic protection devices combined versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

| | | Quality Assessment | | | | | | Summary of Findings | |
|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Number of Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Considerations** | **Quality** | **Importance** |
| Coronary dissection – Not reported | 0 | - | - | - | - | - | - | - | - |
| Perforation - Not reported | 0 | - | - | - | - | - | - | - | - |
| Prolonged procedure time- Not reported | 0 | - | - | - | - | - | - | - | - |
| Side branch occlusion – Not reported | 0 | - | - | - | - | - | - | - | - |

# Appendix H. Applicability of individual studies and of the body of evidence

Table 217. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Liistro, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcomes<br>4. Used intention to treat analysis | Population, Setting | • High male to female ratio (77-78%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (180 d)<br>• Small sample size (N =111)<br>• Conducted in Europe |
| Lipiecki, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Enrolled primary care population | Population, Outcomes, Setting | • Younger population (59 y)<br>• Final health outcomes not reported<br>• Short duration of followup (7 d)<br>• Adverse outcomes not reported<br>• Small sample size (N =44)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |
| Moura, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Less stringent eligibility criteria<br>2. Assessed final health outcomes | Population, Intervention, Outcomes, Setting | • Baseline characteristics not reported<br>• Only patients undergoing primary PCI<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (270 d)<br>• Device name not reported<br>• Adverse outcomes not reported<br>• Small sample size (N =152)<br>• Use of ITT analysis not reported<br>• Conducted in South America |

Table 217. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Sardella, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Adequate study duration with clinically relevant treatments | Population, Outcomes, Setting | • Only patients undergoing primary PCI<br>• Adverse outcomes not reported<br>• Small sample size (N =175)<br>• Use of ITT analysis not reported |
| Chao, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome | Population, Setting | • High male to female ratio (83.78 - 86.49%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (180 d)<br>• Small sample size (N =74)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |
| Chevalier, 2008 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 5 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Adequate sample size<br>5. Used intention to treat analysis | Population, Setting | • High male to female ratio (80-81%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (30 d)<br>• Conducted in Europe and India |
| Ciszewski, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Assessed final health outcomes<br>2. Used intention to treat analysis | Population, Intervention, Outcomes, Setting | • Only patients undergoing primary PCI<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (8 d)<br>• Rescue and Diver devices no longer available<br>• Adverse outcomes not reported<br>• Small sample size (N =135)<br>• Conducted in Europe |

Table 217. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Dudek, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Intervention, Outcomes, Setting | • Younger population (58 y)<br>• High male to female ratio (79-81%)<br>• Only patients undergoing primary PCI<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (180 d)<br>• Diver CE device no longer available<br>• Adverse outcomes not reported<br>• Small sample size (N= 196)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |
| Ikari, 2008 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 5 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Adequate sample size<br>5. Used intention to treat analysis | Population, Intervention, Setting | • High male to female ratio (77.7-80.6%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (240 - 720 d)<br>• TVAC device is not FDA approved<br>• Conducted in Asia |
| Svilaas, 2008 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 6 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Adequate study duration with clinically relevant treatments<br>4. Assessed adverse outcome<br>5. Adequate sample size<br>6. Used intention to treat analysis | Population, Setting | • High male to female ratio (67.9-73.1%)<br>• Only patients undergoing primary PCI<br>• Conducted in Europe |

Table 217. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| DeLuca, 2006 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome | Population, Intervention, Setting | • High male to female ratio (55.3- 71%)<br>• Only patients undergoing primary PCI<br>• Majority of IRAs were LAD (97.4-100%)<br>• Short duration of followup (180 d)<br>• Diver CE device no longer available<br>• Small sample size (N =76)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |
| Kaltoft, 2006 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 5 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Adequate sample size<br>5. Used intention to treat analysis | Population, Intervention, Setting | • High male to female ratio (76- 80%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (30 d)<br>• Rescue device no longer available<br>• Conducted in Europe |
| Lee, 2006 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Enrolled primary care population<br>2. Less stringent eligibility criteria | Population, Outcomes, Setting | • Only patients undergoing primary PCI<br>• Use of antiplatelets and antithrombotic not reported<br>• Final health outcomes not reported<br>• Short duration of followup (in-hospital)<br>• Adverse outcomes not reported<br>• Small sample size (N =133)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |

Table 217. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Silva-Orrego, 2006 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Less stringent eligibility criteria<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Used intention to treat analysis | Population, Setting | • Younger population (57.3- 58.0 y)<br>• High male to female ratio (76- 84%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (180 d)<br>• Small sample size (N =148)<br>• Conducted in Europe |
| Burzotta, 2005 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Used intention to treat analysis | Population, Intervention, Setting | • High male to female ratio (77.6-90%)<br>• Short duration of followup (30 d)<br>• Diver CE device no longer available<br>• Small sample size (N =99)<br>• Conducted in Europe |
| Noel, 2005 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Outcomes, Setting | • Baseline characteristics not reported<br>• Percentage of primary PCI versus rescue PCI not reported<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (1 hr)<br>• Adverse outcomes not reported<br>• Small sample size (N =50)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |

Table 217. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Dudek, 2004 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>1 of 7 | 1. Less stringent eligibility criteria | Population, Intervention, Outcomes, Setting | • Younger population (56.7- 59.1 y)<br>• High male to female ratio (69-80%)<br>• Only patients undergoing primary PCI<br>• IRA not reported<br>• Suboptimal use of anti-thrombotics<br>• Final health outcomes not reported<br>• Short duration of followup (90 d)<br>• Rescue device no longer available<br>• Small sample size (N =72)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |

Abbreviations: d=days; FDA=Food and Drug Administration; IRA=infarct related artery; ITT=intent to treat; LAD=left anterior descending artery; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 218. Evaluation of applicability for individual randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Migliorini, 2010 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 5 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Adequate study duration with clinically relevant treatments<br>4. Assessed adverse outcome<br>5. Adequate sample size | Population | • High male to female ratio (76- 81%)<br>• Only patients undergoing primary PCI<br>• Use of ITT analysis not reported |
| Ali, 2006 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 5 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Adequate sample size<br>5. Used intention to treat analysis | Population | • High male to female ratio (74.2-75.8%)<br>• Short duration of followup (30 -180 d) |
| Lefèvre, 2005 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome<br>3. Adequate sample size<br>4. Used intention to treat analysis | Population, Setting | • High male to female ratio (73-76%)<br>• Only patients undergoing primary PCI<br>• Suboptimal use of antiplatelets<br>• Short duration of followup (180 d)<br>• Conducted in Europe |
| Antoniucci, 2004 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. less stringent eligibility criteria<br>3. Assessed final health outcomes<br>4. Used intention to treat analysis | Outcome, Setting | • High male to female ratio (78-82%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (30 d)<br>• Adverse outcomes not reported<br>• Small sample size (N =100)<br>• Conducted in Europe |
| Napodano, 2003 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcomes<br>3. Used intention to treat analysis | Population, Setting | • High male to female ratio (71.7-82.6%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• IRA not reported<br>• Short duration of followup (30 d)<br>• Small sample size (N =92)<br>• Conducted in Europe |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 219. Evaluation of applicability for individual randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Kelbæk, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Adequate sample size<br>4. Used intention to treat analysis | Population, Intervention, Outcomes, Setting | • High male to female ratio (72-74.4%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (30 - 240 d)<br>• SpiderX device no longer available<br>• Adverse outcomes not reported<br>• Conducted in Europe |
| Cura, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Used intention to treat analysis | Population, Intervention, Setting | • High male to female ratio (77-86%)<br>• Low percentage of rescue PCI (3-4%)<br>• Short duration of followup (180 d)<br>• SpiderX device no longer available<br>• Small sample size (N =140)<br>• Conducted in South America and Asia |
| Guetta, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Assessed final health outcomes<br>2. Used intention to treat analysis | Population, Outcomes, Setting | • Younger population (57-60 y)<br>• High male to female ratio (82%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Short duration of followup (30 d)<br>• Adverse outcomes not reported<br>• Small sample size (N =100)<br>• Conducted in Asia |
| Lefèvre, 2004 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Outcomes, Setting | • High male to female ratio (81- 83%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (30 d)<br>• Adverse outcomes not reported<br>• Small sample size (N =60)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |

Abbreviations: d=days; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 220. Evaluation of applicability for individual randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Tahk, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Intervention, Outcomes, Setting | • Younger population (55.9-58.8 y)<br>• High male to female ratio (71-85 %)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (180 d)<br>• PercuSurge GuardWire device no longer available<br>• Adverse outcomes not reported<br>• Small sample size (N =116)<br>• ITT not used<br>• Conducted in Asia |
| Hahn, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Intervention, Outcomes, Setting | • Younger population (55-56 y)<br>• High male to female ratio (79-95%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (180 d)<br>• GuardWire device no longer available<br>• Adverse outcomes not reported<br>• Small sample size (N =39)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |
| Matsuo, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome | Population, Intervention, Setting | • High male to female ratio (76-86%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Short duration of followup (180 d)<br>• GuardWire device no longer available<br>• Small sample size (N =154)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |
| Muramatsu, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome<br>3. Adequate sample size<br>4. Used intention to treat analysis | Population, Setting | • High male to female ratio (72.9-78.6%)<br>• Only patients undergoing primary PCI<br>• Use of antithrombotic not reported<br>• Short duration of followup (30 d)<br>• Conducted in Asia |

Table 220. Evaluation of applicability for individual randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Zhou, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome | Population, Intervention, Outcomes, Setting | • Younger population (55-57 y)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (in-hospital)<br>• PercuSurge GuardWire device no longer available<br>• Small sample size (N =112)<br>• Use of ITT analysis not reported<br>• Geographic location not reported |
| Okamura, 2005 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 0 of 7 | | Population, Intervention, Outcomes, Setting | • Younger population (59y)<br>• High male to female ratio (75- 88%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Final health outcomes not reported<br>• Short duration of followup (22 d)<br>• PercuSurge GuardWire device no longer available<br>• Adverse outcomes not reported<br>• ITT not used<br>• Conducted in Japan |
| Stone, 2005 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 5 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Adequate sample size<br>5. Used intention to treat analysis | Population | • Younger population (58.5- 59.8 y)<br>• High male to female ratio (76.2-80.7%)<br>• Short duration of followup (180 d) |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 221. Evaluation of applicability for individual randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Haeck, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome<br>3. Adequate sample size<br>4. Used intention to treat analysis | Population, Setting | • Younger population (59-62 y)<br>• High male to female ratio (80%)<br>• Only patients undergoing primary PCI<br>• Short duration of followup (30 d)<br>• Conducted in Europe and North America |

Abbreviations: d=days; PCI=percutaneous coronary intervention; y=years

Table 222. Evaluation of applicability for individual randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes population

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Parikh, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome<br>3. Adequate study duration with clinically relevant treatments | Population, Intervention, Setting | • Younger population (55.17-56.16 y)<br>• High male to female ratio (90-95%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• GuardWire device no longer available<br>• Small sample size (N =67)<br>• Use of ITT analysis not used<br>• Conducted in Asia |
| Gick, 2005 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Adequate sample size<br>4. Used intention to treat analysis | Population, Intervention, Outcomes, Setting | • High male to female ratio (80-86%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Short duration of followup (30 - 180 d)<br>• FilterWire device no longer available<br>• Adverse outcomes not reported<br>• Conducted in Europe |

Table 222. Evaluation of applicability for individual randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes population (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Sardella, 2005 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>0 of 7 | | Population, Intervention, Outcomes, Setting | • High male to female ratio (77.42%)<br>• Only patients undergoing primary PCI<br>• Use of antiplatelets and antithrombotic not reported<br>• Final health outcomes not reported<br>• Short duration of followup (post- PCI)<br>• Diver device no longer available<br>• Adverse outcomes not reported<br>• Small sample size (N =62)<br>• Use of ITT analysis not reported<br>• Geographical location not reported |
| Kunii, 2004 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>2 of 7 | 1. Assessed final health outcomes<br>2. Adequate sample size | Population, Intervention, Outcomes, Setting | • High male to female ratio (76-86 %)<br>• Only patients undergoing primary PCI<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (in-hospital)<br>• Rescue device no longer available<br>• Adverse outcomes not reported<br>• Use of ITT analysis not reported<br>• Conducted in Asia |
| Nanasato, 2004 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>0 of 7 | | Population, Outcomes, Setting | • Baseline characteristics not reported<br>• Final health outcomes not reported<br>• Short duration of followup (post PCI)<br>• Adverse outcomes not reported<br>• Small sample size (N =64)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |

Table 222. Evaluation of applicability for individual randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes population (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | ecific Factors Limiting Applicability |
|---|---|---|---|---|
| Matsushita, 2003 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>1 of 7 | 1. Assessed final health outcomes | Population, Intervention, Outcomes, Setting | • High male to female ratio (76.79-83.33)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (in-hospital to 180 d)<br>• PercuSurge GuardWire not available<br>• Adverse outcomes not reported<br>• Small sample size (N =80)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |
| Beran, 2002 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>3 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Used intention to treat analysis | Population, Outcomes, Setting | • Younger population (53.9-55.9 y)<br>• High male to female ratio (73-77%)<br>• Short duration of followup (30 d)<br>• Adverse outcomes not reported<br>• Small sample size (N =61)<br>• Conducted in Europe |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 223. Evaluation of applicability for individual randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Webster, 2008 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Outcomes, Setting | • Younger population (58- 60 y)<br>• High male to female ratio (83-89%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (30 d)<br>• Adverse outcomes not reported<br>• Small sample size (N =151)<br>• Use of ITT analysis not reported<br>• Conducted in Australia and North America |
| Dudek, 2003 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 1 of 7 | 1. Assessed final health outcomes | Population, Outcomes, Setting | • Younger population (49.3-59.4 y)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• IRA not reported<br>• Short duration of followup (30 d)<br>• AngioGuard not available<br>• Adverse outcomes not reported<br>• Small sample size (N =31)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 224. Evaluation of applicability for individual direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Sardella, 2008 | **Study Designation:** Effectiveness study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Used intention to treat analysis | Population, Intervention, Setting | • High male to female ratio (78.4-78.8%)<br>• Only patients undergoing primary PCI<br>• Diver not available<br>• Small sample size (N =103)<br>• Conducted in Europe |
| Yan, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome<br>3. Used intention to treat analysis | Population, Intervention, Setting | • High male to female ratio (82-84%)<br>• Only patients undergoing primary PCI<br>• Majority of IRAs were RCA (100%)<br>• Short duration of followup (30 d)<br>• Diver CE device no longer available<br>• Small sample size (N =122)<br>• Conducted in Asia |

Abbreviations: d=days; IRA=infarct related artery; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; RCA=right coronary artery

Table 225. Evaluation of applicability for individual randomized controlled trials with selective inclusion/exclusion criteria in patient with ST-segment elevation myocardial infarction

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Wita, 2009 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>1 of 7 | 1. Assessed adverse outcome | Population, Intervention, Outcomes, Setting | • Younger population (56.6- 58.1 y)<br>• High male to female ratio (70.9-79%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• Majority of IRAs were LAD (100%)<br>• Final health outcomes not reported<br>• Short duration of followup (post-PCI - 30 d)<br>• Diver CE device no longer available<br>• Small sample size (N =42)<br>• Use of ITT analysis not reported<br>• Conducted in Europe |
| Ozaki, 2006 | **Study Designation:**<br>Efficacy study<br><br>**Composite Score:**<br>0 of 7 | | Population, Intervention, Outcomes, Setting | • Only male patients (100%)<br>• Only patients undergoing primary PCI<br>• IRA not reported<br>• Final health outcomes not reported<br>• Short duration of followup (180 d)<br>• Rescue, Thrombuster, PercuSurge GuardWire devices no longer available<br>• Adverse outcomes not reported<br>• Small sample size (N =77)<br>• Use of ITT analysis not reported<br>• Conducted in Asia |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; LAD=left anterior descending artery; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 226. Evaluation of applicability for individual observational studies

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Ko, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Assessed final health outcomes<br>2. Adequate sample size | Population, Intervention, Outcomes, Setting | • Younger population (58 y)<br>• High male to female ratio (72.5%)<br>• Percentage of primary PCI versus rescue PCI not reported<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Distal protection device name not reported<br>• Adverse outcomes not reported<br>• ITT analysis not used<br>• Conducted in Asia |
| Nilsen, 2009 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 3 of 7 | 1. Assessed final health outcomes<br>2. Assessed adverse outcome<br>3. Adequate sample size | Population, Intervention, Setting | • Baseline characteristics not reported<br>• Only patients undergoing primary PCI<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (30 d)<br>• Aspiration catheter device name not reported<br>• ITT analysis not used<br>• Geographic location not reported |
| Nakatani, 2007 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Assessed final health outcomes<br>2. Adequate sample size | Population, Interventions, Outcomes, Setting | • High male to female ratio (76.7-79.8%)<br>• Only patients undergoing primary PCI<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (30 d)<br>• Rescue, Thrombuster, TVAC devices no longer available Adverse outcomes not reported<br>• ITT analysis not used<br>• Conducted in Asia |

Table 226. Evaluation of applicability for individual observational studies (continued)

| Study, Year | Effectiveness Study Designation and Composite Score | Effectiveness Study Criteria Met | Applicability Limitation Category | Specific Factors Limiting Applicability |
|---|---|---|---|---|
| Chinnaiyan, 2006 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 4 of 7 | 1. Enrolled primary care population<br>2. Assessed final health outcomes<br>3. Assessed adverse outcome<br>4. Adequate sample size | Population, Setting | • Use of antiplatelets not reported<br>• Short duration of followup (in-hospital)<br>• ITT analysis not used<br>• Geographic location not reported |
| Simonton, 2006 | **Study Designation:** Efficacy study<br><br>**Composite Score:** 2 of 7 | 1. Assessed final health outcomes<br>2. Adequate sample size | Population, Outcomes | • Baseline characteristics not reported<br>• Percentage of primary PCI versus rescue PCI not reported<br>• IRA not reported<br>• Use of antiplatelets and antithrombotic not reported<br>• Short duration of followup (270 d)<br>• Adverse outcomes not reported<br>• ITT analysis not used |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; TVAC=transvascular aspiration catheter; PCI=percutaneous coronary intervention; y=year

Table 227. Strength of applicability for the body of evidence evaluating mortality in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus catheter aspiration | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of mortality. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of mortality. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of mortality. Overall applicability of the data is limited because more than half of the data is derived from studies which evaluate a device that is not currently available in the US, a large majority of studies were conducted outside of the US and did not allow for adequate study duration to assess mortality. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients with other ACS or those undergoing rescue PCI. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of mortality. Overall applicability of data is limited because the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess mortality. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of mortality. Overall applicability of data is limited because all studies were conducted outside of the US, more than half of the data is derived from studies which evaluated a device that is not currently available in the US, and the majority of studies did not allow for adequate duration of followup to assess mortality. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients. |

Table 227. Strength of applicability for the body of evidence evaluating mortality in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of mortality. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess mortality. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI or in patients with other ACS. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of mortality. Applicability of the data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess mortality. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of mortality. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess mortality. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States;Y=years

Table 228. Strength of applicability for the body of evidence evaluating myocardial infarction in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus catheter aspiration | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of myocardial infarction. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of myocardial infarction. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short durtation. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of myocardial infarction. Overall applicability is limited because the majority of data is derived from studies which evaluated a device that is not currently available in the US. A majority of studies were conducted outside of the US and did not allow for adequate study duration to assess myocardial infarction. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients undergoing rescue PCI. Data is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of myocardial infarction. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess myocardial infarction. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI. |
| Distal filter embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk off myocardial infarction. Overall data is limited because all studies were conducted outside of the US and the majority of studies did not allow for adequate duration of followup to assess myocardial infarction. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients. |
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of myocardial infarction. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess myocardial infarction. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS. |

