Table 12. Characteristics and quality assessment of controlled observational studies

| **Study, Year** | **Study Characteristics** | **Population, Intervention, and Followup** | **Outcomes of Interest (Timing)** | **Quality Assessment / Comments** |
| --- | --- | --- | --- | --- |
| Beaudoin,  2010 | **Publication type:**  Full text  **Geographical location:**  Canada  **Study design:**  Retrospective study  **Funding:**  NR  **Number of centers:**  1  **Outcome assessment:**  Angiograms reviewed by two trained investigators  **Number of participants enrolled:**  535 | **Inclusion criteria:**  Patients undergoing primary or rescue PCI for STEMI (chest pain or equivalent symptoms at rest >30 min, with ST-segment elevation in ≥2 contiguous leads); presenting >12h included only if persistent chest pain was present at the time of initial evaluation; patients with ST-segment depressing ≥1mm in precordial leads suggesting posterior MI and new or presumed LBBB were included if coronary occlusion was confirmed on angiography  **Exclusion criteria:**  NR  **Intervention:**  PCI with Export Aspiration Catheter  **Comparator:**  PCI without prior thrombectomy  **Duration of followup (d):**  357 days in intervention and 363 days in control groups  **Covariates/potential confounders adjusted for:**  Killip class, final TIMI flow, age≥60 years, presence of three vessel disease, anterior infarction and ischemia time>4hours for the survival analysis | **Intermediate:**  TIMI 3 (post-procedure)  **Final:**  Mortality, reinfarction, stroke, revascularization, MACE (365 d)  **Safety:**  Procedure time (post-procedure) | 1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? Yes 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Yes 7. Outcome assessment blinded to exposure? Partially 8. Adequate followup period? Yes? 9. Completeness of followup? Yes? 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes   Overall quality rating: Good |
| Kim,  2010 | **Publication type:**  Abstract  **Geographical location:**  South Korea  **Study design:**  Propensity-matched cohort  **Funding:**  NR  **Number of centers:**  NR  **Outcome assessment:**  NR  **Number of participants enrolled:**  858 | **Inclusion criteria:**  STEMI patients  **Exclusion criteria:**  NR  **Intervention:**  PCI with thrombus aspiration  **Comparator:**  PCI without thrombus aspiration  **Duration of followup (d):**  30 days  **Covariates/potential confounders adjusted for:**  NR | **Intermediate:**  TIMI 3, LVEF (post-procedure)  **Final:**  Mortality (in-hospital)  **Safety:**  NR | 1. Unbiased selection of the cohort? Can’t tell 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Can’t tell 7. Outcome assessment blinded to exposure? Can’t tell 8. Adequate followup period? No 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes   Overall quality rating: Poor |
| Ko,  2009  KAMIR | **Publication type:**  Abstract  **Geographical location:**  Korea  **Study design:**  Registry  **Funding:**  NR  **Number of centers:**  NR  **Outcome assessment:**  NR  **Number of participants enrolled:**  1050 | **Inclusion criteria:**  Acute STEMI, PCI within 3 h of symptom onset  **Exclusion criteria:**  NR  **Intervention:**  PCI with distal protection device (device name NR)  **Comparator:**  PCI without distal protection device  **Duration of followup (d):**  365  **Covariates/potential confounders adjusted for:**  NR, subgroup analyses based on LV dysfunction and use of GP2B3Ai | **Intermediate:**  NR  **Final:**  MACE (365 d)  **Safety:**  NR | 1. Unbiased selection of the cohort? Partially 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Can’t tell 7. Outcome assessment blinded to exposure? Can’t tell 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes   Overall quality rating: Poor |
| Nilsen, 2009 | **Publication type:**  Abstract  **Geographical location:**  NR  **Study design:**  Retrospective cohort  **Funding:**  NR  **Number of centers:**  123  **Outcome assessment:**  Core lab analysis1  **Number of participants enrolled:**  3298, 32331 | **Inclusion criteria:**  See table 2 of original study2  **Exclusion criteria:**  See table 2 of original study2  **Intervention:**  PCI with catheter aspiration  (Device name NR)  **Comparator:**  PCI without catheter aspiration  **Duration of followup (d):**  30  **Covariates/potential confounders adjusted for:**  NR | **Intermediate:**  DE1, (post-procedure); STSR > 70%1(60 min)    **Final:**  MACE (mortality, reinfarction, ischemic TVR, stroke), mortality, reinfarction, ischemic TVR, stroke (30 d)  **Safety:**  Dissection1 | 1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Can’t tell 7. Outcome assessment blinded to exposure? Yes 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes   Overall quality rating: Fair |
