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

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

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| --- | --- | --- | --- | --- |
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| Glick,  2005  PROMISE | **Publication type:**  Full text, abstract  **Geographical location:**  Germany  **Funding:**  Boston Scientific  **Number of centers:**  1  **Randomization:**  Randomization sequence set in blocks of 20 by statistician, unknown to the investigators and medical staff  **Outcome assessment:**  MRI images examined by 2 experienced observers who were unaware of the patients’ group assignment, angiographic images analyzed offline by independent core laboratory  **Number of participants enrolled:**  200 | **Inclusion criteria:**  Both at least 1 episode of typical angina pain > 30 min within the preceding 48 h and coronary artery lesion deemed suitable for stent placement and application of filter wire plus at least one of the following: ST-segment elevation ≥ 1 mm in 2 or more ECG leads, elevation of creatinine kinase ≥ 3 times the upper limit with concomitant rise of MB isoenzyme, coronary artery occlusion with angiographic appearance of fresh thrombus  **Exclusion criteria:**  Presumed distal vessel diameter < 3 mm, relevant coronary left main involvement, vessel anatomy interfering with safe placement of filterwire, culprit lesion in saphenous vein graft, contraindication to abxicimab, aspirin, clopidogrel, or heparin, mechanical ventilation or inotropic support, inability to give informed consent  **Intervention:**  PCI with distal filter embolic protection using FilterWire EX  **Comparator:**  PCI  **Duration of followup (d):**  30  **Followup:**  100% | **Intermediate:**  MBG > 1, TIMI-3, DE (post-procedure); EF (3 d,180 d)  **Final:**  MACE (180 d); mortality, reinfarction (30 d,180 d); TVR, stroke (30 d)  **Safety:**  NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes 2. Were outcomes assessed using a valid methodology and criteria? Yes 3. Were outcome assessors blind to exposure/intervention status? Partially 4. Were incomplete outcome data adequately addressed? Yes 5. Was the differential loss to followup between the compared groups low (< 10%)?Yes 6. Was the overall loss to followup low (< 30%)? Yes 7. Conflict of interest reported and insignificant? Yes 8. Were the methods used for randomization adequate? Yes   Overall quality rating: Good |
| Sardella,  2005 | **Publication type:**  Abstract  **Geographical location:**  NR  **Funding:**  NR  **Number of centers:**  NR  **Randomization:**  NR  **Outcome assessment:**  NR  **Number of participants enrolled:**  62 | **Inclusion criteria:**  Anterior MI undergoing primary PCI of de novo coronary lesions with angiographic presence of intracoronary thrombus  **Exclusion criteria:**  NR  **Intervention:**  PCI with catheter aspiration using Diver-Invatec plus stenting  **Comparator:**  Conventional coronary stenting  **Duration of followup (d):**  180  **Followup:**  NR | **Intermediate:**  MBG-3, TIMI-3 (post procedure)  **Final:**  NR  **Safety:**  NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell 2. Were outcomes assessed using a valid methodology and criteria? Can’t tell 3. Were outcome assessors blind to exposure/intervention status? Can’t tell 4. Were incomplete outcome data adequately addressed? Can’t tell 5. Was the differential loss to followup between the compared groups low (< 10%)?Can’t tell 6. Was the overall loss to followup low (< 30%)? Can’t tell 7. Conflict of interest reported and insignificant? No 8. Were the methods used for randomization adequate? Can’t tell   Overall quality rating: Poor |
| Kunii,  2004  NONSTOP | **Publication type:**  Abstract  **Geographical location:**  Japan  **Funding:**  NR  **Number of centers:**  NR  **Randomization:**  NR  **Outcome assessment:**  NR  **Number of participants enrolled:**  258 | **Inclusion criteria:**  < 24 h of symptom onset, lesion diameter > 2.5 mm, no severe calcification at or proximal to the lesion, no proximal tortuosity preventing Rescue use or stent delivery, no cardiogenic shock, no left main disease  **Exclusion criteria:**  NR  **Intervention:**  PCI with catheter aspiration using Rescue PT catheter  **Comparator:**  Primary stenting  **Duration of followup (d):**  In-hospital  **Followup:**  NR | **Intermediate:**  TIMI-3 (post-procedure)  **Final:**  Mortality (in-hospital)  **Safety:**  NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell 2. Were outcomes assessed using a valid methodology and criteria? Can’t tell 3. Were outcome assessors blind to exposure/intervention status? Can’t tell 4. Were incomplete outcome data adequately addressed? Can’t tell 5. Was the differential loss to followup between the compared groups low (< 10%)?Can’t tell 6. Was the overall loss to followup low (< 30%)? Can’t tell 7. Conflict of interest reported and insignificant? Can’t tell 8. Were the methods used for randomization adequate? Can’t tell   Overall quality rating: Poor |