Table 228. Strength of applicability for the body of evidence evaluating myocardial infarction in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of myocardial infarction. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess myocardial infarction. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of myocardial infarction. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess myocardial infarction. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 229. Strength of applicability for the body of evidence evaluating stroke in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of stroke. Applicability is limited by duration of followup as the majority of studies did not allow for adequate duration to stroke. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients undergoing rescue PCI. Data is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of stroke. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to stroke. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is moderate in female patients and patients undergoing rescue PCI. Data is not applicable to other patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients undergoing native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of stroke. Data has limited applicability because all studies were conducted in Europe and mostly devices evaluated are not available in the US. The majority of studies did not allow for adequate duration of followup to assess stroke. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS. |
| Distal balloon embolic protection devices versus control | High | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of stroke. Overall applicability of data is limited because the study did not allow for adequate duration to assess stroke. The data is highly applicable to male patients with STEMI undergoing primary or rescue PCI. The data is moderately applicable to female patients and not applicable to patients with other ACS. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of stroke. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess stroke. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of stroke. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess stroke. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 230. Strength of applicability for the body of evidence evaluating target revascularization in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus catheter aspiration | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of target revascularization. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of target revascularization. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of target revascularization. Overall applicability is limited because the majority of studies were conducted outside of the US and did not allow for adequate study duration to assess target revascularization. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients undergoing rescue PCI. Data is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of target revascularization. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI. |
| Distal filter embolic protection devices versus control | Moderate | Compared to control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of target revascularization. Overall, all studies were conducted outside of the US and the majority of studies did not allow for adequate duration of followup to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and in patients with other ACS, although low in patients undergoing rescue PCI. |

Table 230. Strength of applicability for the body of evidence evaluating target revascularization in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of target revascularization. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of target revascularization. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess target revascularization. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of target revascularization. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 231. Strength of applicability for the body of evidence evaluating major adverse cardiac events in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of major adverse cardiovascular events. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Moderate | Compared to control, patients who undergo native vessel PCI with a catheter aspiration device have a decreased risk of major adverse cardiovascular events. The overall applicability is limited because a majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess major adverse cardiovascular events. The applicability of the data is high in male patients with STEMI undergoing primary PCI and moderate in female patients. Applicability is low in patients undergoing rescue PCI and is not applicable in patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of major adverse cardiovascular events. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Overall data is limited because all studies were conducted outside of the US, the majority of studies did not allow for adequate duration of followup to assess major adverse cardiovascular events, and the majority of the data is derived from studies which evaluated a device that is not currently available in the US. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients. |

Table 231. Strength of applicability for the body of evidence evaluating major adverse cardiac events in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI or in patients with other ACS. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess major adverse cardiovascular events. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 232. Strength of applicability for the body of evidence evaluating resolution of ST-segment elevation in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus catheter aspiration | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of resolving ST-segment elevation. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of resolving ST-segment elevation. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have an increased risk in resolving ST-segment elevation. The overall applicability is limited because the majority of studies were conducted outside of the US. Data is highly applicable in male patients with STEMI undergoing primary PCI and is moderately applicable to female patients. Data has low applicability to patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of resolving ST-segment elevation. Overall applicability of the data is limited because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is moderate in female patients and patients undergoing rescue PCI. Data is not applicable to other patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of resolving ST-segment elevation. Overall applicability of the data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is no longer available in the US. Data is highly applicable to male patients with ST segment elevation myocardial infarction undergoing primary PCI and moderately applicable in female patients. Data is not applicable to patients with other ACS. |

Table 232. Strength of applicability for the body of evidence evaluating resolution of ST-segment elevation in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of resolving ST-segment elevation. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of resolving ST-segment elevation. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 233. Strength of applicability for the body of evidence evaluating ejection fraction in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in ejection fraction. Overall applicability is limited because the majority of data is derived from studies which evaluated devices that are not currently available in the US and most studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable in patients with other ACS. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared with catheter aspiration devices, patients undergoing native vessel PCI with distal balloon embolic protection devices do not have a difference in ejection fraction. Overall data is limited because the data is derived from studies which were conducted in Asia and evaluated devices that are not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in ejection fraction. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI regardless if primary or rescue PCI and moderately applicable in female patients. Data is not applicable in patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in ejection fraction. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is moderately applicable to patients with ACS undergoing primary PCI. |
| Distal balloon embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in ejection fraction. Overall applicability is limited because all studies were conducted outside of the US and close to half of the data is derived from studies which evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS. Data is not applicable to patients undergoing rescue PCI. |

Table 233. Strength of applicability for the body of evidence evaluating ejection fraction in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Embolic protection devices combined versus control | Low | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in ejection fraction. Applicability of the data is limited because a majority of the studies were conducted outside of the US and evaluated devices not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 234. Strength of applicability for the body of evidence evaluating myocardial blush grade of 3 in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus catheter aspiration | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of attaining a MBG-3. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of attaining a MBG-3. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have an increased risk in attaining a MBG-3. Overall applicability is limited because the majority of studies were conducted outside of the US. Data is highly applicable in male patients with STEMI undergoing primary PCI and is moderately applicable to female patients. Data has low applicability to patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of attaining a MBG-3. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable in patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of attaining a MBG-3. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is moderately applicable to patients with ACS undergoing primary PCI. |

Table 234. Strength of applicability for the body of evidence evaluating myocardial blush grade of 3 in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Distal balloon embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device have an increased risk in attaining a MBG-3. Overall applicability is limited because a majority of studies were conducted outside of the US and close to half of the data is derived from studies which evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of attaining a MBG-3. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Low | Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of attaining a MBG-3. Applicability of the data is limited because a majority of the studies were conducted outside of the US and evaluated devices not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI |

Abbreviations: ACS=Acute coronary syndrome; MBG= Myocardial blush grade; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 235. Strength of applicability for the body of evidence evaluating TIMI-3 blood flow in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus catheter aspiration | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of attaining TIMI-3 blood flow. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of attaining TIMI-3 blood flow. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have an increased risk in attaining a TIMI-3 blood flow. The overall applicability is limited because a majority of data is derived from studies using a device which is not currently available in the US and most studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients Data has low applicability in patients with other ACS and in patients undergoing rescue PCI. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of attaining a TIMI-3 blood flow. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients and patient undergoing rescue PCI. Data has low applicability in patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of attaining a TIMI-3 blood flow. Overall data is limited because all studies were conducted outside of the US and more than half of the data is derived from studies which evaluated a device that is not currently available in the US. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients. |

Table 235. Strength of applicability for the body of evidence evaluating TIMI-3 blood flow in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Distal balloon embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk in attaining TIMI-3 blood flow. Overall applicability is limited because a majority of studies were conducted outside of the US and close to half of the data is derived from studies which evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of attaining TIMI-3 blood flow. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Low | Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of attaining TIMI-3 blood flow. Applicability of the data is limited because a majority of the studies were conducted outside of the US and evaluated devices not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; TIMI=Thrombolysis in myocardial infarction; US=United States; Y=years

Table 236. Strength of applicability for the body of evidence evaluating distal embolization in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have a decreased risk of distal embolization. Overall applicability is limited because a majority of data is derived from studies which evaluated devices that are not currently available in the US and most studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of distal embolization. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of distal embolization. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is applicable to patients with ACS undergoing primary PCI. |
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of distal embolization. Overall applicability is limited because a majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI. |
| Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of distal embolization. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |

Table 236. Strength of applicability for the body of evidence evaluating distal embolization in patients with acute coronary syndromes (continued)

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Embolic protection devices combined versus control | Moderate | Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of distal embolization. Applicability of the data is limited because a majority of the studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 237. Strength of applicability for the body of evidence evaluating no reflow in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have a decreased risk of no reflow. Overall applicability is limited because all studies were conducted outside of the US and almost half of the data is derived from studies which evaluate devices that are not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable in patients with other ACS. |
| Catheter aspiration versus distal balloon embolic protection device | Low | Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of no reflow. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of no reflow. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of no reflow. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is applicable to patients with ACS undergoing primary PCI. |
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of no reflow. Overall applicability is limited because a majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of no reflow. Applicability of the data is limited because a majority of the studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=Years

Table 238. Strength of applicability for the body of evidence evaluating coronary dissection in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration device versus catheter aspiration device | Low | Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of coronary dissection. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI. |
| Catheter aspiration devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of coronary dissection. Applicability is limited because all studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and is not applicable to patients with other ACS or those undergoing rescue PCI. |
| Mechanical thrombectomy devices versus control | High | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of coronary dissection. Data is highly applicable to patients with STEMI undergoing primary or rescue PCI. Data is not applicable to patients with other ACS. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 239. Strength of applicability for the body of evidence evaluating coronary perforation in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Mechanical thrombectomy devices versus control | High | Compared with control, patients undergoing native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of coronary perforation. Data is highly applicable to patients with STEMI undergoing primary or rescue PCI although is not applicable to patients with other ACS. |
| Distal balloon embolic protection devices versus control | Low | Compared with control, patients undergoing native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of coronary perforation. Applicability is limited because the trial evaluated a device which is not currently available in the US. Data is highly applicable in patients with STEMI undergoing primary PCI. Data is not applicable to patients undergoing rescue PCI or those with other ACS. |
| Embolic protection devices combined versus control | Low | Compared with control, patients undergoing native vessel PCI with an embolic protection device do not have a difference in the risk of coronary perforation. Applicability is limited because the trial evaluated a device which is not currently available in the US. Data is highly applicable in patients with STEMI undergoing primary PCI. Data is not applicable to patients undergoing rescue PCI or those with other ACS. |

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 240. Strength of applicability for the body of evidence evaluating prolonged procedure time in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration device versus distal balloon embolic protection device | Low | Compared with the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a prolonged procedure time. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery. |
| Catheter aspiration versus control | Moderate | Compared with control, patients undergoing native vessel PCI with a catheter aspiration device do not have a prolonged procedure time. Applicability is limited because all studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. The data is moderately applicable to female patients, has low applicability in patients undergoing rescue PCI, and is not applicable to patients with other ACS. |
| Mechanical thrombectomy devices versus control | High | Compared with control, patients undergoing native vessel PCI with a mechanical thrombectomy device have a prolonged procedure time. Data is highly applicable to male patients with STEMI undergoing primary PCI. The data is moderately applicable to female patients or those undergoing rescue PCI, and is not applicable to patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients undergoing native vessel PCI with a distal filter embolic protection device have a prolonged procedure time. Applicability is limited because this study was conducted in South American and Asia and evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. The data is moderately applicable to female patients, has low applicability to patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients undergoing native vessel PCI with a distal balloon embolic protection device have a prolonged procedure time. Overall data is limited because half is derived from trials conducted in Asia and India. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients or those with other ACS and has low applicability in patients undergoing rescue PCI. |
| Proximal balloon embolic protection device versus control | Low | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of prolonged procedure time. Data is limited because the representative trial was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI. |
| Embolic protection devices combined versus control | Low | Compared with control, patients who undergo native vessel PCI with an embolic protection device have a prolonged procedure time. Applicability is limited because most of the trials were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI with moderate applicability to female patients. Data has low applicability to patients with other ACS or those undergoing rescue PCI. |

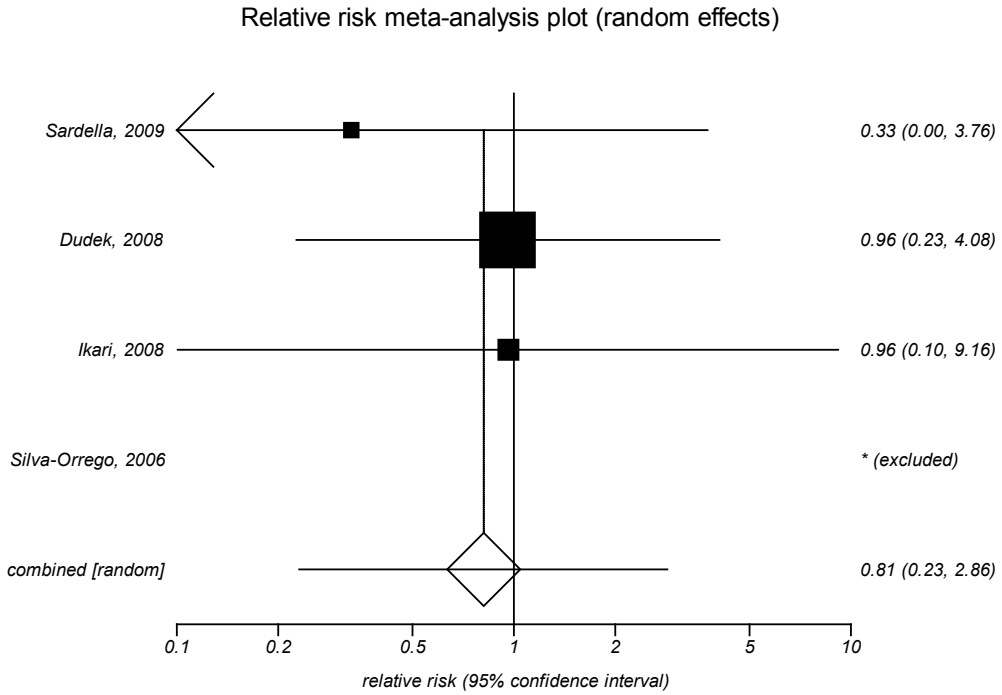
Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 241. Strength of applicability for the body of evidence evaluating side branch occlusion in patients with acute coronary syndromes

| Comparison | Strength of Applicability | Conclusion with Description of Applicability |
|---|---|---|
| Catheter aspiration versus control | Moderate | Compared with control, patients undergoing native vessel PCI with a catheter aspiration device do not have a difference in the risk of side branch occlusion. Overall applicability is limited because data is derived from Europe and India. Data is highly applicable to male patients with STEMI undergoing primary PCI with moderate applicability to female patients. Data is not applicable to patients undergoing rescue PCI or patients with other ACS. |
| Mechanical thrombectomy devices versus control | Low | Compared with control, patients undergoing native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients in Europe with STEMI and moderately applicable to female patients. Data is not applicable to patients with other ACS. |
| Distal filter embolic protection devices versus control | Low | Compared with control, patients undergoing native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients in South America and Asia with STEMI undergoing primary PCI, with moderate applicability in female patients. The device evaluated in this trial is not currently available in the US. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS. |
| Distal balloon embolic protection devices versus control | Moderate | Compared with control, patients undergoing native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients with STEMI undergoing either primary or rescue PCI. Data is moderately applicable to female patients and is not applicable to patients with other ACS. |
| Embolic protection devices combined versus control | Moderate | Compared with control, patients undergoing native vessel PCI with an embolic protection device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to patients undergoing rescue PCI and is not applicable to patients with other ACS. |

# Appendix I. Forest plots for results of final health outcomes analyzed at individual time points

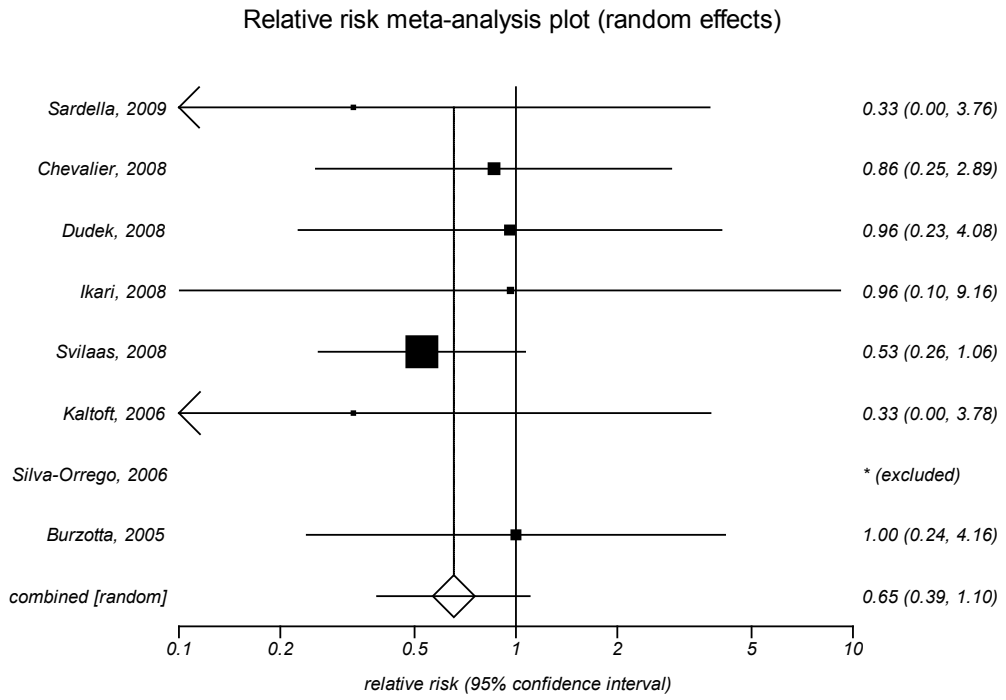
Figure 1. Impact of catheter aspiration devices versus control on in-hospital mortality.




Cochran Q: P = 0.832
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

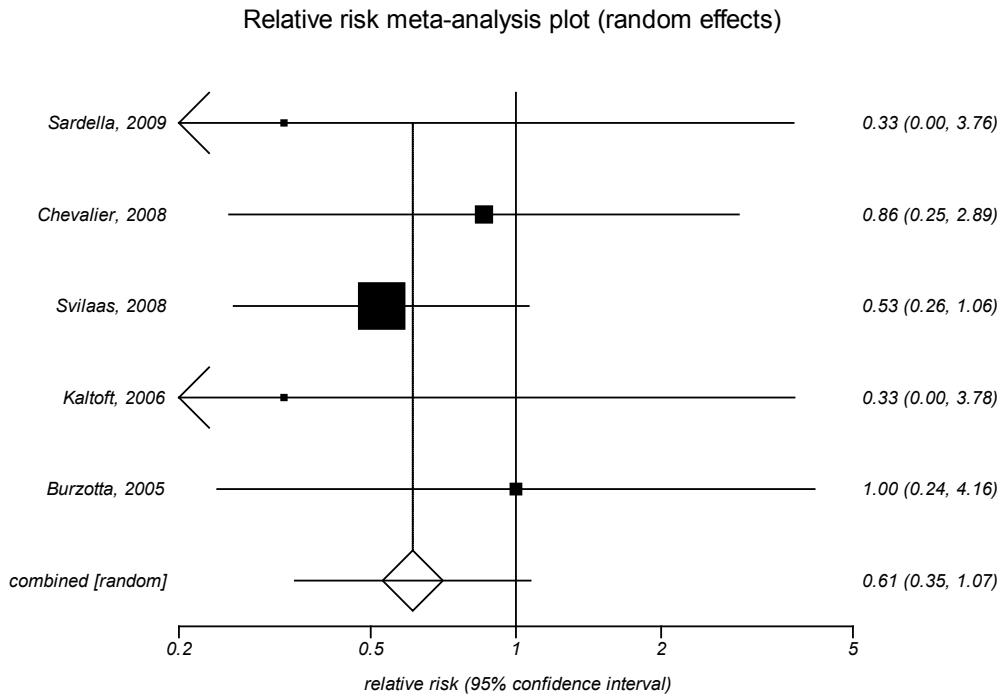
Figure 2. Impact of catheter aspiration devices versus control on ≤30 day mortality.




Cochran Q: P = 0.961
$I^2$: 0%
Egger: P = 0.689

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

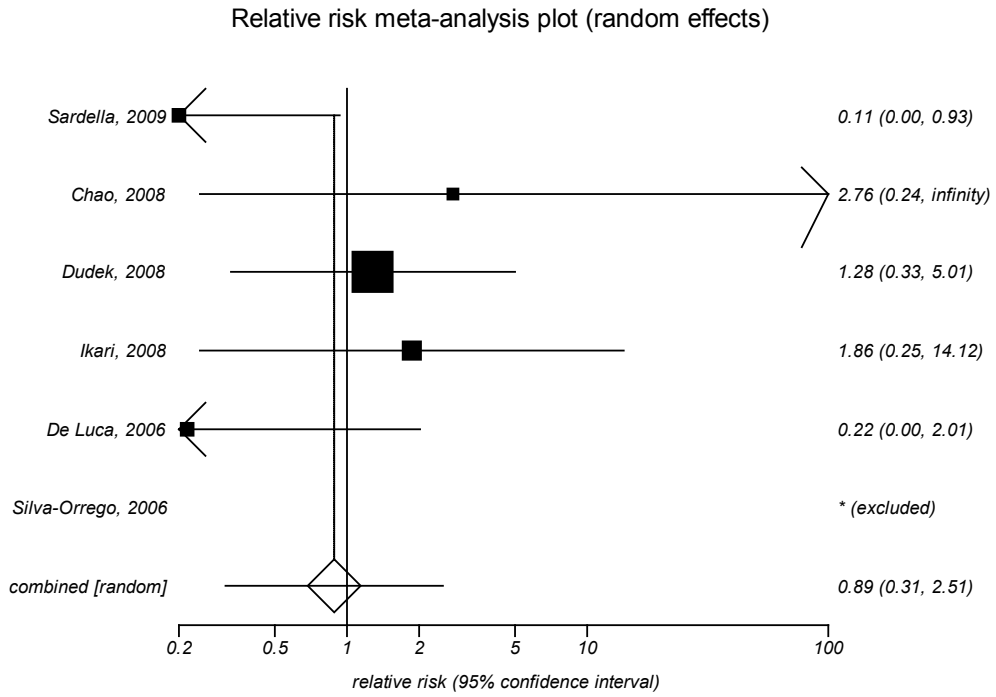
Figure 3. Impact of catheter aspiration devices versus control on 30-day mortality.




