

APPENDIXES

Appendix A: Exact Search Strings

PubMed® search strategy (December 2, 2010)

Set #	Terms
#1	("cardiovascular diseases"[MeSH Terms] OR ("cardiovascular"[All Fields] AND "diseases"[All Fields]) OR "cardiovascular diseases"[All Fields]) OR ("heart diseases"[MeSH Terms] OR ("heart"[All Fields] AND "diseases"[All Fields]) OR "heart diseases"[All Fields]) OR ("heart"[MeSH Terms] OR "heart"[All Fields] OR "coronary"[All Fields]) OR cardiovas*[All fields] OR cardiac*[All fields] OR ("myocardium"[MeSH Terms] OR "myocardium"[All Fields] OR "myocardial"[All Fields]) OR ("acute coronary syndrome"[MeSH Terms] OR ("acute"[All Fields] AND "coronary"[All Fields] AND "syndrome"[All Fields]) OR "acute coronary syndrome"[All Fields]) OR ("myocardial infarction"[MeSH Terms] OR ("myocardial"[All Fields] AND "infarction"[All Fields]) OR "myocardial infarction"[All Fields]) OR ("angina, unstable"[MeSH Terms] OR ("angina"[All Fields] AND "unstable"[All Fields]) OR "unstable angina"[All Fields] OR ("unstable"[All Fields] AND "angina"[All Fields]))
#2	"angioplasty, balloon, coronary"[MeSH Terms] OR ("angioplasty"[All Fields] AND "balloon"[All Fields] AND "coronary"[All Fields]) OR "coronary balloon angioplasty"[All Fields] OR ("percutaneous"[All Fields] AND "transluminal"[All Fields] AND "coronary"[All Fields] AND "angioplasty"[All Fields]) OR "percutaneous transluminal coronary angioplasty"[All Fields] OR "ptca"[All Fields] OR percutaneous coronary intervention[All Fields] OR percutaneous coronary interventional[All Fields] OR percutaneous coronary interventions[All Fields] OR PCI[All Fields] OR stent[All Fields] OR stents[All Fields] OR stent*[All Fields] OR "stents"[MeSH Terms] OR ("balloon"[All Fields] AND "angioplasty"[All Fields]) OR "balloon angioplasty"[All Fields] OR "angioplasty, balloon"[MeSH Terms] OR "balloon dilation"[MeSH Terms] OR ("balloon"[All Fields] AND "dilation"[All Fields]) OR "balloon dilation"[All Fields] OR ("balloon"[All Fields] AND "dilatation"[All Fields]) OR "balloon dilatation"[All Fields] OR ("transluminal"[All Fields] AND "angioplasty"[All Fields]) OR "transluminal angioplasty"[All Fields] OR "angioplasty"[MeSH Terms] OR "angioplasty"[All Fields] OR "atherectomy, coronary"[MeSH Terms] OR ("atherectomy"[All Fields] AND "coronary"[All Fields]) OR "coronary atherectomy"[All Fields] OR ("coronary"[All Fields] AND "atherectomy"[All Fields]) OR ("coronary artery bypass"[MeSH Terms] OR ("coronary"[All Fields] AND "artery"[All Fields] AND "bypass"[All Fields]) OR "coronary artery bypass"[All Fields]) OR CABG[All Fields] OR ("coronary artery bypass"[MeSH Terms] OR ("aortocoronary"[All Fields] AND "bypass"[All Fields]) OR "aortocoronary bypass"[All Fields]) OR "coronary revascularization"[All Fields] OR "myocardial revascularization"[All Fields]
#3	"women"[MeSH Terms] OR "women"[All Fields] OR "woman"[All Fields] OR "female"[MeSH Terms] OR "female"[All Fields] OR "females"[All Fields] OR "sex factors"[MeSH Terms] OR ("sex"[All Fields] AND "factors"[All Fields]) OR "sex factors"[All Fields]
#4	randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR "clinical trials as topic"[MeSH Terms:noexp] OR randomly[tiab] OR trial[ti]
#5	#1 AND #2 AND #3 AND #4
#6	#5 NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp]) NOT Animals[Mesh:noexp]
	Limits: Human, English, Publication Date: 2001- Present

Embase® search strategy (November 16, 2010)

Platform: Embase.com

Set #	Terms
#1	'cardiovascular disease'/exp OR 'heart disease'/exp OR 'heart'/exp OR 'acute coronary syndrome'/exp OR 'heart infarction'/exp OR 'unstable angina pectoris'/exp OR 'cardiovascular diseases':ab OR 'heart diseases':ab OR heart:ab OR cardiovasc*:ab OR cardiac*:ab OR coronary:ab OR myocardial:ab OR 'acute coronary syndrome':ab OR 'myocardial infarction':ab OR 'unstable angina':ab OR 'cardiovascular diseases':ti OR 'heart diseases':ti OR heart:ti OR cardiovasc*:ti OR cardiac*:ti OR coronary:ti OR myocardial:ti OR 'acute coronary syndrome':ti OR 'myocardial infarction':ti OR 'unstable angina':ti
#2	'transluminal coronary angioplasty'/exp OR 'percutaneous coronary intervention'/exp OR 'stent'/exp OR 'balloon dilatation'/exp OR 'percutaneous transluminal angioplasty'/exp OR 'atherectomy'/exp OR 'percutaneous transluminal angioplasty':ti OR ptca:ti OR ('percutaneous coronary' NEXT/1 intervention*):ti OR pci:ti OR stent*:ti OR 'balloon angioplasty':ti OR 'balloon dilation':ti OR 'balloon dilatation':ti OR 'transluminal angioplasty':ti OR 'coronary atherectomy':ti OR 'percutaneous transluminal angioplasty':ab OR ptca:ab OR ('percutaneous coronary' NEXT/1 intervention*):ab OR pci:ab OR stent*:ab OR 'balloon angioplasty':ab OR 'balloon dilation':ab OR 'balloon dilatation':ab OR 'transluminal angioplasty':ab OR 'coronary atherectomy':ab OR 'coronary artery bypass graft'/exp OR 'heart muscle revascularization'/exp OR 'coronary artery bypass':ti OR cabg:ti OR 'aortocoronary bypass':ti OR 'coronary revascularization':ti OR 'myocardial revascularization':ti OR 'coronary artery bypass':ab OR cabg:ab OR 'aortocoronary bypass':ab OR 'coronary revascularization':ab OR 'myocardial revascularization':ab OR 'coronary artery recanalization'/exp
#3	'female'/exp OR female OR women OR woman OR females OR 'sex difference'/exp
#4	'randomized controlled trial'/exp OR 'crossover procedure'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR random* OR factorial* OR crossover* OR cross NEAR/1 over* OR placebo* OR doubl* NEAR/1 blind* OR singl* NEAR/1 blind* OR assign* OR allocat* OR volunteer*
#5	#1 AND #2 AND #3 AND #4
#6	#5 (AND [embase]/lim NOT [medline]/lim)
	Limits: Human, English, Publication Date: 2001- Present

Cochrane search strategy (November 17, 2010)

Platform: Wiley

Databases searched: Cochrane Central Registry of Controlled Trials and Cochrane Database of Systematic Reviews

Set #	Terms
#1	cardiovascular diseases OR heart diseases OR heart OR cardiovas* OR cardiac* OR coronary OR myocardial OR acute coronary syndrome OR myocardial infarction OR unstable angina [in title-abstract-keywords]
#2	percutaneous transluminal coronary angioplasty OR PTCA OR "percutaneous coronary intervention" OR "percutaneous coronary interventions" OR "percutaneous coronary interventional" OR PCI OR Stent* OR stents OR Balloon angioplasty OR Balloon dilatation OR Balloon dilation OR Transluminal angioplasty OR coronary atherectomy OR Coronary Artery Bypass OR CABG OR aortocoronary bypass OR coronary revascularization OR myocardial revascularization [in title-abstract-keywords]
#3	women OR woman OR female OR females OR sex factors [in title-abstract-keywords]
#4	#1 AND #2 AND #3
	Limits: 2001- Present

Grey Literature Searches

ClinicalTrials.gov

Search date: 4-29-2011

Search #1: PCI vs. CABG

Expert Search String:

(NOT ("Recruiting" OR "Not yet recruiting" OR "Available")) [OVERALL-STATUS] AND (heart diseases OR cardiovascular diseases) [DISEASE] AND ((percutaneous transluminal coronary angioplasty OR PTCA OR percutaneous coronary intervention OR PCI OR balloon OR stent) AND (coronary artery bypass OR CABG)) [TREATMENT]

Search #2: CABG vs. Medical Therapy

Expert Search String:

(NOT ("Recruiting" OR "Not yet recruiting" OR "Available")) [OVERALL-STATUS] AND (heart diseases OR cardiovascular diseases) [DISEASE] AND ((coronary artery bypass OR CABG) AND (medical management OR medical therapy OR OMT OR standard of care OR medical treatment OR standard therapy OR usual care)) [TREATMENT]

Search #3: PCI vs. Medical Therapy

Expert Search String:

(NOT ("Recruiting" OR "Not yet recruiting" OR "Available")) [OVERALL-STATUS] AND (heart diseases OR cardiovascular diseases) [DISEASE] AND ((percutaneous transluminal coronary angioplasty OR PTCA OR percutaneous coronary intervention OR PCI OR balloon OR stent) AND (medical management OR medical therapy OR OMT OR standard of care OR medical treatment OR standard therapy OR usual care)) [TREATMENT]

Processing of results

1. Total # of results: 100
2. Duplicates removed: 10
3. All Status categories other than Completed, Terminated, and Withdrawn removed: 34
4. Final number for screening: 56

WHO: International Clinical Trials Registry Platform Search Portal

Search date: 4-29-2011

Condition: heart OR cardiovascular OR coronary artery disease OR CAD

Intervention: percutaneous transluminal coronary angioplasty OR PTCA OR percutaneous coronary intervention OR PCI OR balloon OR stent OR coronary artery bypass OR CABG OR coronary revascularization

Processing of results

1. Total # of results: 1069
2. Removed all entries with “Recruiting” status; retained entries with “Not recruiting” status: 205 removed, 864 remaining
3. Removed all entries with NCT designations (covered by a separate search of clinicaltrials.gov with a more refined search strategy): 505 removed, 359 remaining
4. Final number for screening: 359

ProQuest COS Conference Papers Index

Search date: 5-2-2011

Set #	Terms
#1	(cardiovascular diseases or heart diseases or heart or cardiovas* or cardiac* or coronary or myocardial or acute coronary syndrome or myocardial infarction or unstable angina) [in all fields + text]
#2	(percutaneous transluminal coronary angioplasty or PTCA or percutaneous coronary intervention* or PCI or Stent* or stents or Balloon angioplasty or Balloon dilatation or Balloon dilation or Transluminal angioplasty or coronary atherectomy or Coronary Artery Bypass or CABG or aortocoronary bypass or coronary revascularization or myocardial revascularization) [in all fields + text]
#3	women OR woman OR female OR females OR sex OR gender [in all fields + text]
#4	#1 AND #2 AND #3 AND #4
	Limits: 2001- Present

Appendix B: Data Abstraction Elements

I. Study Characteristics

- Study name and acronym
- Other articles used in this abstraction
- Study dates
- Date enrollment started (Mon and YYYY)
- Date enrollment ended (Mon and YYYY)
- Number of subjects screened/ approached for study participation: Total, Female, Male
- Study site
- Single center, Multicenter, Not reported/Unclear
- Geographic location
- If single center, enter City and State (if US) or City and Country (if outside US). If multicenter, enter number of sites. Enter NR if not reported.
- If multicenter, specify applicable geographic regions
- Funding source: Government, Private foundation, Industry, Not reported, Other.
- Setting: Academic centers, Community hospitals, Outpatient, VA, Not reported/unclear, Other
- Were patients transported from the site of presentation to another location to receive PCI?
- Were patients transported from the site of presentation to another location to receive CABG?
- Qualifications of the study surgeons: Not specified, Minimum case volume (specify), Maximum mortality (specify), Other (specify)
- Qualifications of the study interventional cardiologists: Not specified, Minimum case volume (specify), Maximum mortality (specify), Minimum success rates (specify), Other (specify)
- Qualifications of the sites involved in the trial: Not specified, Minimum case volume (specify), Maximum mortality (specify), Minimum success rates (specify), Other (specify)
- Were guideline-based treatment protocols followed?
- Briefly describe use of guideline-based protocols.
- Length of followup
- Inclusion and exclusion criteria; Copy/paste criteria as reported in the article.
- Clinical presentation: STEMI NSTEMI/ Unstable angina Stable CAD
- Method for interpretation of angiograms: Central laboratory, Local site interpretation, Quantitative angiography, Unclear/ Not reported Other
- Were study patients systematically enrolled in cardiac rehabilitation?
- Does the study report a composite primary endpoint?
- Indicate the components of the composite primary endpoint (check all that apply): Total mortality, Cardiac mortality, Nonfatal myocardial infarction, Stroke, TIA, Unstable angina, Angina/ recurrent symptoms, Angina class, Angina relief, Repeat revascularization, Heart failure, Graft failure, Hospitalization, Length of hospital stay, Bleeding, Quality of life, Cognitive effects, Adverse drug reactions, Radiation exposure, Access site complications, Renal dysfunction, Anaphylaxis, Arrhythmias, Stent thrombosis, Infections, Cost, Employment/ productivity, Other (specify)
- Indicate timing of the components of the composite primary endpoint: Short-term (less than or equal to 30 days), Long-term (greater than 30 days), Mixture of short- and long-term outcomes
- Indicate all short-term (<30 days) primary and secondary endpoints separately reported (i.e. reported singly, rather than only reported as part of a composite primary endpoint): Total

- mortality, Cardiac mortality, Nonfatal myocardial infarction, Stroke, TIA, Unstable angina, Angina/ recurrent symptoms, Angina class, Angina relief, Repeat revascularization, Heart failure, Graft failure, Hospitalization, Length of hospital stay, Bleeding, Quality of life, Cognitive effects, Adverse drug reactions, Radiation exposure, Access site complications, Renal dysfunction, Anaphylaxis, Arrhythmias, Stent thrombosis, Infections, Cost, Employment/ productivity, Other (specify)
- Indicate all long-term (>30 days) primary and secondary endpoints separately reported (i.e. reported singly, rather than only reported as part of a composite primary endpoint): Total mortality, Cardiac mortality, Nonfatal myocardial infarction, Stroke, TIA, Unstable angina, Angina/ recurrent symptoms, Angina class, Angina relief, Repeat revascularization, Heart failure, Graft failure, Hospitalization, Length of hospital stay, Bleeding, Quality of life, Cognitive effects, Adverse drug reactions, Radiation exposure, Access site complications, Renal dysfunction, Anaphylaxis, Arrhythmias, Stent thrombosis, Infections, Cost, Employment/ productivity, Other (specify)
 - Describe how the short- and long-term outcome data is reported (e.g. Kaplan-Meier plots, Cox proportional hazards, hazard ratios, risk ratios, odds ratios, raw numbers, percentages, other methods), including whether p values, confidence intervals, etc are provided.
 - Include timing of outcomes (e.g. 1 yr, 5 yr)
 - Comments (if needed)

II. Intervention characteristics

- Briefly indicate which population/intervention combination is reflected by the data abstracted on this instance of the form.
- PCI Procedural Characteristics
 - Describe the PCI intervention
 - Complete the below for Total, Female, and Male
 - Complete revascularization achieved
 - Vessels treated (mean): 1, 2, 3, or Unclear/ Not specified
 - Access site
 - Radial
 - Femoral
 - Unclear/ Not specified
 - Stents used (mean)
 - 0 stents
 - Bare metal stents
 - 1
 - 2
 - 3
 - More than 3
 - Unclear/ Not specified
 - Drug-eluting stents
 - 1
 - 2
 - 3
 - More than 3
 - Unclear/ Not specified
 - Interventional approach
 - Balloon
 - Atherectomy
 - Unclear/ Not specified

- Were concomitant procedures performed at the time of CABG surgery?
 - If yes, describe the concomitant procedures
- Medical Therapy Intervention Characteristics
 - Describe the medical therapy intervention received by patients in the PCI arm (if applicable)
 - Describe the medical therapy intervention received by patients in the CABG arm (if applicable)
 - Describe the medical therapy intervention received by patients in the OMT arm (if applicable)
 - Medications received in-hospital: record for PCI Subjects, CABG Subjects, and OMT Subjects; If ‘yes’ list drug name(s)/ dosage(s)
 - Acetylsalicylic acid (ASA)
 - Additional antiplatelet agents (e.g. clopidogrel, prasugrel, ticagrelor)
 - Antithrombin drugs (e.g. LMWH, unfractionated heparin, bivalrudin)
 - Glycoprotein IIb/IIIa inhibitors
 - Thrombolytic/ fibrinolytic drugs
 - Statins/ lipid-lowering drugs
 - Beta-blockers
 - ACEIs/ ARBs
 - Calcium channel blockers
 - Nitrates
 - Other #1 (specify)
 - Other #2 (specify)
 - Other #3 (specify)
- Discharge medications
 - Record for PCI Subjects, CABG Subjects, and OMT Subjects; If ‘yes’ list drug name(s)/ dosage(s)
 - Acetylsalicylic acid (ASA)
 - Additional antiplatelet agents (e.g. clopidogrel, prasugrel, ticagrelor)
 - Antithrombin drugs (e.g. LMWH, unfractionated heparin, bivalrudin)
 - Glycoprotein IIb/IIIa inhibitors
 - Thrombolytic/ fibrinolytic drugs
 - Statins/ lipid-lowering drugs
 - Beta-blockers
 - ACEIs/ ARBs
 - Calcium channel blockers
 - Nitrates
 - Other #1 (specify)
 - Other #2 (specify)
 - Other #3 (specify)
- Lifestyle modification
 - Indicate the components of lifestyle modification recommended to patients in the study (check all that apply): Smoking cessation, Diet modification, Exercise, Other (specify)
 - If lifestyle modifications recommended were not consistent across all patients in the study, specify which groups received these recommendations and which did not.
- Therapeutic targets
 - Did the study include consideration of therapeutic target goals?
 - If yes, describe the therapeutic targets considered and whether interventions were adjusted for the purpose of meeting those specific goals.