| Nanasato,  2004 | **Publication type:**  Abstract  **Geographical location:**  Japan  **Funding:**  NR  **Number of centers:**  NR  **Randomization:**  NR  **Outcome assessment:**  NR  **Number of participants enrolled:**  64 | **Inclusion criteria:**  AMI within 12 h of onset  **Exclusion criteria:**  NR  **Intervention:**  PCI with distal balloon embolic protection using GuardWire Plus  **Comparator:**  Conventional PCI  **Duration of followup (d):**  In-hospital  **Followup:**  NR | **Intermediate:**  MBG-3, TIMI-3, EF, (post procedure)  **Final:**  NR  **Safety:**  NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell 2. Were outcomes assessed using a valid methodology and criteria? Can’t tell 3. Were outcome assessors blind to exposure/intervention status? Can’t tell 4. Were incomplete outcome data adequately addressed? Can’t tell 5. Was the differential loss to followup between the compared groups low (< 10%)? Can’t tell 6. Was the overall loss to followup low (< 30%)? Can’t tell 7. Conflict of interest reported and insignificant? Can’t tell 8. Were the methods used for randomization adequate? Can’t tell   Overall quality rating: Poor |
| Matsushita,  2003 | **Publication type:**  Abstract  **Geographical location:**  Japan  **Funding:**  NR  **Number of centers:**  NR  **Randomization:**  NR  **Outcome assessment:**  NR  **Number of participants enrolled:**  80 | **Inclusion criteria:**  First anteroseptal MI undergoing coronary intervention and stenting within 12 h from onset of MI and who had coronary blood flow measurements immediately after the procedure  **Exclusion criteria:**  NR  **Intervention:**  PCI with balloon distal embolic protection using Guard Wire PercuSurge system  **Comparator:**  PCI  **Duration of followup (d):**  180  **Followup:**  100% for MACE and mortality | **Intermediate:**  NR  **Final:**  MACE (180 d); mortality (in-hospital)  **Safety:**  NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes 2. Were outcomes assessed using a valid methodology and criteria? Can’t tell 3. Were outcome assessors blind to exposure/intervention status? Can’t tell 4. Were incomplete outcome data adequately addressed? Can’t tell 5. Was the differential loss to followup between the compared groups low (< 10%)? Yes 6. Was the overall loss to followup low (< 30%)? Yes 7. Conflict of interest reported and insignificant? Can’t tell 8. Were the methods used for randomization adequate? Can’t tell   Overall quality rating: Poor |
| Beran,  2002 | **Publication type:**  Full text, abstract  **Geographical location:**  Austria  **Funding:**  NR  **Number of centers:**  1  **Randomization:**  Randomized on a 1:1 basis  **Outcome assessment:**  Angiographic measurements were performed by 2 experienced observers who were blinded to randomization, ECG recording were analyzed by 2 observers blinded to randomization and angiographic findings  **Number of participants enrolled:**  61 | **Inclusion criteria:**  STEMI with chest pain > 30 min and ST-segment elevation > 1 mm 2 or more ECG leads, patients with UA were allowed if presented with recurrent chest pain at rest associated with ST-segment or T-wave changes, native vessel occlusion or intraluminal filling defect  **Exclusion criteria:**  NR  **Intervention:**  Mechanical thrombectomy withX-Sizer followed by stenting or PTCA  **Comparator:**  PTCA or stenting  **Duration of followup (d):**  30  **Followup:**  90.19% in device group and 93.94% in control group | **Intermediate:**  TIMI-3, STSR > 50% (post-procedure)  **Final:**  MACE, mortality, TVR (30 d)  **Safety:**  NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes 2. Were outcomes assessed using a valid methodology and criteria? Yes 3. Were outcome assessors blind to exposure/intervention status? Partially 4. Were incomplete outcome data adequately addressed? Yes 5. Was the differential loss to followup between the compared groups low (< 10%)?Yes 6. Was the overall loss to followup low (< 30%)? Yes 7. Conflict of interest reported and insignificant? No 8. Were the methods used for randomization adequate? Can’t tell   Overall quality rating: Good |

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

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