Adjunctive Devices in PCI To Remove Thrombi or Protect Against Distal Embolization in Patients With ACS

**Focus of Research for Clinicians**
A systematic review of 175 clinical studies published between January 1996 and March 2011 sought to determine the comparative effectiveness, benefits, and adverse effects of adjunctive devices to remove thrombi or protect against embolization in patients with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) of native vessels. This summary is provided to assist in decisionmaking along with consideration of a patient’s values and preferences. Reviews of evidence should not be construed to represent clinical recommendations or guidelines. The full report is available at www.effectivehealthcare.ahrq.gov/thrombusacs.cfm.

**Background Information**
Outcomes of PCI have improved with the use of coronary stents and adjunctive pharmacologic agents. However, distal embolization caused by the dislodgement of atherothrombotic material from coronary lesions during PCI can lead to the “no-reflow phenomenon,” which results in significantly higher morbidity and mortality for patients with ACS. Several adjunctive devices have been developed to remove thrombi and to protect against distal embolization during PCI (Figure 1). They are classified into catheter aspiration thrombectomy, mechanical thrombectomy, and embolic protection devices. The comparative effectiveness and the risk differences between these devices in patients with ACS undergoing PCI for native coronary arteries are not well established.

**Conclusion**
Catheter aspiration thrombectomy reduces the occurrence of major adverse cardiovascular events, distal embolization, and no reflow and improves ST-segment elevation resolution and coronary flow when used as an adjunctive therapy for patients with ST-segment elevation myocardial infarction (STEMI) who are undergoing primary PCI. Evidence does not support benefits from mechanical thrombectomy or embolic protection devices, which appear to prolong procedure time. Current evidence is too limited to permit conclusions about the comparative benefits and harms of these devices with respect to final health outcomes and adverse events.

**Clinical Bottom Line**
Devices to remove thrombi or protect against distal embolization in patients with ACS who were undergoing PCI of native vessels were compared with standard PCI.

**PATIENTS WITH STEMI**

**Catheter Aspiration**

**Final Health Outcomes:**
- Significantly decreased the risk of MACE* by 27%; 33 people with STEMI need to be treated with a catheter aspiration device to prevent one MACE (NNT=33).
- No significant impact on death, MI, or target lesion revascularization.

**Intermediate Outcomes:**
- Significantly reduced distal embolization by 44% (NNT=12).
- Significantly reduced no reflow by 48% (NNT=15).
- Significantly increased the resolution of ST-segment elevation by 51% (NNT=5), achievement of MBG-3 by 61% (NNT=5), and TIMI-3 flow by 8% (NNT=17).
- Did not significantly impact ejection fraction.
- Reduced the risk for coronary dissection by 70% (NNT=50).
- Does not prolong procedure time.

*Abbreviations are defined on page 2.

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### PATIENTS WITH STEMI (Continued from front)

**Mechanical Thrombectomy**
- Evidence was insufficient to determine the effects on final health outcomes (mortality, MACE, reinfection, stroke, or target lesion revascularization).
- Had no significant effects on these intermediate health outcomes:
  - ST-segment resolution
  - Ejection fraction
  - Achievement of MBG-3
  - TIMI-3 flow
  - Risk of distal embolization
- Average procedure times were prolonged by approximately 9–16 minutes.

**Embolic Protection Devices**
- Evidence was insufficient to determine the effects on some final health outcomes including mortality, reinfection, and stroke for most embolic protection devices.
- Embolic protection devices did not significantly affect MACE.
- Overall, embolic protection devices did not significantly affect these intermediate outcomes:
  - Ejection fraction
  - Risk of distal embolization
  - Achievement of ST-segment resolution
- Distal balloon embolic protection devices significantly increased achievement of MBG-3 by 39% (NNT=7) and TIMI-3 flow by 11% (NNT=13).
- Proximal balloon devices increased the median procedure time by approximately 14 minutes.
- Distal balloon embolic protection devices increased average procedure times by approximately 23 minutes.
- Distal filter embolic protection devices increased target lesion revascularization by 61% (NNH=25).

### PATIENTS WITH MIXED ACS (STEMI, NSTEMI, OR UA)

**Catheter Aspiration**
- Achievement of MBG-3 was almost 4.5-fold more likely with the use of a catheter aspiration device than without it (NNT=3).
- Evidence on catheter aspiration devices was insufficient with respect to final health outcomes and additional intermediate outcomes.
- No available studies evaluated adverse events for this device in this population.

**Mechanical Thrombectomy**
- Mechanical thrombectomy devices significantly improved ST-segment resolution by 58% (NNT=3).
- Evidence supporting mechanical thrombectomy devices was insufficient with respect to final health outcomes and additional intermediate outcomes.
- No available studies evaluated adverse events for this device in this population.

**Embolic Protection Devices**
- Distal balloon embolic protection devices significantly increased the resolution of ST-segment elevation by 58% (NNT=3) and the achievement of MBG-3 by 3-fold (NNT=2), and significantly reduced the risk of no reflow by 64% (NNT=2).
- Procedure times were prolonged by a mean of 7 minutes.

ACS = acute coronary syndrome; MACE = major adverse cardiovascular events (including reinfarction, target lesion revascularization, and stroke); MBG = myocardial blush grade; MI = myocardial infarction; NNH = number needed to harm; NNT = number needed to treat; NSTEMI = non-ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction; TIMI = thrombolysis in myocardial infarction flow grade; UA = unstable angina

### Gaps in Knowledge
- Direct comparative randomized controlled trials are needed that compare one thrombectomy or embolic protection device with another and evaluate final health outcomes.
- Studies examining final health outcomes and using longer followup data are needed to fully determine the comparative effectiveness, benefits, and harms of adjunctive thrombectomy and embolic protection devices in patients with ACS who are undergoing PCI.

### Glossary of Terms

**Myocardial blush grade (MBG):** An angiographic method of grading myocardial tissue perfusion ranging from grade 0 to grade 3.

**Thrombolysis in myocardial infarction (TIMI) blood flow:** An angiographic method of grading blood flow in an epicardial coronary artery with a range from grade 0 to grade 3.
Numerous adjunctive devices have been developed to help improve clinical outcomes by removing thrombi and to protect against distal embolization during PCI. These devices utilize different technologies and are broadly classified as catheter aspiration, mechanical thrombectomy, or embolic protection devices (i.e., distal or proximal embolic balloon or distal filter protection devices).

(A) **Catheter aspiration thrombectomy** uses a catheter that is advanced over a guidewire to the thrombus where manual syringe suction is used to aspirate the debris.

(B) **Mechanical thrombectomy devices** apply energy through saline jets or a rotating catheter head to facilitate breakup of the thrombus before its active aspiration.

(C) **Proximal embolic protection devices** employ an occlusion balloon advanced over a guidewire proximal to the thrombus to trap and aspirate thrombotic debris released during angioplasty and stenting procedures.

(D and E) **Distal embolic protection devices** are similar to proximal devices, except they employ an occlusion balloon (D) or filter (E) advanced over a guidewire distal to the thrombus to trap and aspirate (balloon devices) or capture and retrieve (filter devices) thrombotic debris released during angioplasty and stenting procedures.
Ordering Information
For electronic copies of this clinician research summary and the full systematic review, visit www.effectivehealthcare.ahrq.gov/thrombusacs.cfm. To order free print copies, call the AHRQ Publications Clearinghouse at 800-358-9295.

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