

## **APPENDIXES**

# Appendix A: Exact Search Strings

## PubMed® search strategy (October 5, 2011)

Table A-1. KQ 1: Effectiveness and safety of aspirin and antiplatelets

Set #	Terms	Results
#1	"Peripheral Arterial Disease"[Mesh] OR "Peripheral Vascular Diseases"[Mesh] OR PAD[tiab] OR "peripheral arterial disease"[tiab] OR "peripheral vascular disease"[tiab] OR "arterial occlusive disease"[tiab] OR "intermittent claudication"[MeSH Terms] OR claudication[tiab] OR "rest pain"[tiab] OR (critical[tiab] AND ("extremities"[MeSH Terms] OR "extremities"[tiab] OR "limb"[tiab]) AND ("ischaemia"[tiab] OR "ischemia"[MeSH Terms] OR "ischemia"[tiab])) OR (("ischaemia"[tiab] OR "ischemia"[MeSH Terms] OR "ischemia"[tiab]) AND ("lower extremity"[MeSH Terms] OR ("lower"[tiab] AND "extremity"[tiab]) OR "lower extremity"[tiab])) OR (("extremities"[MeSH Terms] OR "extremities"[tiab] OR "limb"[tiab]) AND ("ischaemia"[tiab] OR "ischemia"[MeSH Terms] OR "ischemia"[tiab])) OR "vascular ulcer"[tiab] OR (vascular[tiab] AND ulcer[tiab]) OR "vascular ulcers"[tiab] OR (vascular[tiab] AND ulcers[tiab]) OR "varicose ulcer"[MeSH] OR "varicose ulcer"[tiab] OR (varicose[tiab] AND ulcer[tiab]) OR "varicose ulcers"[tiab] OR (varicose[tiab] AND ulcers[tiab]) OR "leg ulcer"[MeSH] OR "leg ulcer"[tiab] OR (leg[tiab] AND ulcer[tiab]) OR "leg ulcers"[tiab] OR (leg[tiab] AND ulcers[tiab]) OR gangrene[MeSH] OR gangrene[tiab]	107767
#2	"aspirin"[MeSH Terms] OR "aspirin"[tw] OR ("clopidogrel"[Supplementary Concept] OR "clopidogrel"[tw] OR "plavix"[tw]) OR "prasugrel"[Supplementary Concept] OR "prasugrel"[tw] OR Effient[tw] OR "Ticagrelor"[Supplementary Concept] OR "Ticagrelor"[tw] OR brilinta[tw]	51202
#3	"evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation study"[tw] OR evaluation studies[tw] OR "intervention studies"[MeSH Terms] OR "intervention study"[tw] OR "intervention studies"[tw] OR "case-control studies"[MeSH Terms] OR "case-control"[tw] OR "cohort studies"[MeSH Terms] OR cohort[tw] OR "longitudinal studies"[MeSH Terms] OR "longitudinal"[tw] OR longitudinally[tw] OR "prospective"[tw] OR prospectively[tw] OR "retrospective studies"[MeSH Terms] OR "retrospective"[tw] OR "follow up"[tw] OR "comparative study"[Publication Type] OR "comparative study"[tw] OR systematic[subset] OR "meta-analysis"[Publication Type] OR "meta-analysis as topic"[MeSH Terms] OR "meta-analysis"[tw] OR "meta-analyses"[tw] OR randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR placebo[tiab] OR "drug therapy"[Subheading] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR "clinical trial"[tw] OR "clinical trials"[tw] NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp])	5103944
#4	(#1 AND #2 AND #3 ) not (ANIMALS[MH] not HUMANS[MH])	901
#5	#4 Limits: English, <b>Publication Date from 1995 to 2011</b>	535

**Table A-2. KQ 2: Effectiveness and safety of exercise, medications, endovascular intervention, and surgical revascularization (intermittent claudication)**

Set #	Terms	Results
#1	"intermittent claudication"[MeSH Terms] OR claudication[tiab]	9852
#2	("angioplasty"[MeSH Terms] OR "angioplasty"[tiab] OR ("percutaneous"[tiab] AND "transluminal"[tiab] AND "angioplasty"[tiab]) OR "percutaneous transluminal angioplasty"[tiab] OR PTA[tiab] OR ("stents"[MeSH Terms] OR "stents"[tiab] OR "stent"[tiab]) OR (percutaneous[tiab] AND revascularization[tiab]) OR ("endovascular procedures"[MeSH Terms] OR ("endovascular"[tiab] AND "procedures"[tiab]) OR "endovascular procedures"[tiab]) OR endovascular[tiab] OR ("exercise therapy"[MeSH Terms] OR ("exercise"[tiab] AND "therapy"[tiab]) OR "exercise therapy"[tiab]) OR ("exercise"[MeSH Terms] OR "exercise"[tiab]) AND (program[tiab] OR class[tiab] OR training[tiab] OR prescribed[tiab] OR structure[tiab] OR structured[tiab] OR supervised[tiab])) OR ("aspirin"[MeSH Terms] OR "aspirin"[tiab]) OR ("clopidogrel"[Supplementary Concept] OR "clopidogrel"[tiab]) OR ("cilostazol"[Supplementary Concept] OR "cilostazol"[tiab]) OR ("pentoxifylline"[MeSH Terms] OR "pentoxifylline"[tiab])	240361
#3	"Femoral Artery/surgery"[Mesh] OR "Popliteal Artery/surgery"[Mesh] OR "tibial arteries/surgery"[Mesh Terms] OR "arteries/surgery"[Mesh Terms] OR "transplants"[MeSH Terms] OR transplants[tiab] OR graft[tiab] OR grafts[tiab] OR grafting[tiab] OR bypass[tiab] OR conduit[tiab] OR femoropopliteal[tiab] OR femorotibial[tiab] OR aortobifemoral[tiab] OR ballon[tiab] OR "atherectomy"[MeSH Terms] OR atherectomy[tiab]	327256
#4	"evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation study"[tw] OR evaluation studies[tw] OR "intervention studies"[MeSH Terms] OR "intervention study"[tw] OR "intervention studies"[tw] OR "case-control studies"[MeSH Terms] OR "case-control"[tw] OR "cohort studies"[MeSH Terms] OR cohort[tw] OR "longitudinal studies"[MeSH Terms] OR "longitudinal"[tw] OR longitudinally[tw] OR "prospective"[tw] OR prospectively[tw] OR "retrospective studies"[MeSH Terms] OR "retrospective"[tw] OR "follow up"[tw] OR "comparative study"[Publication Type] OR "comparative study"[tw] OR systematic[subset] OR "meta-analysis"[Publication Type] OR "meta-analysis as topic"[MeSH Terms] OR "meta-analysis"[tw] OR "meta-analyses"[tw] OR randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR placebo[tiab] OR "drug therapy"[Subheading] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR "clinical trial"[tw] OR "clinical trials"[tw] NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp])	5103944
#5	#1 AND (#2 OR #3) AND #4 NOT (animals[mh] NOT humans[mh])	2407
#6	#5 AND Limits: English, Publication Date from 1995 to 2011	1414

**Table A-3. KQ 3: Effectiveness and safety of endovascular intervention and surgical revascularization (critical limb ischemia)**

Set #	Terms	Results
#1	"rest pain"[tiab] OR (critical[tiab] AND ("extremities"[MeSH Terms] OR "extremities"[tiab] OR "limb"[tiab]) AND ("ischaemia"[tiab] OR "ischemia"[MeSH Terms] OR "ischemia"[tiab])) OR (("ischaemia"[tiab] OR "ischemia"[MeSH Terms] OR "ischemia"[tiab]) AND ("lower extremity"[MeSH Terms] OR "lower"[tiab] AND "extremity"[tiab] OR "lower extremity"[tiab])) OR (("extremities"[MeSH Terms] OR "extremities"[tiab] OR "limb"[tiab]) AND ("ischaemia"[tiab] OR "ischemia"[MeSH Terms] OR "ischemia"[tiab]))	18495
#2	"angioplasty"[MeSH Terms] OR "angioplasty"[tiab] OR ("percutaneous"[tiab] AND "transluminal"[tiab] AND "angioplasty"[tiab]) OR "percutaneous transluminal angioplasty"[tiab] OR PTA[tiab] OR "stents"[MeSH Terms] OR "stents"[tiab] OR "stent"[tiab] OR (percutaneous[tiab] AND revascularization[tiab]) OR "endovascular procedures"[MeSH Terms] OR endovascular[tiab]	125370
#3	"Femoral Artery/surgery"[Mesh] OR "Popliteal Artery/surgery"[Mesh] OR "tibial arteries/surgery"[Mesh Terms] OR "arteries/surgery"[Mesh Terms] OR "transplants"[MeSH Terms] OR transplants[tiab] OR graft[tiab] OR grafts[tiab] OR grafting[tiab] OR bypass[tiab] OR conduit[tiab] OR femoropopliteal[tiab] OR femorotibial[tiab] OR aortobifemoral[tiab] OR balloon[tiab] OR "atherectomy"[MeSH Terms] OR atherectomy[tiab]	327418
#4	"evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation study"[tw] OR evaluation studies[tw] OR "intervention studies"[MeSH Terms] OR "intervention study"[tw] OR "intervention studies"[tw] OR "case-control studies"[MeSH Terms] OR "case-control"[tw] OR "cohort studies"[MeSH Terms] OR cohort[tw] OR "longitudinal studies"[MeSH Terms] OR "longitudinal"[tw] OR longitudinally[tw] OR "prospective"[tw] OR prospectively[tw] OR "retrospective studies"[MeSH Terms] OR "retrospective"[tw] OR "follow up"[tw] OR "comparative study"[Publication Type] OR "comparative study"[tw] OR systematic[subset] OR "meta-analysis"[Publication Type] OR "meta-analysis as topic"[MeSH Terms] OR "meta-analysis"[tw] OR "meta-analyses"[tw] OR randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR placebo[tiab] OR "drug therapy"[Subheading] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR "clinical trial"[tw] OR "clinical trials"[tw] NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp])	5106763
#5	#1 AND (#2 OR #3) AND #4 NOT (animals[mh] NOT humans[mh])	3664
#6	#5 AND Limits: Publication Date from 1995 to 2011	2180

**KQ 1 or KQ 2 or KQ 3: 3443 results**

# Embase® search strategy (January 5, 2012)

Platform: Embase.com

**Table A-4. KQ 1: Effectiveness and safety of aspirin and antiplatelets**

Set #	Terms	Results
#1	'peripheral arterial disease':ab,ti OR pad:ab,ti OR 'peripheral artery disease':ab,ti OR 'peripheral occlusive artery disease'/de OR 'claudication'/exp OR 'limb ischemia'/exp OR 'leg ischemia'/exp OR 'leg ulcer'/exp OR 'gangrene'/exp OR 'intermittent claudication':ab,ti OR ((extremity:ab,ti OR limb:ab,ti OR leg:ab,ti) AND (ischemia:ab,ti OR iscaemia:ab,ti))	87283
#2	aspirin:ab,ti OR clopidogrel:ab,ti OR plavix:ab,ti OR prasugrel:ab,ti OR effient:ab,ti OR ticagrelor:ab,ti OR brilinta:ab,ti OR 'acetylsalicylic acid'/exp OR 'clopidogrel'/exp OR 'ticagrelor'/exp OR prasugrel/exp	152567
#3	'randomized controlled trial'/exp OR 'crossover procedure'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR random*:ab,ti OR factorial*:ab,ti OR crossover*:ab,ti OR (cross NEAR/1 over*):ab,ti OR placebo*:ab,ti OR (doubl* NEAR/1 blind*):ab,ti OR (singl* NEAR/1 blind*):ab,ti OR assign*:ab,ti OR allocat*:ab,ti OR volunteer*:ab,ti OR 'clinical study'/exp OR 'clinical trial':ab,ti OR 'clinical trials':ab,ti OR 'controlled study'/exp OR 'evaluation'/exp OR 'evaluation study':ab,ti OR 'evaluation studies':ab,ti OR 'intervention study':ab,ti OR 'intervention studies':ab,ti OR 'case control':ab,ti OR 'cohort analysis'/exp OR cohort:ab,ti OR longitudinal*:ab,ti OR prospective:ab,ti OR prospectively:ab,ti OR retrospective:ab,ti OR 'follow up'/exp OR 'follow up':ab,ti OR 'comparative effectiveness'/exp OR 'comparative study'/exp OR 'comparative study':ab,ti OR 'comparative studies':ab,ti OR 'evidence based medicine'/exp OR 'systematic review':ab,ti OR 'meta-analysis':ab,ti OR 'meta-analyses':ab,ti NOT ('editorial'/exp OR 'letter'/exp OR 'case report'/exp)	7792943
#4	#1 AND #2 AND #3	2,080
#5	#4 AND [humans]/lim AND [1995-2012]/py	1753
#6	#5 AND [embase]/lim NOT [medline]/lim AND [1995-2012]/py	447

**Table A-5. KQ 2: Effectiveness and safety of exercise, medications, endovascular intervention, and surgical revascularization (intermittent claudication)**

Set #	Terms	Results
#1	'claudication'/exp OR claudication:ab,ti	14,663
#2	'angioplasty'/exp OR 'percutaneous transluminal angioplasty'/exp OR 'stent'/exp OR 'endovascular surgery'/de OR angioplasty:ab,ti OR "percutaneous transluminal":ab,ti OR stent:ab,ti OR stents:ab,ti OR endovascular:ab,ti OR revascularization:ab,ti OR percutaneous:ab,ti OR pta:ab,ti OR 'revascularization'/exp OR kinesiotherapy/exp OR ('exercise'/exp AND (therapy:ab,ti OR program:ab,ti OR class:ab,ti OR training:ab,ti OR prescribed:ab,ti OR structure:ab,ti OR structured:ab,ti OR supervised:ab,ti)) OR 'pentoxifylline'/exp OR 'cilostazol'/exp OR pentoxifylline:ab,ti OR cilostazol:ab,ti OR aspirin:ab,ti OR clopidogrel:ab,ti OR 'acetylsalicylic acid'/exp OR clopidogrel/exp	482518
#3	('leg artery'/exp OR femoropopliteal:ab,ti OR femorotibial:ab,ti OR aortobifemoral:ab,ti OR femoral:ab,ti OR popliteal:ab,ti OR tibial:ab,ti) AND (transplant:ab,ti OR graft:ab,ti OR grafts:ab,ti OR grafting:ab,ti OR bypass:ab,ti OR conduit:ab,ti OR ballon:ab,ti OR transplantation:ab,ti) OR 'leg revascularization'/exp	18,591

Set #	Terms	Results
#4	'randomized controlled trial'/exp OR 'crossover procedure'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR random*:ab,ti OR factorial*:ab,ti OR crossover*:ab,ti OR (cross NEAR/1 over*):ab,ti OR placebo*:ab,ti OR (doubl* NEAR/1 blind*):ab,ti OR (singl* NEAR/1 blind*):ab,ti OR assign*:ab,ti OR allocat*:ab,ti OR volunteer*:ab,ti OR 'clinical study'/exp OR 'clinical trial':ab,ti OR 'clinical trials':ab,ti OR 'controlled study'/exp OR 'evaluation'/exp OR 'evaluation study':ab,ti OR 'evaluation studies':ab,ti OR 'intervention study':ab,ti OR 'intervention studies':ab,ti OR 'case control':ab,ti OR 'cohort analysis'/exp OR cohort:ab,ti ORlongitudinal*:ab,ti OR prospective:ab,ti OR prospectively:ab,ti OR retrospective:ab,ti OR 'follow up'/exp OR 'follow up':ab,ti OR 'comparative effectiveness'/exp OR 'comparative study'/exp OR 'comparative study':ab,ti OR 'comparative studies':ab,ti OR 'evidence based medicine'/exp OR 'systematic review':ab,ti OR 'meta-analysis':ab,ti OR 'meta-analyses':ab,ti NOT ('editorial'/exp OR 'letter'/exp OR 'case report'/exp)	7792943
#5	#1 AND (#2 OR #3) AND #4	3375
#6	#5 AND [humans]/lim AND [1995-2012]/py	2312
#7	#6 AND [embase]/lim NOT [medline]/lim	528