Cochran Q: P = 0.892
$I^2$: 0%
Egger: P = 0.976

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

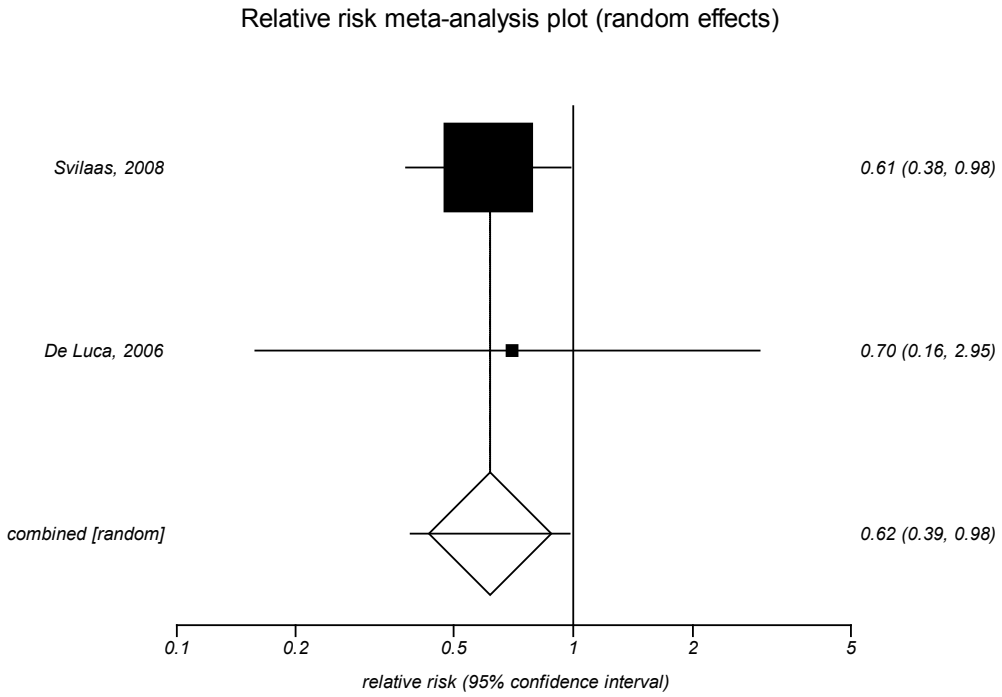
Figure 4. Impact of catheter aspiration devices versus control on 180-day mortality.




Cochran Q: P = 0.391
$I^2$: 2.8%
Egger: P = 0.487

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

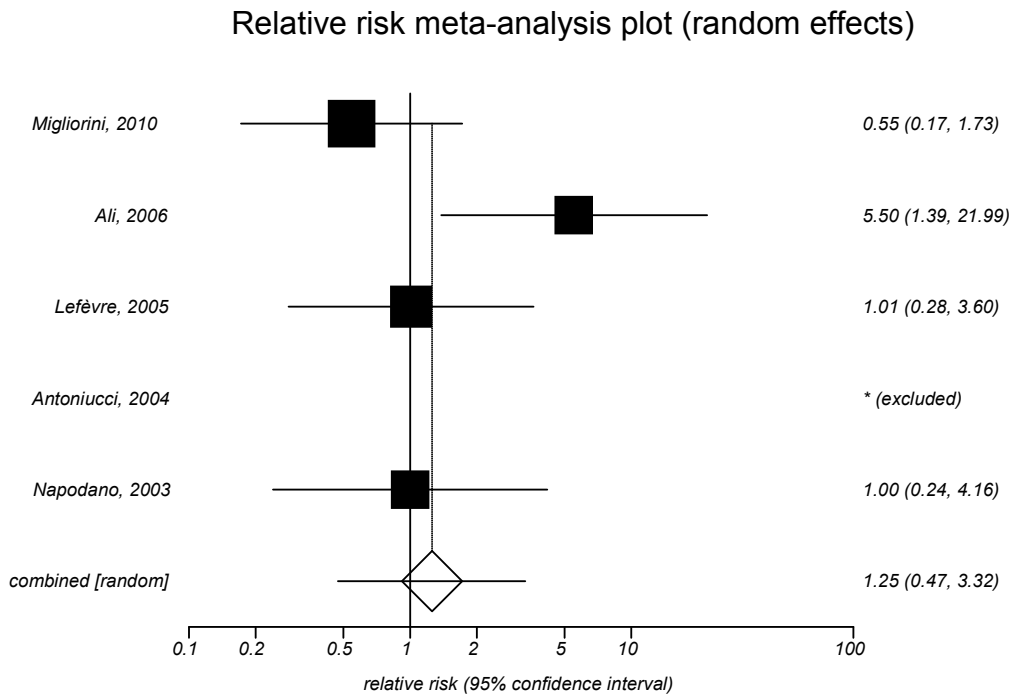
Figure 5. Impact of catheter aspiration devices versus control on 365-day mortality.




Cochran Q: P = 0.873
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

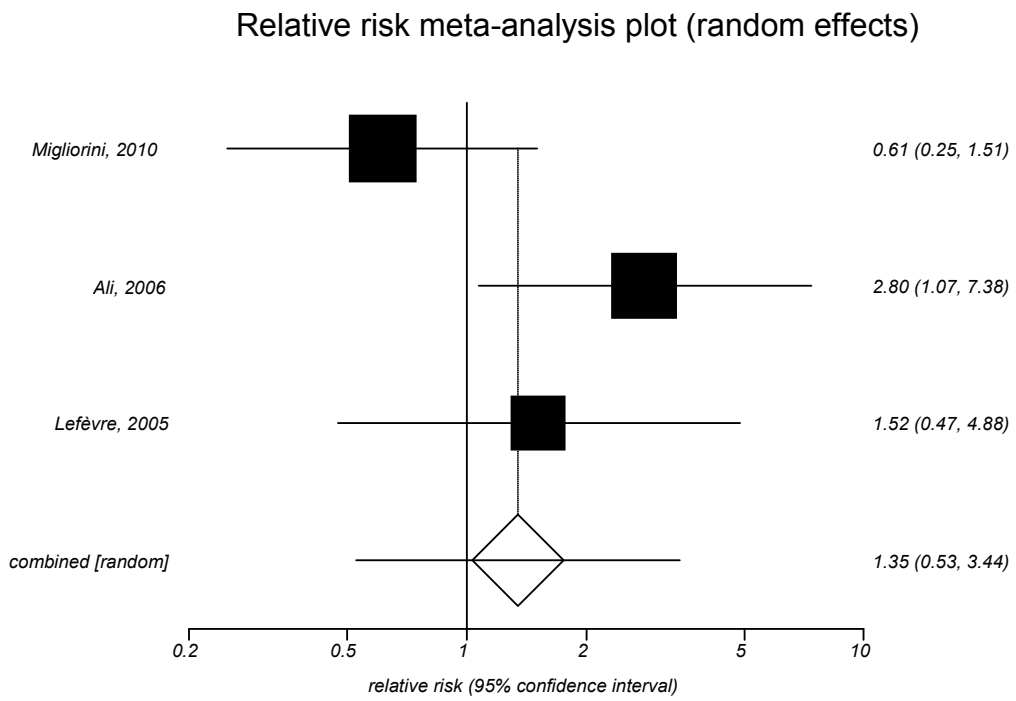
Figure 6. Impact of mechanical thrombectomy devices versus control on ≤ 30-day mortality.




Cochran Q: P = 0.120
$I^2$: 48.7%
Egger: P = 0.329

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

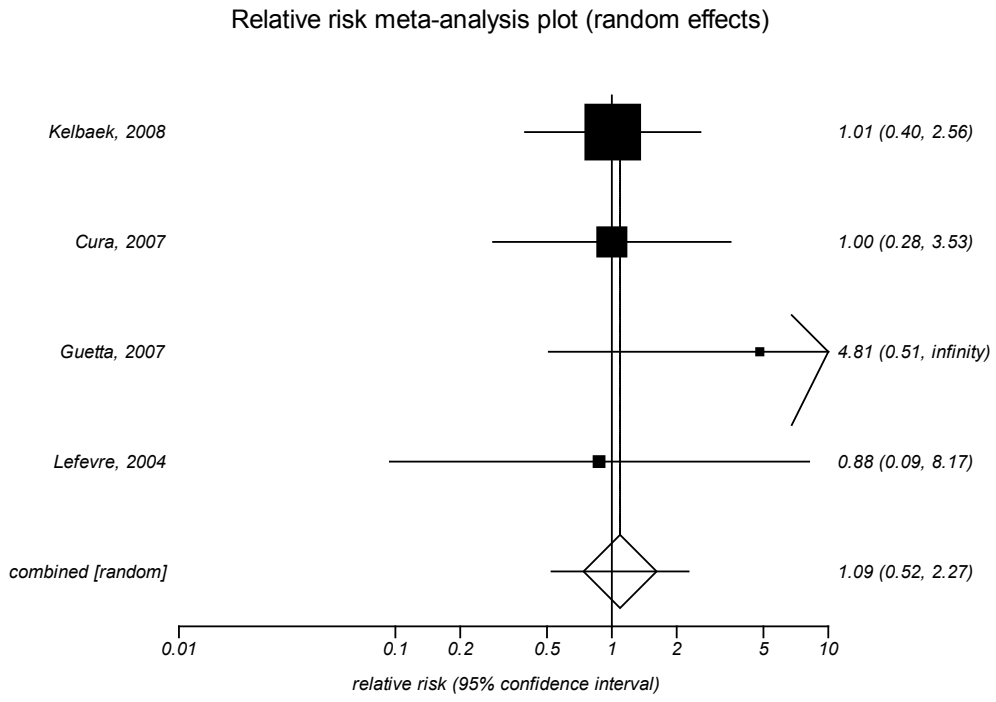
Figure 7. Impact of mechanical thrombectomy devices versus control on 180-day mortality.




Cochran Q: P = 0.090
$I^2$: 58.4%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

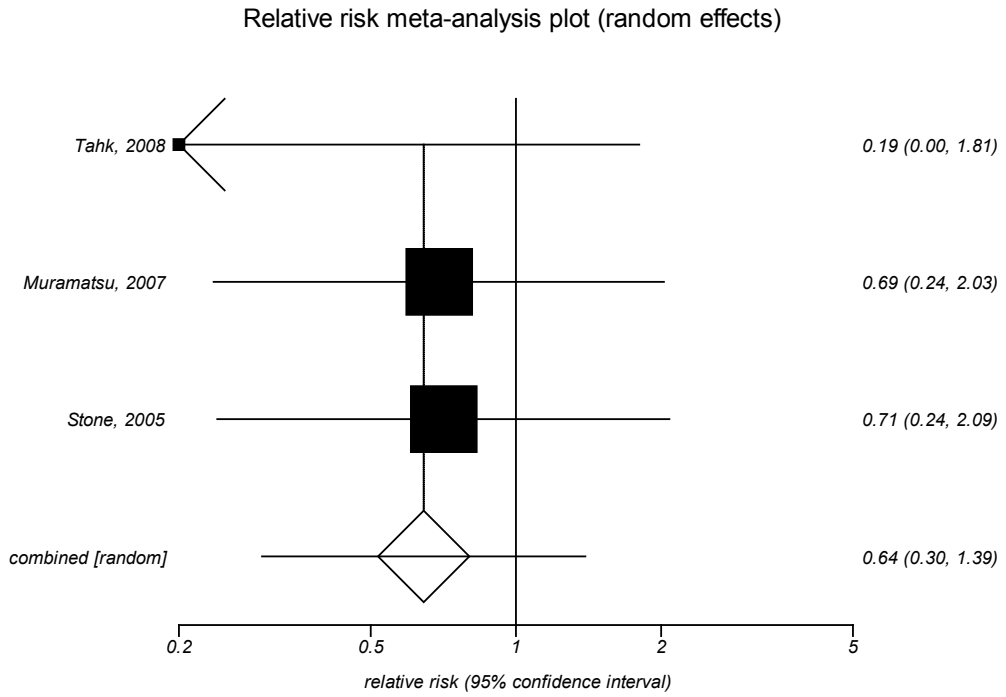
Figure 8. Impact of distal filter embolic protection devices versus control on ≤30 day mortality.




Cochran Q: P = 0.798
$I^2$: 0%
Egger: P = 0.388

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

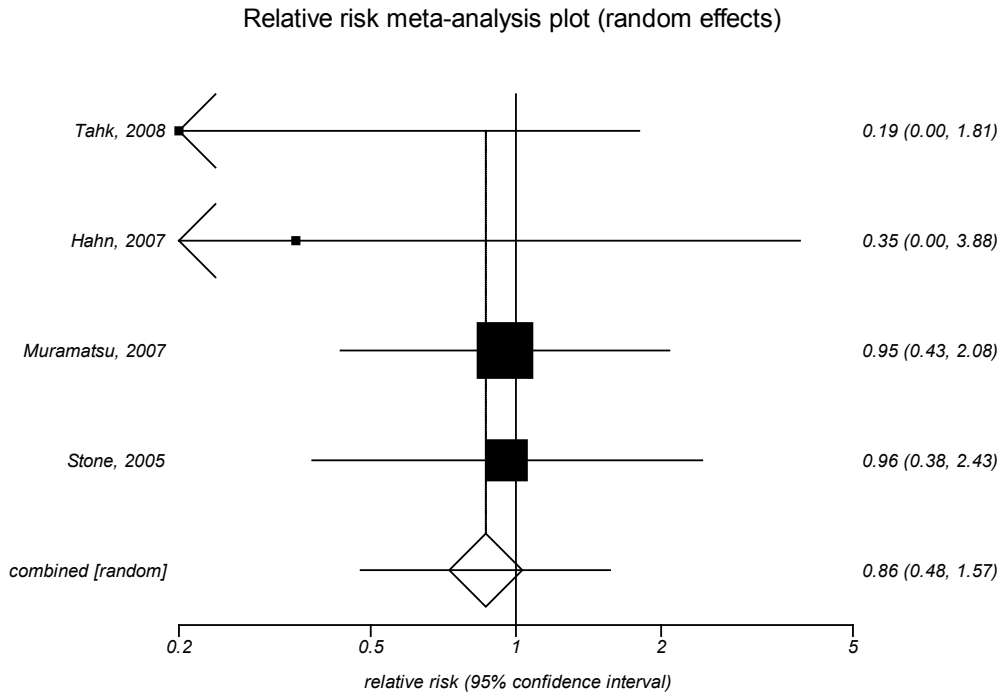
Figure 9. Impact of distal balloon embolic protection devices versus control on ≤30-day mortality.




Cochran Q: P = 0.716
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

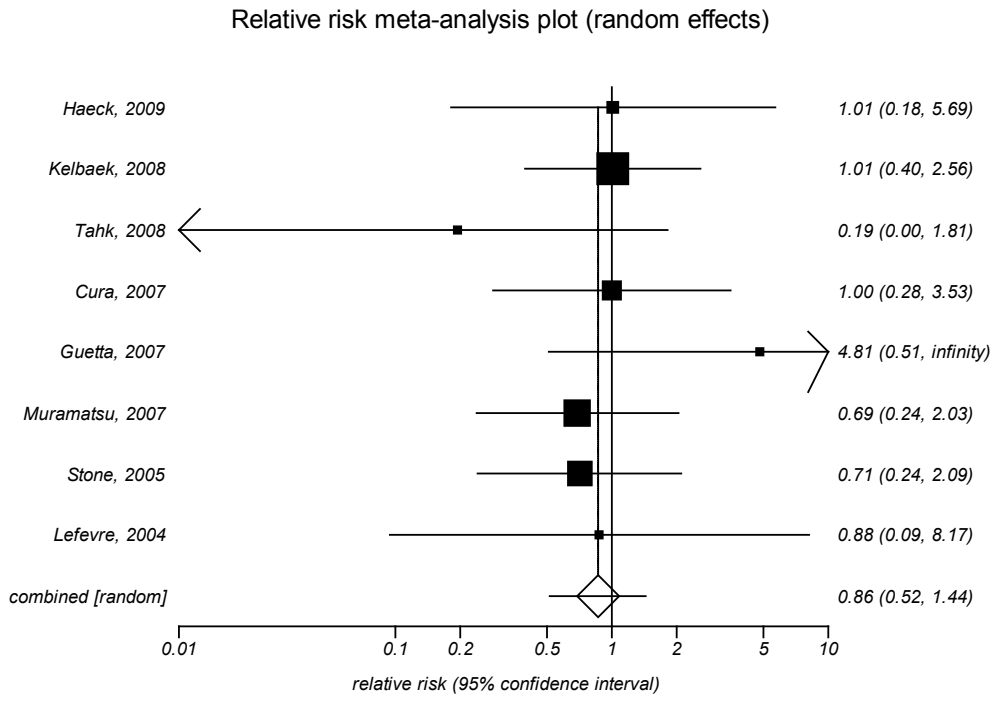
Figure 10. Impact of distal balloon embolic protection devices versus control on 180-day mortality.




Cochran Q: P = 0.709
$I^2$: 0%
Egger: P = 0.044

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

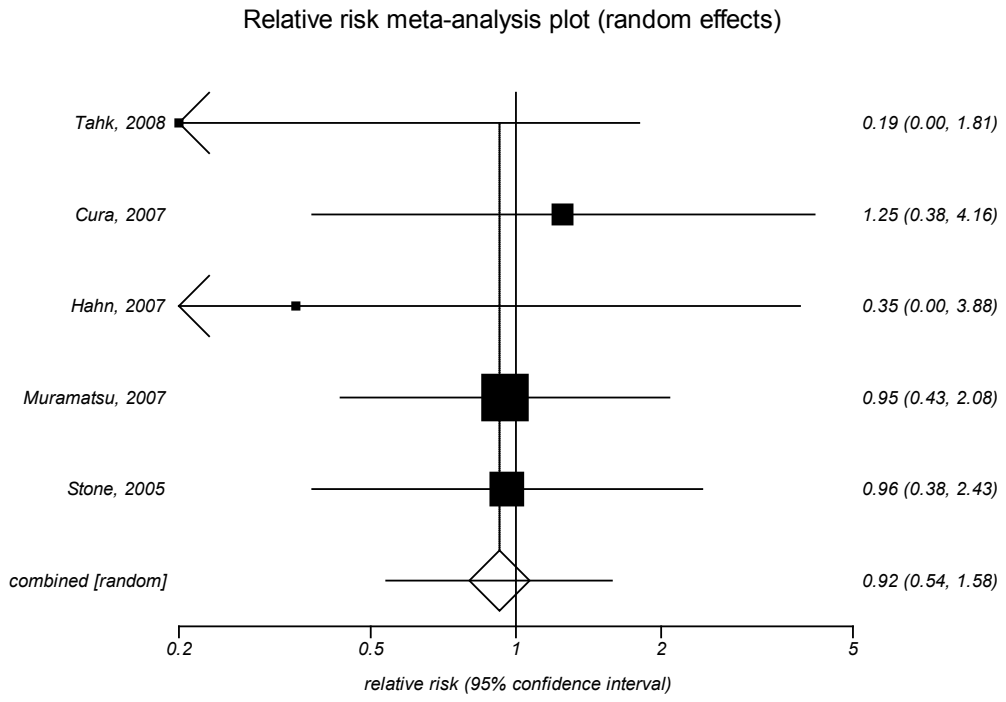
Figure 11. Impact of embolic protection devices versus control combined on ≤30 day mortality.