- Compliance
 - If reported, provide data on in-hospital medication compliance (and lifestyle modification compliance, if available)
 - If reported, provide data on post-discharge medication compliance (and lifestyle modification compliance, if available) at the first follow-up visit after discharge. Include the time point of this follow-up visit (including units)
- Comments (if needed)

III. Outcomes

- Outcomes definitions
 - Authors' definition of procedure-related outcomes
 - Authors' definition of post-CABG MI
 - Authors' definition of post-PCI MI
 - Check all outcomes for which gender-specific data is provided. Include an outcome if (1) data is reported specifically for women, or if (2) data is reported for men that can be used to calculate values for women (Total mortality, Cardiac mortality, Nonfatal myocardial infarction, Stroke, TIA, Unstable angina, Angina/ recurrent symptoms/ refractory angina/ refractory myocardial infarction, Angina class, Angina relief, Repeat revascularization (PCI or CABG), Heart failure, Graft failure, Hospitalization/ Re-hospitalization, Length of hospital stay, Bleeding, Quality of life, Cognitive effects, Adverse drug reactions, Radiation exposure, Access site complications, Renal dysfunction, Anaphylaxis, Arrhythmias, Stent thrombosis, Infections, Cost, Employment/ productivity, Other individual outcome #1 (e.g. CPR, cardioversion, respiratory failure, pulmonary edema) , Other individual outcome #2, Other individual outcome #3.)
 - Comments (if needed)
- Composite outcome data
 - Are one or more composite outcomes reported in such a way that data for women can be abstracted or derived?
 - Is this a Primary or Secondary composite outcome?
 - Refer to the Intervention Characteristics forms completed; indicate which one applies to the outcome data recorded on this form:
 - Indicate the components that make up this composite outcome (check all that apply): Total mortality, Cardiac mortality, Nonfatal myocardial infarction, Stroke, TIA, Unstable angina, Angina/ recurrent symptoms/ refractory angina/ refractory myocardial infarction, Angina class, Angina relief, Repeat revascularization (PCI or CABG), Heart failure, Graft failure, Hospitalization/ Re-hospitalization, Length of hospital stay, Bleeding, Quality of life, Cognitive effects, Adverse drug reactions, Radiation exposure, Access site complications, Renal dysfunction, Anaphylaxis, Arrhythmias, Stent thrombosis, Infections, Cost, Employment/ productivity, Other individual outcome #1 (e.g. CPR, cardioversion, respiratory failure, pulmonary edema) , Other individual outcome #2, Other individual outcome #3.
 - Complete tables to provide data for this outcome/ timepoint(s).
 - Timing of the outcome data reported in the table: Short term \leq 30 days, Long-term $>$ 30 days,
 - Specify timing of short-term outcome: 30 days, Other (specify)
 - Specify timing of long-term outcome: 6 weeks, 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, Other (specify)

- Indicate whether/ how the results reported were adjusted (check all that apply): Results are not adjusted , RCT that did not adjust for any baseline difference, Age, Sex, Race, Comorbidity(ies) (specify), Other (specify all)
 - For each reported group (OMT, PCI, CABG, and/or Mixed Revascularization) record the following for Total, Female, and Male:
 - N for Analysis
 - Result
 - Mean
 - Median
 - Number of patients with outcome
 - % of patients with outcome
 - Relative risk
 - Relative hazard
 - Odds ratio
 - Risk difference
 - Other (specify)
 - Variability
 - Standard Error (SE)
 - Standard Deviation (SD)
 - Other (specify)
 - Confidence Interval (CI) or Interquartile Range (IQR)
 - 95% CI
 - Other %CI
 - IQR
 - p-value between female and male data (within tx group)
 - p-value between tx groups
 - Reference group (for comparisons between tx groups)
 - Comments (if needed)
- Individual outcome data
 - Select the outcome reported: Total mortality, Cardiac mortality, Nonfatal myocardial infarction, Stroke, TIA, Unstable angina, Angina/ recurrent symptoms/ refractory angina/ refractory myocardial infarction, Angina class, Angina relief, Repeat revascularization (PCI or CABG), Heart failure, Graft failure, Hospitalization/ Re-hospitalization, Length of hospital stay, Bleeding, Quality of life, Cognitive effects, Adverse drug reactions, Radiation exposure, Access site complications, Renal dysfunction, Anaphylaxis, Arrhythmias, Stent thrombosis, Infections, Cost, Employment/ productivity, Other individual outcome #1 (e.g. CPR, cardioversion, respiratory failure, pulmonary edema) , Other individual outcome #2, Other individual outcome #3.
 - Complete tables to provide data for this outcome/ timepoint(s).
 - Timing of the outcome data reported in the table: Short term \leq 30 days, Long-term $>$ 30 days,
 - Specify timing of short-term outcome: 30 days, Other (specify)
 - Specify timing of long-term outcome: 6 weeks, 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, Other (specify)
 - Indicate whether/ how the results reported were adjusted (check all that apply): Results are not adjusted , RCT that did not adjust for any baseline difference, Age, Sex, Race, Comorbidity(ies) (specify), Other (specify all)
 - For each reported group (OMT, PCI, CABG, and/or Mixed Revascularization) record the following for Total, Female, and Male:

- N for Analysis
- Result
 - Mean
 - Median
 - Number of patients with outcome
 - % of patients with outcome
 - Relative risk
 - Relative hazard
 - Odds ratio
 - Risk difference
 - Other (specify)
- Variability
 - Standard Error (SE)
 - Standard Deviation (SD)
 - Other (specify)
- Confidence Interval (CI) or Interquartile Range (IQR)
 - 95% CI
 - Other %CI
 - IQR
- p-value between female and male data (within tx group)
- p-value between tx groups
- Reference group (for comparisons between tx groups)
- Comments (if needed)

IV. Subgroup Analyses

- Does the article include subgroup analyses reported in a gender-specific way such that data for women can be abstracted or derived for any outcomes of interest?
- For each outcome record for Total, Female, and Male
- Indicate the nature of the subgroup analysis (i.e. the characteristic factor being considered): Age, Race, Other demographic or socioeconomic factor (specify), Diabetes, Chronic kidney disease, Other comorbid disease (specify), Angiographic-specific factor (specify), CABG-specific factor (specify), Hospital characteristic (specify)
- Specify the categories for this subgroup analysis. Columns are provided to capture up to 5 categories. Complete only the number needed to capture the data presented in the study.
 - Define the categories, then complete the tables with as much information as is provided in the study.
 - Provide data for each outcome. Clearly indicate units (number of patients, %, hazard ratio, etc). Include values for confidence intervals, p values, standard error, standard deviation, etc when available.
- Comments (if needed):

V. Quality Assessment

- Selection Bias
 - Was treatment adequately randomized (e.g. random number table, computer-generated randomization)?
 - Was the allocation of treatment adequately concealed (e.g. pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?
 - Did the strategy for recruiting participants into the study differ across study groups?
 - Are baseline characteristics similar between groups? If not, did the analysis control for differences?

- Performance Bias
 - Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?
 - Did variation from the study protocol compromise the conclusions of the study?
- Attrition Bias
 - Was there a high rate of differential or overall attrition?
 - Did attrition result in a difference in group characteristics between baseline (or randomization) and follow-up?
 - Is the analysis conducted on an intention-to-treat (ITT) basis?
- Detection Bias
 - Were the outcome assessors blinded to the intervention status of participants?
 - Are the inclusion/exclusion criteria measured using valid and reliable measures?
 - Are the inclusion/exclusion criteria implemented consistently across all study participants?
 - Are interventions/exposures assessed using valid and reliable measures?
 - Are interventions/exposures implemented consistently across all study participants?
 - Are primary outcomes assessed using valid and reliable measures?
 - Are primary outcomes implemented consistently across all study participants?
- Reporting Bias
 - Are the potential outcomes pre-specified by the researchers? Are all pre-specified outcomes reported?
- Additional Comments
- Summary Judgment. Assign the study an overall quality rating based on the following definitions:
 - Good (low risk of bias). These studies have the least bias and results are considered valid. A study that adheres mostly to the commonly held concepts of high quality including the following: a formal randomized controlled study; clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; low dropout rate; and clear reporting of dropouts.
 - Fair. These studies are susceptible to some bias, but it is not sufficient to invalidate the results. They do not meet all the criteria required for a rating of good quality because they have some deficiencies, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.
 - Poor (high risk of bias). These studies have significant flaws that imply biases of various types that may invalidate the results. They have serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

VI. Applicability

- Population (P) (select all that apply)
 - Study population not representative of community patients
 - Study population poorly specified
 - Key characteristics not reported
- Intervention (I) (select all that apply)
 - Monitoring practices or visit frequency not used in typical practice
 - Older versions of an intervention no longer in common use
 - Cointerventions that are likely to modify effectiveness of therapy

- Highly selected intervention team or level of training/proficiency not widely available
- Comparator (C) (select all that apply)
 - Inadequate comparison therapy
- Outcomes (O) (select all that apply)
 - Composite outcomes that mix outcomes of different significance
 - Data not stratified or adjusted for key predictors
 - Only short-term or surrogate outcomes reported
- Timing (T) (n/a)
- Setting (S) (select all that apply)
 - Resources available to providers for diagnosis and treatment of condition vary widely
 - Provider type/specialty varies across settings
 - Comparability of care in international settings unclear
 - Standards of care differ markedly from setting of interest
 - Specialty population or level of care differs from that seen in community
- Comments (if needed)