**Table A-6. KQ 3: Effectiveness and safety of endovascular intervention and surgical revascularization (critical limb ischemia)**

Set #	Terms	Results
#1	"rest pain":ab,ti OR 'limb ischemia'/exp AND 'leg ischemia'/exp OR "critical limb ischemia")OR (critical:ab,ti AND ( extremities:ab,ti OR extremity:ab,ti OR limb:ab,ti OR leg:ab,ti) AND ("ischaemia":ab,ti OR "ischemia":ab,ti))	3788
#2	'angioplasty'/exp OR 'percutaneous transluminal angioplasty'/exp OR 'stent'/exp OR 'endovascular surgery'/de OR angioplasty:ab,ti OR 'percutaneous transluminal':ab,ti OR stent:ab,ti OR stents:ab,ti OR endovascular:ab,ti OR revascularization:ab,ti OR percutaneous:ab,ti OR pta:ab,ti OR 'revascularization'/exp	258406
#3	'leg artery'/exp OR femoropopliteal:ab,ti OR femorotibial:ab,ti OR aortobifemoral:ab,ti OR femoral:ab,ti OR popliteal:ab,ti OR tibial:ab,ti AND (transplant:ab,ti OR graft:ab,ti OR grafts:ab,ti OR grafting:ab,ti ORbypass:ab,ti OR conduit:ab,ti OR ballon:ab,ti OR transplantation:ab,ti) OR 'leg revascularization'/exp	18,591
#4	'randomized controlled trial'/exp OR 'crossover procedure'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR random*:ab,ti OR factorial*:ab,ti OR crossover*:ab,ti OR (cross NEAR/1 over*):ab,ti OR placebo*:ab,ti OR (doubl* NEAR/1 blind*):ab,ti OR (singl* NEAR/1 blind*):ab,ti OR assign*:ab,ti OR allocat*:ab,ti OR volunteer*:ab,ti OR 'clinical study'/exp OR 'clinical trial':ab,ti OR 'clinical trials':ab,ti OR 'controlled study'/exp OR 'evaluation'/exp OR 'evaluation study':ab,ti OR 'evaluation studies':ab,ti OR 'intervention study':ab,ti OR 'intervention studies':ab,ti OR 'case control':ab,ti OR 'cohort analysis'/exp OR cohort:ab,ti ORlongitudinal*:ab,ti OR prospective:ab,ti OR prospectively:ab,ti OR retrospective:ab,ti OR 'follow up'/exp OR 'follow up':ab,ti OR 'comparative effectiveness'/exp OR 'comparative study'/exp OR 'comparative study':ab,ti OR 'comparative studies':ab,ti OR 'evidence based medicine'/exp OR 'systematic review':ab,ti OR 'meta-analysis':ab,ti OR 'meta-analyses':ab,ti NOT ('editorial'/exp OR 'letter'/exp OR 'case report'/exp)	7792943
#5	#1 AND (#2 OR #3) AND #4	822
#6	#5 AND [humans]/lim AND [1995-2012]/py	660
#7	#6 AND [embase]/lim NOT [medline]/lim	153

## Cochrane search strategy (January 5, 2012)

Platform: Wiley

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

**Table A-7. KQ 1: Effectiveness and safety of aspirin and antiplatelets**

Set #	Terms	Results
#1	MeSH descriptor Peripheral Arterial Disease explode all trees OR MeSH descriptor Intermittent Claudication explode all trees OR MeSH descriptor Leg Ulcer explode all trees OR MeSH descriptor Varicose Ulcer explode all trees OR MeSH descriptor Gangrene explode all trees OR (Peripheral Arterial Disease):ti,ab,kw or (arterial occlusive disease):ti,ab,kw or (intermittent claudication):ti,ab,kw or (rest pain):ti,ab,kw or (pad):ti,ab,kw OR (occlusive artery disease):ti,ab,kw or (leg ischemia):ti,ab,kw or (limb ischemia):ti,ab,kw or (claudication):ti,ab,kw	7237
#2	MeSH descriptor Aspirin explode all trees OR (aspirin):ti,ab,kw or (clopidogrel):ti,ab,kw or (prasugrel):ti,ab,kw or (ticagrelor):ti,ab,kw or (plavix):kw	7283
#3	#1 AND #2 AND (Cochrane Reviews, other reviews, Clinical trials)	233
#4	#3 AND 1995 - 2012	156

**Table A-8. KQ 2: Effectiveness and safety of exercise, medications, endovascular intervention, and surgical revascularization (intermittent claudication)**

Set #	Terms	Results
#1	MeSH descriptor Intermittent Claudication explode all trees OR claudication):ti,ab,kw	1194
#2	MeSH descriptor Angioplasty explode all trees OR MeSH descriptor Stents explode all trees OR MeSH descriptor Endovascular Procedures explode all trees OR percutaneous transluminal):ti,ab,kw OR (pta):ti,ab,kw OR (endovascular):ti,ab,kw OR (revascularization):ti,ab,kw OR (stent OR stents):ti,ab,kw OR MeSH descriptor Exercise Therapy explode all trees OR (exercise):ti,ab,kw OR MeSH descriptor Aspirin explode all trees OR MeSH descriptor Pentoxifylline explode all trees OR (aspirin):ti,ab,kw or (clopidogrel):ti,ab,kw or (cilostazol):ti,ab,kw or (pentoxifylline):ti,ab,kw	47932
#3	MeSH descriptor Femoral Artery explode all trees with qualifier: SU OR MeSH descriptor Popliteal Artery explode all trees with qualifier: SU OR MeSH descriptor Tibial Arteries explode all trees with qualifier: SU OR MeSH descriptor Arteries explode all trees with qualifier: SU OR (graft*):ti,ab,kw or (transplant*):ti,ab,kw or (bypass):ti,ab,kw or (conduit):ti,ab,kw OR (femoropopliteal):ti,ab,kw or (femorotibial):ti,ab,kw or (aortobifemoral):ti,ab,kw or (atherectomy):ti,ab,kw OR (revascularization):ti,ab,kw	29766
#4	#1 AND (#2 OR #3)	672
#5	#4 AND (Cochrane Reviews, other reviews, Clinical trials)	654
#6	#5 AND 1995-2012	427

**Table A-9. KQ 3: Effectiveness and safety of endovascular intervention and surgical revascularization (critical limb ischemia)**

Set #	Terms	Results
#1	(rest pain):ti,ab,kw or (critical limb ischemia):ti,ab,kw OR (MeSH descriptor Ischemia explode all trees OR (ischemia):ti,ab,kw or (ischaemia):ti,ab,kw) AND ((limb*):ti,ab,kw or (leg*):ti,ab,kw or (extremity*):ti,ab,kw)	3189
#2	MeSH descriptor Angioplasty explode all trees OR MeSH descriptor Stents explode all trees OR MeSH descriptor Endovascular Procedures explode all trees OR (percutaneous transluminal angioplasty):ti,ab,kw or (stent*):ti,ab,kw or (angioplasty):ti,ab,kw or (revascularization):ti,ab,kw or (endovascular):ti,ab,kw	10625

Set #	Terms	Results
#3	MeSH descriptor Femoral Artery explode all trees with qualifier: SU OR MeSH descriptor Popliteal Artery explode all trees with qualifier: SU OR MeSH descriptor Tibial Arteries explode all trees with qualifier: SU OR MeSH descriptor Arteries explode all trees with qualifier: SU OR (transplant*):kw or (bypass):ti,ab,kw or (graft*):ti,ab,kw or (conduit*):ti,ab,kw or (ballon):ti,ab,kw OR (femoropopliteal):ti,ab,kw or (femorotibial):ti,ab,kw or (aortobifemoral):ti,ab,kw or (atherectomy):ti,ab,kw	23869
#4	#1 AND (#2 OR #3)	315
#5	#4 AND (Cochrane Reviews, other reviews, Clinical trials)	301
#6	#5 AND 1995-2012	240

# Appendix B: Data Abstraction Elements

## Study Characteristics

- Study name and acronym
- Other articles used in this abstraction
- Study dates
  - Date enrollment started (MM and YYYY)
  - Date enrollment ended (MM and YYYY)
  - Length of Followup (months or years)
- Enrollment source: Primary care, Cardiology, Radiology, Surgery, NR/NA
- Enrollment approach: consecutive patients, convenience sample, other (specify), unclear/not reported
  - Number of subjects screened/approached for study participation
  - Number eligible for study
  - Number randomized
  - Number completing follow-up
  - Number included in primary outcome analysis
- Study sites: 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: US, Canada, UK, Europe, S. America, C. America, Asia, Africa, Australia/NZ, Not reported/Unclear, Other (specify)
- Funding source: Government, Private foundation, Nonprofit Organization, Industry, Not reported, Other (specify)
- Setting: Academic centers, Community hospitals, Outpatient, VA, Not reported/unclear, Other (specify)
- Inclusion and exclusion criteria; Copy/paste criteria as reported in the article.
- Symptom status of population studied: Asymptomatic, Intermittent claudication, Atypical claudication, Critical limb ischemia
- To which key questions and subquestions does this study apply?
  - KQ1: KQ1a, KQ1b, KQ1c
  - KQ2: KQ2a, KQ2b, KQ2c
  - KQ3: KQ3a, KQ3b, KQ3c
- Subgroup Analysis: Yes/No
- Comments (if needed)

## Baseline Characteristics

- Number of Subjects
  - Total Population and Treatment Arms 1, 2, 3, 4
    - N
      - Total

- Female
    - Male
  - Percentage
    - Female
    - Male
- Total Population – Age in years
  - Total Population and Treatment Arms 1, 2, 3, 4
    - Mean
    - SD
    - SE
    - Median
    - IQR
- Ethnicity
  - Total N and Percentage of Population
    - Hispanic or Latino
    - Not Hispanic or Latino
- Race
  - Total N and Percentage of Population
    - Black/African American
    - American Indian or Alaska Native
    - Asian
    - Native Hawaiian or other Pacific Islander
    - White
    - Multiracial
    - Other (specify)
- Baseline Characteristics
  - Total Population and Treatment Arms 1, 2, 3, 4
    - Diabetes (NR)
    - Tobacco use (NR)
    - Prior MI (NR)
    - Known CAD (NR)
    - Hyperlipidemia (NR)
    - Prior PCI (NR)
    - Prior CABG (NR)
    - Heart failure (NR)
    - Chronic kidney disease (NR)
    - Obesity (NR) – Define
    - Prior stroke (NR)
    - Prior TIA (NR)
    - Prior stroke or TIA (NR)
    - Prior carotid surgery (NR)
    - Claudication (NR)
    - Peripheral vascular disease (NR)
    - Prior lower extremity vascular surgery (NR)
    - Ankle brachial index (NR)
      - Mean/Median

- SD/SE/IQR
  - Fontaine classification
    - Stage I
    - Stage IIa
    - Stage IIb
    - Stage 3
    - Stage 4
  - Rutherford classification
    - Stage 0
    - Stage 1
    - Stage 2
    - Stage 3
    - Stage 4
    - Stage 5
    - Stage 6
  - TASC II classification
    - A
    - B
    - C
    - D
    - A/B
    - C/D
  - Runoff vessels
    - Mean/Median
    - SD/SE/IQR
  - Runoff vessels (N)
    - 1
    - 2
    - 3
- Presentation
  - Total Population and Treatment Arms 1, 2, 3, 4
    - Asymptomatic (NR/NA)
    - Atypical leg pain (NR/NA)
    - Intermittent claudication (NR/NA)
    - Critical limb ischemia (NR/NA)
    - Mixed (specify) (NR/NA)
- Other socioeconomic factors: Yes/No
  - If yes: Specify the factor(s) and categories/units
  - If yes: Enter the characteristics as reported (e.g. range, mean and standard deviation, etc.)
- Comments (if needed)

## Intervention Characteristics

- Briefly indicate which population/intervention combination is reflected by the data abstracted
  - Treatment Arms 1, 2, 3, 4
    - Population
      - Asymptomatic patients
      - Symptomatic patients with atypical leg symptoms
      - Patients with intermittent claudication
      - Patients with critical limb ischemia
      - Other (specify)
      - NR/NA
    - Intervention
      - Aspirin or antiplatelet agents
      - Cilostazol or pentoxifylline
      - Exercise training
      - Endovascular intervention
      - Surgical revascularization
      - Control/placebo
      - Other
      - NR/NA
- Intervention Characteristics: Describe the intervention received by patients in Treatment Arm 1, Treatment Arm 2, Treatment Arm 3, and Treatment Arm 4 (if applicable)
- Cointerventions
  - Acetylsalicylic acid (ASA); Additional antiplatelet agents (e.g. clopidogrel, prasugrel, ticagrelor); Antithrombin drugs (e.g. LMWH, unfractionated heparin, bivalirudin); Glycoprotein IIb/IIIa inhibitors; Thrombolytic/fibrinolytic drugs; Statins/lipid-lowering drugs; Beta-blockers; ACEIs/ARBs; Calcium channel blockers; Nitrates; Other (specify); NR/NA
- Medical Therapy Intervention(s)
  - Treatment Arm 1, 2, 3, 4 (NA)
    - Clopidogrel
      - Yes/No
      - Loading dose
      - Maintenance dose
      - Timing
      - Duration of treatment
    - Prasugrel
      - Yes/No
      - Loading dose
      - Maintenance dose
      - Timing
      - Duration of treatment
    - Ticagrelor
      - Yes/No
      - Loading dose

- Maintenance dose
  - Timing
  - Duration of treatment
- Cilostazol
  - Yes/No
  - Loading dose
  - Maintenance dose
  - Timing
  - Duration of treatment
- Pentoxifylline
  - Yes/No
  - Loading dose
  - Maintenance dose
  - Timing
  - Duration of treatment
- Aspirin
  - Yes/No
  - Loading dose
  - Maintenance dose
  - Timing
  - Duration of treatment
- Glycoprotein IIb/IIIa (abciximab, eptifibatide, tirofiban)
  - Yes/No
  - Loading dose
  - Maintenance dose
  - Timing
  - Duration of treatment
- Dipyridamole
  - Yes/No
  - Loading dose
  - Maintenance dose
  - Timing
  - Duration of treatment
- Other #1, #2, #3 (specify)
  - Yes/No
  - Loading dose
  - Maintenance dose
  - Timing
  - Duration of treatment
- Exercise Therapy
  - Treatment Arm 1, 2, 3, 4
    - Exercise therapy type
      - Walking
      - Strength

- Combined
  - Other
  - NR/NA
- Exercise therapy duration
- Protocol used
- Supervision status
  - Supervised
  - Home
  - NR/NA
- Endovascular Revascularization Procedural Characteristics
  - Treatment Arm 1, 2, 3, 4
    - Complete revascularization achieved
    - Vessels treated (mean)
      - Mean/median
      - SD/SE/IQR
      - 1
      - 2
      - Unclear/Not specified
    - Interventional approach
      - Balloon
        - N or %
        - Type
          - Drug coated
          - Cutting
          - Cryoplasty
          - Standard
          - Other (specify)
      - Atherectomy
        - N or %
        - Type
          - Laser
          - Orbital
          - Rotational
          - Directional
          - Other (specify)
      - Stents
        - N or %
        - Type
          - Drug-eluting
          - Self-expandable open cell
          - Balloon expandable open cell
          - Closed cell (covered)
          - Other (specify)
          - NR
    - Stents used (mean)

- Mean/median
  - SD/SE/IQR
  - 0
  - 1
  - 2
  - More than 2
  - Unclear/not specified
- Surgical Revascularization Procedural Characteristics
  - Treatment Arm 1, 2, 3, 4
    - Type of surgery
      - Axillofem or axillo bifem
      - Aortofem or aorto bifem
      - Fem-fem
      - Fem-pop
      - Fem-distal
      - Other (specify)
    - Type of grafts
      - Vein (native)
      - Synthetic
      - Composite
      - Cadaveric
    - Grafts used (mean)
      - Mean/median
      - SD/SE/IQR
      - 0
      - 1
      - 2
      - Greater than 2

### **Individual Outcomes**

- Select the outcome reported: Total mortality, Cardiovascular mortality, Nonfatal myocardial infarction, Stroke, Repeat revascularization, Hospitalization, Length of hospital stay, Discharge status, Cost of hospital stay, Bleeding, Quality of life, Adverse drug reactions, Vessel patency, Wound healing, Pain, Major Amputation, Minor Amputation, Contrast nephropathy, Radiation, Infection, Exercise-related harms, Periprocedural complications, Maximal Walking distance, Peak Walking Time, Mean or 6-minute walking time, Claudication onset time, Absolute claudication distance, Mean claudication distance, Other 1, 2, 3, 4
  - Additional/alternate outcome name (if applicable)
  - Authors' definition of outcome (if applicable)
  - Was the post-procedure success rate measured? Yes/No/Unknown
    - If yes: Post-procedure success rate
  - Was the outcome reported at the patient level or limb level? Patient level/limb level/Other (specify)/(NR/NA)
  - Complete tables (1-5) to provide data for this outcome/time point(s).