Cochran Q: P = 0.917
$I^2$: 0%
Egger: P = 0.843

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

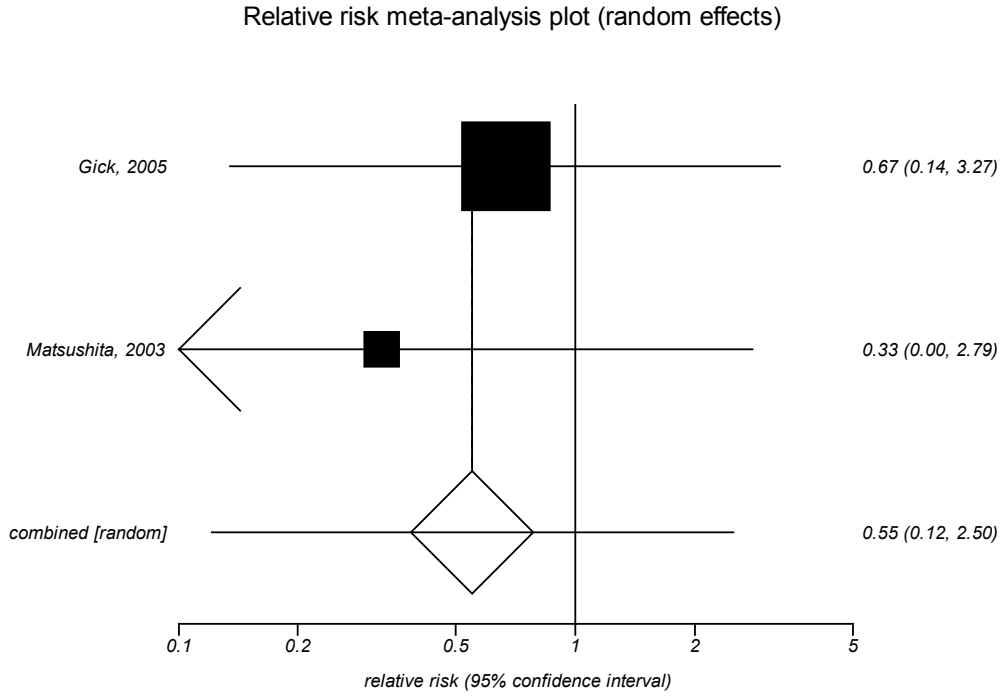
Figure 12. Impact of embolic protection devices combined versus control on 180-day mortality.




Cochran Q: P = 0.800
$I^2$: 0%
Egger: P = 0.108

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

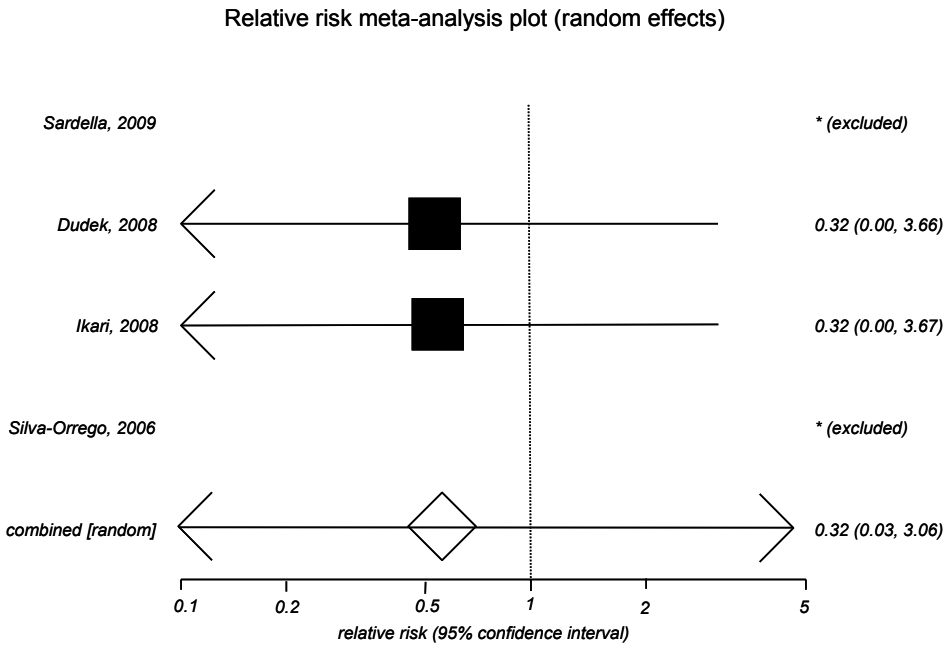
Figure 13. Impact of embolic protection devices combined versus control on ≤30 day mortality in patients with mixed acute coronary syndromes.




Cochran Q: P = 0.677
$I^2$: Too few strata
Egger: P = Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

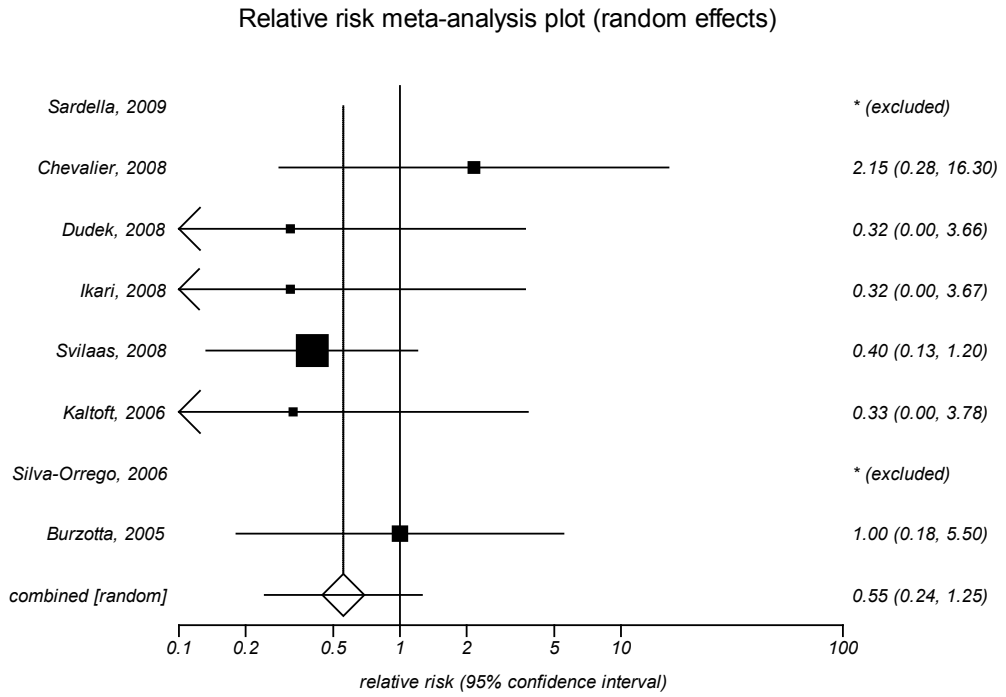
Figure 14. Impact of catheter aspiration devices versus control on in-hospital myocardial infarction.




Cochran Q: P = 1.000
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

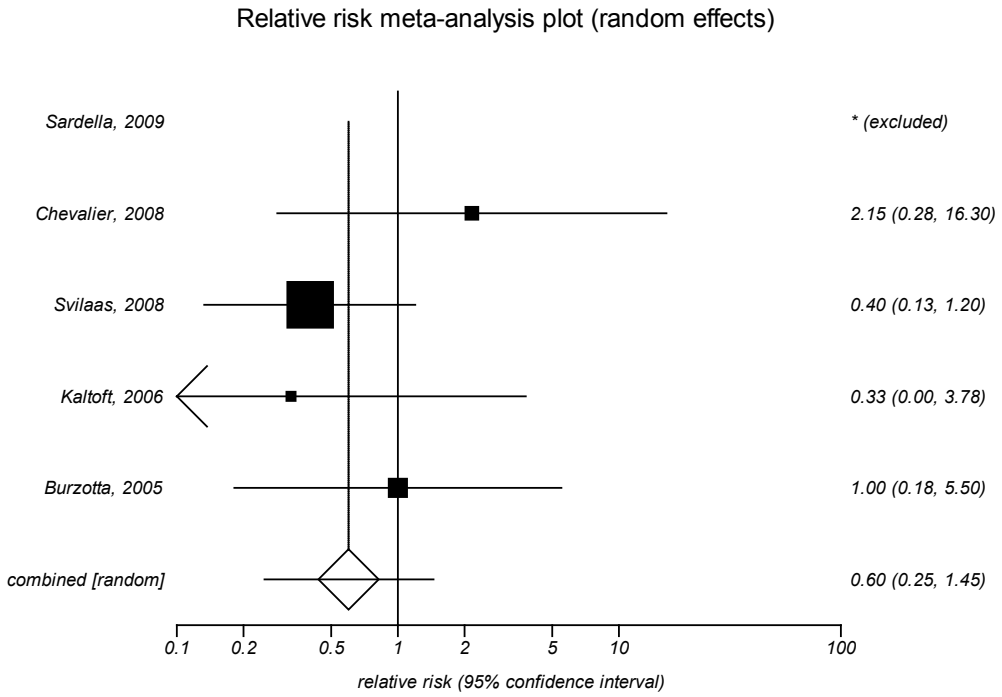
Figure 15. Impact of catheter aspiration devices versus control on ≤30 day myocardial infarction.




Cochran Q: P = 0.816
$I^2$: 0%
Egger: P = 0.809

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

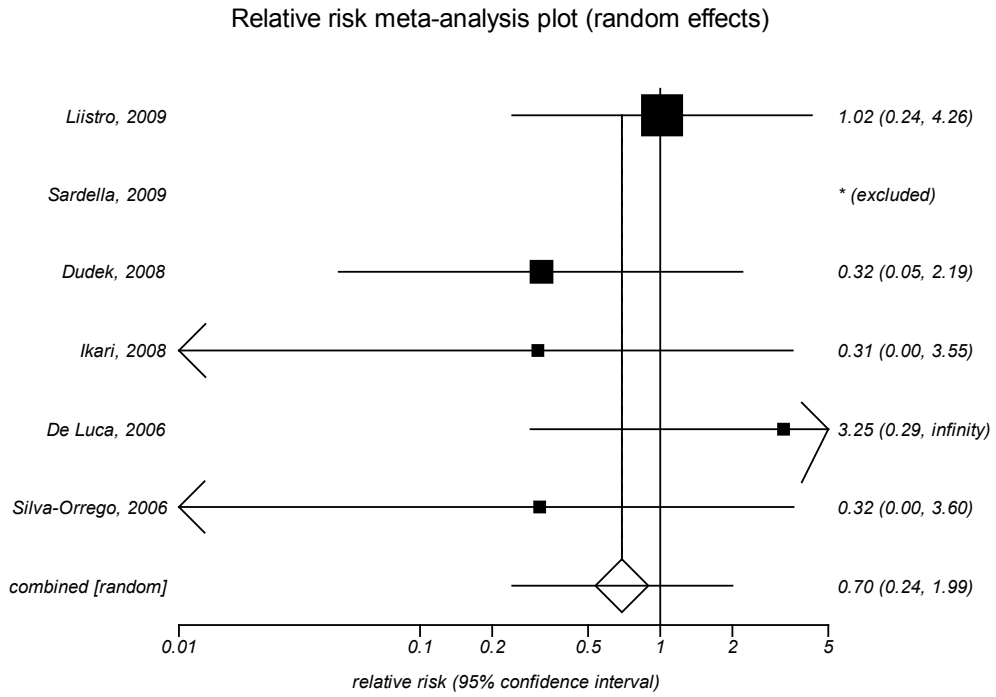
Figure 16. Impact of catheter aspiration devices versus control on 30-day myocardial infarction.




Cochran Q: P = 0.578
$I^2$: 0%
Egger: P = 0.499

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

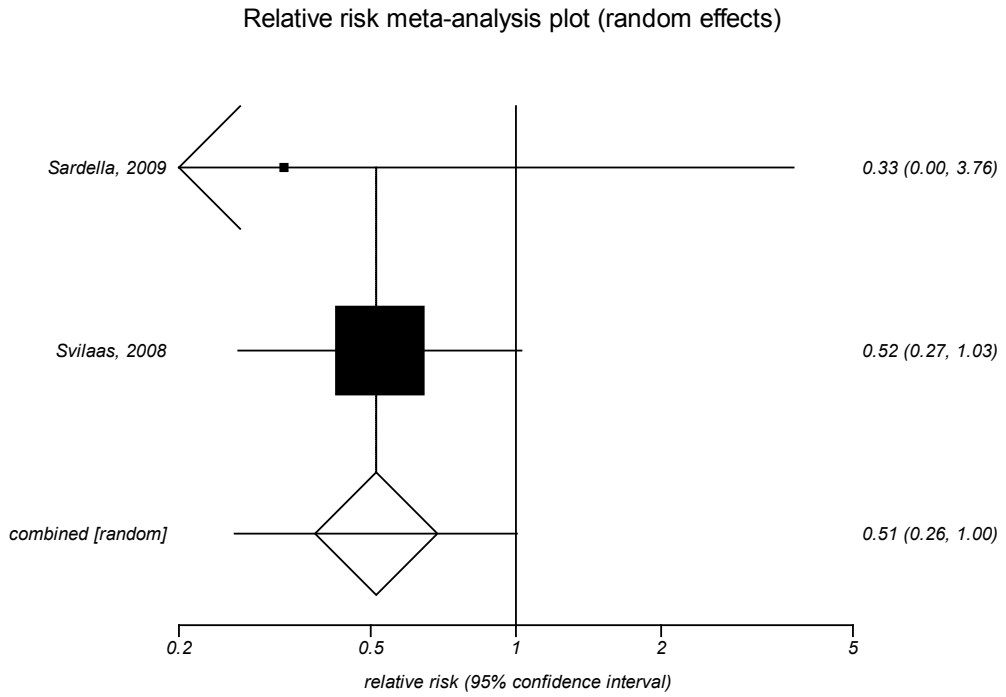
Figure 17. Impact of catheter aspiration devices versus control on 180-day myocardial infarction.




Cochran Q: P = 0.721
$I^2$: 0%
Egger: P = 0.708

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

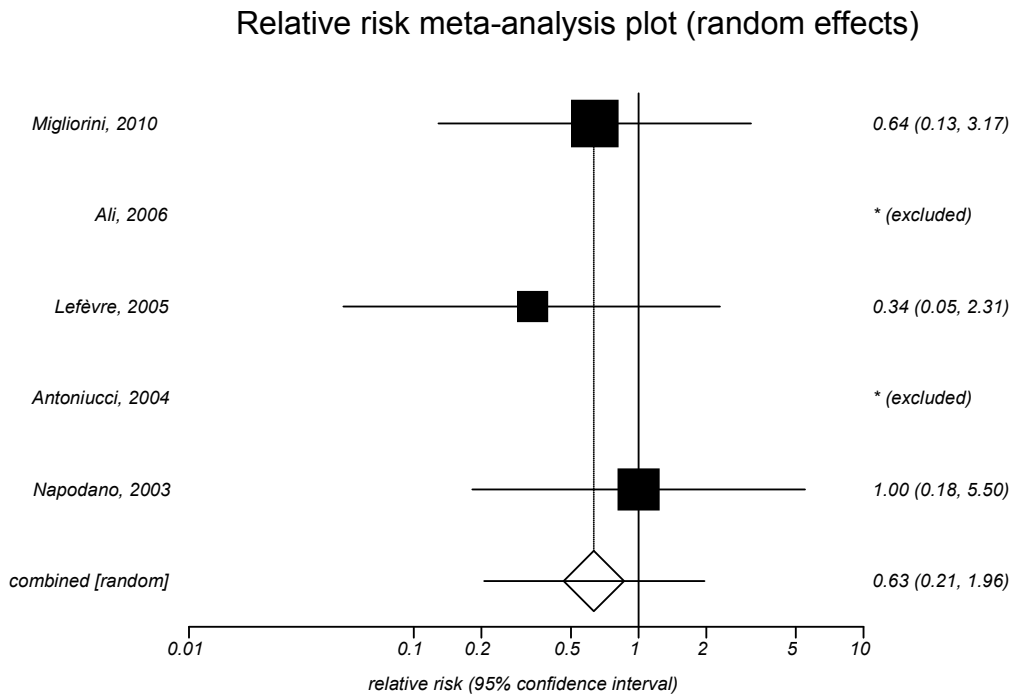
Figure 18. Impact of catheter aspiration devices versus control on 365-day myocardial infarction.




Cochran Q: P = 0.782
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

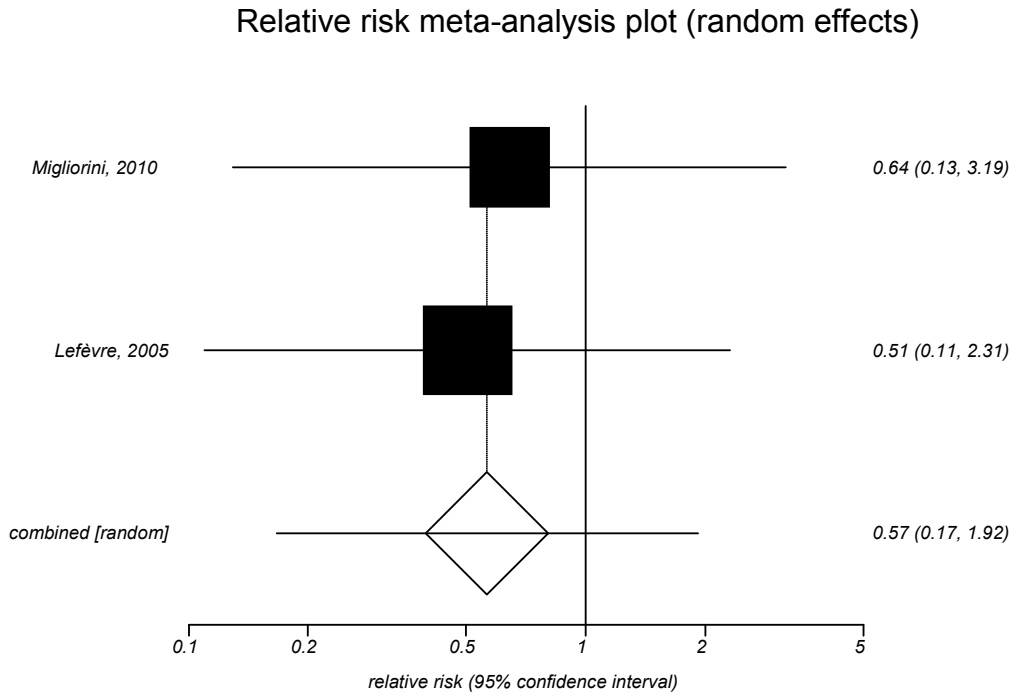
Figure 19. Impact of mechanical thrombectomy devices versus control on ≤ 30-day myocardial infarction.




