Coronary Revascularization: An Ongoing Evolution

PCI Without On-site Surgery

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Cardiology Associates
My Annual Reminder

- I am N-N-NOT N-N-N-N-Nervous

- Yea right
PCI Without On Site Surgery

- Came to Baldwin County on January 5, 2015
Coronary Revascularization: The History

Figure 1: Major milestones in percutaneous coronary intervention
Coronary Revascularization: The Risk - Initially

- Gruntzig’s initial article 1977 – total 50 patients
  - 36% procedural failure rate
  - 10% emergency bypass rate
  - Conclusion – only suitable for 10-15% of patient’s needing revascularization
Coronary Revascularization: The Risk – Before Stents

- Data from early 1990s
  - 7% abrupt occlusion rate
  - 1.5-3% emergency bypass rate
  - 5-7% myocardial infarction rate
  - 1-2% stroke risk
  - 1.5-2% death risk

Current NIH web site still list these percentages!
Game Changer
Coronary Revascularization: The Risk - Now

- Recent data suggest
  - 0.29 - 0.5% risk of emergency bypass
  - 0.26 - 0.5% risk of stroke
  - 3-5% risk of myocardial infarction
  - 1.4 - 1.8 % risk of death
Current State of Coronary Revascularization

Interesting Facts

- PCI now account for 80% of coronary revascularizations.
- From 2006 to 2012 there was a 30% decline in PCI procedures (secondary to DES, statins, COURAGE trial, FFR trials, etc).
- Therefore many operators and hospitals now have low-volume practices (recommendation is >200 cases/yr for the hospital and >75 cases/yr for the operator).
- >60% of Interventional Cardiologist perform < 40 cases/yr.
- > 30% of Hospitals perform < 200 cases/yr.
- Approximately 33% of PCI facilities have no on-site surgery.
- > 65% of hospitals without on-site surgery do < 200 cases/yr.
- In United Kingdom 58% of all PCI done without on-site surgery.
PCI Without On-site Surgery

Significant variation in the approach state to state

Figure Changes From 2007 to 2013

The figure below depicts changes in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and non-primary PCI without on-site surgery are allowed:

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both allowed</td>
<td>28</td>
<td>45</td>
</tr>
<tr>
<td>Primary PCI only</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Not allowed</td>
<td>10</td>
<td>1</td>
</tr>
</tbody>
</table>

PCI Without On-site Surgery: Trials

- The C-Port Trial
  - Over 18,000 randomized and well matched
  - Exclusion – unprotected LM, EF <20%, MD judged high risk

<table>
<thead>
<tr>
<th></th>
<th>No-SOS (%)</th>
<th>SOS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Success</td>
<td>90.8</td>
<td>91.9*</td>
</tr>
<tr>
<td>Partial Success</td>
<td>5.7</td>
<td>5.5</td>
</tr>
<tr>
<td>Failure</td>
<td>3.4</td>
<td>2.5*</td>
</tr>
</tbody>
</table>

Patient Success $P=0.0096$


## Adverse Events - 6-Weeks

<table>
<thead>
<tr>
<th>Event</th>
<th>No-SOS (%)</th>
<th>SOS (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.91</td>
<td>0.93</td>
<td>0.94</td>
</tr>
<tr>
<td>Bleeding</td>
<td>3.41</td>
<td>3.00</td>
<td>0.18</td>
</tr>
<tr>
<td>Vascular repair</td>
<td>0.38</td>
<td>0.40</td>
<td>0.86</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.27</td>
<td>0.15</td>
<td>0.16</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0.50</td>
<td>0.37</td>
<td>0.28</td>
</tr>
</tbody>
</table>

**Cardiology Associates**
### Unplanned Procedures

<table>
<thead>
<tr>
<th></th>
<th>No-SOS (%)</th>
<th>SOS (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG</td>
<td>0.48</td>
<td>0.68</td>
<td>0.10</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>0.10</td>
<td>0.22</td>
<td>0.05</td>
</tr>
<tr>
<td>Unplanned Cath</td>
<td>4.41</td>
<td>3.35</td>
<td>0.002</td>
</tr>
<tr>
<td>Unplanned PCI</td>
<td>2.11</td>
<td>1.32</td>
<td>0.001</td>
</tr>
</tbody>
</table>
PCI Without On-site Surgery: Trials

- MASS COMM trial
  - Just under 3,700 patients randomized
  - Exclusion criteria – LM disease, EF < 20%, high risk vessel, SVG lesions
  - 30 days MACE endpoint equivalent (9.5% to 9.4%)

- Multiple small trials exist since 2006
  - Emergency bypass rate 0.1% to 2.7%
  - Mortality rate 0.97% to 7.0%
PCI Without On-site Surgery: Recommendations

- SCAI Expert Consensus Document 2007 first society to propose guidelines
- 2011 ACC/AHA/SCAI PCI Guidelines dedicated 1 page out of 86 to it – mirrored the SCAI `07 document but first multi-organizational position paper
  - The most current recommendations
PCI Without On-site Surgery:
Recommendations

  - 20 page document
  - Facility requirements (quality assessment program, transfer agreement, specific informed consent, appropriate inventory, clinical and angiographic selection criteria, participation in national registry, full support services – echo, dialysis, etc)
  - Personnel requirements (board certified or eligible Interventional Cardiologist, Cardiologist with minimal of 50 elective PCIs/yr and 11 primary PCIs/yr, well trained cath lab and ICU personnel).
  - **Ideal** Institutional volume is > 200/yr elective PCI cases and > 36/yr primary PCI cases.
Recommendations - Case Selection and Management

Avoid intervention in patients with:

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired.
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography.
- Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms).
- Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI.
- Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.
- Chronic total occlusion.
PCI Without On-site Surgery: Recommendations

  - “Could be unsuited” for elective PCI without on-site surgery.
    - High risk patients
      - CHF, EF<30%, VEA, single target lesion in only vessel or vessel that jeopardizes large amount of myocardium.
    - High risk lesions
      - LM disease, diffuse disease, angulated (>90%) segment proximal to lesion, more than moderate calcification, major side branches, old SVG lesions, substantial thrombus.
  - Recommended Strategy
    - High risk patient with high risk lesion should **not** be done without on-site surgery.
    - High risk patient without high risk lesion confirm OR room available if you elect to do without on-site surgery.
PCI Without On-site Surgery

- PCI Risk tools and apps exist
  - Mayo Clinic Risk Score
  - SCAI PCI Risk app
  - These programs are geared to predict in-hospital MACE, but not procedural risk and do not take lesion characteristics into consideration at all – therefore limited value.

- **Bottom line**: Physician judgment is very important.
PCI Without On-site Surgery: STEMI

- More data supporting primary PCI than elective PCI.
  - Each community should have a STEMI system of care
  - Must be provided 24/7 with response time within 30 minutes
  - Should participate with AHA Mission Lifeline program
PCI Without On-site Surgery Locally

- SBRMC went live with PCI without On-site Surgery on January 5th 2015.

- 2 years plus process getting this in place with a commitment to build a quality program.

- Transfer agreement in place with Thomas Hospital and Cardio-Thoracic & Vascular Associates

- CARDIAC STAT for STEMI patients part of the process
Coronary Revascularization: An Ongoing Evolution

The only way to make sense out of change is to plunge into it, move with it, and join the dance. Alan Watts

Change is the law of life. And those who look only to the past or present are certain to miss the future. John F. Kennedy
2001 Prediction

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U.S. News & World Report

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