- Timing of the outcome data reported in the table: Short term  $\leq 30$  days/ Intermediate term  $> 30$  days and  $\leq 1$  year/Long-term  $> 1$  year
  - If short term: In-hospital/30 days/Other (specify)
  - If intermediate term: 6 weeks/6 months/1 year/Other (specify)
  - If long term: 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, Age, Sex, Race/ethnicity, Comorbidity(ies) (specify), Bodyweight/BMI, Risk factors (smoking), PAD classification, Anatomy-specific factor (disease burden, location/pattern of stenosis, degree of calcification, # of below knee vessel runoff), Hospital characteristics (patient volume, setting, guideline-based treatment protocol), Other (specify all)
- For each reported group (Antiplatelet therapy, Exercise therapy, Endovascular revascularization, Surgical revascularization, Medication, Other, NR/NA) record the following:
  - 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
      - LL (25% if IQR)
      - UL (75% if IQR)
    - Other %CI
      - LL (25% if IQR)
      - UL (75% if IQR)
    - IQR
      - LL (25% if IQR)
      - UL (75% if IQR)
  - p-value between tx groups
  - Reference group (for comparisons between tx groups)
    - Treatment Arm 1, Treatment Arm 2, Treatment Arm 3, Treatment Arm 4, No Comparison
  - Comments (if needed)

## Composite Outcomes

- Composite outcome data #1, #2, #3, #4
  - Is this a Primary or Secondary composite outcome? Primary/Secondary/Unclear
  - Indicate the components that make up this composite outcome (check all that apply): Total mortality, Cardiovascular mortality, Nonfatal myocardial infarction, Stroke, Repeat revascularization, Hospitalization, Length of hospital stay, Discharge status, Cost of hospital stay, Bleeding, Quality of life, Adverse drug reactions, Vessel patency, Wound healing, Pain, Major Amputation, Minor Amputation, Contrast nephropathy, Radiation, Infection, Exercise-related harms, Periprocedural complications, Maximal Walking distance, Peak Walking Time, Mean or 6-minute walking time, Claudication onset time, Absolute claudication distance, Mean claudication distance, Other 1, 2, 3, 4
  - Was the outcome reported at the patient level or limb level?
  - Complete tables (1-5) to provide data for this outcome/time point(s).
    - Timing of the outcome data reported in the table: Short term  $\leq 30$  days/ Intermediate term  $> 30$  days and  $\leq 1$  year/Long-term  $> 1$  year
      - If short term: In-hospital/30 days/Other (specify)
      - If intermediate term: 6 weeks/6 months/1 year/Other (specify)
      - If long term: 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, Age, Sex, Race/ethnicity, Comorbidity(ies) (specify), Bodyweight/BMI, Risk factors (smoking), PAD classification, Anatomy-specific factor (disease burden, location/pattern of stenosis, degree of calcification, # of below knee vessel runoff), Hospital characteristics (patient volume, setting, guideline-based treatment protocol), Other (specify all)
    - For each reported group (Antiplatelet therapy, Exercise therapy, Endovascular revascularization, Surgical revascularization, Medication, Other, NR/NA) record the following:
      - 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

- LL (25% if IQR)
    - UL (75% if IQR)
  - Other %CI
    - LL (25% if IQR)
    - UL (75% if IQR)
  - IQR
    - LL (25% if IQR)
    - UL (75% if IQR)
- p-value between tx groups
- Reference group (for comparisons between tx groups)
  - Treatment Arm 1, Treatment Arm 2, Treatment Arm 3, Treatment Arm 4, No Comparison
- Comments (if needed)

### Quality Assessment

- Was this study randomized? Yes/No
  - If yes:
    - Were study subjects randomized? Yes/No/Unclear
    - Was the randomization process described? Yes/No/Unclear
    - Was the outcome assessor blinded to study assignment? Yes/No/Unclear
    - Were patients blinded to study intervention? Yes/No/Unclear
    - Were results adjusted for clustering? Yes/No/Unclear
    - Were measures of outcomes based on validated procedures or instruments? Yes/No/Unclear
    - Conducted an intent to treat analysis? Yes/No/Unclear
    - Were all outcomes reported (i.e. was there evidence of selective outcome reporting)? Yes/No/Unclear
    - Were incomplete data adequately addressed (i.e. no systematic difference between groups in withdrawals/loss to follow-up AND no high drop-out or loss to follow-up rate [ $>30\%$ ])? Yes/No/Unclear
    - Was there adequate power (either based on pre-study or post-hoc power calculations [80% power for primary outcome])? Yes/No/Unclear
    - Were systematic differences observed in baseline characteristics and prognostic factors across the groups compared? Yes/No/Unclear
    - Were comparable groups maintained (Includes crossovers, adherence, and contamination. Consider issues of crossover [e.g. from one intervention to another], adherence [major differences in adherence to the interventions being compared], contamination [e.g. some members of control group get intervention], or other systematic difference in care that was provided.)? Yes/No/Unclear
    - Was there absence of potential important conflict-of-interest (Focus on financial conflicts with for-profit capacities; government or non-profit funding = 'yes')? Yes/No/Unclear



- not clearly described; analysis adjusted for some)/No (important baseline differences; unadjusted analysis)/Insufficient reporting to be able to determine
- Comparison Group
  - Is the selection of the comparison group appropriate? Yes/No/Cannot determine (no description of the derivation of the comparison cohort)/NA (study does not include a comparison cohort – case series, one-arm study)
- Performance Bias
  - Intervention implementation
    - What is the level of detail in describing the intervention or exposure? High (very clear, all PI-required details provided)/Medium (somewhat clear, majoring of PI-required details provided)/Low (unclear, many PI-required details missing)
  - Concurrent/concomitant interventions
    - Did researchers isolate the impact from a concurrent intervention or unintended exposure that might bias the results, e.g., through multivariate analysis, stratification, or subgroup analysis? Yes/Partially (only some concurrent interventions eliminated)/Not described
- Attrition Bias
  - Equality of length of follow-up for participants
    - In cohort studies, is the length of follow-up different between groups? Yes/No or cannot determine/not applicable (cross-sectional or only one group followed over time)
  - Completeness of follow-up
    - Was there a high rate of differential or overall attrition? Yes/No/Cannot determine
  - Attrition affecting participant composition
    - Did attrition result in a difference in group characteristics between baseline and follow-up? Yes/No/Cannot determine
  - Any attempt to balance
    - Any attempt to balance the allocation between groups (e.g. through stratification, matching, propensity scores)? Yes/No/Cannot determine
  - Intention-to-treat analysis
    - Is the analysis conducted on an intention-to-treat (ITT) basis, that is, the intervention allocation status rather than the actual intervention received? Yes/No/Cannot determine/NA (retrospective study)

- Detection Bias
  - Source of information re: outcomes
    - Are procedural outcomes (e.g. vessel patency, wound healing) assessed using valid and reliable measure and implemented consistently across all study participants? Yes/No/Cannot determine (measurement approach not reported)
    - Are event outcomes (e.g. mortality, MI, CVA, repeat revascularization, amputation) assessed using valid and reliable measures and implemented consistently across all study participants? Yes/No/Cannot determine (measurement approach not reported)
    - Are patient-reported outcomes (e.g. pain scores, quality of life) assessed using valid and reliable measures implemented consistently across all study participants? Yes/No/Cannot determine (measurement approach not reported)
    - Are functional capacity outcomes (e.g. walking time/distance, claudication time/distance) assessed using valid and reliable measures, implemented consistently across all study participants? Yes/No/Cannot determine (measurement approach not reported)
- Reporting Bias
  - Are any important primary outcomes missing from the results? Yes/No/Cannot determine/Primary outcomes not pre-specified
- Other risk of bias issues
  - Are the statistical methods used to assess the primary outcomes appropriate to the data? Yes/Partially/No/Cannot determine
  - Power and sample size
    - Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted? Yes/No/NA (primary outcomes statistically significant)
- Overall Rating of the study
  - A “**Low Risk of Bias**” study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses recruitment and eligibility criteria that minimizes selection bias; has a low attrition rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results. These studies will meet the majority of items in each domain.
  - A “**Moderate Risk of Bias**” study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results

of some fair-quality studies are possibly valid, while others are probably valid. These studies will meet the majority of items in most but not all domains.

- A “**High Risk of Bias**” rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

## Appendix C: Quality and Applicability of Included Studies

Table C-1. Quality and applicability for KQ 1: Effectiveness and safety of antiplatelet therapy for adults with PAD

Study	Intervention/Comparator	Quality	Limitations to Applicability
<b><i>Aspirin versus placebo or no antiplatelet</i></b>			
Belch, 2008 <sup>1</sup> POPADAD Study	<ul style="list-style-type: none"> <li>• ASA 100 mg daily</li> <li>• Placebo</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Catalano, 2007 <sup>2</sup> CLIPS Study	<ul style="list-style-type: none"> <li>• ASA 100 mg daily</li> <li>• Placebo</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• None</li> </ul>
Fowkes, 2010 <sup>3</sup>	<ul style="list-style-type: none"> <li>• ASA 100 mg daily</li> <li>• Placebo</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Mahmood, 2003 <sup>4</sup>	<ul style="list-style-type: none"> <li>• ASA</li> <li>• No ASA</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> </ul>
<b><i>Clopidogrel/aspirin comparisons</i></b>			
Anonymous, 1996 <sup>5</sup> CAPRIE Study	<ul style="list-style-type: none"> <li>• Clopidogrel 75 mg plus ASA 325 mg daily</li> <li>• Placebo plus ASA 325 mg daily</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Belch, 2010 <sup>6</sup> CASPAR Study	<ul style="list-style-type: none"> <li>• Clopidogrel 75 mg plus ASA 75-100 mg daily</li> <li>• Placebo plus ASA 75-100 mg daily</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Cacoub, 2009 <sup>7</sup> Bhatt, 2007 <sup>8</sup> CHARISMA Study	<ul style="list-style-type: none"> <li>• Clopidogrel 75 mg plus ASA 75-162 mg daily</li> <li>• Placebo plus ASA 75-162 mg daily</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Cassar, 2005 <sup>9</sup>	<ul style="list-style-type: none"> <li>• Clopidogrel 75 mg plus ASA 75 mg daily</li> <li>• Placebo plus ASA 75 mg daily</li> </ul>	Good	<ul style="list-style-type: none"> <li>• Study did not use a clinically relevant surrogate outcome where applicable.</li> </ul>
<b><i>Other antiplatelet comparisons</i></b>			
Horrocks, 1997 <sup>10</sup>	<ul style="list-style-type: none"> <li>• ASA 300 mg daily</li> <li>• No antiplatelet</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>• Duration of participant followup was inadequate.</li> </ul>
Minar, 1995 <sup>11</sup>	<ul style="list-style-type: none"> <li>• ASA 1000 mg daily</li> <li>• ASA 100 mg daily</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>• Study was conducted only at a single site.</li> </ul>

Abbreviations: ASA=acetylsalicylic acid (aspirin)

**Table C-2. Quality and applicability for KQ 2: Effectiveness and safety exercise, medical therapy, and endovascular and surgical revascularization for intermittent claudication**

Study	Intervention/Comparator	Quality	Limitations to Applicability
<b>Medical therapy versus usual care</b>			
Beebe, 1999 <sup>12</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Cilostazol 50 mg twice daily</li> <li>• Placebo</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Belcaro, 2002 <sup>13</sup>	<ul style="list-style-type: none"> <li>• Pentoxifylline 400 mg four times daily</li> <li>• Placebo</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>• Study's cointerventions did not adequately reflect routine clinical practice (e.g., use of medical therapy for secondary prevention – antiplatelet agents, HTN/DM/lipid control).</li> <li>• Study conducted solely outside the US.</li> </ul>
Dawson, 1998 <sup>14</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Placebo</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Dawson, 2000 <sup>15</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Pentoxifylline 400 mg three times daily</li> <li>• Placebo</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• None</li> </ul>
De Sanctis, 2002 <sup>16,17</sup>	<ul style="list-style-type: none"> <li>• Pentoxifylline 600 mg three times daily</li> <li>• Placebo</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study did not report participants' comorbid conditions.</li> <li>• Participant diagnosis and identification for eligibility screening before random allocation was not appropriate/Cohort selection was not appropriate.</li> <li>• Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>• Study conducted solely outside the US.</li> </ul>
Hiatt, 2008 <sup>18</sup> Stone, 2008 <sup>19</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Placebo</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
CASTLE Study Hobbs, 2007 <sup>20</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily + best medical therapy</li> <li>• Best medical therapy</li> </ul>	Good	<ul style="list-style-type: none"> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Money, 1998 <sup>21</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Placebo</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study did not report participants' comorbid conditions.</li> </ul>
Soga, 2009 <sup>22</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Placebo</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Strandness, 2002 <sup>23</sup>	<ul style="list-style-type: none"> <li>• Cilostazol 100 mg twice daily</li> <li>• Cilostazol 50 mg twice daily</li> <li>• Placebo</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• None</li> </ul>

Study	Intervention/Comparator	Quality	Limitations to Applicability
<b>Exercise training versus usual care</b>			
Bronas, 2011 <sup>24</sup>	<ul style="list-style-type: none"> <li>Supervised exercise</li> <li>Control</li> </ul>	Good	<ul style="list-style-type: none"> <li>None</li> </ul>
Crowther, 2008 <sup>25</sup>	<ul style="list-style-type: none"> <li>Supervised Exercise</li> <li>Control</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Gardner, 2011 <sup>26</sup>	<ul style="list-style-type: none"> <li>Supervised exercise</li> <li>Home exercise</li> <li>Control</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study was conducted only at a single site.</li> </ul>
Gelin, 2001 <sup>27</sup>	<ul style="list-style-type: none"> <li>Supervised exercise</li> <li>Control</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Gibellini, 2000 <sup>28</sup>	<ul style="list-style-type: none"> <li>Supervised exercise</li> <li>Control</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Participant diagnosis and identification for eligibility screening before random allocation was not appropriate/Cohort selection was not appropriate.</li> <li>Study eligibility criteria were poorly described or not appropriate.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Hobbs, 2006 <sup>29</sup> EXACT Study	<ul style="list-style-type: none"> <li>Supervised Exercise + BMT</li> <li>Best Medical Therapy (BMT)</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Hobbs, 2007 <sup>20</sup> INEXACT Study	<ul style="list-style-type: none"> <li>Supervised Exercise + BMT</li> <li>Best Medical Therapy (BMT)</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Lee, 2007 <sup>30</sup>	<ul style="list-style-type: none"> <li>Supervised exercise</li> <li>Medical therapy</li> </ul>	Poor	<ul style="list-style-type: none"> <li>Study did not report participants' baseline characteristics.</li> <li>Study did not report participants' comorbid conditions.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Murphy, 2012 <sup>31</sup> CLEVER Study	<ul style="list-style-type: none"> <li>Supervised Exercise + optimal medical therapy</li> <li>Optimal Medical Therapy (optimal medical therapy)</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> </ul>

<b>Study</b>	<b>Intervention/Comparator</b>	<b>Quality</b>	<b>Limitations to Applicability</b>
Sugimoto, 2010 <sup>32</sup>	<ul style="list-style-type: none"> <li>Supervised exercise + medical therapy</li> <li>Medical therapy</li> </ul>	Poor	<ul style="list-style-type: none"> <li>Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>Comparator(s) not well described.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Tsai, 2002 <sup>33</sup>	<ul style="list-style-type: none"> <li>Supervised exercise</li> <li>Control</li> </ul>	Poor	<ul style="list-style-type: none"> <li>Study did not report participants' comorbid conditions.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
<b><i>Endovascular intervention versus usual care</i></b>			
Feinglass, 2000 <sup>34</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Medical therapy</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study exclusion criteria were poorly described or not appropriate.</li> <li>Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>Diagnostic or therapeutic advances have been made in routine practice since the study was conducted.</li> <li>Comparator(s) not well described.</li> </ul>
Gelin, 2001 <sup>27</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Control</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Hobbs, 2006 <sup>29</sup> EXACT Study	<ul style="list-style-type: none"> <li>Endovascular revascularization + best medical therapy</li> <li>Best medical therapy</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Hobbs, 2007 <sup>20</sup> INEXACT Study	<ul style="list-style-type: none"> <li>Endovascular revascularization + best medical therapy</li> <li>Best medical therapy</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Koivunen, 2008 <sup>35</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Control</li> </ul>	Poor	<ul style="list-style-type: none"> <li>Comparator(s) not well described.</li> <li>Study did not use a clinically relevant surrogate outcome where applicable.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Murphy, 2012 <sup>31</sup> CLEVER Study	<ul style="list-style-type: none"> <li>Endovascular revascularization + optimal medical therapy</li> <li>Optimal medical therapy</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> </ul>

<b>Study</b>	<b>Intervention/Comparator</b>	<b>Quality</b>	<b>Limitations to Applicability</b>
Nylen, 2007 <sup>36</sup> OBACT Study	<ul style="list-style-type: none"> <li>Endovascular revascularization + optimal medical therapy</li> <li>Optimal medical therapy</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Pell, 1997 <sup>37</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Conservative treatment</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study did not report participants' baseline characteristics.</li> <li>Study did not report participants' comorbid conditions.</li> <li>Study exclusion criteria were poorly described or not appropriate.</li> <li>Comparator(s) not well described.</li> <li>Study conducted solely outside the US.</li> </ul>
Whyman, 1997 <sup>38</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization + optimal medical therapy</li> <li>Control</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
<b><i>Endovascular intervention versus exercise training</i></b>			
Gelin, 2001 <sup>27</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Supervised exercise</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Greenhalgh, 2008 <sup>39</sup> MIMIC Study	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Supervised exercise</li> </ul>	Fair	<ul style="list-style-type: none"> <li>None</li> </ul>
Hobbs, 2006 <sup>29</sup> EXACT Study	<ul style="list-style-type: none"> <li>Supervised Exercise + BMT</li> <li>Endovascular Revascularization + BMT</li> </ul>	Fair	<ul style="list-style-type: none"> <li>Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Hobbs, 2007 <sup>20</sup> INEXACT Study	<ul style="list-style-type: none"> <li>Supervised Exercise + BMT</li> <li>Endovascular Revascularization + BMT</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Kruidenier, 2011 <sup>40</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Endovascular revascularization + supervised exercise</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Mazari, 2012 <sup>41</sup> Mazari, 2010 <sup>42</sup>	<ul style="list-style-type: none"> <li>Endovascular revascularization</li> <li>Endovascular revascularization + supervised exercise</li> <li>Supervised exercise</li> </ul>	Good	<ul style="list-style-type: none"> <li>Comparator(s) not well described.</li> <li>Study conducted solely outside the US.</li> <li>Study was conducted only at a single site.</li> </ul>
Murphy, 2012 <sup>31</sup> CLEVER Study	<ul style="list-style-type: none"> <li>Supervised exercise + optimal medical therapy</li> <li>Endovascular revascularization + optimal medical therapy</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> </ul>
Nordanstig, 2011 <sup>43</sup>	<ul style="list-style-type: none"> <li>Revascularization (surgical or endovascular) + optimal medical therapy</li> <li>Optimal medical therapy</li> </ul>	Good	<ul style="list-style-type: none"> <li>Study conducted solely outside the US.</li> </ul>

<b>Study</b>	<b>Intervention/Comparator</b>	<b>Quality</b>	<b>Limitations to Applicability</b>
Perkins, 1996 <sup>44</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Supervised exercise</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Diagnostic or therapeutic advances have been made in routine practice since the study was conducted.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Spronk, 2009 <sup>45</sup> Spronk, 2008 <sup>46</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Supervised exercise</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
<b><i>Endovascular intervention versus surgical revascularization</i></b>			
Feinglass, 2000 <sup>34</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>• Diagnostic or therapeutic advances have been made in routine practice since the study was conducted.</li> <li>• Comparator(s) not well described.</li> </ul>
Koivunen, 2008 <sup>35</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Comparator(s) not well described.</li> <li>• Study did not use a clinically relevant surrogate outcome where applicable.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Pell, 1997 <sup>37</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Comparator(s) not well described.</li> <li>• Study conducted solely outside the US.</li> </ul>

Abbreviations: BMT=best medical therapy; HTN=hypertension; DM=diabetes mellitus

**Table C-3. Quality and applicability for KQ 3: Effectiveness and safety of endovascular and surgical revascularization for critical limb ischemia and mixed population (IC-CLI)**

Study	Intervention/Comparator	Quality	Limitations to Applicability
<b><i>Endovascular intervention versus usual care</i></b>			
Lawall, 2009 <sup>47</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Usual care</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' severity of disease.</li> <li>• Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>• Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>• Use of substandard alternative therapy (e.g., standard of treatment not from current practice).</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study conducted solely outside the US.</li> </ul>
Kamiya, 2008 <sup>48</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Usual care</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Use of substandard alternative therapy (e.g., standard of treatment not from current practice).</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Varty, 1996 <sup>49</sup> Varty, 1998 <sup>50</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Conservative management</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
<b><i>Endovascular intervention versus surgical revascularization</i></b>			
Adam, 2005 <sup>51</sup> Bradbury, 2010 <sup>52-56</sup> Forbes, 2010 <sup>57</sup>  BASIL Study	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Good	<ul style="list-style-type: none"> <li>• None</li> </ul>
Ah Chong, 2009 <sup>58</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>

Study	Intervention/Comparator	Quality	Limitations to Applicability
Dorigo, 2009 <sup>59</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Dosluoglu, 2010 <sup>60</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> <li>• Hybrid revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>• Study was conducted only at a single site.</li> </ul>
Hoshino, 2010 <sup>61</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Hynes, 2004 <sup>62</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Janne d'Othee, 2008 <sup>63</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study selectively recruited participants who demonstrated a history of favorable or unfavorable response to drug or other interventions for the condition.</li> <li>• Study was conducted only at a single site.</li> </ul>

Study	Intervention/Comparator	Quality	Limitations to Applicability
Jerabek, 2003 <sup>64</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' severity of disease.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study eligibility criteria were poorly described or not appropriate.</li> <li>• Study's cointerventions did not adequately reflect routine clinical practice (e.g., use of medical therapy for secondary prevention – antiplatelet agents, HTN/DM/lipid control).</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Kashyap, 2008 <sup>65</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Khan, 2009 <sup>66</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Comparator(s) not well described.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study was conducted only at a single site.</li> </ul>
Korhonen, 2011 <sup>67</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Good	<ul style="list-style-type: none"> <li>• Study did not report participants' severity of disease.</li> <li>• Study eligibility criteria were poorly described or not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>

Study	Intervention/Comparator	Quality	Limitations to Applicability
Kudo, 2006 <sup>68</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Participant diagnosis and identification for eligibility screening before random allocation was not appropriate/Cohort selection was not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study was conducted only at a single site.</li> </ul>
Laurila, 2000 <sup>69</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• None</li> </ul>
Lepantalo, 2009 <sup>70</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study conducted solely outside the US.</li> </ul>
Loor, 2009 <sup>71</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study was conducted only at a single site.</li> </ul>
McQuade, 2009 <sup>72</sup> McQuade, 2010 <sup>73</sup> Kedora, 2007 <sup>74</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Participant diagnosis and identification for eligibility screening before random allocation was not appropriate/Cohort selection was not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study was conducted only at a single site.</li> </ul>
Rossi, 1998 <sup>75</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study eligibility criteria were poorly described or not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Sachs, 2011 <sup>76</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' severity of disease.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Duration of participant follow-up was inadequate.</li> </ul>

Study	Intervention/Comparator	Quality	Limitations to Applicability
Soderstrom, 2010 <sup>77</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• None</li> </ul>
Stoner, 2008 <sup>78</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study was conducted only at a single site.</li> </ul>
Sultan, 2009 <sup>79</sup> Sultan, 2011 <sup>80</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Participant diagnosis and identification for eligibility screening before random allocation was not appropriate/Cohort selection was not appropriate.</li> <li>• Study eligibility criteria were poorly described or not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Taylor, 2005 <sup>81</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• None</li> </ul>
Taylor, 2006 <sup>82</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' severity of disease.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study eligibility criteria were poorly described or not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study interventions (active arm) were not similar to interventions used in routine clinical practice.</li> <li>• Study was conducted only at a single site.</li> </ul>

<b>Study</b>	<b>Intervention/Comparator</b>	<b>Quality</b>	<b>Limitations to Applicability</b>
Timaran, 2003 <sup>83</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study was conducted only at a single site.</li> </ul>
Varela, 2011 <sup>84</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study centers and/or clinicians were not selected on the basis of their skill or experience.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Varty, 1996 <sup>49</sup> Varty, 1998 <sup>50</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Fair	<ul style="list-style-type: none"> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Venermo, 2011 <sup>85</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• None</li> </ul>
Whatling, 2000 <sup>86</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• Study did not report participants' baseline characteristics.</li> <li>• Study did not report participants' comorbid conditions.</li> <li>• Study eligibility criteria were poorly described or not appropriate.</li> <li>• Study exclusion criteria were poorly described or not appropriate.</li> <li>• Study conducted solely outside the US.</li> <li>• Study was conducted only at a single site.</li> </ul>
Wolfe, 2000 <sup>87</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• None</li> </ul>
Zdanowski, 1998 <sup>88</sup>	<ul style="list-style-type: none"> <li>• Endovascular revascularization</li> <li>• Surgical revascularization</li> </ul>	Poor	<ul style="list-style-type: none"> <li>• None</li> </ul>

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## Appendix D: Study Characteristics Tables

**Table D-1. Study characteristics table for KQ 1: Effectiveness and safety of antiplatelet therapy for adults with PAD**

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>ASYMPTOMATIC OR HIGH-RISK PATIENTS</b>					
<b><i>Aspirin versus placebo or no antiplatelet</i></b>					
Belch, 2008 <sup>1</sup>  POPADAD Study	RCT Single center, UK Funding: Government, Industry  <u>Population</u> Diabetics with PAD  Total N: 636 Mean Age: 60 yr N Female: 363 % Female: 57% Race: Not reported	ASA 100 mg daily (N=318)  Concomitant therapy: Standard therapy: (statins, beta blockers) at discretion of investigator or clinician.	Placebo (N=318)  Concomitant therapy: Standard therapy: (statins, beta blockers) at discretion of investigator or clinician.	Timing: median 6.7 yr  <u>Composite</u> (primary) Cardiovascular mortality Nonfatal myocardial infarction Stroke Major amputation  (secondary) Cardiovascular mortality Fatal stroke  <u>Individual</u> Total mortality Cardiovascular mortality Nonfatal myocardial infarction Stroke Adverse drug reactions Major amputation TIA CLI Intermittent claudication Peripheral revascularization	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Fowkes, 2010 <sup>2</sup>	RCT Setting: Not reported Funding: Nonprofit, Industry  <u>Population</u> Asymptomatic PAD (low ABI) no previous CAD  Total N: 3350 Mean Age: 62 yr N Female: 2396 % Female: 72% Race: Not reported	ASA 100 mg daily (N=1675)  Concomitant therapy: Could include diuretic, beta-blocker, nitrate or calcium channel blocker, ACE inhibitor or ARB, or lipid-lowering agent at discretion of physician	Placebo (N=1675)  Concomitant therapy: Could include diuretic, beta-blocker, nitrate or calcium channel blocker, ACE inhibitor or ARB, or lipid-lowering agent at discretion of physician	Timing: 5 yr, 10 yr  <u>Composite</u> (primary) Cardiovascular mortality Nonfatal myocardial infarction Stroke Initial peripheral revascularization Coronary revascularization  (secondary) Angina Intermittent claudication TIA  <u>Individual</u> Total mortality Cardiovascular mortality Nonfatal myocardial infarction Stroke Bleeding Adverse drug reactions Initial peripheral revascularization TIA Angina Intermittent claudication	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b><i>Clopidogrel/aspirin comparisons</i></b>					
Anonymous, 1996 <sup>3</sup>  CAPRIE Study	RCT Multicenter 384 sites in the US, Canada, and Europe Funding: Industry  <u>Population</u> PAD subset of high-risk vascular population (prior MI, CVA, PAD)  Total N: 6452 Mean Age: 64 yr N Female: 1774 % Female: 28% Race: Not reported	Clopidogrel 75 mg plus placebo daily (N=3223)  Concomitant therapy: None specified	ASA 325 mg daily plus placebo (N=3229)  Concomitant therapy: None specified	Timing: 1 to 3 yr, Mean 1.9 yr  <u>Composite (primary)</u> Cardiovascular mortality Nonfatal myocardial infarction Stroke  <u>Individual</u> Nonfatal myocardial infarction Nonfatal stroke Fatal Stroke Fatal MI Other Vascular Death	Good
Cacoub, 2009 <sup>4</sup> Bhatt, 2007 <sup>5</sup> Berger, 2010 <sup>6</sup>  CHARISMA Study	RCT Multicenter Location: Not reported # sites: Not reported Funding: Not reported  <u>Population</u> PAD subset of high-risk vascular population (prior MI, CVA, PAD)  Total N: 3096 (2838 symptomatic, 258 asymptomatic) Mean Age: Not reported N Female: Not reported % Female: Not reported Race: Not reported	Clopidogrel 75 mg plus ASA 75-162 mg daily (N=1575)  Concomitant therapy: Could include diuretic, beta-blocker, nitrate or calcium channel blocker, ACE inhibitor or ARB, or lipid-lowering agent at discretion of physician	Placebo plus ASA 75-162 mg daily (N=1551)  Concomitant therapy: Could include diuretic, beta-blocker, nitrate or calcium channel blocker, ACE inhibitor or ARB, or lipid-lowering agent at discretion of physician	Timing: 28 mo  <u>Composite (primary)</u> Cardiovascular mortality Nonfatal myocardial infarction Stroke  <u>Individual</u> Total mortality Cardiovascular mortality Stroke Hospitalization Bleeding Myocardial infarction (fatal + nonfatal) Ischemic stroke	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>PATIENTS WITH INTERMITTENT CLAUDICATION</b>					
<b><i>Aspirin versus placebo or no antiplatelet</i></b>					
Catalano, 2007 <sup>7</sup>  CLIPS Study	RCT Multicenter Multiple sites in Europe Funding: Industry  <u>Population</u> Asymptomatic PAD or IC  Total N: 181 (Claudication= 142 Asymptomatic=39) Mean Age: 65 yr N Female: 40 % Female: 22% Race: Not reported	ASA 100 mg daily (N=91)  Concomitant therapy: Anti-oxidants (600 mg vitamin E, 250 mg vitamin C and 20 mg beta-carotene) daily	Placebo (N=90)  Concomitant therapy: Anti-oxidants (600 mg vitamin E, 250 mg vitamin C and 20 mg beta-carotene) daily	Timing: 2 yr  <u>Composite</u> Stroke Myocardial infarction Vascular death  <u>Individual</u> Cardiovascular mortality Nonfatal myocardial infarction Stroke Bleeding Nonvascular Death Hemorrhagic stroke Ischemic stroke	Fair
<b><i>Clopidogrel/aspirin comparisons</i></b>					
Cassar, 2005 <sup>8</sup>	RCT Single center, UK Funding: Nonprofit, Industry  <u>Population</u> IC for endovascular procedure  Total N: 132 Mean Age: 66 yr N Female: 30 % Female: 23% Race: Not reported	Loading dose clopidogrel 300mg then clopidogrel 75 mg plus ASA 75 mg daily (N=67)  Concomitant therapy: None specified	Loading dose of placebo then placebo plus ASA 75 mg daily (N=65)  Concomitant therapy: None specified	Timing: 30 days  <u>Composite</u> None  <u>Individual</u> Adverse drug reactions	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>PATIENTS WITH CRITICAL LIMB ISCHEMIA</b>					
<i>Aspirin versus placebo or no antiplatelet</i>					
Mahmood, 2003 <sup>9</sup>	Retrospective cohort Single center, UK Funding: Not reported  <u>Population</u> CLI for infrainguinal bypass  Total N: 113 Mean Age: 72 yr N Female: Not reported % Female: Not reported Race: Not reported	ASA (N=79; 47 preop, 32 postop)  Concomitant therapy: None specified	No ASA (N=34)  Concomitant therapy: None specified	Timing: 2 yr  <u>Composite</u> None  <u>Individual</u> Cardiovascular mortality Nonfatal myocardial infarction Stroke Vessel patency	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>PATIENTS WITH IC or CLI</b>					
<b><i>Clopidogrel/aspirin comparisons</i></b>					
Belch, 2010 <sup>10</sup>  CASPAR Study	RCT Multicenter 87 sites in Europe, Australia, and New Zealand Funding: Industry  <u>Population</u> IC-CLI (undergoing unilateral below the knee bypass)  Total N: 851 Mean Age: 66 yr N Female: 207 % Female: 24% Race: Not reported	Clopidogrel 75 mg plus ASA 75-100 mg daily (N=425)  Concomitant therapy: High-dose unfractionated heparin (UFH) or low molecular weight heparin (LMWH) was used during surgery and was permitted for use for prevention of DVT when indicated	Placebo plus ASA 75-100 mg daily (N=426)  Concomitant therapy: High-dose unfractionated heparin (UFH) or low molecular weight heparin (LMWH) was used during surgery and was permitted for use for prevention of DVT when indicated	Timing: 1 yr, 2 yr  <u>Composite</u> (primary) Total mortality Repeat revascularization Major amputation Occlusion of index bypass graft  (secondary) Repeat revascularization Major amputation Occlusion of graft  (secondary) Cardiovascular mortality Nonfatal myocardial infarction Stroke  <u>Individual</u> Total mortality Cardiovascular mortality Nonfatal myocardial infarction Stroke Bleeding Major amputation Occlusion of index bypass graft	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>Other antiplatelet comparisons</b>					
Horrocks, 1997 <sup>11</sup>	<p>RCT (open label) 2 UK university hospitals Funding: Not reported</p> <p><u>Population</u> IC or CLI after femoral PTA</p> <p>Total N: 38 Mean Age: 68 yr N Female: 12 % Female: 32% Race: Not reported</p>	<p>ASA 300 mg daily (N=13)</p> <p>Iloprost 2.0 ng/kg/min x 3 days, then ASA 300 mg daily (N=11)</p> <p>Concomitant therapy: None specified</p>	<p>No antiplatelet (N=14)</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 3 mo, 1 yr</p> <p><u>Composite</u> None</p> <p><u>Individual</u> Restenosis Reocclusion</p>	Fair
Minar, 1995 <sup>12</sup>	<p>RCT Single center, Austria Funding: Not reported</p> <p><u>Population</u> IC or CLI for femoropopliteal PTA</p> <p>Total N: 216 Mean Age: 66 yr N Female: 95 % Female: 44% Race: Not reported</p>	<p>ASA 1000 mg daily (N=107)</p> <p>Concomitant therapy: 500 mg aspirin IV at least 1 hour before the planned procedure, and the same dosage was applied for 2 additional days. During the intervention 5000 IU heparin was administered and the patients also received heparin intravenously for 3 days starting at a dosage of 1000 IU/h and was adjusted twice daily according to the thrombin time (prolongation to at least three times the normal value).</p>	<p>ASA 100 mg daily (N=109)</p> <p>Concomitant therapy: 500 mg aspirin IV at least 1 hour before the planned procedure, and the same dosage was applied for 2 additional days. During the intervention 5000 IU heparin was administered and the patients also received heparin intravenously for 3 days starting at a dosage of 1000 IU/h and was adjusted twice daily according to the thrombin time (prolongation to at least three times the normal value).</p>	<p>Timing: 24 mo</p> <p><u>Composite</u> None</p> <p><u>Individual</u> Total mortality Vessel patency</p>	Fair

**Table D-2. Study characteristics table for KQ 2: Effectiveness and safety of exercise, medications, and endovascular and surgical revascularization for IC**

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>Medical therapy versus usual care</b>					
Beebe, 1999 <sup>13</sup>	<p>RCT Multicenter 37 sites in US Funding: industry</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 516 Mean Age: 65 yr N Female: 124 % Female: 24% Race: 9.1% African American, 0.4% Asian, 88.6% White, 1.9% Other</p>	<p>Cilostazol 100 mg twice daily (N=175) 50 mg twice daily (N=171)</p> <p>Concomitant therapy: None specified</p>	<p>Placebo (N=170)</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 6 mo</p> <p><u>Individual</u> Mortality Myocardial infarction Stroke QOL Amputation MWD PFWD</p>	Good
Belcaro, 2002 <sup>14</sup>	<p>RCT Multicenter Multiple centers in Europe Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 60 Mean Age: 56 yr N Female: 29 % Female: 54.7% Race: NR</p>	<p>Pentoxifylline 400 mg four times daily (N=27)</p> <p>Concomitant therapy: Antiplatelet treatment 300mg daily</p>	<p>Placebo (N=26)</p> <p>Concomitant therapy: Antiplatelet treatment 300mg daily</p>	<p>Timing: 2 wk, 3 mo, 6 mo</p> <p><u>Individual</u> MWD</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Dawson, 1998 <sup>15</sup>	<p>RCT Multicenter 3 sites in US Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 81 Mean Age: 67 yr N Female: 19 % Female: 23.4% Race: 1% African American, 99% White</p>	<p>Cilostazol 100 mg twice daily (N=54)</p> <p>Concomitant therapy: Could include ACE inhibitors, beta-blockers, or calcium channel blockers,</p>	<p>Placebo (N=27)</p> <p>Concomitant therapy: Could include ACE inhibitors, beta-blockers, or calcium channel blockers,</p>	<p>Timing: 2 wk, 4 wk, 8 wk, 12 wk</p> <p><u>Individual</u> ACD ICD Adverse events</p>	Good
Dawson, 2000 <sup>16</sup>	<p>RCT Multicenter 54 sites in US Funding: Otsuka America Pharmaceuticals</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 699 Mean Age: 66 yr N Female: 169 % Female: 24.2% Race: NR</p>	<p>Cilostazol 100 mg twice daily (N=227), pentoxifylline 400 mg three times daily (232 patients)</p> <p>Concomitant therapy: None specified</p>	<p>Placebo (N=239)</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 4 wk, 8 wk, 12 wk, 16 wk, 24 wk</p> <p><u>Individual</u> MWD PFWD Change in ABI</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
De Sanctis, 2002 <sup>17,18</sup> Cesarone, 2002 <sup>19</sup>	RCT Multicenter Multiple centers in Europe Funding: independent  <u>Population</u> PAD patients with IC  Total N: 194 Mean Age: 64 yr N Female: 51 % Female: 37.8% Race: NR	Pentoxifylline 600 mg three times daily (N=75)  Concomitant therapy: None specified	Placebo (N=60)  Concomitant therapy: None specified	Timing: 6 mo, 12 mo  <u>Individual</u> Total Walking Distance	Fair
Hiatt, 2008 <sup>20</sup> Stone, 2008 <sup>21</sup>  CASTLE Study	RCT Multicenter 117 sites in US Funding: industry  <u>Population</u> PAD patients with IC  Total N: 1439 Mean Age: 66 yr N Female: 495 % Female: 34.4% Race: 80% White, 4% Hispanic, 16% African American, 1% Other	Cilostazol 100 mg twice daily (N=717)  Concomitant therapy: Could include aspirin, clopidogrel, statin or warfarin	Placebo (N=718)  Concomitant therapy: Could include aspirin, clopidogrel, statin or warfarin	Timing: 36 mo  <u>Composite</u> (primary) Stroke TIA Carotid revascularization  <u>Individual</u> Mortality Stroke Adverse events	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Hobbs, 2007 <sup>22</sup>  INEXACT Study	RCT Single center Location: England Funding: NR  <u>Population</u> PAD patients with IC  Total N: 38 Median Age: 67 yr N Female: 7 % Female: 30.4% Race: NR	Cilostazol 100 mg twice daily + best medical therapy (N=9)  Best Medical Therapy (BMT): Smoking cessation via repeated advice and/or nicotine replacement / bupropion/smoking cessation classes; statin therapy for 25% reduction in cholesterol; aspirin 75 mg daily or clopidogrel 75 mg daily if intolerant of aspirin; tx/screen for diabetes; blood pressure < 140/85; ACE-I considered for all patients; and written advice regarding exercise	Best medical therapy (N=9)  Best Medical Therapy (BMT): Smoking cessation via repeated advice and/or nicotine replacement / bupropion/smoking cessation classes; statin therapy for 25% reduction in cholesterol; aspirin 75 mg daily or clopidogrel 75 mg daily if intolerant of aspirin; tx/screen for diabetes; blood pressure < 140/85; ACE-I considered for all patients; and written advice regarding exercise	Timing: 3 mo, 6 mo  <u>Individual</u> Adverse drug reaction Change in ABI ACD ICD	Good
Money, 1998 <sup>23</sup>	RCT Multicenter 17 sites in US Funding: NR  <u>Population</u> PAD patients with IC  Total N: 239 Mean Age: 65 yr N Female: 59 % Female: 24.6% Race: 9% African American, 0.4% Asian, 87% White, 3.6% Other	Cilostazol 100 mg twice daily (N=119)  Concomitant therapy: None specified	Placebo (N=120)  Concomitant therapy: None specified	Timing: 8 wk, 12 wk, 16 wk  <u>Individual</u> Mortality QOL Adverse events ACD	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Soga, 2009 <sup>24</sup>	<p>RCT Multicenter Multiple centers in Asia Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 78 Mean Age: 71 yr N Female: 13 % Female: 16.7% Race: NR</p>	<p>Cilostazol 100 mg twice daily (N=39)</p> <p>Concomitant therapy: Percutaneous transluminal angioplasty +/- stent ASA 81-100mg daily +/- ticlopidine 200mg daily (in some stent patients). Also could include statin, beta-blocker, ACE inhibitor or ARB.</p>	<p>Placebo (N=39)</p> <p>Concomitant therapy: Percutaneous transluminal angioplasty +/- stent ASA 81-100mg daily +/- ticlopidine 200mg daily (in some stent patients). Also could include statin, beta-blocker, ACE inhibitor or ARB.</p>	<p>Timing: 24 mo</p> <p><u>Composite</u> (secondary) Total mortality Cardiovascular mortality Nonfatal myocardial infarction Stroke Repeat revascularization Major amputation Minor amputation</p> <p><u>Individual</u> Mortality Myocardial infarction Stroke Repeat revascularization Bleeding Amputation</p>	Good
Strandness, 2002 <sup>25</sup>	<p>RCT Multicenter 34 sites in US Funding: industry</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 394 Mean Age: 64 yr N Female: 94 % Female: 24% Race: 86.3% White</p>	<p>Cilostazol 100 mg twice daily (N=133) 50 mg twice daily (N=132)</p> <p>Concomitant therapy: None specified</p>	<p>Placebo (N=129)</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 6 mo</p> <p><u>Composite</u> (secondary) Total mortality Cardiovascular mortality</p> <p><u>Individual</u> MWD Adverse drug reactions</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>Exercise training versus usual care</b>					
Bronas, 2011 <sup>26</sup>	<p>RCT Single center Location: US (MN) Funding: American Heart Association</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 45 Mean Age: 68 yr N Female: 11 % Female: 25% Race: 85% White</p>	<p>Supervised exercise (N=20)</p> <p>Treadmill walking group: 3x/wk for 12 weeks</p> <p>Arm-ergometry cycle training group: 3x/wk for 12 weeks</p> <p>Concomitant therapy: Could be on cilostazol, antiplatelet agent, lipid-lowering agent, beta-blocker or ACE inhibitor at discretion of physician</p>	<p>Control (N=8)</p> <p>Instructed to follow care given by their physician, received written instructions on how to exercise independently if they chose to do so and were asked to keep a daily record of any exercise</p> <p>Concomitant therapy: Could be on cilostazol, antiplatelet agent, lipid-lowering agent, beta-blocker or ACE inhibitor at discretion of physician</p>	<p>Timing: 12 wk, 24 wk</p> <p><u>Individual</u> MWD PFWD</p>	Good
Crowther, 2008 <sup>27</sup>	<p>RCT Single center Location: Australia Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 21 Mean Age: 69 yr N Female: 12 % Female: 53% Race: NR</p>	<p>Supervised Exercise (N=10)</p> <p>Treadmill walking group: 3x/wk for 12 months</p> <p>Concomitant therapy: Could include beta-blocker</p>	<p>Control (N=11)</p> <p>No specific instructions given</p> <p>Concomitant therapy: Could include beta-blocker</p>	<p>Timing: 12 mo</p> <p><u>Individual</u> PFWT</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Gardner, 2011 <sup>28</sup>	RCT Single center Location: US (OK) Funding: Government  <u>Population</u> PAD patients with IC  Total N: 119 Mean Age: 65 yr N Female: 62 % Female: 52% Race: 57% White	Supervised exercise (N=40); Home exercise (N=40)  Supervised treadmill walking group: 3x/wk at specified pace for specified duration of time for 12 weeks  Home treadmill walking group: 3x/wk at self-selected pace for specified duration of time for 12 weeks  Concomitant therapy: None specified	Control (N=39)  Encouraged to walk more on their own but did not receive specific recommendations about an exercise program during the study.  Concomitant therapy: None specified	Timing: 12 wk  <u>Individual</u> Myocardial infarction Stroke QOL PWT COT	Good
Gelin, 2001 <sup>29</sup> Taft, 2001 <sup>30</sup>	RCT Single center Location: Sweden Funding: Government  <u>Population</u> PAD patients with IC  Total N: 264 Mean Age: 67 yr N Female: 91 % Female: 34.3% Race: NR	Supervised exercise (N=88)  Treadmill walking training 3x/wk for 6 months, then 2x/wk  Concomitant therapy: None specified	Control (N=89)  Received no other specific advice or treatment apart from the general advice given to the two treatment groups  Concomitant therapy: None specified	Timing: 12 mo  <u>Individual</u> Mortality QOL Vessel patency Amputation MWD	Fair
Gibellini, 2000 <sup>31</sup>	RCT Study centers: NR Funding: NR  <u>Population</u> PAD patients with IC  Total N: 40 Mean Age: 68 yr N Female: 4 % Female: 10% Race: NR	Supervised exercise (N=20)  Treadmill walking training 5x/wk for 4 weeks  Concomitant therapy: ASA 325mg daily	Control (N=20)  No specific instructions given  Concomitant therapy: ASA 325mg daily	Timing: 1 mo, 6 mo  <u>Individual</u> ACD ICD	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Hobbs, 2006 <sup>32</sup> EXACT Study	RCT Multicenter Location: England Funding: NR  <u>Population</u> PAD patients with IC  Total N: 23 Median Age: 67 yr N Female: 7 % Female: 20.6% Race: NR	Supervised Exercise + BMT(N=7)  Circuit of moderate intensity exercises 2x/wk for 12 weeks  Concomitant therapy: Could include antiplatelet agents, statin, ACE inhibitor or other antihypertensive agent	Best Medical Therapy (BMT) (N=7)  Not defined but could include antiplatelet agents, statin, ACE inhibitor or other antihypertensive agent	Timing: 3 mo, 6 mo  <u>Individual</u> Adverse drug reaction ACD ICD	Fair
Hobbs, 2007 <sup>22</sup> INEXACT Study	RCT Single center Location: England Funding: NR  <u>Population</u> PAD patients with IC  Total N: 38 Median Age: 67 yr N Female: 7 % Female: 30.4% Race: NR	Supervised Exercise + BMT (N=9)  Circuit of moderate intensity exercises 2x/wk for 12 weeks  Best Medical Therapy (BMT): Smoking cessation via repeated advice and/or nicotine replacement / bupropion/smoking cessation classes; statin therapy for 25% reduction in cholesterol; aspirin 75 mg daily or clopidogrel 75 mg daily if intolerant of aspirin; treatment/screen for diabetes; blood pressure < 140/85; ACE-I considered for all patients; and written advice regarding exercise	Best Medical Therapy (BMT) (N=9)  Best Medical Therapy (BMT): Smoking cessation via repeated advice and/or nicotine replacement / bupropion/smoking cessation classes; statin therapy for 25% reduction in cholesterol; aspirin 75 mg daily or clopidogrel 75 mg daily if intolerant of aspirin; treatment/screen for diabetes; blood pressure <140/85; ACE-I considered for all patients; and written advice regarding exercise	Timing: 3 mo, 6 mo  <u>Individual</u> Adverse drug reaction Change in ABI ACD ICD	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Lee, 2007 <sup>33</sup>	<p>Observational Single center Location: England Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 70 Median Age: 68 yr N Female: 22 % Female: 31.4% Race: NR</p>	<p>Supervised exercise (N=33)</p> <p>Circuit of exercises 3x/wk for 12 wk</p> <p>Concomitant therapy: Prescribed an antiplatelet, received smoking cessation advice and support (including nicotine replacement therapy), and risk factor modification (appropriate management of hypertension, hypercholesterolemia and diabetes. All patients also received an advice leaflet regarding exercise.</p>	<p>Conservative medical therapy (N=37)</p> <p>Prescribed an antiplatelet, received smoking cessation advice and support (including nicotine replacement therapy), and risk factor modification (appropriate management of hypertension, hypercholesterolemia and diabetes. All patients also received an advice leaflet regarding exercise.</p>	<p>Timing: 6 mo</p> <p><u>Individual</u> MWD ICD QOL</p>	Poor
<p>Murphy, 2012<sup>34</sup></p> <p>CLEVER Study</p>	<p>RCT Multicenter 22 sites in US and Canada Funding: Government</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 119 Mean Age: 63 yr N Female: 42 % Female: 37.8% Race: NR</p>	<p>Supervised Exercise + optimal medical therapy (N=43)</p> <p>Exercises 3x/wk for 26 wk</p> <p>Concomitant therapy: Could include ASA, thienopyridine, and statin</p>	<p>Optimal Medical Therapy (N=22)</p> <p>Optimal medical therapy: Cilostazol 100mg bid; advice about home exercise and diet</p> <p>Concomitant therapy: Could include ASA, thienopyridine, and statin</p>	<p>Timing: 30 days, 6 mo</p> <p><u>Individual</u> PWT COT QOL Change in ABI Safety</p>	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Sugimoto, 2010 <sup>35</sup>	<p>Observational Single center Location: Japan Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 100 Mean Age: 68 yr N Female: 4 % Female: 4% Race: NR</p>	<p>Supervised exercise + medical therapy (N=61)</p> <p>Treadmill walking 2x/day for 3 weeks plus medical therapy which could include the following medications or combinations: Cilostazol alone or with beraprost, warfarin, or aspirin; beraprost alone or with aspirin or ticlopidine; limaprost alone or with aspirin+ticlopidine; sarpogrelate alone or with ethyl icosapentate or aspirin; aspirin alone or with ticlopidine; warfarin alone</p>	<p>Medical therapy (N=39)</p> <p>Could include the following medications or combinations: Cilostazol alone or with beraprost, warfarin, or aspirin; beraprost alone or with aspirin or ticlopidine; limaprost alone or with aspirin+ticlopidine; sarpogrelate alone or with ethyl icosapentate or aspirin; aspirin alone or with ticlopidine; warfarin alone</p>	<p>Timing: 6 mo</p> <p><u>Individual</u> ACD Change in ABI</p>	Poor
Tsai, 2002 <sup>36</sup>	<p>RCT Multicenter 2 sites in Asia Funding: NR</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 64 Mean Age: 76 yr N Female: 11 % Female: 17% Race: NR</p>	<p>Supervised exercise (N=27)</p> <p>Treadmill walking 3x/wk for 12 weeks</p> <p>Concomitant therapy: None specified</p>	<p>Control (N=26)</p> <p>No specific instructions noted</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 3 mo</p> <p><u>Individual</u> PWT COT QOL</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>Endovascular intervention versus usual care</b>					
Feinglass, 2000 <sup>37</sup>	Observational Multicenter 16 sites in US Funding: Government  <u>Population</u> PAD patients with IC  Total N: 526 Mean Age: 69 yr N Female: 105 % Female: 20% Race: 16% African American	Endovascular revascularization (N=44)  Angioplasty  Concomitant therapy: Could include ASA, statin, pentoxifylline, warfarin, diuretics, ACE inhibitors, vasodilators, nitrates, calcium channel blockers and beta-blockers	Medical therapy (N=277)  Not defined  Concomitant therapy: Could include ASA, statin, pentoxifylline, warfarin, diuretics, ACE inhibitors, vasodilators, nitrates, calcium channel blockers and beta-blockers	Timing: 18 mo  <u>Individual</u> Cardiovascular mortality Stroke QOL Major amputation Change in ABI	Fair
Gelin, 2001 <sup>29</sup> Taft, 2001 <sup>30</sup>	RCT Single center Location: Sweden Funding: Government  <u>Population</u> PAD patients with IC  Total N: 264 Mean Age: 67 yr N Female: 91 % Female: 34.3% Race: NR	Endovascular revascularization (N=87)  No description of endovascular procedures  Concomitant therapy: Not specified	Control (N=89)  No specific information given  Concomitant therapy: Not specified	Timing: 12 mo  <u>Individual</u> Mortality QOL Vessel patency Amputation MWD	Fair
Hobbs, 2006 <sup>32</sup>  EXACT Study	RCT Multicenter Location: England Funding: Government  <u>Population</u> PAD patients with IC  Total N: 23 Median Age: 67 yr N Female: 7 % Female: 20.6% Race: NR	Endovascular Revascularization + BMT (N=9)  Percutaneous transluminal angioplasty BMT: not defined  Concomitant therapy: None specified	BMT (N=7)  BMT: not defined  Concomitant therapy: None specified	Timing: 6 mo  <u>Individual</u> ACD ICD	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Hobbs, 2007 <sup>22</sup>  INEXACT Study	RCT Single center Location: England Funding: NR  <u>Population</u> PAD patients with IC  Total N: 38 Median Age: 67 yr N Female: 7 % Female: 30.4% Race: NR	Endovascular Revascularization + BMT (N=9)	BMT (N=9)	Timing: 3 mo, 6 mo  <u>Individual</u> Adverse drug reaction Change in ABI ACD ICD	Good
Koivunen, 2008 <sup>38</sup>	Observational Single center Location: Finland Funding: Academy of Finland  <u>Population</u> PAD patients with IC  Total N: 180 Mean Age: 67 yr N Female: 62 % Female: 34.4% Race: NR	Endovascular revascularization (N=85)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Conservative treatment (N=64)  Lifestyle modification and medication  Concomitant therapy: None specified	Timing: 12 mo  <u>Individual</u> QOL PFWD	Poor
Murphy, 2012 <sup>34</sup>  CLEVER Study	RCT Multicenter 22 sites in US and Canada Funding: Government  <u>Population</u> PAD patients with IC  Total N: 119 Mean Age: 63 yr N Female: 42 % Female: 37.8% Race: NR	Endovascular revascularization + optimal medical therapy (N=46)  Revascularization with stent (not otherwise specified)  Optimal medical therapy: Cilostazol 100mg bid; advice about home exercise and diet  Concomitant therapy: Could include ASA, thienopyridine, and statin	Optimal medical therapy (N=22)  Optimal medical therapy: Cilostazol 100mg bid; advice about home exercise and diet  Concomitant therapy: Could include ASA, thienopyridine, and statin	Timing: 30 days, 6 mo  <u>Individual</u> PWT COT QOL Change in ABI Safety	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Nyłaende, 2007 <sup>39</sup>  OBACT Study	RCT Single center Location: Norway Funding: industry  <u>Population</u> PAD patients with IC  Total N: 56 Mean Age: 69 yr N Female: 25 % Female: 44.6% Race: NR	Endovascular revascularization + optimal medical therapy (N=28)  Percutaneous transluminal angioplasty +/- stent  Optimal medical therapy: Nicotine plaster and bupropion prescribed to smokers if not contraindicated; instructions for a home-based exercise training program; nutritional advice given; ASA 160mg daily (or Plavix in pts with h/o PUD); statins for pts with hypercholesterolemia; individualized hypertension tx	Optimal medical therapy (N=28)  Optimal medical therapy: Nicotine plaster and bupropion prescribed to smokers if not contraindicated; instructions for a home-based exercise training program; nutritional advice given; ASA 160mg daily (or Plavix in pts with h/o PUD); statins for pts with hypercholesterolemia; individualized hypertension tx	Timing: 3 mo, 12 mo, 24 mo  <u>Individual Mortality</u> QOL MWD PFWD	Good
Pell, 1997 <sup>40</sup>	Observational Multicenter 11 sites in Europe Funding: Government  <u>Population</u> PAD patients with IC  Total N: 201 Mean Age: 67 yr N Female: 78 % Female: 38.8% Race: NR	Endovascular revascularization (N=19)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Conservative treatment (N=119)  No description provided  Concomitant therapy: None specified	Timing: 6 mo  <u>Individual Mortality</u> QOL	Fair
Whyman, 1997 <sup>41</sup> Whyman, 1996 <sup>42</sup>	RCT Single center Location: England Funding: Government  <u>Population</u> PAD patients with IC  Total N: 62 Mean Age: 62 yr N Female: 11 % Female: 17.7% Race:	Endovascular revascularization + conventional medical therapy (N=30) Percutaneous transluminal angioplasty  Conventional medical therapy: Low dose aspirin plus advice on smoking and exercise	Conventional medical therapy (N=32)  Conventional medical therapy: Low dose aspirin plus advice on smoking and exercise	Timing: 6 mo, 24 mo  <u>Individual MWD</u> ICD Change in ABI	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b>Endovascular intervention vs. exercise training</b>					
Gelin, 2001 <sup>29</sup> Taft, 2001 <sup>30</sup>	RCT Single center Location: Sweden Funding: Government  <u>Population</u> PAD patients with IC  Total N: 264 Mean Age: 67 yr N Female: 91 % Female: 34.3% Race: NR	Endovascular revascularization (N=87)  A variety of procedures were performed.  Concomitant therapy: None specified	Supervised exercise (N=88)  Treadmill walking training 3x/wk for 6 months  Concomitant therapy: None specified	Timing: 12 mo  <u>Individual</u> Mortality QOL Vessel patency Amputation MWD	Fair
Greenhalgh, 2008 <sup>43</sup>  MIMIC Study	RCT Multicenter 9 sites in Europe (UK) Funding: Government  <u>Population</u> PAD patients with IC; 93 patients with femoropopliteal disease, 34 patients with aortoiliac disease  Total N: 127 Mean Age: 64 yr N Female: 46 % Female: 36.2% Race: NR	Endovascular revascularization (N=67)  Percutaneous transluminal angioplasty ± stent  Concomitant therapy: Counseling regarding smoking cessation and nicotine replacement therapy was prescribed where necessary. Optimal medical management of hypertension, hyperlipidemia, diabetes, and medication management including antiplatelet therapy was coordinated through the patient's primary physician.	Supervised exercise (N=60)  Walking circuit interspersed with seven lower limb training stations at least 1x/wk for 6 months.  Concomitant therapy: Counseling regarding smoking cessation and nicotine replacement therapy was prescribed where necessary. Optimal medical management of hypertension, hyperlipidemia, diabetes, and medication management including antiplatelet therapy was coordinated through the patient's primary physician.	Timing: 6 mo, 12 mo, 24 mo  <u>Individual</u> Mortality Myocardial infarction Stroke Repeat revascularization QOL MWD ICD	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Hobbs, 2006 <sup>32</sup> EXACT Study	RCT Multicenter Location: England Funding: Government  <u>Population</u> PAD patients with IC  Total N: 23 Median Age: 67 yr N Female: 7 % Female: 20.6% Race: NR	Supervised Exercise + BMT (N=7)  Circuit of moderate intensity exercises 2x/wk for 12 weeks  BMT: Could include antiplatelet agents, statin, ACE inhibitor or other antihypertensive agent	Endovascular Revascularization + BMT (N=9)  Percutaneous transluminal angioplasty  BMT: Could include antiplatelet agents, statin, ACE inhibitor or other antihypertensive agent	Timing: 6 mo  <u>Individual</u> ACD ICD	Fair
Hobbs, 2007 <sup>22</sup> INEXACT Study	RCT Single center Location: England Funding: NR  <u>Population</u> PAD patients with IC  Total N: 38 Median Age: 67 yr N Female: 7 % Female: 30.4% Race: NR	Supervised Exercise + BMT (N=9)	Endovascular Revascularization + BMT (N=9)	Timing: 3 mo, 6 mo  <u>Individual</u> Adverse drug reaction Change in ABI ACD ICD	Good
Kruidenier, 2011 <sup>44</sup>	RCT Single center Location: Netherlands Funding: NR  <u>Population</u> PAD patients with IC  Total N: 70 Mean Age: 62 yr N Female: 27 % Female: 38.6% Race: NR	Endovascular revascularization (N=35)  Consisted of iliac angioplasty with selective stent placement for iliac stenoses, angioplasty with primary stent placement for superficial femoral artery stenoses, or recanalization with primary stent placement for iliac and femoral occlusions  Concomitant therapy: None specified	Endovascular revascularization + supervised exercise (N=35)  Endovascular intervention as per intervention plus a nonspecified exercise program 2x/wk for 6 months  Concomitant therapy: None specified	Timing: within 3 wk of procedure, 3 mo, 6 mo  <u>Individual</u> ACD QOL Change in ABI Vessel patency Repeat revascularization	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Mazari, 2012 <sup>45</sup> Mazari, 2010 <sup>46</sup>	RCT Single center Location: United Kingdom Funding: European Society of Vascular Surgery  <u>Population</u> PAD patients with IC  Total N: 178 Median Age: 70 yr N Female: 71 % Female: 39.9% Race: NR	Endovascular revascularization (N=60),  Endovascular revascularization + supervised exercise (N=58)  Endovascular therapy: Percutaneous transluminal angioplasty  Supervised exercise therapy: Circuit of exercises 3x/wk for 12 weeks  Concomitant therapy: All patients were prescribed antiplatelet therapy (aspirin and/or clopidogrel), received smoking cessation advice and support (including nicotine replacement therapy and NHS smoking cessation program), and risk factor modification (target oriented management of hypertension, hypercholesterolemia, and diabetes. All patients also received an advice leaflet regarding exercise.	Supervised exercise (N=60)  Supervised exercise therapy: Circuit of exercises 3x/wk for 12 weeks  Concomitant therapy: All patients were prescribed antiplatelet therapy (aspirin and/or clopidogrel), received smoking cessation advice and support (including nicotine replacement therapy and NHS smoking cessation program), and risk factor modification (target oriented management of hypertension, hypercholesterolemia, and diabetes. All patients also received an advice leaflet regarding exercise.	Timing: 3 mo, 6 mo, 12 mo  <u>Individual</u> Repeat revascularization Periprocedural complications QOL Vessel patency MWD ICD	Good
Murphy, 2012 <sup>34</sup>  CLEVER Study	RCT Multicenter 22 sites in US and Canada Funding: Government  <u>Population</u> PAD patients with IC  Total N: 119 Mean Age: 63 yr N Female: 42 % Female: 37.8% Race: NR	Supervised exercise + optimal medical therapy (N=43)  Exercises 3x/wk for 26 weeks  Optimal medical therapy: Cilostazol 100mg bid; advice about home exercise and diet  Concomitant therapy: Could include ASA, thienopyridine, and statin	Endovascular revascularization + optimal medical therapy (N=46)  Revascularization with stent (not otherwise specified)  Optimal medical therapy: Cilostazol 100mg bid; advice about home exercise and diet  Concomitant therapy: Could include ASA, thienopyridine, and statin	Timing: 30 days, 6 mo  <u>Individual</u> PWT COT QOL Change in ABI Safety	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Nordanstig, 2011 <sup>47</sup>	<p>RCT Multicenter 2 sites in Europe Funding: Government</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 201 Mean Age: 68 yr N Female: 74 % Female: 37% Race: NR</p>	<p>Revascularization (surgical or endovascular) + optimal medical therapy (N=100)</p> <p>Revascularization: In general, aorto-iliac TASC A and B lesions were treated endovascularly and TASC C and D lesions with surgery. Femoropopliteal TASC A lesions were offered angioplasty, whereas TASC BeD lesions usually were treated surgically. For lesions in the common femoral artery, endarterectomy with or without patch angioplasty was used.</p> <p>Optimal medical therapy: ASA 75 mg daily (or ticlopidine if contraindication to aspirin). Smokers were offered participation in a smoking cessation support programme and received verbal and written information with smoking cessation advice. Hypertension, diabetes and hyperlipidaemia were managed according to national guidelines. Verbal training advice and a written training programme for IC. Instructed to walk at least 1 h/day and to walk up to their maximal claudication distance as often as possible and to perform an additional exercise programme at home several times a day.</p>	<p>Optimal medical therapy (N=100)</p> <p>Optimal medical therapy: ASA 75 mg daily (or ticlopidine if contraindication to aspirin). Smokers were offered participation in a smoking cessation support programme and received verbal and written information with smoking cessation advice. Hypertension, diabetes and hyperlipidemia were managed according to national guidelines. Verbal training advice and a written training programme for IC. Instructed to walk at least 1 h/day and to walk up to their maximal claudication distance as often as possible and to perform an additional exercise programme at home several times a day.</p>	<p>Timing: 24 mo</p> <p><u>Individual</u> Mortality Repeat revascularization QOL Vessel patency Major amputation MWD</p>	Good