Cochran Q: P = 0.769
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

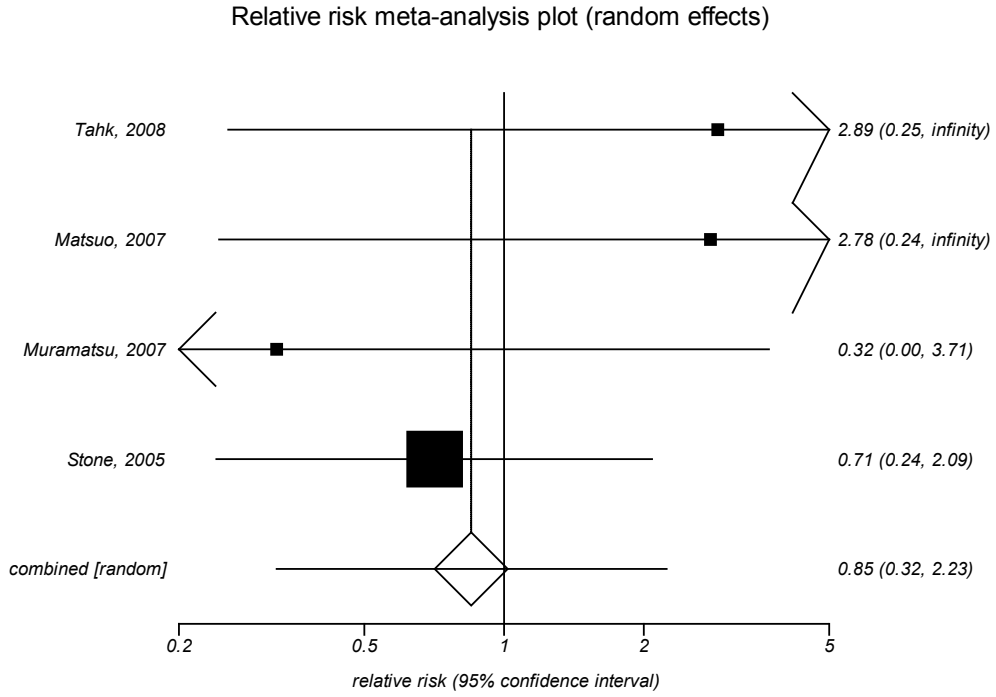
Figure 20. Impact of mechanical thrombectomy devices versus control on 180-day myocardial infarction.




Cochran Q: P = 0.847
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

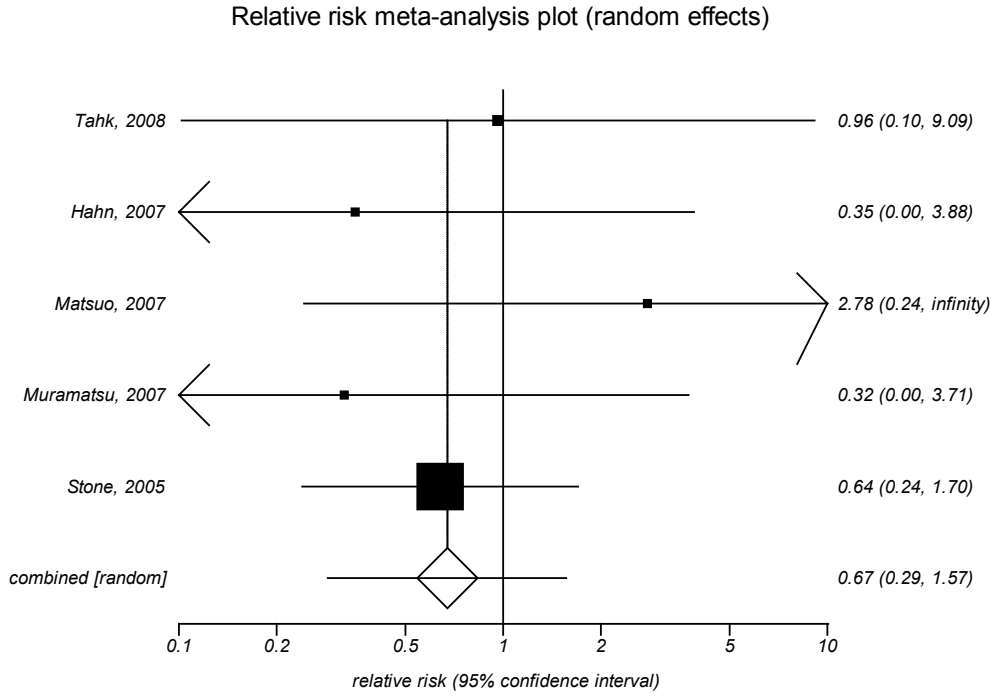
Figure 21. Impact of distal balloon embolic protection devices versus control on ≤30-day myocardial infarction.




Cochran Q: P = 0.670
$I^2$: 0%
Egger: P = 0.517

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

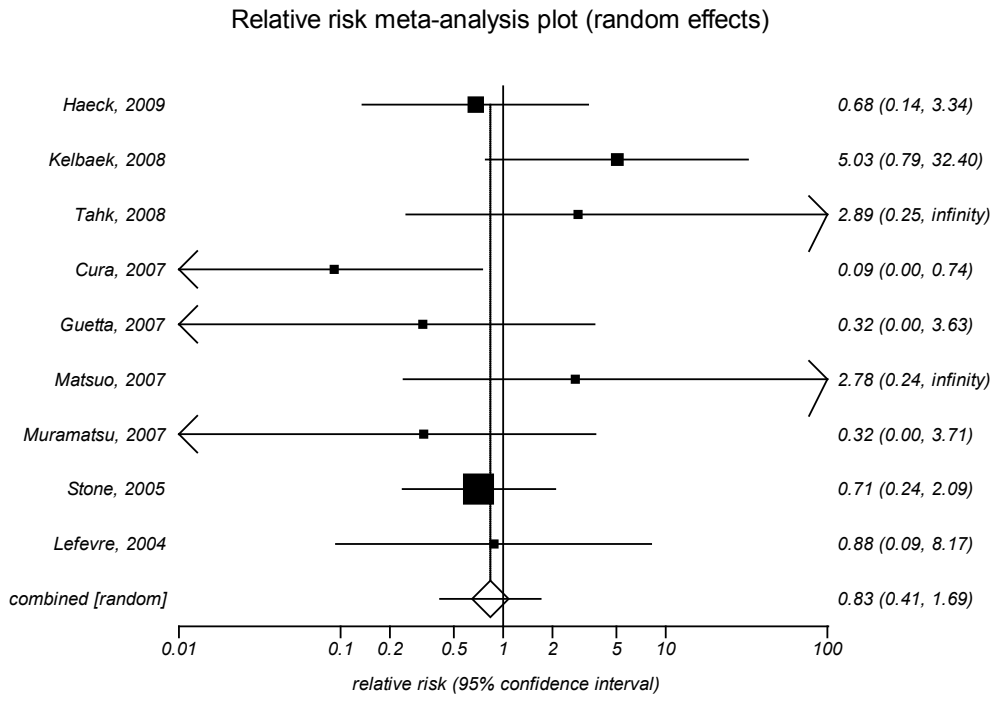
Figure 22. Impact of distal balloon embolic protection devices versus control on 180-day myocardial infarction.




Cochran Q: P = 0.877
$I^2$: 0%
Egger: P = 0.820

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

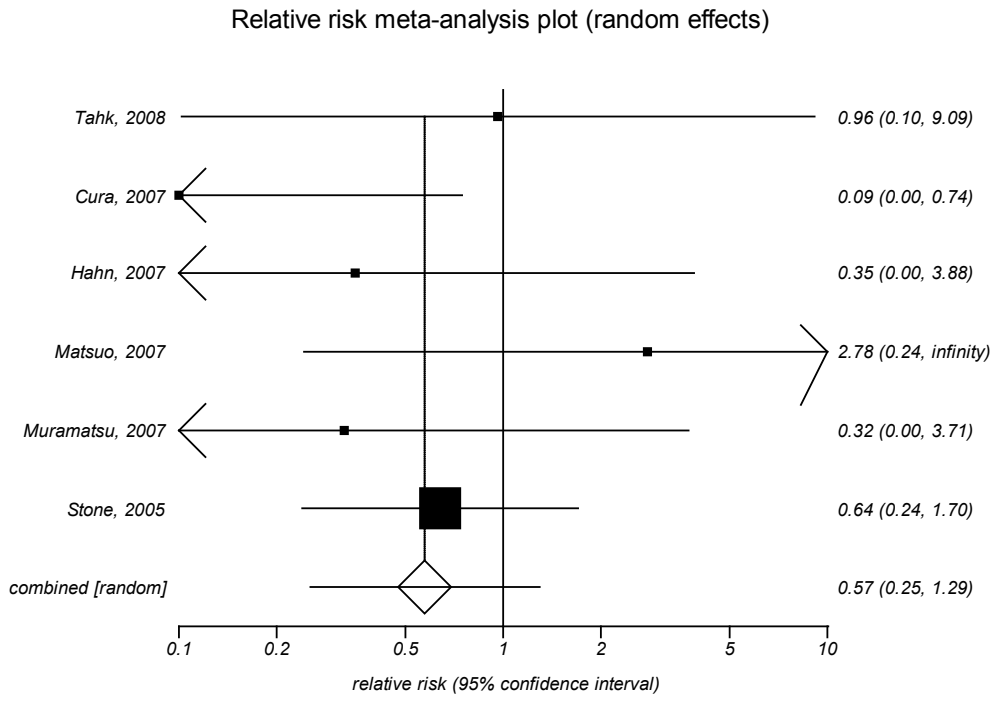
Figure 23. Impact of embolic protection devices combined versus control on ≤30 day myocardial infarction.




Cochran Q: P = 0.542
$I^2$: 0%
Egger: P = 0.982

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

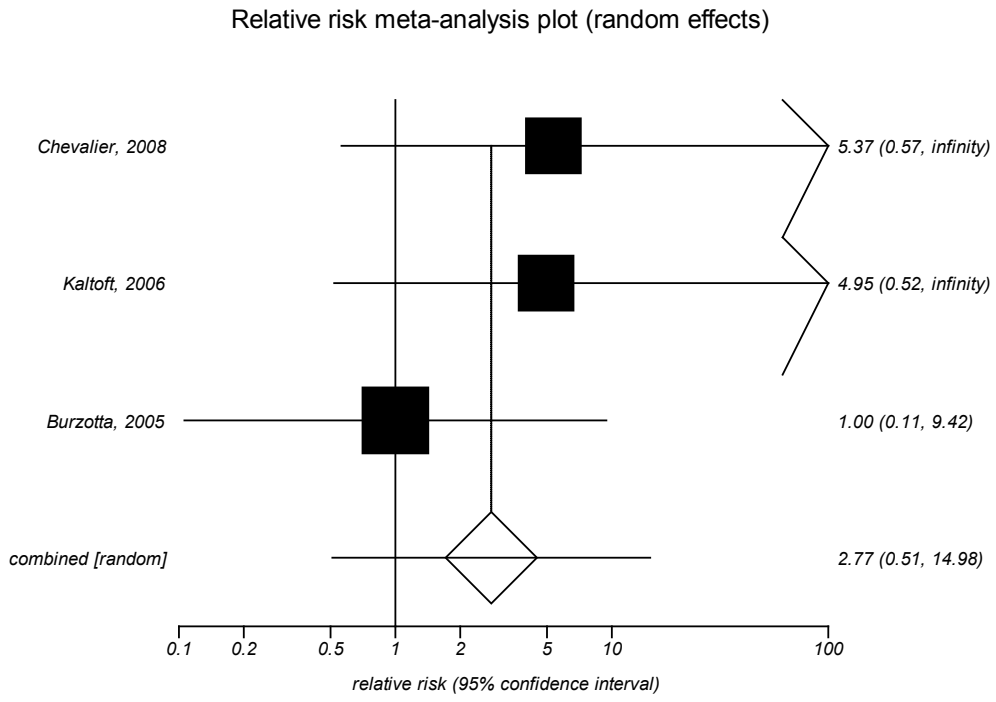
Figure 24. Impact of embolic protection devices combined versus control on 180-day myocardial infarction.




Cochran Q: P = 0.700
$I^2$: 0%
Egger: P = 0.732

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

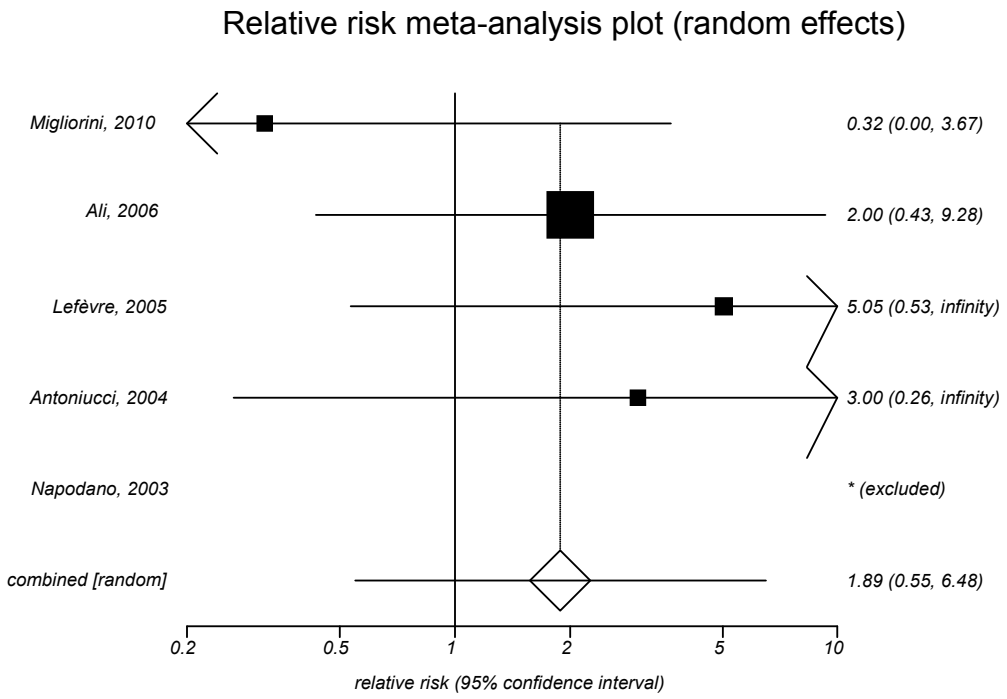
Figure 25. Impact of catheter aspiration devices versus control on 30-day stroke.




Cochran Q: P = 0.647
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

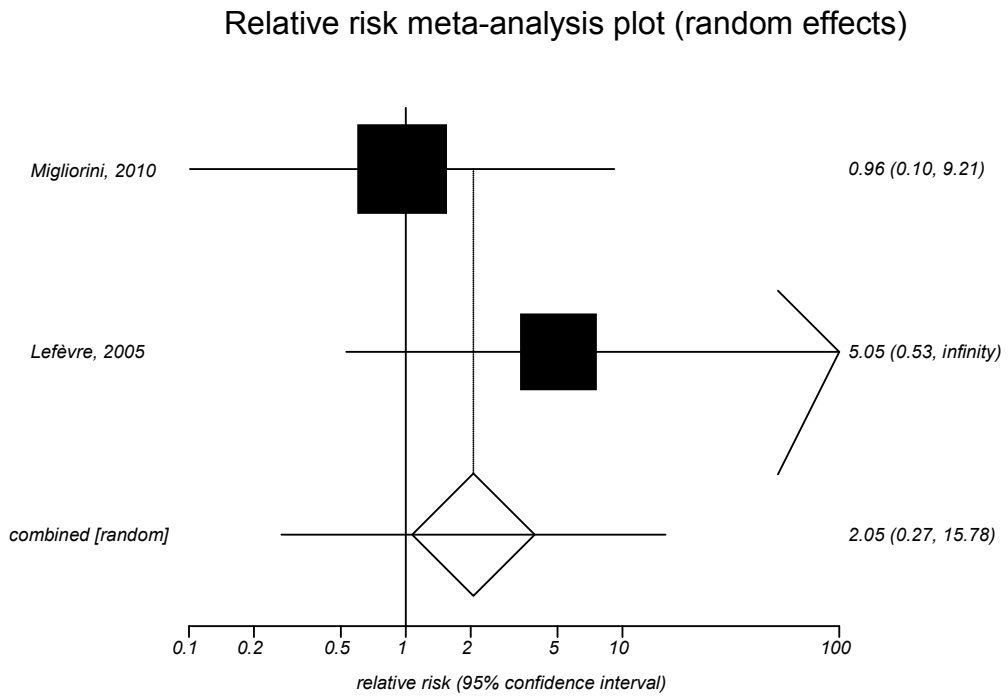
Figure 26. Impact of mechanical thrombectomy devices versus control on ≤ 30-day stroke.




Cochran Q: P = 0.641
$I^2$: 0%
Egger: P = 0.870

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

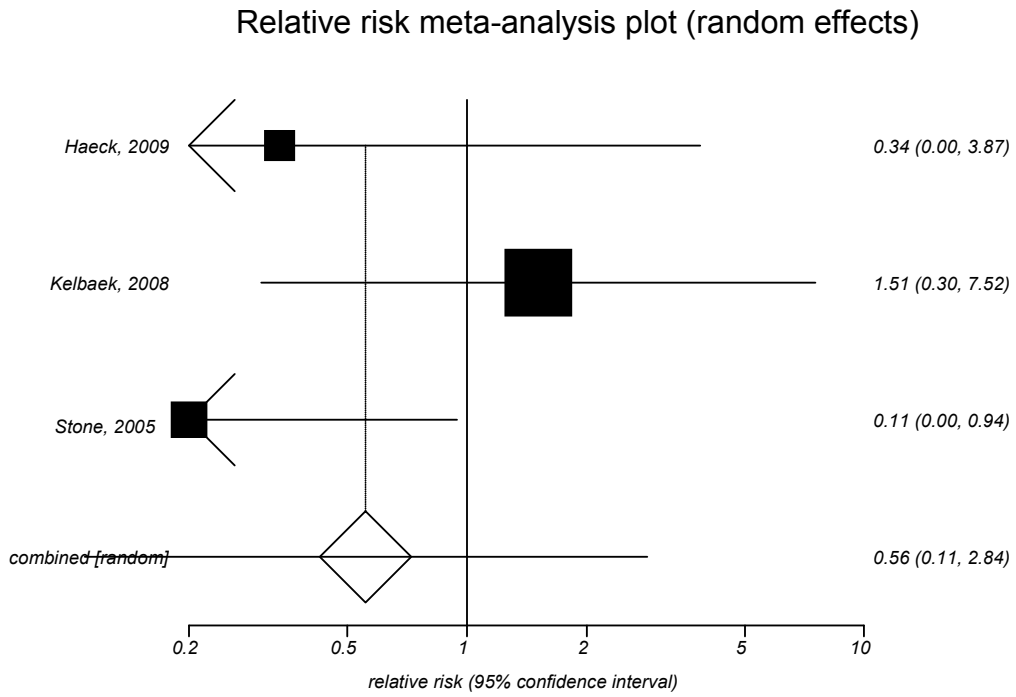
Figure 27. Impact of mechanical thrombectomy devices versus control on 180-day stroke.




Cochran Q: P = 0.424
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

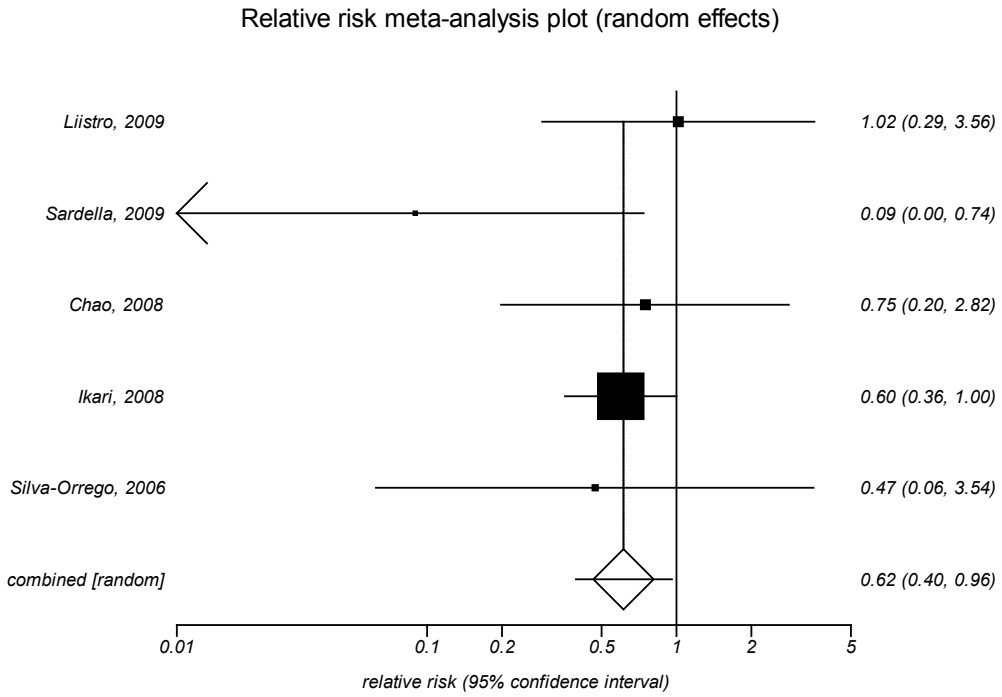
Figure 28. Impact of embolic protection devices combined versus control on ≤30 day stroke.