Appendix C: List of Included Studies

- Allen KB, Dowling RD, Angell WW, et al. Transmyocardial revascularization: 5-year follow-up of a prospective, randomized multicenter trial. *Ann Thorac Surg* 2004;77(4):1228-34. 15063241
- Allen KB, Dowling RD, Fudge TL, et al. Comparison of transmyocardial revascularization with medical therapy in patients with refractory angina. *N Engl J Med* 1999;341(14):1029-36. 10502592
- Andersen HR, Nielsen TT, Rasmussen K, et al. A comparison of coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. *N Engl J Med* 2003;349(8):733-42. 12930925
- Anderson HV, Cannon CP, Stone PH, et al. One-year results of the Thrombolysis in Myocardial Infarction (TIMI) IIIb clinical trial. A randomized comparison of tissue-type plasminogen activator versus placebo and early invasive versus early conservative strategies in unstable angina and non-Q wave myocardial infarction. *J Am Coll Cardiol* 1995;26(7):1643-50. 7594098
- Anonymous. Effects of tissue plasminogen activator and a comparison of early invasive and conservative strategies in unstable angina and non-Q-wave myocardial infarction. Results of the TIMI IIIb Trial. Thrombolysis in Myocardial Ischemia. *Circulation* 1994;89(4):1545-56. 8149520
- Anonymous. First-year results of CABRI (Coronary Angioplasty versus Bypass Revascularisation Investigation). CABRI Trial Participants. *Lancet* 1995;346(8984):1179-84. 7475656
- Anonymous. Comparison of coronary bypass surgery with angioplasty in patients with multivessel disease. The Bypass Angioplasty Revascularization Investigation (BARI) Investigators. *N Engl J Med* 1996;335(4):217-25. 8657237
- Anonymous. Coronary angioplasty versus medical therapy for angina: the second Randomised Intervention Treatment of Angina (RITA-2) trial. RITA-2 trial participants. *Lancet* 1997;350(9076):461-8. 9274581
- Anonymous. The ARTS (Arterial Revascularization Therapies Study): Background, goals and methods. *Int J Cardiovasc Intervent* 1999;2(1):41-50. 12623386
- Anonymous. Invasive compared with non-invasive treatment in unstable coronary-artery disease: FRISC II prospective randomised multicentre study. FRagmin and Fast Revascularisation during InStability in Coronary artery disease Investigators. *Lancet* 1999;354(9180):708-15. 10475181
- Anonymous. Seven-year outcome in the Bypass Angioplasty Revascularization Investigation (BARI) by treatment and diabetic status. *J Am Coll Cardiol* 2000;35(5):1122-9. 10758950
- Anonymous. The final 10-year follow-up results from the BARI randomized trial. *J Am Coll Cardiol* 2007;49(15):1600-6. 17433949
- Boden WE, O'Rourke R A, Teo KK, et al. Design and rationale of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial Veterans Affairs Cooperative Studies Program no. 424. *Am Heart J* 2006;151(6):1173-9. 16781214
- Boden WE, O'Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med* 2007;356(15):1503-16. 17387127
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Appendix D: Quality and Applicability of Included Studies

Table D-1. Quality and applicability for RCTs evaluating women with STEMI (KQ 1)

Study Name	Study Author/Year	Comparator	Quality	Limitations to Applicability
CARESS-in-AMI	Di Mario et al., 2008 ¹	Fibrinolysis vs. PCI	Good	None
DANAMI-2	Andersen et al., 2003 ²	Fibrinolysis vs. PCI	Good	None
Dobrzycki	Dobrzycki et al., 2007 ³	Fibrinolysis vs. PCI	Good	<ul style="list-style-type: none"> • Comparability of care in international settings unclear
GUSTO II-B	Tamis-Holland et al., 2004 ⁴	Fibrinolysis vs. PCI	Good	<ul style="list-style-type: none"> • Comparability of care in international settings unclear
Minai	Minai et al., 2002 ⁵	Conservative/supportive medical therapy (without fibrinolysis) vs. PCI	Fair	<ul style="list-style-type: none"> • Comparability of care in international settings unclear
PAMI	Stone et al., 1995 ⁶	Fibrinolysis vs. PCI	Good	<ul style="list-style-type: none"> • Comparability of care in international settings unclear
SHOCK	Hochman et al., 2001 ⁷	Conservative/supportive medical therapy (fibrinolysis optional) vs. PCI	Good	None

Abbreviations: CABG = coronary artery bypass grafting; PCI = percutaneous coronary revascularization; STEMI = ST elevation myocardial infarction

Table D-2. Quality and applicability for RCTs evaluating women with UA/NSTEMI (KQ 2)

Study Name	Study Author/Year	Comparator	Quality	Limitations to Applicability
FRISC II	Lagerqvist et al., 2001 ⁸	Initial conservative vs. early invasive	Good	<ul style="list-style-type: none"> Comparability of care in international settings unclear
GUSTO IV-ACS	Ottervanger et al., 2004 ⁹	Initial conservative vs. early invasive	Good	<ul style="list-style-type: none"> Older versions of an intervention no longer in common use Resources available to providers for diagnosis and treatment of condition varied widely Comparability of care in international settings unclear
ICTUS	de Winter et al., 2005 ¹⁰	Initial conservative vs. early invasive	Good	<ul style="list-style-type: none"> Comparability of care in international settings unclear
RITA-2	Anonymous, 1997 ¹¹	Initial conservative vs. early invasive	Fair	<ul style="list-style-type: none"> Provider type/specialty varied across settings Comparability of care in international settings unclear
RITA-3	Clayton et al., 2004 ¹²	Initial conservative vs. early invasive	Good	None
TACTICS TIMI-18	Cannon et al., 2001 ¹³	Initial conservative vs. early invasive	Good	None
TIMI III-B	Anonymous, 1994 ¹⁴	Initial conservative vs. early invasive	Good	<ul style="list-style-type: none"> Older versions of an intervention no longer in common use

Abbreviations: CABG = coronary artery bypass grafting; PCI = percutaneous coronary revascularization

Table D-3. Quality and applicability for RCTs evaluating women with stable angina (KQ 3 Strategy 1)

Study Name	Study Author/Year	Comparator	Quality	Limitations to Applicability
Allen	Allen et al., 2004 ¹⁵	Optimal medical therapy vs. revascularization	Good	<ul style="list-style-type: none"> Older versions of an intervention no longer in common use Cointerventions that were likely to modify effectiveness of therapy
COURAGE	Boden et al., 2007 ¹⁶	Optimal medical therapy vs. PCI (or CABG for failed PCI or worsening symptoms)	Good	None
OAT	Hochman et al., 2006 ¹⁷	Optimal medical therapy vs. PCI (or CABG for failed PCI)	Good	None
MASS II	Hueb et al., 2010 ¹⁸	Optimal medical therapy vs. PCI Optimal medical therapy vs. CABG	Good	<ul style="list-style-type: none"> Study population not representative of community patients Cointerventions that were likely to modify effectiveness of therapy
STICH	Velazquez et al., 2011 ¹⁹	Optimal medical therapy vs. CABG	Good	<ul style="list-style-type: none"> Cointerventions that were likely to modify effectiveness of therapy Comparability of care in international settings unclear

Abbreviations: CABG = coronary artery bypass grafting; PCI = percutaneous coronary revascularization

Table D-4. Quality and applicability for RCTs evaluating women with stable/unstable angina (KQ 3 Strategy 2)

Study Name	Study Author/Year	Comparator	Quality	Limitations to Applicability
ARTS I	Vaina et al., 2009 ²⁰	PCI vs. CABG	Good	None
BARI	Jacobs et al., 1998 ²¹	PCI vs. CABG	Good	<ul style="list-style-type: none"> • Study population not representative of community patients • Older versions of an intervention no longer in common use • Cointerventions that were likely to modify effectiveness of therapy
CABRI	Anonymous, 1995 ²²	PCI vs. CABG	Good	None
CARDia	Kapur et al., 2010 ²³	PCI vs. CABG	Good	<ul style="list-style-type: none"> • Key characteristics not reported • Provider type/specialty varied across settings
EAST	King et al., 2000 ²⁴	PCI vs. CABG	Good	<ul style="list-style-type: none"> • Study population not representative of community patients • Older versions of an intervention no longer in common use • Cointerventions that were likely to modify effectiveness of therapy
GABI	Kaehler et al., 2005 ²⁵	PCI vs. CABG	Good	<ul style="list-style-type: none"> • Cointerventions that were likely to modify effectiveness of therapy
MASS II	Hueb et al., 2010 ¹⁸	PCI vs. CABG	Good	<ul style="list-style-type: none"> • Study population not representative of community patients • Cointerventions that were likely to modify effectiveness of therapy
PRECOMBAT	Park et al., 2011 ²⁶	PCI vs. CABG	Good	<ul style="list-style-type: none"> • Comparability of care in international settings unclear

Study Name	Study Author/Year	Comparator	Quality	Limitations to Applicability
SOS	Zhang et al., 2004 ²⁷	PCI vs. CABG	Fair	<ul style="list-style-type: none"> • Study population not representative of community patients • Cointerventions that were likely to modify effectiveness of therapy
SYNTAX	Morice et al., 2010 ²⁸	PCI vs. CABG	Fair	<ul style="list-style-type: none"> • Data not stratified or adjusted for key predictors • Comparability of care in international settings unclear

Abbreviations: CABG = coronary artery bypass grafting; PCI = percutaneous coronary revascularization

References Cited in Appendix D

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Appendix E: List of Excluded Studies

All studies listed below were reviewed in their full-text version and excluded. Following each reference, in italics, is the reason for exclusion. Reasons for exclusion signify only the usefulness of the articles for this study and are not intended as criticisms of the articles.