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Perkins, 1996 <sup>48</sup>	RCT Single center Location: England Funding: Oxford Direct Research Committee  <u>Population</u> PAD patients with IC  Total N: 56 Mean Age: 63 yr N Female: 6 % Female: 10.7% Race: NR	Endovascular revascularization (N=30)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Supervised exercise (N=26)  Dynamic leg exercises 2x/wk for 6 months  Concomitant therapy: None specified	Timing: 3 mo, 6 mo, 9 mo, 12 mo, 15 mo, 6 yr  <u>Individual Mortality</u> Repeat revascularization MWD Periprocedural complications	Fair
Spronk, 2009 <sup>49</sup> Spronk, 2008 <sup>50</sup>	RCT Single center Location: Netherlands Funding: NR  <u>Population</u> PAD patients with IC  Total N: 151 Median Age: 70 yr N Female: 67 % Female: 44.7% Race: NR	Endovascular revascularization (N=75)  Percutaneous transluminal angioplasty +/- stent  Concomitant therapy: ASA 100mg daily	Supervised exercise (N=75)  Hospital based treadmill exercise 2x/wk for 24 weeks  Concomitant therapy: ASA 100mg daily	Timing: 6 mo, 12 mo  <u>Individual Mortality</u> QOL MWD PFWD Change in ABI	Fair
<b>Endovascular intervention versus surgical revascularization</b>					
Feinglass, 2000 <sup>37</sup>	Observational Multicenter 16 sites in US Funding: Government  <u>Population</u> PAD patients with IC  Total N: 526 Mean Age: 67 yr N Female: 105 % Female: 20% Race: 16% African American	Endovascular revascularization (N=44)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Surgical revascularization (N=60)  Bypass grafting +/- angioplasty  Concomitant therapy: None specified	Timing: 18 mo  <u>Individual</u> Cardiovascular mortality Stroke QOL Major amputation Change in ABI	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Koivunen, 2008 <sup>38</sup>	<p>Observational Single center Location: Finland Funding: Academy of Finland</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 180 Mean Age: 67 yr N Female: 62 % Female: 34.4% Race: NR</p>	<p>Endovascular revascularization (N=85)</p> <p>Percutaneous transluminal angioplasty +/- stent</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=31)</p> <p>Surgical bypass or endarterectomy</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 12 mo</p> <p><u>Individual</u> QOL PFWD</p>	Poor
Pell, 1997 <sup>40</sup>	<p>Observational Multicenter 11 sites in Europe Funding: Government</p> <p><u>Population</u> PAD patients with IC</p> <p>Total N: 201 Mean Age: 67 yr N Female: 78 % Female: 38.8% Race: NR</p>	<p>Endovascular revascularization (N=19)</p> <p>Percutaneous transluminal angioplasty</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=19)</p> <p>Arterial reconstruction</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 6 mo</p> <p><u>Individual</u> Mortality QOL</p>	Fair

**Table D-3. Study characteristics table for KQ 3: Effectiveness and safety of endovascular and surgical revascularization for CLI and mixed IC-CLI population**