Cochran Q: P = 0.277
$I^2$: 22.1%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

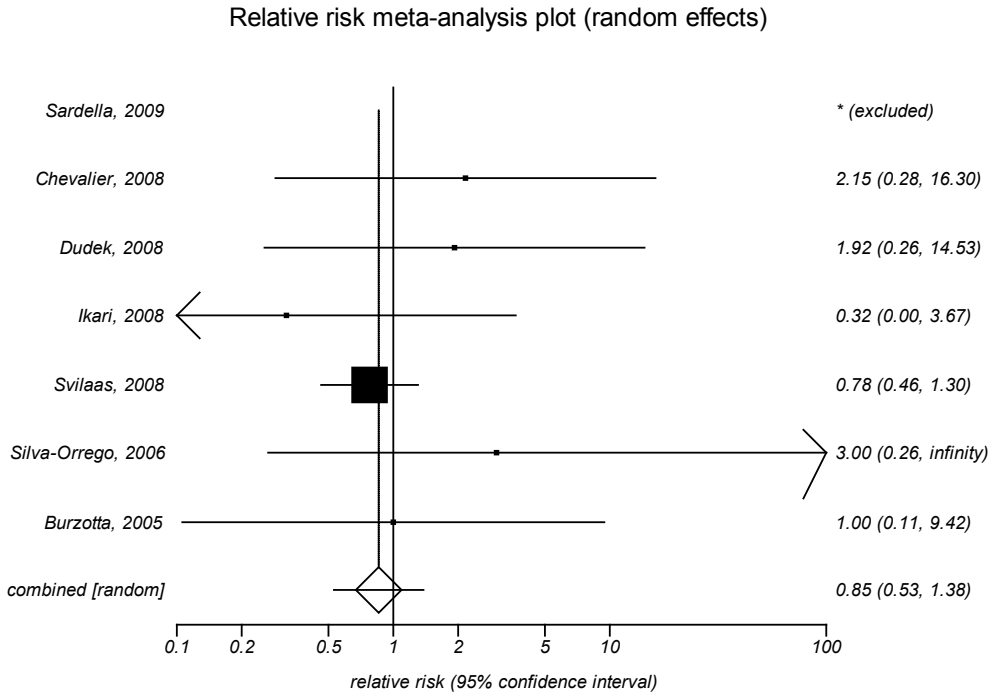
Figure 29. Impact of catheter aspiration devices versus control on 180-day target revascularization.




Cochran Q: P = 0.653
$I^2$: 0%
Egger: P = 0.604

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

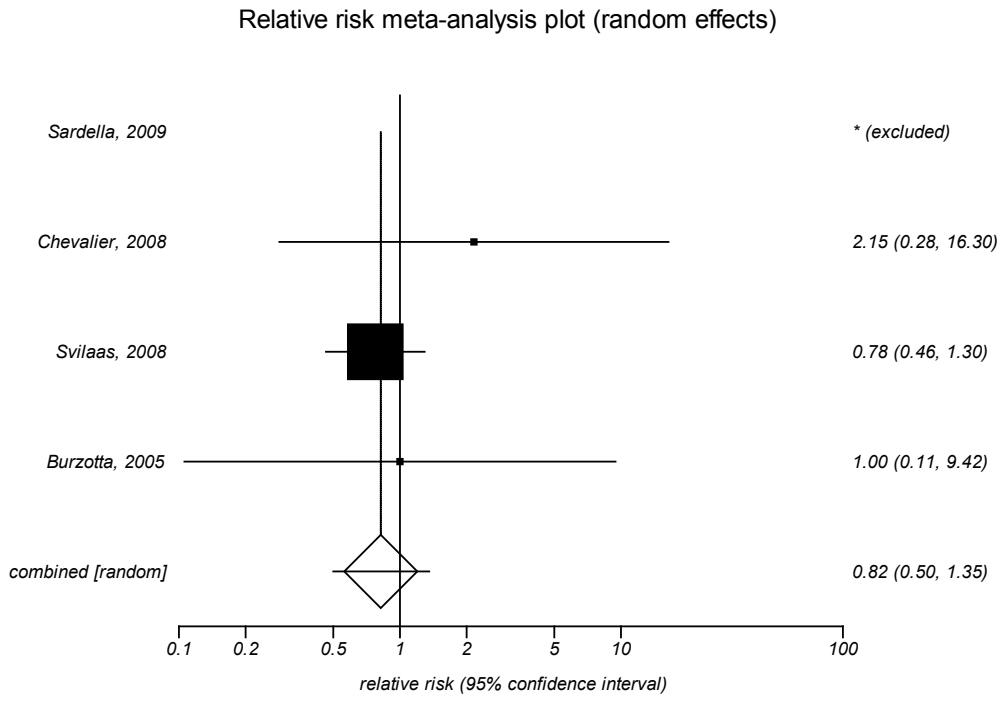
Figure 30. Impact of catheter aspiration devices versus control on ≤ 30 day target revascularization.




Cochran Q: P = 0.832
$I^2$: 0%
Egger: P = 0.254

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

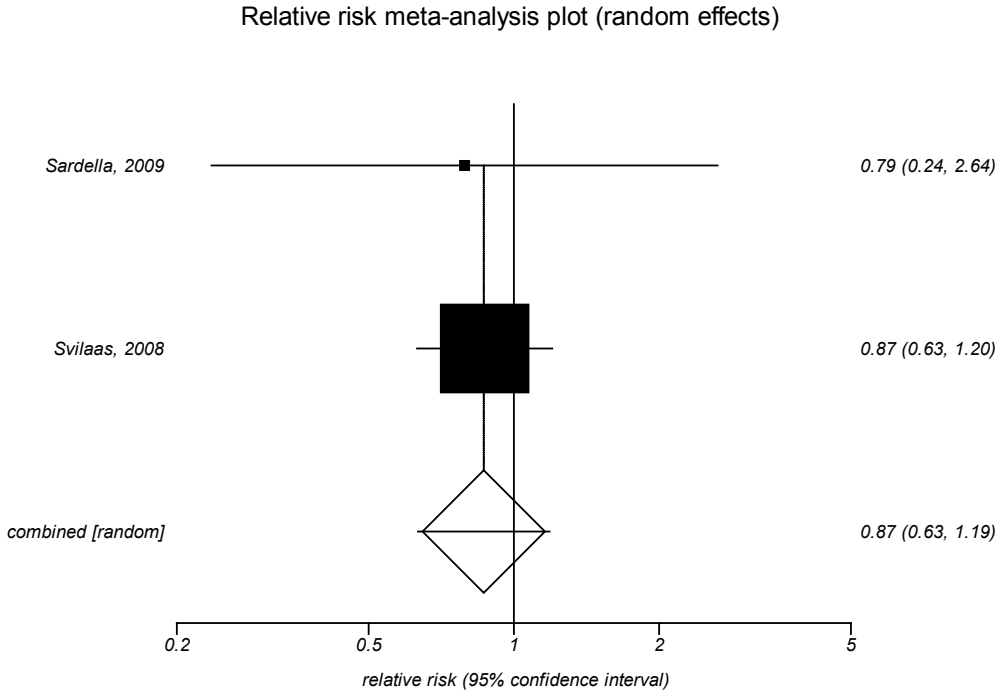
Figure 31. Impact of catheter aspiration devices versus control on 30-day target revascularization.




Cochran Q: P = 0.709
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

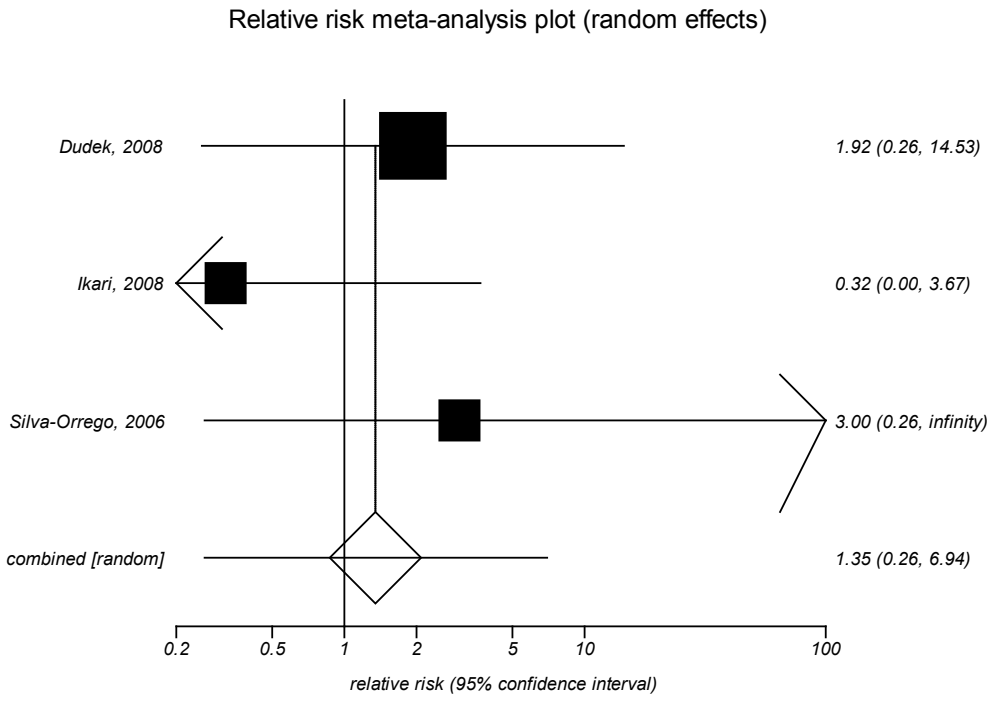
Figure 32. Impact of catheter aspiration devices versus control on 365-day target revascularization.




Cochran Q: P = 0.886
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

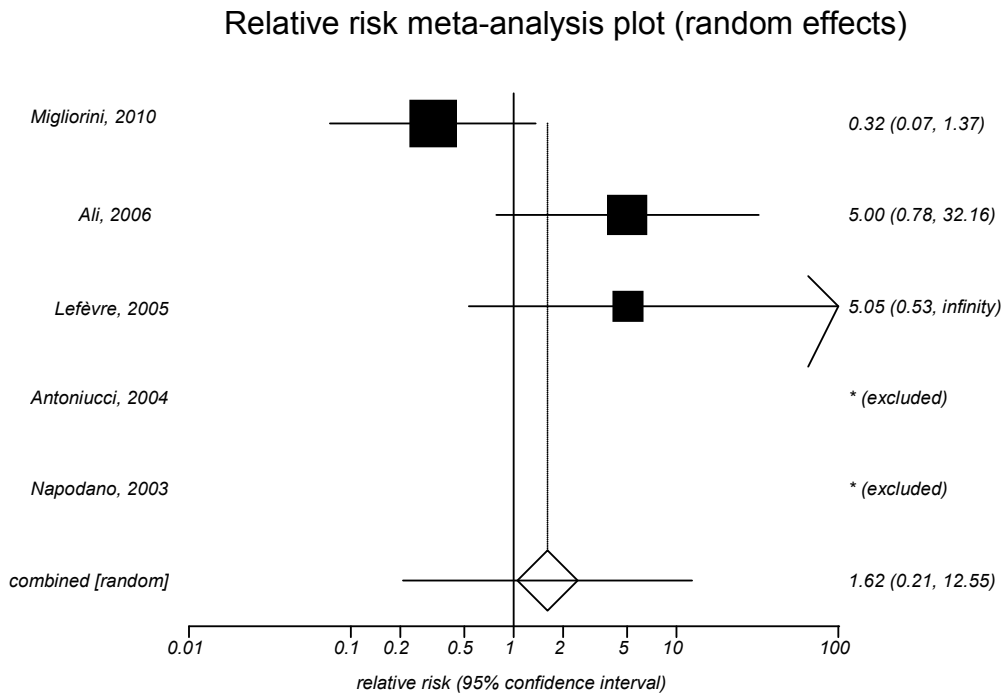
Figure 33. Impact of catheter aspiration devices versus control on in-hospital target revascularization.




Cochran Q: P = 0.575
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

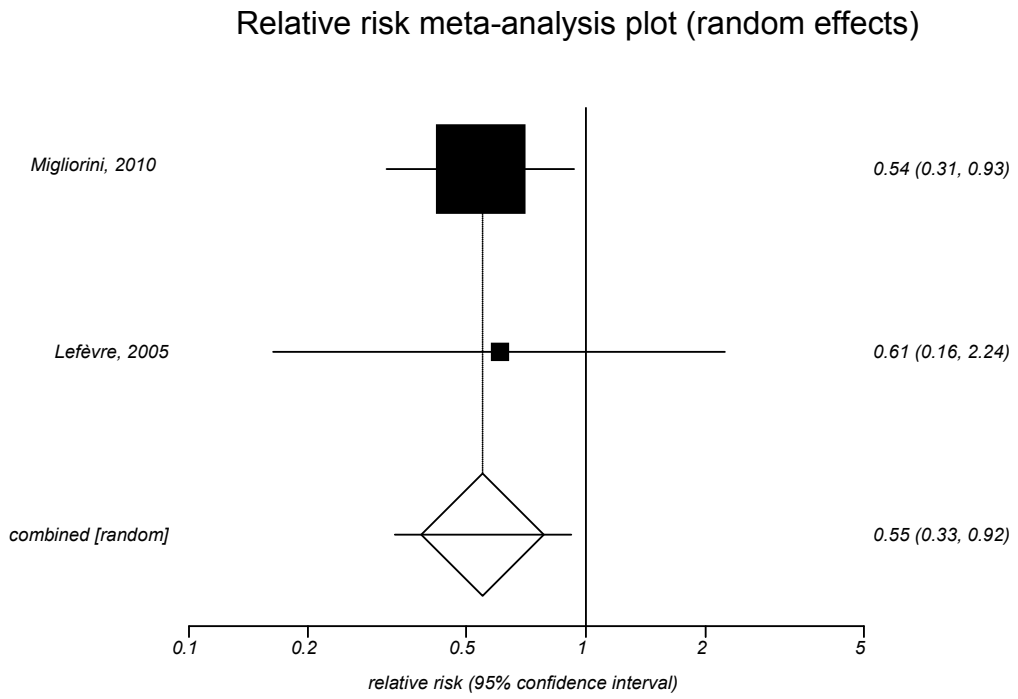
Figure 34. Impact of mechanical thrombectomy devices versus control on ≤ 30-day target revascularization.




Cochran Q: P = 0.072
$I^2$: 62%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

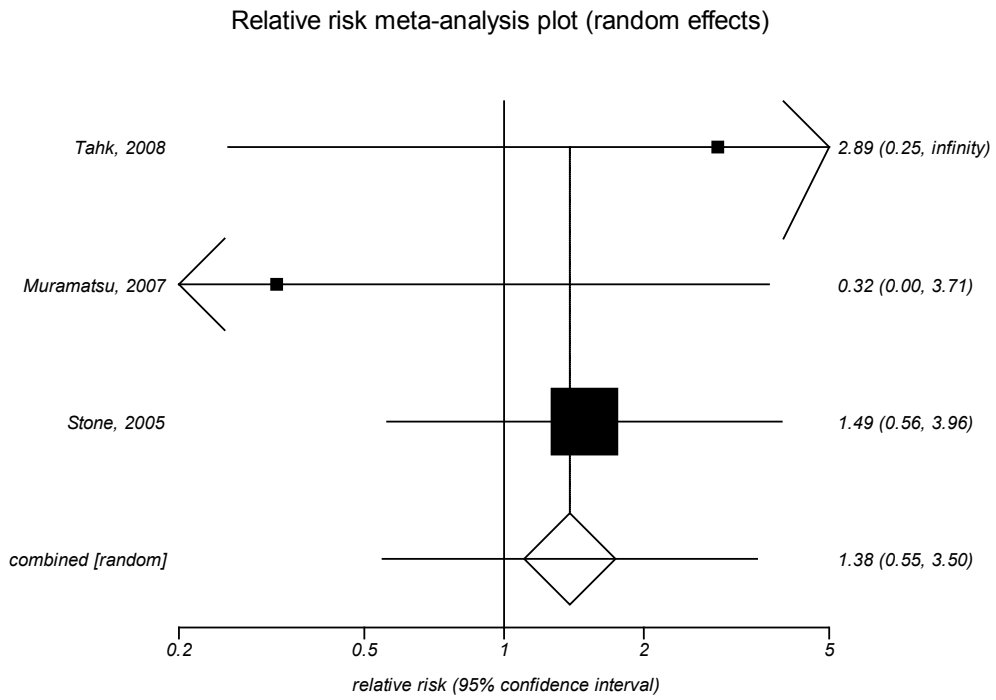
Figure 35. Impact of mechanical thrombectomy devices versus control on 180-day target revascularization.




Cochran Q: P = 0.885
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

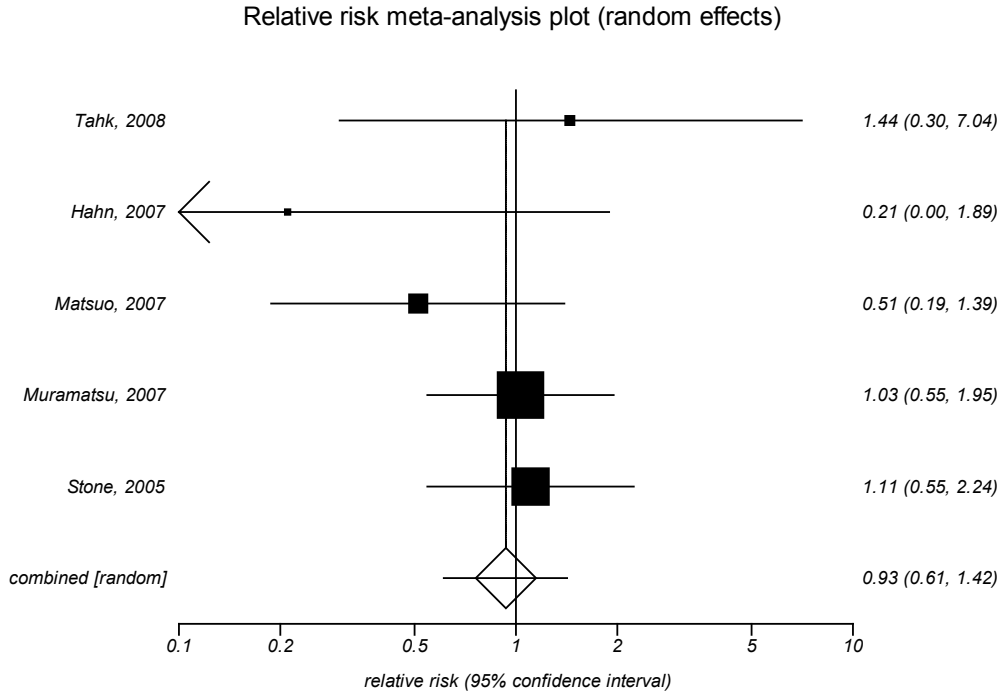
Figure 36. Impact of distal balloon embolic protection devices versus control on ≤30-day target revascularization.