Aaberge L, Aakhus S, Nordstrand K, et al. Myocardial performance after transmyocardial revascularization with CO(2)laser. A dobutamine stress echocardiographic study. *Eur J Echocardiogr* 2001;2(3):187-96. *Full-text Exclude - Does not include outcome data reported in a gender-specific fashion for a study population that includes women 18 or older with angiographically proven CAD w/ STEMI, NSTEMI or stable CAD.*

Aaberge L, Nordstrand K, Dragsund M, et al. Transmyocardial revascularization with CO(2) laser in patients with refractory angina pectoris. *Journal of the American College of Cardiology* 2000;35(5):1170-1177. *Full-text Exclude - Does not include outcome data reported in a gender-specific fashion for a study population that includes women 18 or older with angiographically proven CAD w/ STEMI, NSTEMI or stable CAD.*

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Appendix F: Summary Tables for Sex-specific Clinical Outcomes

Table F-1. Summary of RCTs reporting clinical outcomes for STEMI (KQ 1)

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
CARESS-in-AMI Di Mario et al., 2008¹ and Di Mario et al., 2004²	STEMI	Fibrinolysis (reteplase) plus immediate PCI vs. fibrinolysis (reteplase) plus rescue PCI	Total: 600 Women: 128	<u>1) Composite outcome</u> (total mortality, reinfarction, and refractory MI within 30 days) HR (95%CI) Women: 0.4 (0.12 to 1.31) Men: 0.39 (0.18 to 0.85) Overall: 0.40 (0.21 to 0.76) <u>2) Cumulative event rate</u> (total mortality, reinfarction, and refractory MI within 30 days) Women: 6.2 vs. 14.5 Men: 3.9 vs. 9.7 Overall: 4.4 vs. 10.7	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
<p>DANAMI-2 Andersen et al., 2003³</p> <p>and</p> <p>Mortensen et al., 2007⁴ Nielsen et al., 2010⁵ Busk et al., 2009⁶ Busk et al., 2008⁷</p>	STEMI	Primary PCI vs. fibrinolysis (accelerated t-PA)	Total: 1572 Women: 417	<p><u>1) Composite outcome</u> (total mortality, nonfatal MI, stroke) 30 days OR (95% CI) Women: 0.47 (0.27 to 0.81) Men: 0.59 (0.39 to 0.90) Overall: 0.55 (0.39 to 0.76)</p> <p>3 years HR (95% CI) Women: 0.62 (0.42 to 0.90) Men: 0.81 (0.63 to 1.04) Overall: 0.74 (0.60 to 0.92)</p> <p>Median 7.8 years HR (95% CI) Women: 0.73 (0.53 to 0.99) Men: 0.80 (0.66 to 0.97) Overall: 0.78 (0.66 to 0.92)</p> <p><u>2) Angina</u> (angina/recurrent symptoms/refractory angina/refractory MI) 30 days Women: 25.3% vs. 30.7% Men: 18.8% vs. 26.4%</p> <p>1 year Women: 18.5% vs. 21.3% Men: 15.5% vs. 17.6%</p> <p><u>3) General health SF-36</u> 30 days Women: 62 vs. 61.1 Men: 69.2 vs. 65.1</p> <p>1 year Women: 61.5 vs. 66.4 Men: 68.2 vs. 63.1</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
Dobrzycki et al., 2007⁸	STEMI	Fibrinolysis (streptokinase) onsite vs. tirofiban plus transfer for primary PCI	Total: 401 Women: 105	<p><u>1) Composite outcome</u> (total mortality, nonfatal MI, and stroke): 30 days RR (95% CI) Women: 2.04 (0.85 to 4.90) Men: 1.79 (0.85 to 3.79) Overall: 1.95 (1.1 to 3.45)</p> <p>1 year Women: 2.48 (1.06 to 5.79) Men: 1.61 (0.92 to 2.85) Overall: 1.88 (1.18 to 3.00)</p> <p><u>2) Total mortality</u> 30 days RR (95% CI) Women: 2.19 (0.73 to 6.53) Men: 1.41 (0.50 to 3.96) Overall: 1.81 (0.86 to 3.82)</p> <p>1 year Women: 2.41 (0.82 to 7.07) Men: 1.48 (0.68 to 3.22) Overall: 1.79 (0.96 to 3.35)</p>	Good
GUSTO II-B Tamis-Holland et al., 2004⁹	STEMI	PCI vs. fibrinolysis (accelerated t-PA)	Total: 1137 Women: 260	<p><u>1) Composite outcome</u> (total mortality, nonfatal MI, nonfatal disabling stroke) OR (95% CI) Women: 0.685 (0.36 to 1.32) Men: 0.562 (0.35 to 0.91)</p> <p><u>2) Total mortality</u> Women: 10.9% vs. 11.6% Men: 4% vs. 5.8%</p> <p><u>3) Nonfatal MI:</u> Women: 6.5% vs. 6.6% Men: 3.8% vs. 6.4%</p> <p><u>4) Nonfatal disabling stroke:</u> Women: 0 vs. 2.5% Men: 0.2% vs. 0.4%</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
Minai et al., 2002¹⁰	STEMI age ≥ 80 years	PCI vs. conservative/supportive medical therapy (without fibrinolysis)	Total: 120 Women: 60	<p><u>Composite outcome</u> (total mortality, heart failure, repeat MI, stroke) 3 years 46 of the PCI subjects vs. 31 of the no PCI subjects; p = 0.06</p> <p>Multivariate analysis was done to look at factors associated with the composite endpoint in the overall study (i.e., not treatment specific) and found that male gender was NOT a factor significantly associated with outcome in the overall population.</p>	Fair
PAMI Stone et al., 1995¹¹	STEMI	PCI vs. fibrinolysis (t-PA)	Total: 395 Women: 107	<p><u>1) In-hospital death or reinfarction</u> Women: 6% vs. 17.5%; p = 0.07 Men: 4.8% vs. 9.8%; p = 0.11</p> <p><u>2) In-hospital total mortality</u> Women: 4.0% vs. 14%; p = 0.07 Men: 2.1% vs. 3.5%; p = 0.46</p> <p><u>3) In-hospital nonfatal MI</u> Women: 2.0% vs. 3.5%; p = 0.64 Men: 2.8% vs. 7.7%; p = 0.06</p> <p><u>4) In-hospital recurrent ischemia</u> Women: 16% vs. 28.1%; p = 0.14 Men: 8.2% vs. 28%; p = 0.001</p> <p><u>5) In-hospital stroke</u> Women: 0 vs. 5.3%; p = 0.10 Men: 0 vs. 2.8%; (p = 0.04</p> <p><u>6) Length of stay</u> Women: 7.8 ± 3.4 days vs. 8.5 ± 4.1 days; p = 0.34 Men: 7.4 ± 3.3 days vs. 8.3 ± 4.8 days; p = 0.05</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
SHOCK Hochman et al., 2001 ¹² and Hochman et al., 2006 ¹³ Hochman et al., 1999 ¹⁴ Hochman et al., 1999 ¹⁵	STEMI	Early revascularization (PCI or CABG within 6 hours) vs. initial medical stabilization (thrombolysis, IABP)	Total: 302 Women: 97	Relative risk (95% CI) for death with early revascularization vs. initial medical stabilization: 0.72 (0.54 to 0.95) There was no interaction between treatment effect and sex.	Good

Abbreviations: BMS = bare metal stent; CABG = coronary artery bypass graft; CAD = coronary artery disease; CI = confidence interval; DES = drug-eluting stent; HR = hazard ratio; IABP = intra-aortic balloon pump; MI = myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trial; RR = relative risk; UA = unstable angina

Table F-2. Summary of RCTs reporting clinical outcomes for UA/NSTEMI (KQ 2)

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
<p>FRISC II Lagerqvist et al., 2001¹⁶</p> <p>and</p> <p>Lagerqvist et al., 2006¹⁷ Wallentin et al., 2000¹⁸ Anonymous, 1999¹⁹</p>	UA/NSTEMI	Early invasive treatment with revascularization vs. initial conservative strategy	Total: 2457 Women: 749	<p><u>Primary endpoint</u> (death or MI or both) 6 months RR (95% CI) Invasive vs. conservative Women: 1.26 (0.80 to 1.97) Men: 0.64 (0.49 to 0.84) Overall: 0.78 (0.62 to 0.98); p = 0.031</p> <p>1 year Women: 12.4% vs. 10.5%; p = not significant Men: 9.6% vs. 15.8%; p < 0.001 Interaction by sex: p = 0.008 (significant) OR (95% CI) 0.91 (0.68 to 1.22) for effect of women on primary endpoint adjusted for treatment group</p> <p>Women did not benefit from early invasive strategy partly because of higher mortality related to CABG.</p> <p>5 years (95% CI) Women: 1.12 (0.83 to 1.50) Men: 0.70 (0.59 to 0.86) Overall: 0.81 (0.69 to 0.95); p = 0.009 Interaction by sex p = 0.010 (significant)</p>	Good
<p>GUSTO IV-ACS Ottervanger et al., 2004²⁰</p>	NSTEMI Acute coronary syndrome	Revascularization within 30 days (early invasive) vs. initial conservative strategy	Total: 7800 Women: 2896	<p><u>Death, 1 year</u> Women: adj HR (95% CI) 0.53 (0.28 to 1.00) Men: adj HR (95% CI) 0.55 (0.35 to 0.85) Overall: adj RR (95% CI) 0.53 (0.37 to 0.77)</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
ICTUS de Winter et al., 2005²¹ and Damman et al., 2010²²	NSTEMI-acute coronary syndrome	Early invasive therapy with revascularization vs. selective invasive strategy (initial conservative)	Total: 1200 Women: 320	<p>1) <u>Death, MI, or rehospitalization for angina 1 year</u> Early invasive vs. selective Total: RR (95% CI) 1.07 (0.87 to 1.33); p = 0.33 No significant difference among sex groups</p> <p>2) <u>Death or spontaneous MI 5 years HR (95% CI)</u> Women: 0.87 (0.53 to 1.43); p = 0.59 Men: 1.22 (0.87 to 1.71); p = 0.24 Overall: 1.10 (0.83 to 1.45); p = 0.52</p>	Good
RITA-2 Anonymous, 1997²³	UA/stable CAD (no recent MI)	Early invasive therapy with PCI (PTCA) vs. initial conservative	Total: 1018 Women: 183	<p>1) <u>Death or MI</u> Median followup of 2.7 years PTCA vs. optimal medical therapy Total: RR (95% CI) 1.92 (1.08 to 3.41); p = 0.02 No significant interaction by sex</p> <p>2) <u>Secondary outcomes</u> Angina grade 2+ at 6 months Women: 22.8% vs. 39.8% Men: 20.5% vs. 31.4%</p> <p>3) <u>Exercise time</u> 6 months mean (SE) Women: 6.72 (0.25) vs. 6.52 (0.26); Men: 9.34 (0.13) vs. 8.90 (0.15)</p>	Fair