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
<b><i>Endovascular intervention versus usual care</i></b>					
Lawall, 2009 <sup>51</sup>	<p>Observational Multicenter 3 sites in Germany Funding: Industry</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 155 Mean Age; 72 yr N Female: % Female: 30% Race: Not reported</p>	<p>Endovascular intervention (N=56)</p> <p>Percutaneous transluminal angioplasty with locoregional lysis and stent</p> <p>Concomitant therapy: Could include antibiotics</p>	<p>Usual care (N=17)</p> <p>Received analgesics and antibiotics</p>	<p>Timing: 18 months</p> <p><u>Individual</u> Mortality Hospitalization Major amputation Amputation-free survival</p>	Poor
Kamiya, 2008 <sup>52</sup>	<p>Observational Single center Location: Japan Funding: Government</p> <p><u>Population:</u> IC: 3 patients CLI: 55 patients</p> <p>Total N: 107 Mean Age: 71 yr N Female: 15 % Female: 14% Race: Not reported</p>	<p>Endovascular revascularization (N=55)</p> <p>Percutaneous balloon angioplasty +/- stent</p> <p>Concomitant therapy: Could include aspirin, cilostazol, ticlopidine, beraprost, sarpogrelate, limaprost, and warfarin</p>	<p>Usual care (N=52)</p> <p>Not defined</p> <p>Concomitant therapy: Could include aspirin, cilostazol, ticlopidine, beraprost, sarpogrelate, limaprost, and warfarin</p>	<p>Timing: Average followup 30.6 mo</p> <p><u>Individual</u> Mortality Myocardial infarction Stroke Repeat revascularization Length of stay Major amputation</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Varty, 1996 <sup>53</sup> Varty, 1998 <sup>54</sup>	Observational Single center Location: England Funding: Not reported  <u>Population</u> PAD patients with CLI  Total N: 188 Mean Age: Not reported N Female: % Female: 43% Race: Not reported	Endovascular intervention (N=108)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Conservative management (N=38)  Sympathectomy, analgesia, antibiotics, ulcer dressings or rehabilitation  Concomitant therapy: None specified	Timing: 12 months  <u>Individual</u> Mortality Major amputation Limb salvage	Fair
<b><i>Endovascular intervention versus surgical revascularization</i></b>					
Adam, 2005 <sup>55</sup> Bradbury, 2010 <sup>56-60</sup> Forbes, 2010 <sup>61</sup>  BASIL Study	RCT Multicenter 27 sites in Europe Funding: Government  <u>Population</u> PAD patients with CLI  Total N: 452 Mean Age: Not reported N Female: 183 % Female: 38% Race: Not reported	Endovascular intervention (N=224)  Percutaneous transluminal angioplasty  Concomitant therapy: Could include antiplatelet agent, statin, or warfarin	Surgical revascularization (N=228)  Surgical bypass  Concomitant therapy: Could include antiplatelet agent, statin, or warfarin	Timing: 36 mo  <u>Individual</u> Mortality Amputation-free survival Myocardial infarction Stroke Length of stay QOL	Good
Ah Chong, 2009 <sup>62</sup>	Observational Single center Location: Hong Kong Funding: Not reported  <u>Population</u> PAD patients with CLI  Total N: 464 Mean Age: Not reported N Female: 175 % Female: 48% Race: Not reported	Endovascular intervention (N=92)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Surgical revascularization (N=364)  Surgical bypass  Concomitant therapy: None specified	Timing: 24 mo  <u>Individual</u> Mortality Length of stay Vessel patency Limb salvage	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Dorigo, 2009 <sup>63</sup>	<p>Observational Single center Location: Italy Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 73 Mean Age: 74 yr N Female: % Female: 29% Race: Not reported</p>	<p>Endovascular intervention (N=34)</p> <p>Percutaneous transluminal angioplasty +/- stent</p> <p>Concomitant therapy (postprocedure): Could include oral anticoagulant, antiplatelet drug(s), or LMWH</p>	<p>Surgical revascularization (N=39)</p> <p>Surgical bypass</p> <p>Concomitant therapy (postoperative): Could include oral anticoagulant, antiplatelet drug(s), or LMWH</p>	<p>Timing: 13 mo</p> <p><u>Individual</u> Mortality Repeat revascularization Length of stay Major amputation QOL</p>	Fair
Dosluoglu, 2010 <sup>64</sup>	<p>Observational Single center Location: US (NY) Funding: Not reported</p> <p><u>Population:</u> IC: 38% in endovascular arm, 25% in surgical and hybrid arms CLI: 62% in endovascular arm, 75% in surgical and hybrid arms</p> <p>Total N: 654 Mean Age: 69 yr N Female: Not reported % Female: Not reported Race: Not reported</p>	<p>Endovascular revascularization (N=356)</p> <p>Not defined</p> <p>Concomitant therapy: Clopidogrel 75mg daily for at least 30 days, lifelong aspirin 81mg daily</p>	<p>Surgical revascularization (N=207); hybrid revascularization (N=91)</p> <p>Included a variety of procedures</p> <p>Concomitant therapy: Clopidogrel 75mg daily for at least 30 days, lifelong aspirin 81mg daily</p>	<p>Timing: 30 days, 1 yr, 3 yr</p> <p><u>Individual</u> Mortality Myocardial infarction Stroke Length of stay Bleeding Major amputation Limb salvage</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Hoshino, 2010 <sup>65</sup>	<p>Observational Single center Location: Japan Funding: Private foundation</p> <p><u>Population:</u> IC: 148 patients CLI: 32 patients</p> <p>Total N: 180 Mean Age: Not reported N Female: 21 % Female: 12% Race: Not reported</p>	<p>Endovascular revascularization (N not reported)</p> <p>Percutaneous transluminal angioplasty</p> <p>Concomitant therapy: Anticoagulants and/or aspirin; may include statin</p>	<p>Surgical revascularization (N not reported)</p> <p>Surgical bypass</p> <p>Concomitant therapy: Anticoagulants and/or aspirin; may include statin</p>	<p>Timing: 1 yr, 3 yr, 5 yr</p> <p><u>Individual</u> Mortality Vessel patency Amputation-free survival</p>	Fair
Hynes, 2004 <sup>66</sup>	<p>Observational Single center Location: Ireland Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI; 28 patients with femoropopliteal disease and 35 patients with aortoiliac disease</p> <p>Total N: 137 Mean Age: 70 yr N Female: 74 % Female: 54% Race: Not reported</p>	<p>Endovascular intervention (N=88)</p> <p>Subintimal angioplasty</p> <p>Concomitant therapy: Aspirin, pravastatin, and cardioselective beta-blockers during and after treatment. Postoperatively, clopidogrel was added for 1 year.</p>	<p>Surgical revascularization (49)</p> <p>Surgical bypass</p> <p>Concomitant therapy: Aspirin, pravastatin, and cardioselective beta-blockers during and after treatment. Postoperatively, clopidogrel was added for 1 year.</p>	<p>Timing: 15 mo</p> <p><u>Individual</u> Mortality Myocardial infarction Length of stay Limb salvage Vessel patency Change in ABI</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Janne d'Othee, 2008 <sup>67</sup>	<p>Observational Single center Location: Not reported Funding: Nonprofit organization</p> <p><u>Population:</u> IC: 97 patients CLI: Not reported</p> <p>Total N: 97 Mean Age: 63 yr N Female: 33 % Female: 36% Race: Not reported</p>	<p>Endovascular revascularization (N=64)</p> <p>Included a variety of percutaneous procedures (mainly percutaneous transluminal angioplasty +/- stent)</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=33)</p> <p>Included a variety of surgical procedures (mainly bypass and endarterectomy)</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 30 days, 1 yr, 2 yr</p> <p><u>Individual</u> Mortality Vessel patency Periprocedural complications</p>	Fair
Jerabek, 2003 <sup>68</sup>	<p>Observational Single center Location: Czech Republic Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 131 Mean Age: 62 yr N Female: 30 % Female: 23% Race: Not reported</p>	<p>Endovascular intervention (N=36)</p> <p>Percutaneous transluminal angioplasty +/- stent</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=95)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 2 to 105 days</p> <p><u>Individual</u> Length of stay</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Kashyap, 2008 <sup>69</sup>	<p>Observational Single center Location: US (OH) Funding: Not reported</p> <p><u>Population:</u> IC: 54% in endovascular arm, 51% in surgical arm CL: 46% in endovascular arm, 49% in surgical arm</p> <p>Total N: 169 Mean Age: 62 yr N Female: 58 % Female: 34% Race: Not reported</p>	<p>Endovascular revascularization (N=83)</p> <p>Recanalization, percutaneous transluminal angioplasty and stent</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=86)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 30 days, 1 yr, 2 yr, 3 yr</p> <p><u>Individual</u> Mortality Myocardial infarction Vessel patency Contrast nephropathy Periprocedural complications Limb salvage</p>	Fair
Khan, 2009 <sup>70</sup>	<p>Observational Single center Location: US (NY) Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 358 patients, 412 limbs Mean Age: 70 yr N Female: 3 % Female: 1% Race: Not reported</p>	<p>Endovascular intervention (N=197 patients, 236 limbs)</p> <p>Successful endovascular (not otherwise specified)</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=161 patients, 176 limbs)</p> <p>Successful surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 36 mo</p> <p><u>Individual</u> Limb salvage</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Korhonen, 2011 <sup>71</sup>	<p>Observational Single center Location: Finland Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 858 Mean Age: 73 yr N Female: 374 % Female: 44% Race: Not reported</p>	<p>Endovascular intervention (N=517)</p> <p>Percutaneous transluminal angioplasty +/- stent</p> <p>Concomitant therapy (postprocedure): Clopidogrel 300mg once, then 75mg daily x at least 1 month (unless already on anticoagulation); ASA 100mg daily</p>	<p>Surgical revascularization (N=341)</p> <p>Surgical bypass</p> <p>Concomitant therapy (postoperative): LMWH during hospital; ASA 100mg daily</p>	<p>Timing: 2.6 yr</p> <p><u>Individual</u> Mortality Limb salvage Amputation-free survival Freedom from repeat revascularization</p>	Good
Kudo, 2006 <sup>72</sup>	<p>Observational Single center Location: US (CA) Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 192 patients, 237 limbs Mean Age: 70 yr N Female: 96 % Female: 40% Race: Not reported</p>	<p>Endovascular intervention (N=153 limbs)</p> <p>Angioplasty +/- stent</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=84 limbs)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 23 mo</p> <p><u>Individual</u> Mortality Length of stay Vessel patency Limb salvage Clinical improvement</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Laurila, 2000 <sup>73</sup>	<p>Observational Multicenter Multiple centers in Europe Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 124 limbs Mean Age: 72 yr N Female: % Female: Not reported Race: Not reported</p>	<p>Endovascular intervention (N=86)</p> <p>Percutaneous transluminal angioplasty</p> <p>Concomitant therapy: ASA 50-100mg daily</p>	<p>Surgical revascularization (N=38)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 20 mo</p> <p><u>Individual</u> Mortality</p>	Poor
Lepantalo, 2009 <sup>74</sup>	<p>RCT Multicenter 8 sites in Europe Funding: Not reported</p> <p><u>Population:</u> IC: 87% in endovascular arm, 90% in surgical arm CLI: 13% in endovascular arm, 10% in surgical arm</p> <p>Total N: 44 Mean Age: 65 yr N Female: 19 % Female: 43% Race: Not reported</p>	<p>Endovascular revascularization (N=23)</p> <p>Endoluminal thrapass</p> <p>Concomitant therapy: Aspirin and/or clopidogrel; postoperative LMWH x2 days; may include prophylactic antibiotic</p>	<p>Surgical revascularization (N=21)</p> <p>Surgical bypass</p> <p>Concomitant therapy: Aspirin and/or clopidogrel; postoperative LMWH x2 days; may include prophylactic antibiotic</p>	<p>Timing: 30 days, 12 mo, 17 mo, 18 mo</p> <p><u>Individual</u> Mortality Repeat revascularization Length of stay Vessel patency Major amputation Periprocedural complications</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Loor, 2009 <sup>75</sup>	<p>Observational Single center Location: US (IL) Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 92 patients, 99 procedures Mean Age: 65 yr N Female: % Female: 44% Race: 66% African American</p>	<p>Endovascular intervention (N=33 patients, 34 procedures)</p> <p>Atherectomy</p> <p>Concomitant therapy (postprocedure): Antiplatelet agents (ASA or clopidogrel or anticoagulants (warfarin, heparin or enoxaparin)</p>	<p>Surgical revascularization (N=59 patients, 65 procedures)</p> <p>Surgical bypass</p> <p>Concomitant therapy (postoperative) Antiplatelet agents (ASA or clopidogrel) or anticoagulants (warfarin, heparin or enoxaparin)</p>	<p>Timing: 17 mo</p> <p><u>Individual</u> Mortality Length of stay Vessel patency Limb salvage</p>	Fair
McQuade, 2009 <sup>76</sup> McQuade, 2010 <sup>77</sup> Kedora, 2007 <sup>78</sup>	<p>RCT Single center Location: US (TX) Funding: Industry</p> <p><u>Population:</u> IC: 82% in endovascular arm, 62% in surgical arm CLI: 18% in endovascular arm, 38% in surgical arm</p> <p>Total N: 86 Mean Age: 69 yr N Female: Not reported % Female: Not reported Race: Not reported</p>	<p>Endovascular revascularization (N=40)</p> <p>Percutaneous angioplasty with stent</p> <p>Concomitant therapy: Aspirin 81-325mg daily and clopidogrel 75mg daily for at least 3 months (unless previously on warfarin which was continued in place of clopidogrel)</p>	<p>Surgical revascularization (N=46)</p> <p>Surgical bypass</p> <p>Concomitant therapy: Aspirin 81-325mg daily and clopidogrel 75mg daily for at least 3 months (unless previously on warfarin which was continued in place of clopidogrel)</p>	<p>Timing: 1 yr, 18 mo, 2 yr, 3 yr, 4 yr</p> <p><u>Individual</u> Mortality Repeat revascularization Length of stay Vessel patency Major amputation Periprocedural complications Graft failure Change in ABI</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Rossi, 1998 <sup>79</sup>	<p>Observational Single center Location: Italy Funding: Other (CNR grant)</p> <p><u>Population:</u> IC: 24% in endovascular arm, 0% in surgical arm CLI: 76% in endovascular arm, 100% in surgical arm</p> <p>Total N: 48 Mean Age: 68 yr N Female: Not reported % Female: Not reported Race: Not reported</p>	<p>Endovascular revascularization (N=37)</p> <p>Percutaneous balloon angioplasty or atherectomy</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=11)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 12 mo, 18 mo</p> <p><u>Individual</u> Mortality Myocardial infarction Periprocedural complications Limb salvage</p>	Poor
Sachs, 2011 <sup>80</sup>	<p>Observational Multicenter Multiple sites in US Funding: Not reported</p> <p><u>Population:</u> IC: NR CLI: NR</p> <p>Total N: 563,143 Mean Age: 67 yr N Female: 225,820 % Female: 40% Race: 8.7% African American, 83.7% White</p>	<p>Endovascular revascularization (N=128,937)</p> <p>Percutaneous transluminal angioplasty +/- stent</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (24,033 aorto-femoral bypass; 102,604 peripheral bypass)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: In-hospital</p> <p><u>Individual</u> Mortality Length of stay Discharge status Major amputation Amputation-free survival</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Stoner, 2008 <sup>81</sup>	<p>Observational Single center Location: US (NC) Funding: Not complete</p> <p><u>Population:</u> IC: 57% in endovascular arm, 44% in surgical arm CLI: 43% in endovascular arm, 56% in surgical arm</p> <p>Total N: 359 patients, 381 lesions Mean Age: Not reported N Female: 144 % Female: 40% Race: Not reported</p>	<p>Endovascular revascularization (198 procedures)</p> <p>Included a variety of procedures (percutaneous transluminal angioplasty +/- stent, subintimal angioplasty, atherectomy)</p> <p>Concomitant therapy: Could include aspirin, clopidogrel, warfarin and lipid-lowering medications</p>	<p>Surgical revascularization (183 procedures)</p> <p>Surgical bypass</p> <p>Concomitant therapy: Could include aspirin, clopidogrel, warfarin and lipid-lowering medications</p>	<p>Timing: 1 yr</p> <p><u>Individual:</u> Vessel patency</p>	Poor
Sultan, 2009 <sup>82</sup> Sultan, 2011 <sup>83</sup>	<p>Observational Single center Location: Ireland Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 309 Mean Age: 72 yr N Female: % Female: 47% Race: Not reported</p>	<p>Endovascular intervention (N=190)</p> <p>Subintimal angioplasty</p> <p>Concomitant therapy: (Preprocedure) ASA, pravastatin, cardioselective beta-blocker and/or calcium channel blocker (Postprocedure) Clopidogrel</p>	<p>Surgical revascularization (N=119)</p> <p>Surgical bypass</p> <p>Concomitant therapy: (Preoperative) ASA, pravastatin, cardioselective beta-blocker and/or calcium channel blocker (Postoperative) Clopidogrel</p>	<p>Timing: 5 yr</p> <p><u>Composite</u> Total mortality Nonfatal myocardial infarction Stroke Major amputation</p> <p><u>Individual</u> Mortality Length of stay Major amputation Amputation-free survival Clinical improvement Repeat revascularization</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Soderstrom, 2010 <sup>84</sup>	Observational Single center Location: Finland Funding: Not reported  <u>Population</u> PAD patients with CLI  Total N: 1023 Mean Age: 74 yr N Female: % Female: 57% Race: Not reported	Endovascular intervention (N=262)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Surgical revascularization (N=761)  Surgical bypass  Concomitant therapy: None specified	Timing: 2.4 yr  <u>Individual</u> Mortality Repeat revascularization Limb salvage Amputation-free survival Freedom from repeat revascularization	Fair
Taylor, 2006 <sup>85</sup>	Observational Single center Location: US (SC) Funding: Not reported  <u>Population</u> PAD patients with CLI  Total N: 841 Mean Age: 68 yr N Female: 362 % Female: 43% Race: 76.1% White	Endovascular intervention (N=299)  Not further specified  Concomitant therapy: None specified	Surgical revascularization (N=519)  Surgical bypass  Concomitant therapy: None specified	Timing: 24 mo, 60 mo  <u>Individual</u> Vessel patency Limb salvage Maintenance of ambulation	Poor
Taylor, 2005 <sup>86</sup>	Observational Single center Location: US (SC) Funding: Not reported  <u>Population</u> PAD patients with CLI  Total N: 122 Mean Age: 83 yr N Female: % Female: 40% Race: 80% White	Endovascular intervention (N=65)  Percutaneous transluminal angioplasty +/- stent  Concomitant therapy: None specified	Surgical revascularization (N=57)  Surgical bypass  Concomitant therapy: None specified	Timing: 36 mo  <u>Individual</u> Vessel patency Wound healing Mortality Limb salvage Amputation-free survival Maintenance of ambulation	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Timaran, 2003 <sup>87</sup>	<p>Observational Single center Location: US (TN) Funding: Not reported</p> <p><u>Population:</u> IC: 61% of endovascular arm, 84% of surgical arm CLI: 39% of endovascular arm, 16% of surgical arm</p> <p>Total N: 188 Mean Age: Not reported N Female: 87 % Female: 45% Race: Not reported</p>	<p>Endovascular revascularization (N=136)</p> <p>Angioplasty with stent</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=52)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 1 yr, 3 yr, 5 yr</p> <p><u>Individual</u> Vessel patency</p>	Fair
Varela, 2011 <sup>88</sup>	<p>Observational Single center Location: Spain Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 88 patients, 91 limbs Mean Age: Not reported N Female: % Female: 31% Race: Not reported</p>	<p>Endovascular intervention (N=42 limbs)</p> <p>Not further specified</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=49 limbs)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 310 days</p> <p><u>Individual</u> Mortality Hospitalization Vessel patency Wound healing Major amputation Limb salvage Amputation-free survival</p>	Fair
Varty, 1996 <sup>53</sup> Varty, 1998 <sup>54</sup>	<p>Observational Single center Location: England Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 188 Mean Age: Not reported N Female: % Female: 43% Race: Not reported</p>	<p>Endovascular intervention (N=108 procedures)</p> <p>Percutaneous transluminal angioplasty</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=68 procedures)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 12 mo</p> <p><u>Individual</u> Mortality Major amputation Limb salvage</p>	Fair

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Venermo, 2011 <sup>89</sup>	<p>Observational Single center Location: Finland Funding: Not reported</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 597 patients, 732 procedures Mean Age: 72 yr N Female: % Female: 52% Race: Not reported</p>	<p>Endovascular intervention (N=377 procedures)</p> <p>Percutaneous transluminal angioplasty</p> <p>Concomitant therapy: None specified</p>	<p>Surgical revascularization (N=355 procedures)</p> <p>Surgical bypass</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 2.8 yr</p> <p><u>Individual</u> Limb salvage</p>	Poor
Whatling, 2000 <sup>90</sup>	<p>Observational Single center Location: United Kingdom</p> <p>Funding: Not reported</p> <p><u>Population:</u> IC: 121 patients of total population CLI: 17 patients of total population</p> <p>Total N: 138 Mean Age: 66 yr N Female: 45 % Female: 33% Race: Not reported</p>	<p>Endovascular revascularization (N=51)</p> <p>Percutaneous transluminal angioplasty with stent</p> <p>Concomitant therapy: Aspirin 75mg daily</p>	<p>Surgical revascularization (N=87)</p> <p>Surgical crossover grafting</p> <p>Concomitant therapy: None specified</p>	<p>Timing: 6 mo</p> <p><u>Individual</u> Length of stay Vessel patency</p>	Poor
Wolfe, 2000 <sup>91</sup>	<p>Observational Single center Location: Germany Funding: Government</p> <p><u>Population</u> PAD patients with CLI</p> <p>Total N: 209 Mean Age: 69 yr N Female: % Female: Not reported Race: Not reported</p>	<p>Endovascular intervention (N=84)</p> <p>Percutaneous transluminal angioplasty</p> <p>Concomitant therapy (postprocedure): ASA 100mg daily</p>	<p>Surgical revascularization (N=125)</p> <p>Surgical bypass</p> <p>Concomitant therapy (postoperative): ASA 100mg daily</p>	<p>Timing: 84 mo</p> <p><u>Individual</u> Mortality Limb salvage</p>	Poor

Study	Study Details	Intervention (N)	Comparator (N)	Timing Outcomes Reported	Quality
Zdanowski, 1998 <sup>92</sup>	Observational Single center Location: Sweden Funding: Not reported  <u>Population</u> PAD patients with CLI  Total N: 4929 Mean Age: 76 yr N Female: % Female: 53% Race: Not reported	Endovascular intervention (N=1199)  Percutaneous transluminal angioplasty  Concomitant therapy: None specified	Surgical revascularization (N=3730)  Surgical bypass  Concomitant therapy: None specified	Timing: 12 mo  <u>Individual</u> Mortality Amputation-free survival	Poor

Abbreviations: ABI=ankle-brachial index; IC=intermittent claudication; min=minute/minutes; mo=month/months; N=number; NR=not reported; PAD=peripheral artery disease; QOL=quality of life; RCT=randomized controlled trial; SD=standard deviation; sec=second/seconds; wk=week/weeks; yr=year/years

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## Appendix E: List of Included Studies

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## Appendix F: List of Excluded Studies

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

### Non-English language

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## No outcomes of interest $\geq 30$ days

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