Cochran Q: P = 0.600
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

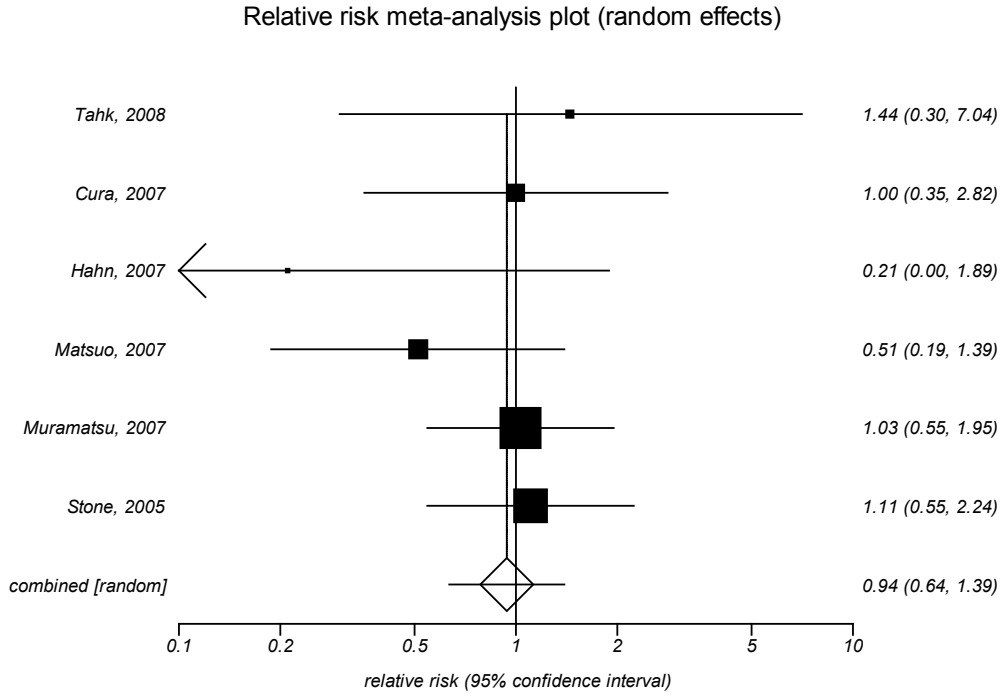
Figure 37. Impact of distal balloon embolic protection devices versus control on 180-day target revascularization.




Cochran Q: P = 0.600
$I^2$: 0%
Egger: 0.369

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

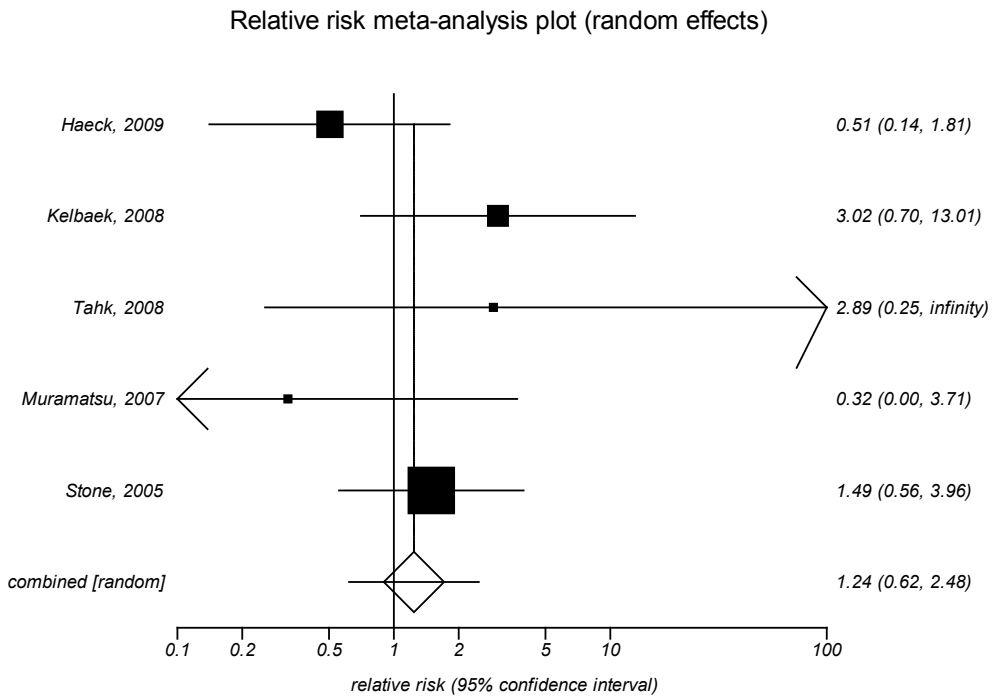
Figure 38. Impact of embolic protection devices combined versus control on 180-day target revascularization.




Cochran Q: P = 0.733
$I^2$: 0%
Egger: P = 0.320

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 39. Impact of embolic protection devices combined versus control on ≤30 day target revascularization.

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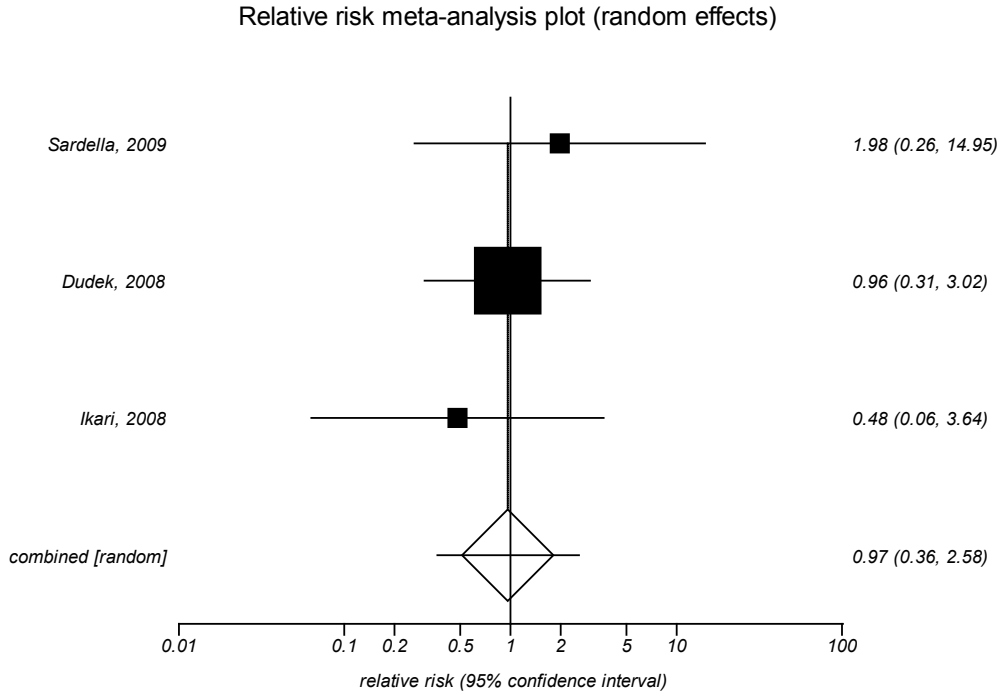
Cochran Q: P = 0.417
$I^2$: 0%
Egger: P = 0.900

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

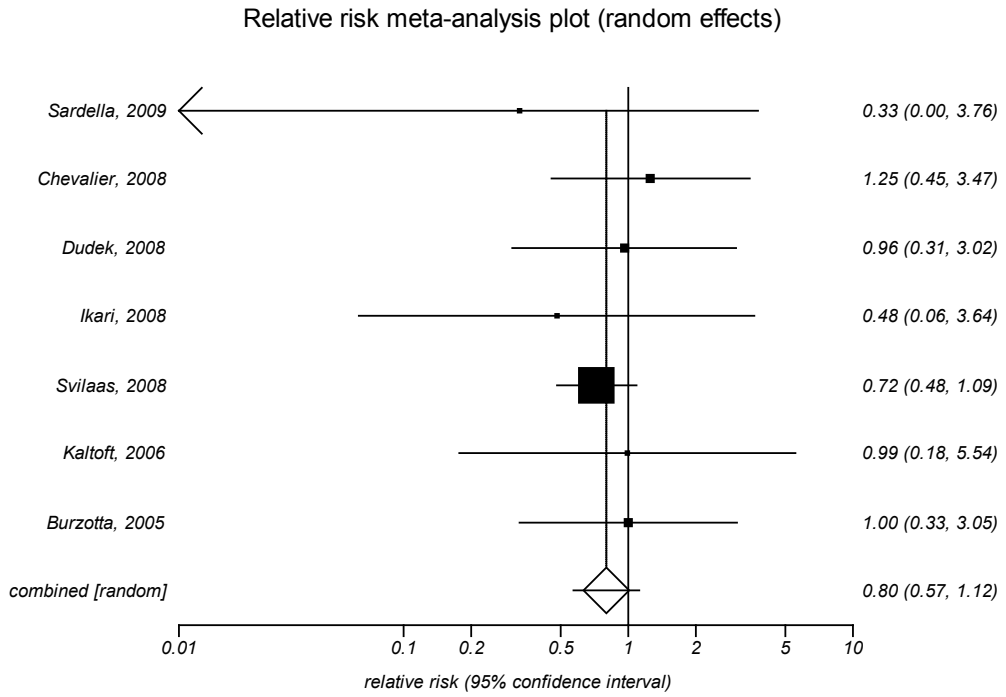
Figure 40. Impact of catheter aspiration devices versus control on in-hospital MACE.




Cochran Q: P = 0.713
$I^2$: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

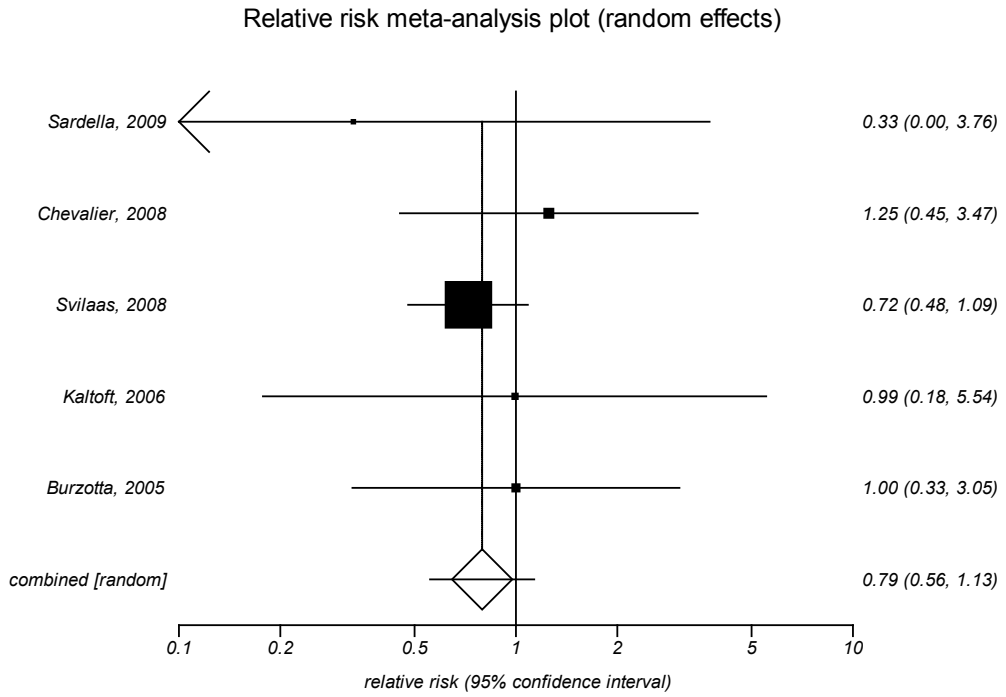
Figure 41. Impact of catheter aspiration devices versus control on ≤ 30 day MACE.




Cochran Q: P = 0.948
$I^2$: 0%
Egger: P = 0.739

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

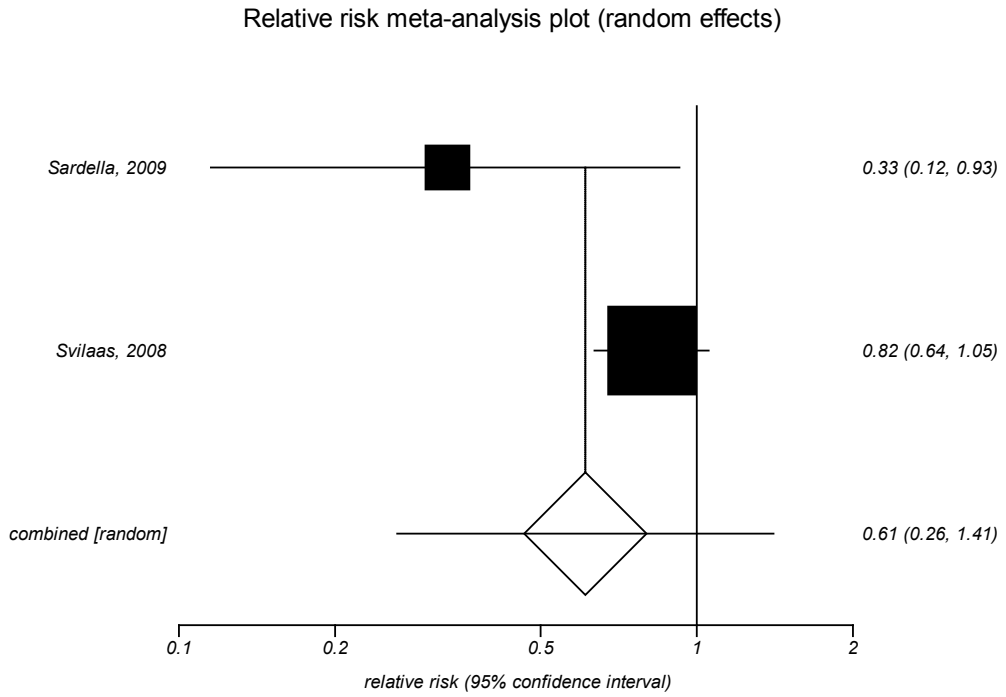
Figure 42. Impact of catheter aspiration devices versus control on 30-day MACE.




Cochran Q: P = 0.844
$I^2$: 0%
Egger: P = 0.619

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

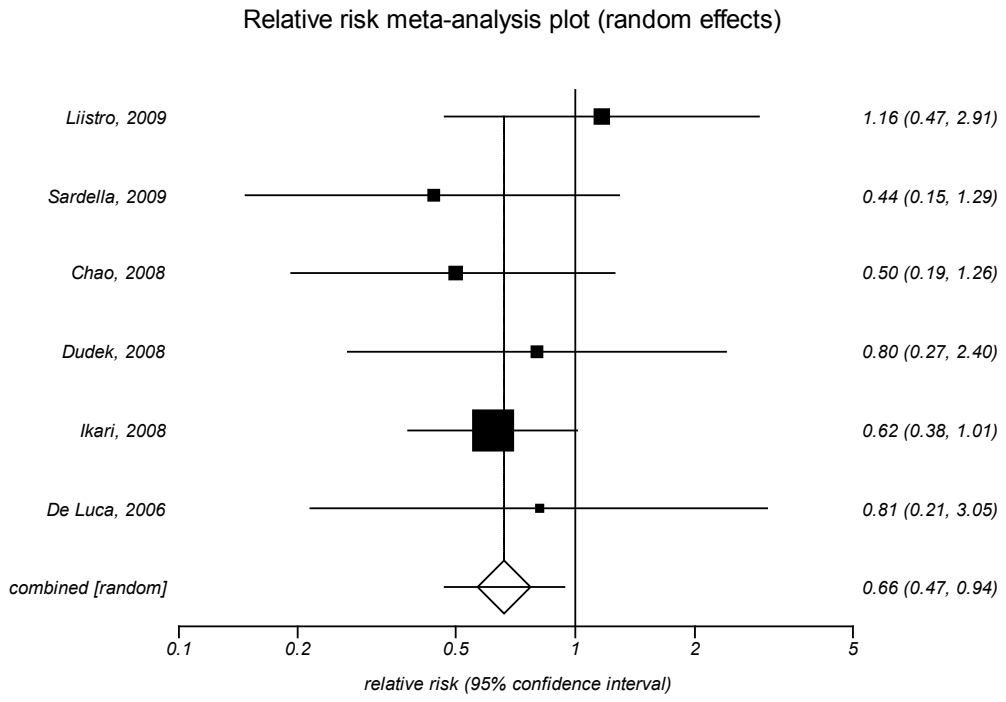
Figure 43. Impact of catheter aspiration devices versus control on 365-day MACE.




Cochran Q: 0.111
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

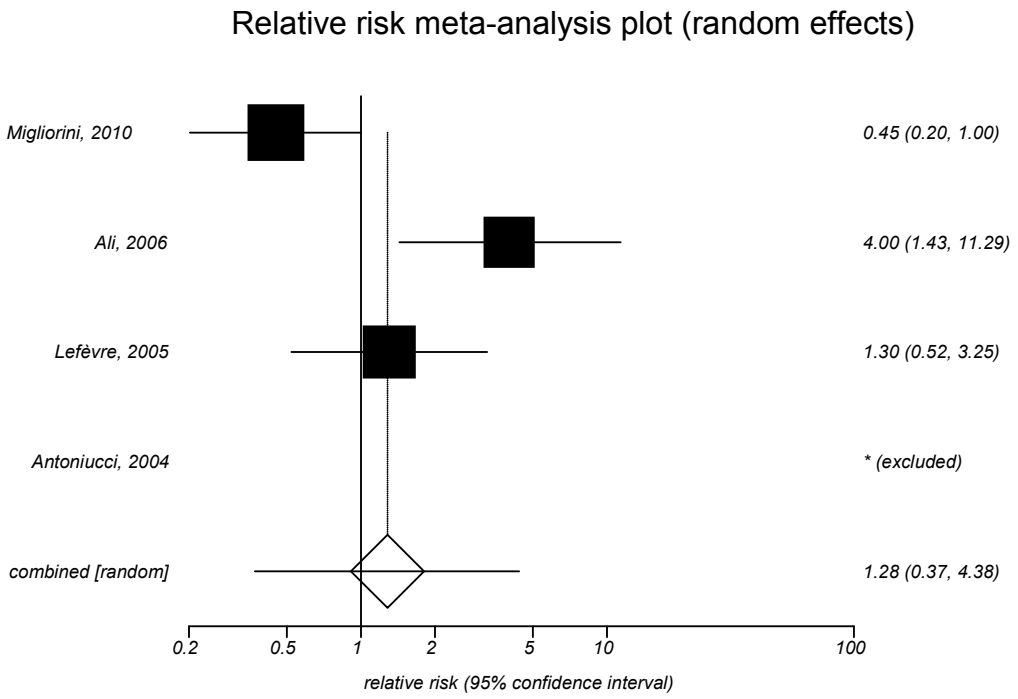
Figure 44. Impact of catheter aspiration devices versus control on 180-day MACE.




Cochran Q: P = 0.785
$I^2$: 0%
Egger: P = 0.733

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

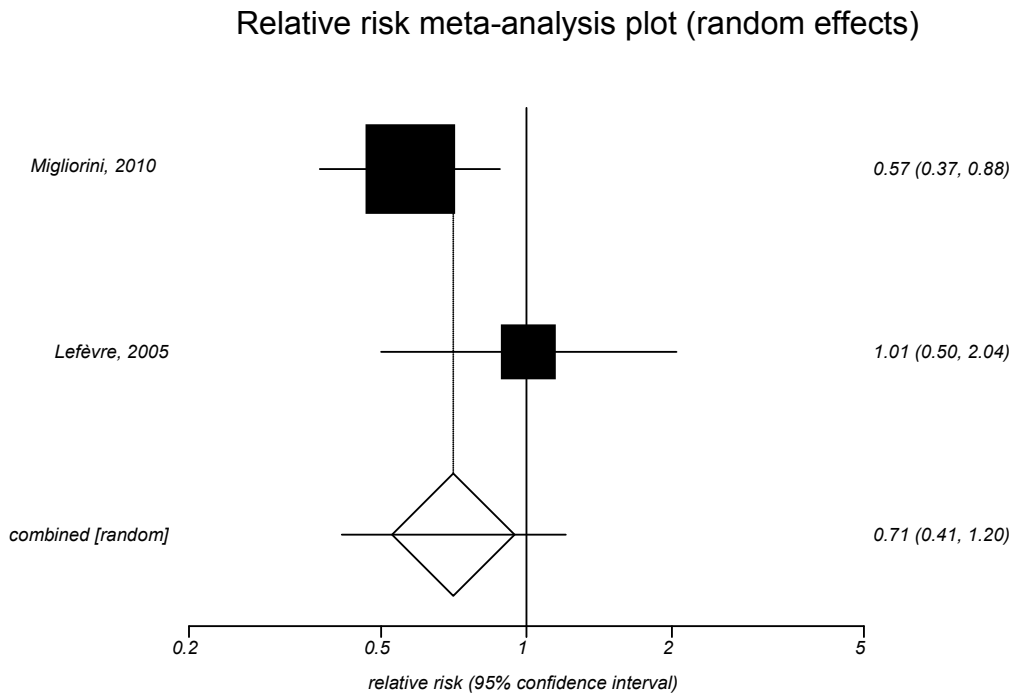
Figure 45. Impact of mechanical thrombectomy devices versus control on ≤ 30-day MACE.