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
<p>RITA-3 Clayton et al., 2004²⁴</p> <p>and</p> <p>Fox et al., 2002²⁵</p>	UA/NSTEMI	Early invasive (PCI) vs. initial conservative	Total: 1810 Women: 682	<p><u>1) Primary outcome</u> (death, MI, or refractory angina) Early invasive vs. initial conservative 4 months Women: 10.9% vs. 9.6% (similar) Men: 8.8% vs. 17.3% Overall: 9.6% vs. 14.5% p = 0.001 RR (95% CI) 0.66 (0.51 to 0.85) Significant interaction by sex: p = 0.004</p> <p>1 year Women: adj OR (95% CI) 1.14 (0.74 to 1.76) Men: adj OR (95% CI) 0.48 (0.34 to 0.67) Overall: RR (95% CI) 0.72 (0.58 to 0.90); p = 0.003</p> <p><u>2) Secondary outcomes</u> (death or MI) Early invasive vs. initial conservative 1 year Women: adj OR (95% CI) 1.79 (0.95 to 3.35) Men: adj OR (95% CI) 0.63 (0.41 to 0.98) Overall: RR (95% CI) 0.91 (0.67 to 1.25); p = 0.58</p> <p><u>3) Death</u> Women: adj OR (95% CI) 2.43 (1.01 to 5.84) Men: adj OR (95% CI) 0.78 (0.44 to 1.41) Overall: RR (95% CI) 1.16 (0.75 to 1.80); p = 0.50</p> <p>Significant interaction by sex for all 3 outcomes</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
<p>TACTICS TIMI-18 Cannon et al., 2001²⁶</p> <p>and</p> <p>Glaser et al., 2002²⁷ Cannon et al., 1998²⁸</p>	UA./NSTEMI	Early invasive (PCI) vs. initial conservative	Total: 2220 Women: 757	<p><u>1) Primary endpoint</u> (death, MI, rehospitalization for acute coronary syndrome) Early invasive vs. initial conservative 6 months Adj OR (95% CI) Women: 0.72 (0.47 to 1.11) Men: 0.64 (0.47 to 0.88) Overall: 0.78 (0.62 to 0.97)</p> <p><u>2) Secondary outcomes</u> (death or MI) Early invasive vs. initial conservative 6 months Adj OR (95% CI) Women: 0.45 (0.24 to 0.88) Men: 0.68 (0.43 to 1.05) Overall: 0.74 (0.54 to 1.00); p < 0.05</p> <p><u>3) Death</u> Early invasive vs. initial conservative Adj OR (95% CI) Women: 0.94 (0.37 to 2.44) Men: 0.75 (0.36 to 1.56)</p> <p>Women less likely to undergo CABG even after adjustment for 3-vessels and left main disease</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
TIMI III-B Anonymous, 1994²⁹ and Anderson et al., 1995³⁰	UA/NSTEMI	Early invasive vs. initial conservative	Total: 1425 Women: 497	<u>1) Primary endpoint</u> (death, MI, or failed symptom-limited exercise treadmill test) 6 weeks Overall: 16.2% vs. 18.1%; p = 0.33 <u>2) Secondary outcomes</u> (death or MI) Early invasive vs. initial conservative 6 weeks Women: 6.1% vs. 8.9%; p = 0.24 Men: 7.8% vs. 7.3%; p = 0.73 1 year Women: 9.7% vs. 15.4%; p = 0.06 Men: 11.3% vs. 10.6%; p = 0.68 Overall: 10.8% vs. 12.2%; p = 0.42 No interaction by sex	Good

Abbreviations: CABG = coronary artery bypass graft; CAD = coronary artery disease; CI = confidence interval; HR = hazard ratio; MI = myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trial; RR = risk ratio; SD = standard deviation; SE = standard error; t-PA = tissue plasminogen activator; UA = unstable angina

Table F-3. Summary of RCTs reporting clinical outcomes for stable angina (KQ 3 Strategy 1—optimal medical therapy vs. revascularization)

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
<p>Allen et al., 2004³¹ and Allen et al., 1999³²</p>	Stable angina	Optimal medical therapy vs. surgical revascularization (CABG with transmyocardial revascularization)	Total: 222 Women: 61	<p>1) <u>Death</u> 5.7 years (SD 0.8) Men: OR (95% CI) 1.4 (0.4 to 5.0); p = 0.63</p> <p>2) <u>Angina relief</u> 5.7 years (SD 0.8) Men: OR (95% CI) 1.1 (0.7 to 1.8); p = 0.41</p>	Good
<p>COURAGE Boden et al., 2007³³ and Mancini et al., 2009³⁴ Boden et al., 2006³⁵</p>	Stable angina	Optimal medical therapy vs. PCI (type not specified) or CABG if PCI failed	Total: 2287 Women: 338	<p>1) <u>Death or MI</u> 4.6 years (median followup) PCI vs. optimal medical therapy: Women: 18% vs. 26% Men: 19% vs. 18% p = 0.03</p> <p>Women: HR (95% CI) 0.65 (0.40 to 1.06) Men: HR (95% CI) 1.15 (0.93 to 1.42)</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
MASS II Hueb et al., 2010³⁶ and Hueb et al., 2004³⁷ Hueb et al., 2007³⁸	Stable angina with multiple-vessel CAD	Optimal medical therapy vs. PCI Optimal medical therapy vs. CABG	Total: 611 Women: 196	<u>Primary endpoint</u> (death, MI, angina requiring mechanical revascularization) 10 years Adj HR (95% CI) Women: Optimal medical therapy vs. PCI: 1.57 (1.01 to 2.46); p = 0.047(favoring PCI) CABG vs. optimal medical therapy: 0.43 (0.26 to 0.72); p = 0.001 Men: Optimal medical therapy vs. PCI: 1.13 (0.84 to 1.53); p = 0.410 CABG vs. optimal medical therapy: 0.43 (0.31 to 0.60); p = 0.001 Overall: PCI vs. optimal medical therapy: 0.79 (0.62-1.01) CABG vs. optimal medical therapy: 0.43 (0.32 to 0.58) p < 0.001	Good
OAT Hochman et al., 2006³⁹ and Hochman et al., 2005⁴⁰	Stable angina	Optimal medical therapy vs. PCI (or CABG if PCI failed)	Total: 2166 Women: 476	<u>Death</u> 4 years PCI vs. optimal medical therapy: Women: 18.3% vs. 22.9% Men: 16.8% vs. 13.5% p = 0.13 Women: HR < 1.0 (favoring PCI, but not significant) Men: HR > 1.0 (favoring optimal medical therapy, but not significant)	Good
STICH Velazquez et al., 2011⁴¹ and Velazquez et al., 2007⁴²	Stable angina	Optimal medical therapy vs. CABG	Total: 1212 Women:148	<u>Death</u> 5 years HR (95% CI) Women: 0.75 (0.42 to 1.31) Men: 0.87 (0.72 to 1.06) p = 0.61	Good

Abbreviations: BMS = bare metal stent; CABG = coronary artery bypass graft; CAD = coronary artery disease; CI = confidence interval; DES = drug-eluting stent; HR = hazard ratio; MI = myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trial; SD = standard deviation; UA = unstable angina

Table F-4. Summary of RCTs reporting clinical outcomes for stable/unstable angina (KQ 3 Strategy 2–PCI vs. CABG)

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
ARTS I Vaina et al., 2009⁴³ and van den Brand, et al., 2002⁴⁴ Serruys et al., 1999⁴⁵ Voudris et al., 2006⁴⁶ Anonymous, 1999⁴⁷	Unstable angina	PCI (BMS) vs. CABG	Total: 1205 Women: 283	<u>1) Composite outcome</u> (death, CVA, MI, CABG, repeat PCI) 30 days Women: PCI 13.0% vs. CABG 8.3% Men: PCI 8.0% vs. CABG 5.7% 1 year Women: PCI 29.0% vs. CABG 14.5% Men: PCI 25.8% vs. CABG 10.7% 3 years Women: PCI 35.5% vs. CABG 19.3% Men: PCI 33.5% vs. CABG 15.1% <u>2) Composite death/CVA</u> 30 days Women: PCI 4.3% vs. CABG 4.8% Men: PCI 1.9% vs. CABG 1.5% 1 year Women: PCI 8.0% vs. CABG 7.6% Men: PCI 3.5% vs. CABG 3.5% Women: PCI 10.9% vs. CABG 9.7% Men: PCI 5.8% vs. 5.9%	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
ARTS I (continued)				<p><u>3) Composite death/MI/CVA 30 days</u> Women: PCI 7.2% vs. 6.9% Men: PCI 4.5% vs. 5.0%</p> <p>1 year Women: PCI 11.6% vs. 11.0% Men: PCI 8.9% vs. CABG 7.0%</p> <p>3 years Women: PCI 14.5% vs. CABG 14.5% Men: PCI 12.3% vs. CABG 9.6%</p> <p><u>4) Death—5 years</u> PCI: women 7.4% vs. men 9.0%; p = 0.29 CABG: women 7.2% vs. men 10.1%; p = 0.48</p> <p>PCI: OR (95% CI) 1.1 (0.5 to 2.8); p = 0.86 CABG: OR (95% CI) 1.4 (0.5 to 4.1); p = 0.54</p> <p><u>5) MI—5 years</u> PCI: OR (95% CI) 1.4 (0.7 to 3.2); p = 0.44 CABG: OR (95%CI) 0.6 (0.3 to 1.3); p = 0.17</p> <p><u>6) CVA—5 years</u> PCI: OR (95% CI) 0.8 (0.3 to 2.2); p = 0.58 CABG: OR (95%CI) 0.6 (0.3 to 1.9); p = 0.39</p> <p><u>7) Revascularization—5 years</u> PCI: OR (95% CI) 1.0 (0.6 to 1.5); p = 0.92 CABG: OR (95%CI) 0.7 (0.4 to 1.4); p = 0.32</p>	
ARTS I (continued)				<p><u>8) Composite death/MI/CVA</u> Men vs. women PCI: OR (95% CI) 1.2 (0.7 to 1.2); p = 0.57 CABG: OR (95%CI) 0.8 (0.5 to 1.5); p = 0.57</p> <p><u>9) Composite MI/CVA/PTCA</u> Men vs. women PCI : OR (95% CI) 0.9 (0.6 to 1.4); p = 0.77 CABG : OR (95% CI) 0.8 (0.5 to 1.3); p = 0.38</p>	

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
ARTS I (continued)				<p><u>10) In-hospital outcomes</u> PCI: OR 95% CI 0.6 (0.3 to 1.2); p = 0.14 CABG: OR 95%CI 1.8 (0.7 to 6.2); p = 0.29</p> <p><u>11) In-hospital MI</u> PCI: OR 95% CI 0.7 (0.2 to 2.6); p = 0.58 CABG: OR 95%CI 1.2 (0.4 to 4.3); p = 0.72</p> <p><u>12) In-hospital CVA</u> PCI: OR 95% CI 0.6 (0.1 to 12.5); p = 0.65 CABG: OR 95%CI 1.8 (0.3 to 34.9); p = 0.57</p> <p><u>13) Quality of life—3 years</u> Euro-Qol summary: PCI: Men 86 ± 16 vs. women 83 ± 19 P = 0.08</p> <p>CABG: Men 86 ± 20 vs. women 82 ± 20 P = 0.02</p> <p><u>14) Composite outcome</u> (death/CVA, MI, CABG, repeat CABG) 5 years Men vs. women PCI: OR (95%CI) 0.9 (0.6 to 1.4); p = 0.77 CABG: OR (95%CI) 0.8 (0.5 to 1.3) p = 0.38</p>	

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
ARTS I (continued)				<p>15) <u>Individual outcomes</u> 30 days Death: Women: PCI 2.9% vs. CABG 4.1% Men: PCI 1.3% vs. CABG 0.4%</p> <p>CVA: Women: PCI 2.2% vs. CABG 0.7% Men: PCI 0.6% vs. CABG 1.1%</p> <p>MI: Women: PCI 3.6% vs. CABG 4.1% Men: PCI 3.2% vs. CABG 3.7%</p> <p>Revascularization: Women: PCI 7.2% vs. CABG 1.4% Men: PCI 5.2% vs. CABG 0.7%</p> <p>Major cardiovascular adverse event- free survival: Women: PCI 87.0% vs. CABG 91.7% Men: PCI 92.0% vs. CABG 94.3%</p>	

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
ARTS I (continued)				<p>1 year</p> <p>Death: Women: PCI 5.8% vs. CABG 6.2% Men: PCI 1.7% vs. CABG 1.5%</p> <p>CVA: Women: PCI 2.9% vs. CABG 2.1% Men: PCI 1.7% vs. CABG 2.0%</p> <p>MI: Women: PCI 5.1% vs. CABG 5.5% Men: PCI 6.1% vs. CABG 3.7%</p> <p>Revascularization: Women: PCI 20.3% vs. CABG 4.1% Men: PCI 21.2% vs. CABG 4.2%</p> <p>Major cardiovascular adverse event- free survival: Women: PCI 71.0% vs. CABG 85.5% Men: PCI 74.2% vs. CABG 89.3%</p>	
ARTS I (continued)				<p>3 years</p> <p>Death: Women: PCI 7.2% vs. CABG 6.9% Men: PCI 3.0% vs. CABG 3.5%</p> <p>CVA: Women: PCI 4.3% vs. CABG 4.1% Men: PCI 3.0% vs. CABG 2.8%</p> <p>MI: Women: PCI 5.8% vs. CABG 7.6% Men: PCI 7.1% vs. CABG 4.2%</p> <p>Revascularization: Women: PCI 24.6% vs. CABG 6.2% Men: PCI 26.8% vs. CABG 6.6%</p> <p>Major cardiovascular adverse event- free survival: Women: PCI 64.5% vs. CABG 80.7% Men: PCI 66.5% vs. CABG 84.9%</p>	

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
BARI Jacobs et al., 1998 ⁴⁸ and Gibbons et al., 2001 ⁴⁹ Anonymous, 2007 ⁵⁰ Lombardero et al., 2002 ⁵¹ Anonymous, 2000 ⁵² Hlatky et al., 1995 ⁵³ Rogers et al., 1995 ⁵⁴ Sutton-Tyrrell et al., 1998 ⁵⁵ Mullany et al., 1999 ⁵⁶ Anonymous, 1996 ⁵⁷	Stable/unstable angina Diabetics	PCI (type not specified) vs. CABG	Total: 915 Women: 249	<u>1) 5-year cumulative survival rate</u> Women: PCI 86.3% vs. CABG 89.3% Men: PCI 86% vs. CABG 89% Survival free of MI: Women: PCI 74% vs. CABG 76% In-hospital death: PCI 1.1% vs. CABG 1.3% Women: PCI 0.8% vs. CABG 1.3% Men: PCI 1.2% vs. CABG 1.4% Q-waves MI: Women : PCI 1.2% vs. CABG 4.7% Men : PCI 2.4% vs. CABG 4.6% Congestive heart failure: Women: PCI 4.8% vs. CABG 9.8% Men: PCI 1.4% vs. CABG 1.8% <u>2) 7-year survival rate</u> Women: PCI 79.2% vs. CABG 82.6% Men: PCI 81.6% vs. CABG 85.1%	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
BARI (continued)				<p><u>3) 10-year survival rate</u> Women: PCI 70.2% vs. CABG 67.8% Men: PCI 71.3% vs. CABG 75.5%</p> <p><u>4) 4-year angina status</u> Women: PCI 23.3% vs. CABG 18.8% Men: PCI 19.7% vs. CABG 13.2%</p> <p>At 5 years, anginal status was not significantly different between men and women.</p> <p><u>5) Repeat revascularization</u> CABG: Women RR 1.74 p = 0.043 PCI: Women RR 0.74 p = 0.011</p> <p>Women were less likely than men to undergo repeat revascularization with an initial strategy of CABG compared with PTCA (11.2% versus 51.9%, respectively; p < 0.001)</p>	
CABRI Anonymous, 1995⁵⁸	Stable/unstable angina with multiple-vessel disease	PCI (PTCA) vs. CABG	Total: 1054 Women: 234	<p><u>1) Primary endpoint of mortality, 1 year</u> PTCA 3.9% vs. CABG 2.7% RR 95%CI 1.42 (0.731 to 2.74); p = 0.297</p> <p>Women had higher risk of 1-year mortality RR (95% CI) 2.07 (1.07 to 4.01); p=0.031</p> <p><u>2) Angina</u> PTCA 13.9% vs. CABG 10.1% RR (95% CI) 1.54 (1.09 to 2.16) Women: 3.12 (1.41 to 6.54) p = 0.002 Men: 1.25 (0.85 to 1.85); p = 0.256</p> <p><u>3) Crude absolute risk of angina</u> PTCA Women: 0.214 Men: 0.131</p> <p>CABG Women: 0.069 Men: 0.104</p>	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
CARDia Kapur et al., 2010 ⁵⁹ and Kapur et al., 2005 ⁶⁰	UA/NSTEMI Stable angina Diabetic Multiple-vessel disease or complex single lesion	PCI (BMS or DES) vs. CABG	Total: 510 Women: 132	<u>1) Primary endpoint, 1 year</u> (death, MI, stroke) HR (95%CI) Women: 2.13 (0.68 to 6.68) Men: 1.07 (0.59 to 1.93) Overall: 1.25 (0.75 to 2.09) <u>2) Secondary endpoint</u> (death, MI, stroke and repeat revascularization) HR (95%CI) Women: 2.4 (0.87 to 6.61) Men: 1.62 (0.95 to 2.74) Overall: 1.77 (1.11 to 2.09)	Good
EAST King et al., 2000 ⁶¹ and King et al., 1995 ⁶² King et al., 1994 ⁶³ Zhao et al., 1996 ⁶⁴	Stable angina with multiple-vessel disease	PCI (type not specified) vs. CABG	Total: 392 Women: 103	<u>Single outcome survival</u> 3 years CABG 93.8% vs. PTCA 92.9% 8 years CABG 82.7% vs. PTCA 79.3% Comparisons were made for other baseline variables including sex, and no survival differences by treatment assignment were seen.	Good
GABI Kaehler et al., 2005 ⁶⁵ and Hamm et al., 1994 ⁶⁶	Stable angina	PCI (type not specified) vs. CABG	Total: 359 Women: 66	<u>Death</u> 13 years No significant sex differences in hazard ratio for death.	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
MASS II Hueb et al., 2010³⁶ and Hueb et al., 2004³⁷ Hueb et al., 2007³⁸	Stable angina with multiple-vessel coronary artery disease	PCI (type not specified) vs. CABG	Total: 611 Women: 196	<u>Primary endpoint</u> (death, MI, angina requiring mechanical revascularization) 10 years Adj HR (95% CI) Women: CABG vs. PCI: 0.68 (0.40 to 1.15); p = 0.015 Men: CABG vs. PCI: 0.49 (0.34 to 0.69); p = 0.001 Overall: CABG vs. PCI: 0.53 (0.39 to 0.72); p < 0.001	Good
PRECOMBAT Park et al., 2011⁶⁷	Stable/unstable angina	PCI (DES) vs. CABG	Total: 600 Women: 141	<u>1) Composite endpoint, 1 year</u> (death, MI, stroke, ischemia driven target-vessel revascularization) PCI 8.7% vs. CABG 6.7% <u>2) Composite endpoint, 2 years</u> PCI 12.2% vs. CABG 8.1% HR (95% CI) 1.50 (0.90 to 2.52); p = 0.12 Women: PCI 13.9% vs. CABG 11.7 % HR (95% CI) 1.22 (0.48 to 3.08); p = 0.68 Men: PCI 11.7% vs. CABG 7.0% HR (95%CI) 1.65 (0.88 to 3.07); p = 0.12	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Outcomes	Quality
SOS Zhang et al., 2004 ⁶⁸ and Zhang et al., 2003 ⁶⁹ Stables et al., 1999 ⁷⁰	Stable angina	PCI (BMS) vs. CABG	Total: 908 Women: 206	<u>1) Quality of life</u> (adjusted relative difference of CABG vs. PCI) 6 months Women: 39.3 Men: 18.3 1 year Women: 0.6 Men: 15.3 <u>2) Angina frequency</u> (adjusted relative difference of CABG vs. PCI) 6 months Women: 43.2 Men: 31.3 1 year Women: 11.1 Men: 19.7 <u>3) Physical limitation</u> (adjusted relative difference of CABG vs. PCI) 6 months Women: 11.6 Men: 54.7 1 year Women: 1.6 Men: 50.6	Fair
SYNTAX Morice et al., 2010 ⁷¹	Triple-vessel or left main coronary artery disease	PCI (type not specified) vs. CABG	Total: 705 Women: 185	<u>1) Primary endpoint , 1 year</u> (death, MI, stroke and repeat revascularization) CABG vs. PCI 13.6% vs. 15.8% OR (95% CI) 2.1 (-3.2 to 7.4); p = 0.44 <u>2) Predictors of 1-year major adverse cardiovascular events</u> OR (95% CI) Women: 0.50 (0.27 to 0.91); p = 0.02	Fair

