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

| Study, Year | Trial Characteristics | Population, Interventions and Followup\* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
| --- | --- | --- | --- | --- |
| Duan, 2010 | **Publication type:** Full text**Geographical location:** China**Funding:** NR**Number of centers:** 1**Randomization:** Randomly assigned to either of the two groups**Outcome assessment:** Echocardiography was performed by observers who were blind to all clinical and angiographic data**Number of participants enrolled:** 96 | **Inclusion criteria:** First anterior MI defined as chest pain lasting >30 min but <6h in conjunction with persistent ST-segment elevation in precordial leads; proximal lesionof LAD present and diameter of infarct lesion known or expected >3mm without extensive tortuosity or lesion/vessel calcification, with 30mm or more of distal vessel**Exclusion criteria:** LVEF≤25%; significant valve disease, pericardial disease; major surgery or active bleeding within last 6w; aspirin or heparin allergy; severe coexisting conditions that interfered with the ability of the patient to comply with the protocol**Intervention:** PCI with distal balloon embolic protection (PercuSurge Guardwire Plus)**Comparator:** Standard PCI**Duration of followup (d):** 180 days**Followup:** 100%  | **Intermediate:** TIMI-3; EF (post-procedure)**Final:** NR**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? Yes
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 |

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| Study, Year | Trial Characteristics | Population, Interventions and Followup\* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
| --- | --- | --- | --- | --- |

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| Pan,2010 | **Publication type:** Full text**Geographical location:** China**Funding:** NR**Number of centers:** 1**Randomization:** Randomly assigned to either of the two groups**Outcome assessment:** NR**Number of participants enrolled:** 104 | **Inclusion criteria:** 65-81 years old admitted within 2-14h after symptom onset of acute STEMI (typical chest pain>30min, ST-elevation ≥1mm in 2 contiguous leads and or >2mm in precordial leads with visible thrombus) proven angiographically **Exclusion criteria:** History of MI, prior PCI or CABG, cardiogenic shock, atrial fibrillation, cardiac arrest, hepatic or renal dysfunction, culprit lesion not suitable for PCI plus percutaneous thrombectomy**Intervention:** PCI with distal balloon protection (PercuSurge Guardwire)**Comparator:** Standard PCI**Duration of followup (d):** Post-procedure**Followup:** 100%  | **Intermediate:** TIMI-3 (post-procedure)**Final:** NR**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? Can’t tell
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 |
| Tahk, 2008 | **Publication type:** Full text, abstract**Geographical location:** Korea**Funding:** Supported in part by Medtronic Inc.**Number of centers:** 7**Randomization:** NR**Outcome assessment:** NR**Number of participants enrolled:** 116 | **Inclusion criteria:** First-time STEMI, chest pain > 30 min, presentation within 12 h after symptom onset, ST-segment elevation > 2 mV in 2 or more ECG leads, reference vessel diameter of target lesion 2.75 - 4.5 mm, diameter stenosis > 70%, lesion length short enough to be covered by a single stent deployment**Exclusion criteria:** Saphenous vein or arterial graft lesion, contraindication to GP2B3Ai, cardiogenic shock, pregnancy, LVEF ≤ 25%, left main disease, bifurcation lesion, history of bleeding tendency or coagulopathy, allergy to radiocontrast dye, aspirin, clopidogrel or heparin, co-morbidity with expected survival < 1 y**Intervention:** Primary PCI with PercuSurge GuardWire system**Comparator:** Primary PCI**Duration of followup (d):** 180**Followup:** 100%  | **Intermediate:** TMP-3; TIMI-3 (post-procedure); EF (post-procedure, 180 d)**Final:** MACE (mortality, reinfarction, ischemia-driven TVR), mortality, TVR, reinfarction (30 d,180 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? Can’t tell
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? Can’t tell
8. Were the methods used for randomization adequate? Can’t tell

Overall quality rating: Good |
| Hahn, 2007 | **Publication type:** Full text, abstract**Geographical location:** South Korea**Funding:** NR**Number of centers:** 1**Randomization:** NR**Outcome assessment:** Coronary angiograms analyzed by 2 blinded observers, MRI analyzed independently by 2 experienced radiologists blinded to the clinical information **Number of participants enrolled:** 39 | **Inclusion criteria:** Chest pain > 30 min but < 12 h after symptom onset, ST-segment elevation > 1 mm in 2 or more ECG leads or presumably new LBBB, IRA lesion eligible for primary PCI with stenting, distal vessel > 2.5 mm in diameter and suitable for balloon occlusion and aspiration device**Exclusion criteria:** Previous MI, hemodynamic instability, requirement for multivessel intervention during index PCI, contraindication to aspirin, clopidogrel or heparin**Intervention:** Primary PCI with GuardWire**Comparator:** Primary PCI**Duration of followup (d):** 180 **Followup:** 100% | **Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (3 d,180 d); STSR > 50% (90 min)**Final:** MACE (mortality, MI, TLR), mortality, TLR, reinfarction (180 d)**Safety:** NR | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No
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 |
| Matsuo, 2007MICADO | **Publication type:** Full text**Geographical location:** Japan**Funding:** NR**Number of centers:** 14**Randomization:** Randomized using envelope method**Outcome assessment:** NR**Number of participants enrolled:** 154 | **Inclusion criteria:** STEMI within 24 h after onset with chest pain > 30 min, age ≥ 18 y, ST-segment elevation in 2 or more ECG leads, vascular diameter 3 cm distal to culprit lesion was 3 mm or more, no severe tortuosity or kinks**Exclusion criteria:** Severe blood, hepatic, or renal disease with history of internal organ bleeding within the past month, allergy to antiplatelets or anticoagulants, chronic renal failure (Cr 2.6 mg/dL or greater)**Intervention:** PCI with GuardWire Plus**Comparator:** Conventional PCI**Duration of followup (d):** 180**Followup:** 100% | **Intermediate:** MBG-3, TIMI-3, DE, no reflow (post procedure); EF (post procedure,180 d); STSR > 70% (30 min)**Final:** MACE (mortality, non-lethal MI, heart failure, ischemic-driven revascularization), mortality, TVR, reinfarction (30 d,180 d)**Safety:** Procedure time, side branch occlusion | 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? Can’t tell
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? Can’t tell
8. Were the methods used for randomization adequate? Yes