Cochran Q: P = 0.006
$I^2$: 80.4%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

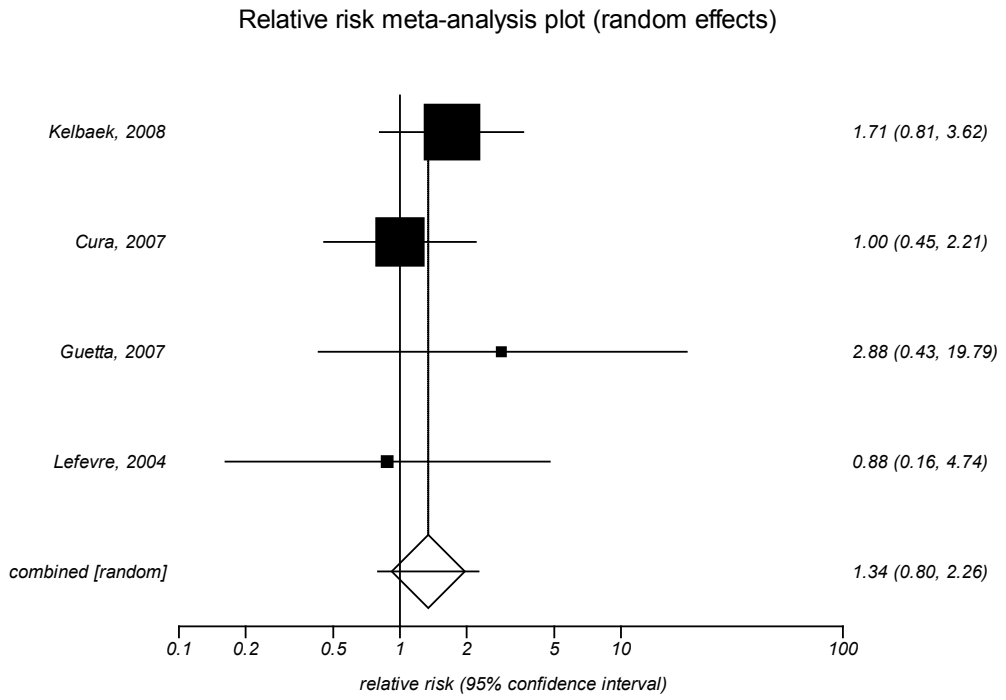
Figure 46. Impact of mechanical thrombectomy devices versus control on 180-day MACE.




Cochran Q: P = 0.187
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

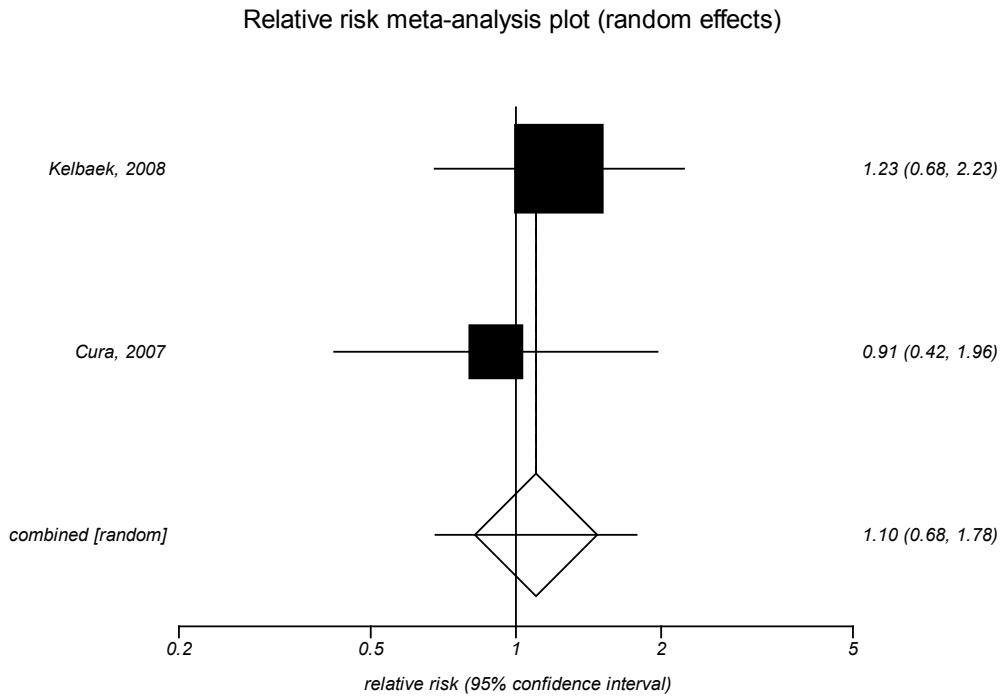
Figure 47. Impact of distal filter embolic protection devices versus control on ≤30 day MACE.




Cochran Q: P = 0.671
$I^2$: 0%
Egger: P = 0.865

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

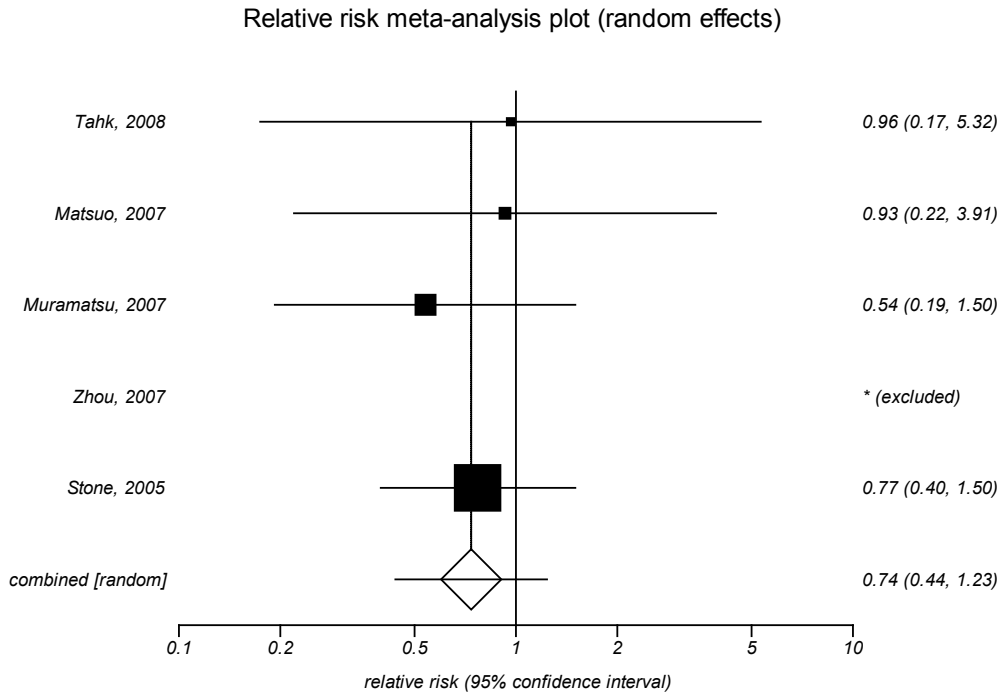
Figure 48. Impact of distal filter embolic protection devices versus control on 180-day MACE events.




Cochran Q: P = 0.550
$I^2$: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

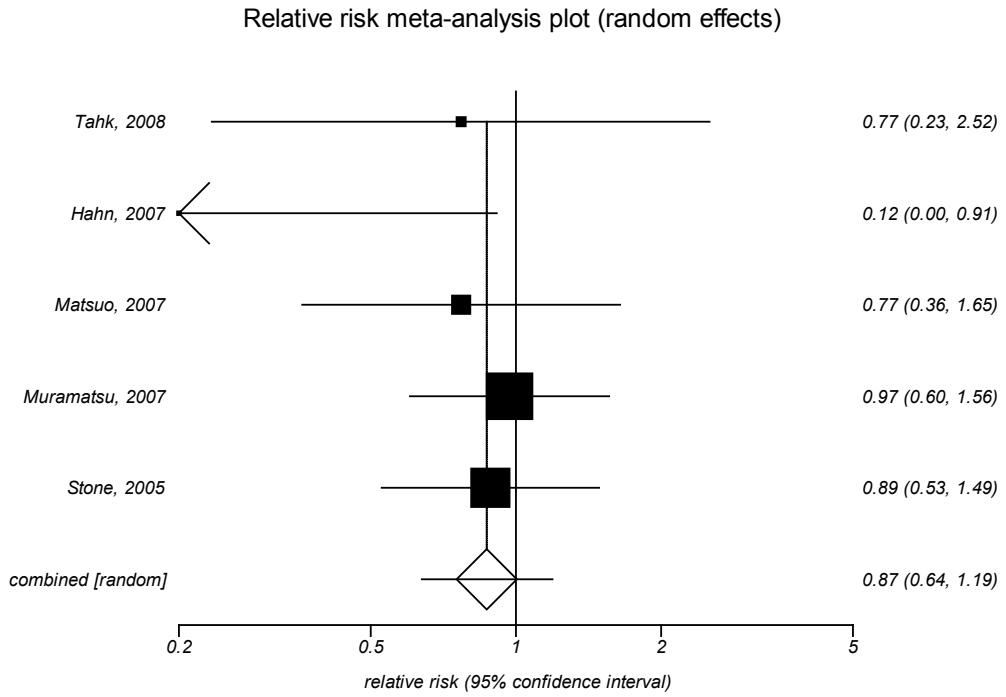
Figure 49. Impact of distal balloon embolic protection devices versus control on ≤30-day MACE.




Cochran Q: P = 0.919
$I^2$: 0%
Egger: P = 0.758

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

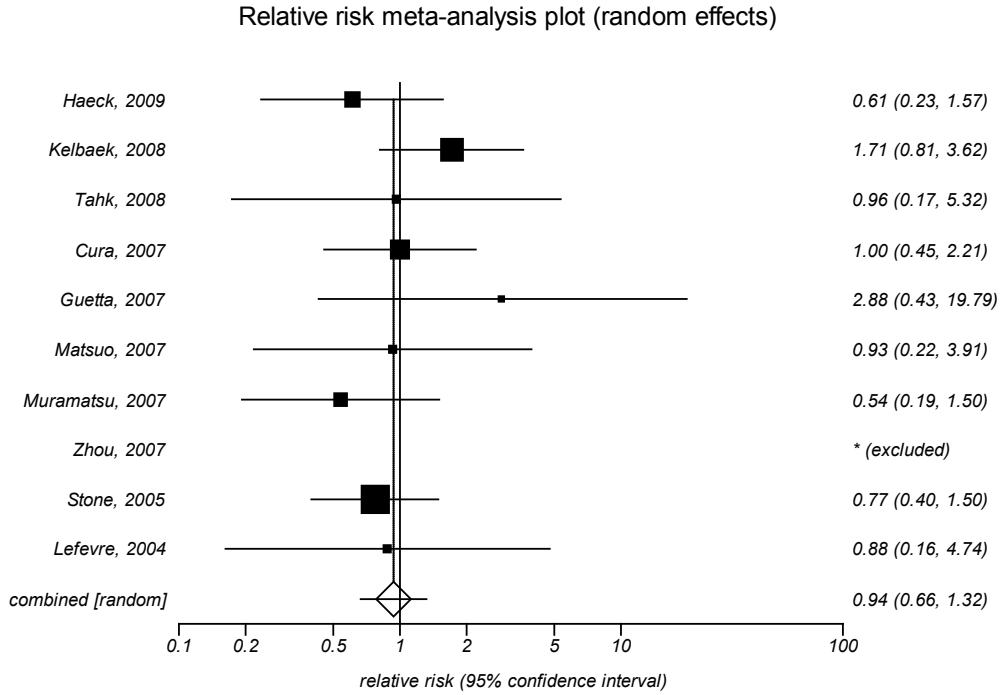
Figure 50. Impact of distal balloon embolic protection devices combined versus control on 180-day MACE.




Cochran Q: P = 0.685
$I^2$: 0%
Egger: P = 0.032

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

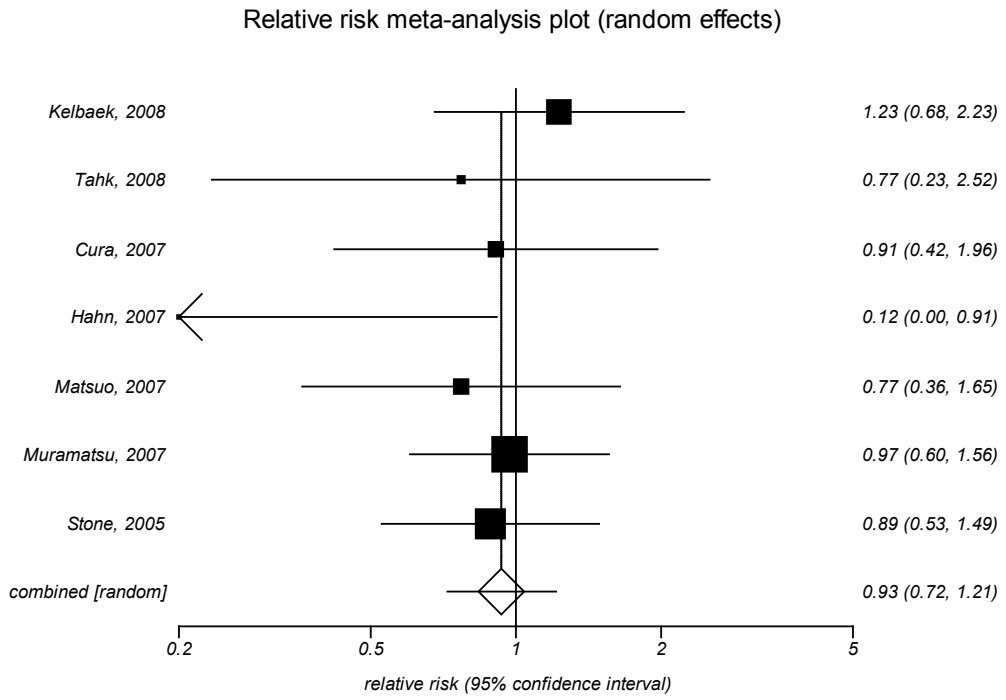
Figure 51. Impact of embolic protection devices combined versus control on ≤30 day MACE.




Cochran Q: P = 0.707
$I^2$: 0%
Egger: P = 0.827

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 52. Impact of embolic protection devices combined versus control on 180-day MACE.




Cochran Q: P = 0.777
$I^2$: 0%
Egger: P = 0.047

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

# Appendix J. Glossary

**Acute Coronary Syndrome:** Any group of clinical symptoms compatible with acute myocardial ischemia. Acute coronary syndrome includes the spectrum of clinical conditions ranging from unstable angina to non-Q-wave myocardial infarction and Q-wave myocardial infarction.

**Catheter Aspiration Device:** Including the Diver, Diver CE, Export, Pronto, Rescue, Thrombuster, and TransVascular Aspiration Catheter devices.

**Confidence Intervals (CIs)**: A range that is likely to include the given value. Usually presented as a percent (%). For example, a value with 95% confidence interval implies that when a measurement is made 100 times, it will fall within the given range 95% of the time.

**Correlation Coefficient**: A value (which usually ranges from zero to one) that indicates the degree of relationship between two variables. For example, a correlation coefficient of one would indicate a strong relationship.

**DerSimonian and Laird Random-Effects Model**: A statistical method based on the assumption that the effects observed in different studies (in a meta-analysis) are truly different.

**Embolic Protection Device:** Included the following devices: FilterWire EX, FilterWire EZ, SpideRX, AngioGuard, AngioGuard XP, PercuSurge GuardWire, PercuSurge GuardWire Plus, Proxis

**Egger's Weighted Regression Statistics**: A method of identifying and measuring publication bias.

**$I^2$**: Measure of degree of variation due to statistical heterogeneity. Usually reported as a percent ranging from 0 to100.

**Mechanical Thrombectomy Device:** Including the AngioJet and X-Sizer devices.

**Meta-Analysis**: The process of extracting and pooling data from several studies investigating a similar topic to synthesize a final outcome.

**Myocardial Blush Grade**: An angiographic method of grading myocardial tissue perfusion ranging from grade 0 to grade 3. In grade 0, the dye fails to enter the microvasculature with either minimal or no ground glass appearance ("blush") or opacification of the myocardium in the distribution of the culprit artery indicating lack of tissue level perfusion. In grade 1, the dye slowly enters but fails to exit the microvasculature. There is the ground glass appearance ("blush") or opacification of the myocardium in the distribution of the culprit lesion that fails to clear from the microvasculature and dye staining is present on the next injection (approximately 30 seconds between injections). In grade 2, there is delayed entry and exit of dye from the microvasculature. There is the ground glass appearance ("blush") or opacification of the myocardium in the distribution of the culprit lesion that is strongly persistent at the end of the washout phase (i.e. dye is strongly persistent after 3 cardiac cycles of the washout phase and either does not or only minimally diminishes in intensity during washout). In grade 3, there is

normal entry and exit of dye from the microvasculature. There is a ground glass appearance ("blush") or opacification of the myocardium in the distribution of the culprit lesion that clears normally, and is either gone or only mildly/moderately persistent at the end of the washout phase (i.e. dye is gone or is mildly/moderately persistent after 3 cardiac cycles of the washout phase and noticeably diminishes in intensity during the washout phase), similar to that in an uninvolved artery. Blush that is of only mild intensity throughout the washout phase but fades minimally is also classified as grade 3.

**Non-ST Segment Myocardial Infarction:** An acute coronary syndrome characterized by myocardial ischemia without an elevation of the ST-segment on the electrocardiograph. Most patients who have non-ST-segment elevation will ultimately develop a non Q-wave acute myocardial infarction.

**Publication Bias**: The possibility that published studies may not represent all the studies that have been conducted, and therefore, create bias by being left out of a meta-analysis.

**Q Statistic**: A test to assess the presence of statistical heterogeneity among several studies.

**Relative Risks (RRs)**: The ratio of an event occurring in an exposed group to an event occurring in a non-exposed group in a given population. A ratio of one indicates no difference in the risk between the two groups.

**Risk difference:** The absolute difference in the event rate between two comparison groups. A risk difference of zero indicates no difference between comparison groups.

**Sensitivity Analyses**: A 'what if' analysis that helps determine the robustness of a study. Helps determine the degree of importance of each variable for a given outcome.

**Standard Deviations (SDs)**: A measure of the variability of a data set. For a simple data set with numbers, can be calculated using the following formula:

$$\sigma = ((\sum(x-x_m))^2/N)^{0.5}$$

$\sigma$ is standard deviation
$x_m$ is the average
$\sum(x-x_m)$ is the sum of $x_m$ subtracted from each individual number x
N is the total number of values
Note: Other formulas also exist.

**Statistical Heterogeneity**: Variability in the observed effects among studies in a meta-analysis.

**ST-Segment Myocardial infarction:** An acute coronary syndrome characterized by myocardial ischemia with elevation of the ST-segment on the electrocardiograph. Most patients who have ST-segment elevation will ultimately develop a Q-wave acute myocardial infarction.

**Target Revascularization**: Any repeat percutaneous intervention or surgical bypass of the target lesion or segment of the target vessel.

**TIMI-3 Blood Flow**: Thrombolysis in myocardial infarction graded with a range from 0 to 3. A grade of 0 is defined as complete occlusion of the infarct related artery. A grade of 1 is defined as some penetration of contrast material beyond the point of obstruction but without perfusion of the distal coronary bed. A grade of 2 is defined as perfusion of the entire infarct vessel into the distal bed but with delayed flow compared with a normal artery. A grade of 3 is defined as full perfusion of the infarct vessel with normal flow.

**Unstable Angina**: An acute coronary syndrome characterized by chest pain which occurs unexpectedly and at rest. The most common cause of the chest pain is due to reduced blood flow to the myocardiam caused by either atherosclerotic narrowing or constriction of the coronary arteries or partial blockage of the coronary arteries by a blood clot.