2015 ACC/AHA/SCAI Focused Update on Primary PCI for Patients with STEMI:

An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

Developed in Collaboration with the American College of Emergency Physicians

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Journal of the American College of Cardiology [http://content.onlinejacc.org/article.aspx?doi=10.1016/j.jacc.2015.10.005]

and Circulation

[http://circ.ahajournals.org/lookup/doi/10.1161/CIR.000000000000336]

The full-text guidelines are also available on the following Web sites: ACC (<u>www.acc.org</u>) and AHA (<u>my.americanheart.org</u>)





Focused Update on Primary PCI for Patients with STEMI Guideline Writing Committees

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Applying Class of Recommendation and Level of Evidence

CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG)

Benefit >>> Risk

Suggested phrases for writing recommendations:

- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
 - Treatment/strategy A is recommended/indicated in preference to treatment B
 - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE

Benefit >> Ris

Suggested phrases for writing recommendations:

- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
 - Treatment/strategy A is probably recommended/indicated in preference to treatment B
 - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK)

Benefit ≥ Risk

Suggested phrases for writing recommendations:

- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE)

Benefit = Risk

Suggested phrases for writing recommendations:

- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG)

Risk > Benefit

Suggested phrases for writing recommendations:

- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A

- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R

(Randomized)

- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR

(Nonrandomized)

- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD

(Limited Data)

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO

Expert Opinion

Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

- * The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).
- † For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
- ‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

Culprit Artery – Only Versus Multivessel PCI

COR	LOE	Recommendation
IIb	B-R	PCI of a noninfarct artery may be considered in selected patients with STEMI and multivessel disease who are hemodynamically stable, either at the time of primary PCI or as a planned staged procedure. ¹

^{1.} Modified recommendation from 2013 Guideline (changed class from III: Harm to IIb and expanded time frame in which multivessel PCI could be performed).





Culprit Artery – Only Versus Multivessel PCI

- Previous clinical practice guidelines recommended against PCI of nonculprit artery stenoses at the time of primary PCI in hemodynamically stable patients with STEMI, based primarily on the results of nonrandomized studies and meta-analyses and safety concerns.
- Four RCTs (PRAMI, CvLPRIT, DANAMI 3 PRIMULTI, PRAGUE-13) have since suggested that a strategy of multivessel PCI, either at the time of primary PCI or as a planned, staged procedure, may be safe and beneficial in *selected patients* with STEMI.
- On the basis of these findings, the prior Class III-harm recommendation with regard to multivessel primary PCI in hemodynamically stable patients with STEMI has been upgraded and modified to a Class IIb recommendation to include consideration of multivessel PCI, either at the time of primary PCI or as a planned, staged procedure.
- The writing committee emphasizes that this change should not be interpreted as endorsing the routine performance of multivessel PCI in all patients with STEMI and multivessel disease. Rather, when considering the indications for and timing of multivessel PCI, physicians should integrate clinical data, lesion severity/complexity, and risk of contrast nephropathy to determine the optimal strategy.





Aspiration Thrombectomy

COR	LOE	Recommendations
IIb	C-LD	The usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established. ¹
III: No Benefit	Α	Routine aspiration thrombectomy before primary PCI is not useful. ²

- 1. Modified recommendation from 2013 guideline (Class changed from IIa to IIb for selective and bailout aspiration thrombectomy before PCI)
- 2. New recommendation





Aspiration Thrombectomy

- The 2011 PCI and 2013 STEMI guidelines' Class IIa recommendation for aspiration thrombectomy before primary PCI was based on the results of 2 RCTs and 1 metaanalysis and was driven in large measure by the results of TAPAS, a single-center study.
- Since formulation of that recommendation, 3 multicenter trials (INFUSE-AMI, TASTE, TOTAL), 2 of which enrolled significantly more patients than prior aspiration thrombectomy trials, have prompted re-evaluation of this recommendation.
- These 3 more recent trials, as well as an updated meta-analysis, found no significant reduction in adverse events with routine aspiration thrombectomy.
- Based on these 3 trials, routine aspiration thrombectomy before primary PCI is now designated as Class III-No Benefit.
- Subgroup analysis in TASTE and TOTAL did not identify any specific subgroup (e.g., anterior MI, high thrombus burden) that benefited from routine aspiration thrombectomy.
- Based on these and other considerations, a Class IIb recommendation was established stating that the usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established.