Overall quality rating: Good |
| Muramatsu, 2007ASPARAGUS | **Publication type:** Full text**Geographical location:** Japan**Funding:** Medtronic Japan Co. Ltd**Number of centers:** 22**Randomization:** Randomized according to envelope method**Outcome assessment:** Clinical and basic angiographic data collected and case report forms sent to and reviewed by reviewed by core laboratory**Number of participants enrolled:** 341 | **Inclusion criteria:** Native vessel, AMI within 12 h of chest pain onset, age ≥ 18 y, ST-segment elevation, patients considered treatable by stenting**Exclusion criteria:** SVG, left main trunk disease, reference vessel diameter < 2.5 mm, cardio-pulmonary arrest**Intervention:** Primary PCI with GuardWire Plus**Comparator:** Primary PCI**Duration of followup (d):** 30**Followup:** 100%  | **Intermediate:** MBG-3, TIMI-3, DE, no reflow (post- procedure); EF (post- procedure, 30 d, 180 d); STSR > 70% (90 min)**Final:** MACE (mortality, myocardial infarction or TVR) (30 d, 180 d); mortality, TVR, reinfarction (in-hospital, 30 d, 180 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? Yes
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? Yes

Overall quality rating: Good |
| Zhou, 2007 | **Publication type:** Full text**Geographical location:** NR**Funding:** NR**Number of centers:** NR**Randomization:** Randomized using sealed envelopes**Outcome assessment:** TIMI flow grade and MBG evaluated by 2 experienced investigators who were blinded to all clinical data**Number of participants enrolled:** 112 | **Inclusion criteria:** Continuous chest pain > 30 min, < 12 h from symptom onset, ST- segment elevation ≥ 0.1 mV in 2 or more contiguous ECG leads, culprit lesion with diameter stenosis ≥ 70% and TIMI flow grade ≤ 2**Exclusion criteria:** Thrombolytic treatment before PCI, GP2B3Ai before PCI, reference vessel diameter < 3.0 mm, KiIlip IV or cardiogenic shock, left main coronary artery lesion**Intervention:** Primary stenting with PercuSurge GuardWire**Comparator:** Primary stenting**Duration of followup (d):** In-hospital**Followup:** 100% | **Intermediate:** MBG-3, TIMI-3 (post-procedure)**Final:** MACE (in-hospital)**Safety:** Coronary dissection, perforation | 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? Yes
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? Yes

Overall quality rating: Good |
| Okamura,2005 | **Publication type:** Full text**Geographical location:** Japan**Funding:** NR**Number of centers:** 1**Randomization:** NR**Outcome assessment:** Data assessed using an offline personal computer**Number of participants enrolled:** 16 | **Inclusion criteria:** Chest pain > 30 min, and presentation ≤ 24 h after symptom onset, ST-segment elevation ≥ 2 mm in 2 or more ECG leads, TIMI 0,1 or 2 on initial angiogram, reference luminal diameter ≥ 3 mm in IRA**Exclusion criteria:** Cardiogenic shock, previous CABG, atrial fribrillation**Intervention:** PCI with PercuSurge Guidewire **Comparator:** PCI**Duration of followup (d):** In-hospital until discharge, 22 ± 4**Followup:** 100%  | **Intermediate:** TIMI-3 (post-procedure); EF (discharge)**Final:** NR**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? Yes
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 |
| Stone, 2005EMERALD | **Publication type:** Full text, abstract, slide presentation**Geographical location:** USA, Canada, France, Italy, Germany, Switzerland, Japan**Funding:** Medtronic**Number of centers:** 38**Randomization:** Telephone randomization in random blocks of 4 or 6 patients stratified by intention to use GP2B3Ai and by primary versus rescue PCI | **Inclusion criteria:** AMI > 30 min but < 6 h from symptom onset, age ≥ 18 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads or presumably new LBBB, primary or rescue PCI, vessel diameter at the infarct lesion 2.5 - 5.0 mm without excess tortuosity or lesion/vessel calcification with 3 cm or more of distal vessel available**Exclusion criteria:** Cardiogenic shock, CABG within 30 d, unprotected left main disease, renal insufficiency (SCr > 2.5 mg/dL), hepatic dysfunction, multivessel intervention required during index PCI, cardiogenic shock, major surgery or active bleeding within 6 wk, allergy to aspirin, thienopyridine or heparin, neutropenia (< 1000 neutrophils/mm3), thrombocytopenia (< 100,000 platelets/mm3), non-cardiac condition with expected survival < 1 y, current participation in another study | **Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 70% (30 min)**Final:** MACE related to ischemic complications, mortality, TVR, reinfarction, stroke (30 d, 180 d); **Safety:** Perforation**,** procedure time, side branch occlusion | 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? Yes
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 |
|  | **Outcome assessment:** STSR by core laboratory, infarct size by a staff blinded to treatment assignment at a central core laboratory and all primary and secondary clinical endpoints adjudicated by a clinical events committee blinded to treatment allocation**Number of participants enrolled:** 501 | **Intervention:** PCI GuardWire Plus**Comparator:** PCI**Duration of followup (d):** 180**Followup:** 93.06% in device group and 89.76% in control group |  |  |

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

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