Abbreviations: BMS = bare metal stent; CABG = coronary artery bypass graft; CAD = coronary artery disease; CI = confidence interval; CVA = cerebrovascular accident; DES = drug-eluting stent; HR = hazard ratio; MI = myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trial; UA = unstable angina

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Appendix G: Summary Tables for Modifiers of Effectiveness

Table G-1. Summary of RCTs reporting modifiers of effectiveness (subgroup analyses)

Study Author/Year Related Articles	Population	Comparison	# Subjects	Subgroup Analyses	Quality
BARI Jacobs et al., 1998¹ and Gibbons et al., 2007² Anonymous, 2007³ Lombardero et al., 2002⁴ Anonymous, 2000⁵ Hlatky et al., 1995⁶ Rogers et al., 1995⁷ Sutton-Tyrrell et al., 1998⁸ Mullany et al., 1999⁹ Anonymous, 1996¹⁰	Stable/unstable angina Diabetics	PCI vs. CABG	Total: 915 Women: 249	<u>7-year survival rates</u> Women: PCI 61.0% vs. CABG 74.3% Men: PCI 51.5% vs. CABG 77.9%	Good
Minai et al., 2002¹¹	STEMI age ≥ 80 years	PCI vs conservative/supportive therapy	Total: 120 Women: 60	No difference in composite outcome (death, congestive heart failure, repeat MI, or cerebrovascular accident at 3 years between treatment groups).	Fair
PAMI Stone et al., 1995¹²	STEMI	PCI vs. fibrinolysis (t-PA)	Total: 395 Women: 107	<u>In-hospital mortality</u> Women aged <65: 0% vs. 4%; p = 0.42 Women aged ≥65: 5.9% vs. 21.9%; p = 0.58 Men aged <65: 0.9% vs. 0%; p = 0.74 Men aged ≥65: 5.6% vs. 10.4%; p = 0.42	Good

Study Author/Year Related Articles	Population	Comparison	# Subjects	Subgroup Analyses	Quality
RITA-3 Clayton et al., 2004¹³ and Fox et al., 2002¹⁴	UA/NSTEMI	Early invasive (PCI) vs. initial conservative	Total: 1810 Women: 682	<p>Lower TIMI risk scores, both men and women had similar event rates in early invasive vs. initial conservative treatment arms.</p> <p>In those with moderate to high risk, men had lower event rates in intervention arm compared to conservative arm while women had higher even rates in the intervention arm.</p> <p>Moderate risk (women) Invasive: 13.4% Conservative: 3.4%</p> <p>High risk (women) Invasive: 11.7% Conservative: 8.2%</p> <p>Moderate risk (men) Invasive: 5.4% Conservative: 9.4%</p> <p>High risk (men) Invasive: 10.3% Conservative: 17.9%</p> <p>No benefit of intervention was seen in any BMI group for women.</p>	Good
TACTICS TIMI-18 Cannon et al., 2001¹⁵ and Glaser et al., 2002¹⁶ Cannon et al., 1998¹⁷	UA/NSTEMI	Early invasive (PCI) vs. initial conservative	Total: 2220 Women: 757	<p><u>Primary endpoint</u> (death, MI, rehospitalization for acute coronary syndrome by risk) Women with intermediate (3-4) and high (5-7) TIMI risk scores did not have significantly different outcomes in early invasive vs. initial conservative group. OR (95% CI) 0.72 (0.45 to 1.16) vs. 0.56 (0.23 to 1.32)</p>	Good

Abbreviations: BMS = bare metal stent; CABG = coronary artery bypass graft; CAD = coronary artery disease; CI = confidence interval; DES = drug-eluting stent; HCT = hematocrit; MI = myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trial; TIMI = thrombolysis in myocardial infarction; t-PA = tissue plasminogen activator; UA = unstable angina

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Appendix H: Summary Tables for Safety Concerns

Table H-1. Summary of RCTs reporting safety concerns (harms)

Study Author/Year Related Articles	Population	Comparison	# Subjects	Harms	Quality
ARTS I Vaina et al., 2009¹ and van den Brand, et al., 2002² Serruys et al., 1999³ Voudris et al., 2006⁴ Anonymous, 1999⁵	UA/NSTEMI	PCI vs. CABG	Total: 1205 Women: 283	<u>Major bleeding</u> PCI (men vs. women): OR (95% CI) 29.4 (5.3 to 500); p = 0.001 CABG (men vs. women): OR (95%CI) 1.5 (0.4 to 10.1); p = 0.58	Good
GUSTO II-B Tamis-Holland et al., 2004⁶	STEMI	PCI vs. fibrinolysis (accelerated t-PA)	Total: 1137 Women: 260	<u>Intracranial hemorrhage</u> Women PCI: 0 Optimal medical therapy: 4.1% Men PCI: 0 Optimal medical therapy: 0.7%	Good
PAMI Stone et al., 1995⁷	STEMI	PCI vs. fibrinolysis (t-PA)	Total: 395 Women: 107	<u>Nadir HCT (PCI vs. fibrinolysis)</u> Women: 30 ± 5% vs. 33 ± 5%; p = 0.002 Men: 35 ± 6% vs. 35 ± 6%; p = 0.17 <u>Requirement for blood transfusion (PCI vs. fibrinolysis)</u> Women: 18% vs. 8.8%; p = 0.16 Men: 9.7% vs. 8.4%; p = 0.71	Good
TACTICS TIMI-18 Cannon et al., 2001⁸ and Glaser et al., 2002⁹ Cannon et al., 1998¹⁰	UA/NSTEMI	Early invasive vs. initial conservative	Total: 2220 Women: 757	Bleeding in women undergoing PTCA was higher compared to men; adjusted OR (95% CI) 3.6 (1.6 to 8.3). Bleeding related to CABG was similar in women and men (12.6% vs. 15%). Occurrence of stroke at 30 days related to CABG also was similar in women and men (2.1% vs. 1.5%).	Good

Abbreviations: BMS = bare metal stent; CABG = coronary artery bypass graft; CAD = coronary artery disease; CI = confidence interval; DES = drug-eluting stent; HCT = hematocrit; NSTEMI = non-ST elevation myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trial; t-PA = tissue plasminogen activator; UA = unstable angina

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