Focused Update on Primary PCI for Patients with STEMI

Patrick T. O’Gara, MD, MACC, FAHA

On behalf of
Glenn N. Levine, MD, FACC, FAHA
and
The PCI and STEMI Writing Committees

*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry may apply; see Appendix 1 for detailed information. †ACC/AHA Representative. ‡SCAI Representative. § ACC/AHA Task Force on Clinical Practice Guidelines Liaison. ||ACP Representative.
Multi-Vessel PCI

- At time of P-PCI
- Planned, Staged
- Ischemia + stress
### 2011 PCI / 2013 STEMI Guidelines

#### Primary PCI

<table>
<thead>
<tr>
<th>Condition</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic symptoms &lt;12 h</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Ischemic symptoms &lt;12 h and contraindications to fibrinolytic therapy irrespective of time delay from FMC</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Cardiogenic shock or acute severe HF irrespective of time delay from MI onset</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Evidence of ongoing ischemia 12 to 24 h after symptom onset</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>PCI of a noninfarct artery at the time of primary PCI in patients without hemodynamic compromise</td>
<td>III: Harm</td>
<td>B</td>
</tr>
</tbody>
</table>
PRAMI

Cardiac Death
MI
Refr. Angina

Hazard ratio, 0.35 (95% CI, 0.21–0.58); P<0.001

No. at Risk
Preventive PCI 234 196 166 146 118 89 67
No preventive PCI 231 168 144 122 96 74 50

Wald DS et al NEJM 2013; 369:1115-23
# Evidence

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>N</th>
<th>Comparison with COR Primary Endpoint</th>
<th>Hazard Ratio</th>
</tr>
</thead>
</table>
| PRAMI          | 2013 | 465 | MV-PPCI  
Cardiac death, non-fatal MI, refractory angina @ 23 m                                               | 0.35 (0.21-0.58) P< 0.001     |
| CvLPRIT        | 2015 | 296 | MV-PPCI or staged in-hosp. MV PCI  
Death, MI, HF, revasc for isch @ 12m                                                                  | 0.45 (0.24-0.84) P=0.009     |
| DANAMI-3 PRIMULTI | 2015 | 627 | Staged in-hosp MV-PCI (+ FFR)  
Death, MI, revasc for isch @ 12 m                                                                       | 0.56 (0.38-0.83) P=0.001     |
| PRAGUE*        | 2015 | 214 | Staged MV PCI (3-40 days)  
Death, non-fatal MI, stroke @ 38 m                                                                      | 1.35 (0.66-2.74) P=0.407     |

* Abstract EuroPCR
Culprit Artery – Only Versus Multivessel PCI

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIb</td>
<td>B-R</td>
<td>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</td>
</tr>
</tbody>
</table>

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

Insufficient data to inform recommendation regarding optimal timing of staged PCI
Aspiration
Thrombectomy

Routine

Bail-Out
Manual aspiration thrombectomy is reasonable for patients undergoing primary PCI.
Aspiration Thrombectomy: TOTAL

N=10,732

1^o Outcome
CV Death
MI
Shock
NYHA IV HF

Jolly SS et al. NEJM 2015; 372:1389-98
### Thrombectomy Meta-Analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>RR (95% CI)</th>
<th>Events, Treatment</th>
<th>Events, Control</th>
<th>% Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL</td>
<td>2015</td>
<td>0.90 (0.73, 1.11)</td>
<td>157/5033</td>
<td>174/5030</td>
<td>52.86</td>
</tr>
<tr>
<td>TASTE</td>
<td>2013</td>
<td>0.94 (0.72, 1.22)</td>
<td>103/3621</td>
<td>110/3623</td>
<td>33.95</td>
</tr>
<tr>
<td>MUSTELA</td>
<td>2012</td>
<td>0.83 (0.17, 4.14)</td>
<td>2/50</td>
<td>5/104</td>
<td>0.92</td>
</tr>
<tr>
<td>INFUSE-AMI</td>
<td>2012</td>
<td>1.14 (0.39, 3.33)</td>
<td>7/229</td>
<td>6/223</td>
<td>2.06</td>
</tr>
<tr>
<td>Ciszewski et al</td>
<td>2011</td>
<td>0.70 (0.12, 4.04)</td>
<td>2/67</td>
<td>3/70</td>
<td>0.77</td>
</tr>
<tr>
<td>PIHRATE</td>
<td>2010</td>
<td>1.28 (0.29, 5.57)</td>
<td>4/100</td>
<td>3/96</td>
<td>1.10</td>
</tr>
<tr>
<td>Liistro et al</td>
<td>2009</td>
<td>3.05 (0.13, 73.38)</td>
<td>1/55</td>
<td>0/56</td>
<td>0.24</td>
</tr>
<tr>
<td>EXPIRA</td>
<td>2009</td>
<td>0.11 (0.01, 2.01)</td>
<td>0/88</td>
<td>4/87</td>
<td>0.28</td>
</tr>
<tr>
<td>VAMPIRE</td>
<td>2008</td>
<td>0.97 (0.06, 15.42)</td>
<td>1/180</td>
<td>1/175</td>
<td>0.31</td>
</tr>
<tr>
<td>EXPORT</td>
<td>2008</td>
<td>0.64 (0.16, 2.64)</td>
<td>3/120</td>
<td>5/129</td>
<td>1.20</td>
</tr>
<tr>
<td>Chao et al</td>
<td>2008</td>
<td>3.00 (0.13, 71.34)</td>
<td>1/37</td>
<td>0/37</td>
<td>0.24</td>
</tr>
<tr>
<td>TAPAS</td>
<td>2008</td>
<td>0.52 (0.26, 1.08)</td>
<td>11/535</td>
<td>21/536</td>
<td>4.60</td>
</tr>
<tr>
<td>De Luca et al</td>
<td>2006</td>
<td>0.20 (0.01, 4.03)</td>
<td>0/38</td>
<td>2/38</td>
<td>0.26</td>
</tr>
<tr>
<td>Kaltoft et al</td>
<td>2006</td>
<td>0.33 (0.01, 8.02)</td>
<td>0/108</td>
<td>1/107</td>
<td>0.23</td>
</tr>
<tr>
<td>REMEDIA</td>
<td>2005</td>
<td>0.98 (0.21, 4.62)</td>
<td>3/50</td>
<td>3/49</td>
<td>0.99</td>
</tr>
<tr>
<td>TROFI</td>
<td>2013</td>
<td>(Excluded)</td>
<td>0/71</td>
<td>0/70</td>
<td>0.00</td>
</tr>
<tr>
<td>DEAR-MI</td>
<td>2006</td>
<td>(Excluded)</td>
<td>0/74</td>
<td>0/74</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Overall (I-squared = 0.0%, p = 0.917)**

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<th>Events, Treatment</th>
<th>Events, Control</th>
<th>% Weight</th>
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<tr>
<td>0.89 (0.76, 1.04)</td>
<td>295/10456</td>
<td>338/10504</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis

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Aspiration Thrombectomy

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<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIb</td>
<td>C-LD</td>
<td>The usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established.¹</td>
</tr>
<tr>
<td>III: No Benefit</td>
<td>A</td>
<td><strong>Routine</strong> aspiration thrombectomy before primary PCI is not useful.²</td>
</tr>
</tbody>
</table>

1. Modified recommendation from 2013 guideline (Class changed from IIa to IIb for selective and bailout aspiration thrombectomy before PCI)
2. New recommendation
Focused Update on Primary PCI for Patients with STEMI Guideline Writing Committees

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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.
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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 meta-analysis 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.
PRAMI + CvLPRIT

Bhatt DL. JACC 2015;65:973-5
Update in STEMI

Deepak L. Bhatt, MD, MPH

Executive Director of Interventional Cardiovascular Programs, BWH Heart and Vascular Center
Professor of Medicine, Harvard Medical School
PRAMI + CvLPRIT
**DANAMI 3-PRIMULTI**

**Trial design:** Following PCI of the culprit infarct related artery (IRA) in patients with STEMI, patients were randomized in a 1:1 fashion to either FFR-guided complete revascularization or no further revascularization prior to discharge. They were followed for 27 months.

**Results**
- Primary outcome: MACE (all-cause mortality, MI, ischemia driven revascularization of non-IRA lesions): 13% vs. 22%, HR = 0.56, p=0.004
- Ischemia-driven revascularization: 5% vs. 17%, p<0.001; non-fatal MI: 5% vs. 5%, p=0.87
- Periprocedural stroke: 1.3% vs. 0.3%, p=0.2; urgent PCI: 2% vs. 6%, p=0.03

**Conclusions**
- Among patients with multivessel disease presenting with STEMI and undergoing primary PCI, FFR-guided complete revascularization prior to hospital discharge superior to culprit IRA only PCI
- Adds to the literature on multivessel PCI in patients with STEMI

Presented by Dr. Hans Thyregod at ACC 2015
TOTAL – Aspiration Thrombectomy


A Primary Outcome

Cumulative Hazard Rate

PCI alone
Thrombectomy

Hazard ratio, 0.99 (95% CI, 0.85–1.15)
P = 0.86

No. at Risk
Thrombectomy 5033 4734 4696 4678 4662 4647 4628
PCI alone 5030 4727 4688 4666 4653 4642 4618

Months of Follow-up