| Nakatani, 2007  OACIS | **Publication type:**  Full text, abstract  **Geographical location:**  Japan  **Study design:**  Prospective registry  **Funding:**  Government (Japanese Ministry of Education, Culture, Sports, Sciences, and Technology); Foundation (Japan Arteriosclerosis Prevention Fund)  **Number of centers:**  25  **Outcome assessment:**  NR  **Number of participants enrolled:**  3913 | **Inclusion criteria:**  Undergoing PCI, AMI/symptoms within 24 h  **Exclusion criteria:**  Admittance > 24 h (or time unknown) after onset of AMI, treated conservatively, with thrombolytic therapy, emergent CABG, or with distal protection  **Intervention:**  PCI with catheter aspiration (RESCUE catheter, Thrombuster catheter, TVAC catheter, Export PercuSurge System)  **Comparator:**  PCI without catheter aspiration  **Duration of followup (d):**  30  **Covariates/potential confounders adjusted for:**  Mortality adjusted for hospital volume, age, male gender, diabetes mellitus, hypertension, hyperlipidemia, smoking, body mass index ≥ 25 kg/m2, a history of myocardial infarction, preangina, Killip class ≥ II, ST-segment elevation myocardial infarction, onset to admission < 12 h, angiographic findings (including multivessel disease, collateral circulation, and initial TIMI grade flow), use of stenting | **Intermediate:**  NR  **Final:**  Mortality (cardiac and non-cardiac) (30 d)  **Safety:**  NR | * Unbiased selection of the cohort? Yes * Selection minimizes baseline differences in prognostic factors? Yes * Sample size calculated? No * Adequate description of the cohort? Yes * Validated method to ascertain exposure? Yes * Validated method for ascertaining clinical outcomes? Yes * Outcome assessment blinded to exposure? Can’t tell * Adequate followup period? Yes * Completeness of followup? Yes * Analysis controls for confounding? Yes * Analytic methods appropriate? Yes   Overall quality rating: Fair |
| Chinnaiyan, 2006 | **Publication type:**  Full text  **Geographical location:**  NR  **Study design:**  Retrospective cohort  **Funding:**  NR  **Number of centers:**  1  **Outcome assessment:**  Examined according to whether patient received mechanical thrombectomy or not  **Number of participants enrolled:**  1260 | **Inclusion criteria:**  Undergoing primary or rescue PCI, symptoms consistent with AMI lasting < 24 h, ST-segment elevation ≥ 1 mm in two contiguous leads  **Exclusion criteria:**  SVG culprit, stent thrombosis  **Intervention:**  PCI with mechanical thrombectomy (AngioJet XMI or XVG catheter)  **Comparator:**  PCI without mechanical thrombectomy  **Duration of followup (d):**  In-hospital  **Covariates/potential confounders adjusted for:**  MACE and mortality adjusted for baseline clinical and angiographic characteristics | **Intermediate:**  TIMI-3 (post-procedure)  **Final:**  MACE (mortality, reinfarction, TVR, stroke), mortality, TVR, stroke, reinfarction (in-hospital)  **Safety:**  Coronary artery perforation | 1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? Yes 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Yes 7. Outcome assessment blinded to exposure? No 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes   Overall quality rating: Fair |
| Simonton, 2006 | **Publication type:**  Full text  **Geographical location:**  United States  **Study design:**  Prospective registry  **Funding:**  Unknown  **Number of centers:**  9  **Outcome assessment:**  Patient contact by phone for clinical outcome assessment, physician adjudicated MACE events, routine data audits  **Number of participants enrolled:**  1368 | **Inclusion criteria:**  Undergoing PCI, TIMI thrombus grade ≥ 3, 9 m followup available, no use of distal protection device  **Exclusion criteria:**  Inability to provide informed consent  **Intervention:**  PCI with mechanical thrombectomy (AngioJet)  **Comparator:**  PCI without mechanical thrombectomy or distal protection  **Duration of followup (d):**  270  **Covariates/potential confounders adjusted for:**  Unadjusted | **Intermediate:**  TIMI-3 (post-procedure)  **Final:**  MACE (mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event), mortality, TVR, MI (270 d)  **Safety:**  NR | 1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Yes 7. Outcome assessment blinded to exposure? Can’t tell 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? No 11. Analytic methods appropriate? No   Overall quality rating: Poor |

Abbreviations: AMI=acute myocardial infarction; CABG=coronary artery bypass graft; d=days; DE=distal embolization; h=hours; GP2B3Ai=glycoprotein IIb IIIa inhibitor; Kg/m2=kilogram-meter squared; LV=left ventricular; m=months; MACE=major adverse cardiac events; MI=myocardial infarction; min=minutes; mm=millimeter; NR=not reported; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft ; TVAC=transvacular aspiration catheter; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization