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

| Study, Year | Trial Characteristics | Population, Interventions and Followup\* | Outcomes of Interest (Timing) | Quality Assessment / Comments |
| --- | --- | --- | --- | --- |
| Haeck, 2009PREPARE | **Publication type:** Full text, abstract, slide presentation**Geographical location:** Netherlands and Canada**Funding:** St. Jude Medical, University of Amsterdam**Number of centers:** 2**Randomization:** Randomized on a 1:1 basis**Outcome assessment:** STSR analysis performed by a central core laboratory, coronary angiograms assessed by 2 experienced investigators blinded to all other data, clinical event data obtained from hospital records and telephone interviews**Number of participants enrolled:** 284 | **Inclusion criteria:** Symptoms of MI < 6 h after onset, persistent ST-segment elevation of ≥ 200 µV in 2 or more contiguous leads, TIMI 0/1 after first angiogram, coronary anatomy suitable for treatment with the Proxis system**Exclusion criteria:** Age < 18 y, contraindication to use of GP2B3Ai, co-existent condition with limited life expectancy, prior CABG or lytics, recurrent MI in the same myocardial area, ECG unsuitable for STSR evaluation (LBBB, ventricular pacemaker, atrial fibrillation), left main occlusion, left main stenosis > 30%, heavy proximal calcification, small infarct related artery (< 2.5 mm in diameter), proximal location of lesion with insufficient landing zone for Proxis system (generally < 10-12 mm)**Intervention:** Primary PCI with Proxis device**Comparator:** Primary PCI**Duration of followup (d):** 30**Followup:** 89.36% in device group, 90.21% in control group | **Intermediate:** MBG-3, TIMI-3, DE, (post-procedure); STSR ≥ 70% (60 min); ejection fraction (120-180d)**Final:** MACE (death, spontaneous or procedural MI, stroke, percutaneous or surgical TVR), mortality, reinfarction, TVR, stroke (30d, 180d)**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: Good |

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

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