Mitigating Operator Risk in Complex Interventional Procedures

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• Risk assessment
• Documentation
• Informed consent
• Public reporting
• Steps to reduce risk and improve patient outcomes
Who is at risk?

**Risk to the patient**

- Is the procedure indicated?
- Does it fit guidelines?
- AUC (NEW-ACS focus only)
- SCAI risk scoring
- ACEF (CABG pts)
- SYNTAX I and II (predicts outcomes of PCI vs CABG)
- Radiation and contrast use

**Risk to you**

- Reporting in Cath/PCI registry (NCDR)
- State reporting
- Risk Adjusted Mortality Rate (RAMR)
- Radiation safety

**Institutional**

- State reporting
- Payors
CRITERIA FOR HRPCI

1. Severe myocardial dysfunction (LVEF < 35 %)
2. Extensive zones of myocardial jeopardy during PCI
   • Last patent vessel
   • Unprotected LM and distal LM bifurcation
   • Target vessel supplying collaterals to a vessel that supplies 40 % of the myocardium
   • 3 VD with SYNTAX score > 33
3. Surgically ineligible
4. Other high-risk scenarios (CTO, ?Atherectomy)
BCIS Myocardial Jeopardy Score for Classification of Coronary Disease Burden and Completeness of Revascularization

*BCIS JSTOP < 6 vs. BCIS JSTOP > 6 by Fishers Exact Test

American Journal of Cardiology
Volume 111, Issue 2, Pages 172-177 (January 2013)
Pre procedure steps in non-emergent HRPCI that is referred to you from another MD or there is an ‘urgent’ transfer

- Ideally review film online with referring MD prior to transfer
  
  *(Often patients are referred with significant co morbidities and limited life expectancy)*

- Separate pre-PCI note in chart (either outpatient or inpatient)
  
  *(This is important whether patient is seen in clinic or pre procedure. Document conversation, preferably witnessed and expectations)*

- Describe risk elements in cath report
  
  *(As a minimum, mortality risk and risk of complications and documentation of discussion with patient. Heart Team or consultation with another MD, should be documented provided they give permission)*
Informed consent

1. Is it always possible?
   Ad hoc in STEMI, Cardiac arrest and Cardiogenic Shock

2. Post procedure risk documentation
   Is this right?
   No other choice but to document
Elements of Informed Consent: Signature on a consent form is not enough

1. The interventionalist should obtain consent
2. Use standardized consent form specific for complex PCI

Consent form or separate note should include:

• Estimated mortality and stroke risk
• Utilization of MCS and adjunctive tools e.g. RA
• Potential complications such as renal failure, bleeding, tamponade, vascular injury and complications from MCS devices
• The potential for post procedure dialysis, ICU care, ventilatory support and prolonged hospitalization

3. Emergent procedures may require 2 MD consent witnessed by a nurse in some states
4. Telephone consents from relatives should be witnessed by a nurse and another MD
A personalized consent document improved the process of informed consent and shared decision-making with more frequent review (72% for ePRISM vs 45% for original consents). Marked heterogeneity across hospitals highlights that consent documents are but one aspect of engaging patients in understanding and participating in treatment.

Did not address HRPCI, but a step in the right direction

Online or IPAD based video descriptions of procedures, electronic and customized consent forms are in evolution.
Mortality is “Risk-Adjusted”

Table 4. NCDR CathPCI Registry Bedside Risk Scoring System

<table>
<thead>
<tr>
<th>Scoring Response Categories</th>
<th>Cardiogenic shock/PCI status</th>
<th>Sustained shock and salvage</th>
<th>Sustained shock alone or salvage alone</th>
<th>Transient shock but not salvage</th>
<th>Emergency PCI without shock/salvage</th>
<th>Urgent PCI without shock/salvage</th>
<th>Elective PCI without shock/salvage</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>No</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Age</td>
<td>&lt;60</td>
<td>0</td>
<td>4</td>
<td>9</td>
<td>15</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>BMI</td>
<td>&lt;20</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>CVD</td>
<td>No</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>PAD</td>
<td>No</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>No</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>No</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>No</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>GFR</td>
<td>Renal failure</td>
<td>16</td>
<td>11</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EF</td>
<td>&lt;30</td>
<td>9</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NCDR

Brennan. JACC CVI 2013; 6: 790-9
Complex CAD with coexistent morbidities and concomitant terminal disease are not included in risk adjusted mortality

- ESRD or Liver failure
- End state lung disease
- Anemia or thrombocytopenia
- Terminal cancers
- Recent surgery
- Trauma
- Stroke
- Transplant
- Estimated survival and DAPT use
- Frailty
<table>
<thead>
<tr>
<th>Procedural indication</th>
<th>Timing</th>
<th>AUC</th>
<th>Mortality risk</th>
<th>Heart team approach</th>
<th>Informed consent</th>
<th>Public reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest</td>
<td>Emergent</td>
<td>A</td>
<td>&gt; 50 %</td>
<td>Not possible</td>
<td>Generally none</td>
<td>Likely institutional</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>Emergent</td>
<td>A</td>
<td>30-50 %</td>
<td>Often not possible</td>
<td>Often not possible</td>
<td>Likely institutional</td>
</tr>
<tr>
<td>Ad hoc HRPCI</td>
<td>Emergent</td>
<td>M</td>
<td>5-15 %</td>
<td>Possible</td>
<td>On the table discussion with Patient and family Post hoc documentation</td>
<td>Yes</td>
</tr>
<tr>
<td>Left Main</td>
<td>Elective to urgent</td>
<td>A</td>
<td>0.6-2 %</td>
<td>Recommended</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Multi-vessel HRPCI</td>
<td>Elective</td>
<td>M</td>
<td>5-15 %</td>
<td>Recommended</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Surgical turn down and post graft failure HRPCI</td>
<td>Elective or emergent</td>
<td>A</td>
<td>5-15 %</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CTO</td>
<td>Elective</td>
<td>TBD</td>
<td>1.1 %</td>
<td>Maybe</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
How do you reduce risk?

In elective cases:
1. Proper case selection
2. Case discussion and angiographic evaluation (e.g. CTO’s) Heart Team Approach
3. Informed consent and shared decision making with patients
4. Discussion of complications and outcomes with patient
5. Be facile with vascular access and large bore closure
6. Available tools at your disposal e.g. RA
7. Decide early on MCS use
Bleeding and vascular complications are the largest outliers

- Understand large bore access
- Utilize micropuncture needle, fluoroscopic and US guidance
- Be facile with Pre close (e.g. utilizing 2 Percloses for large sheath access)
- If adequate hemostasis is not achieved with Perclose after the sheath is removed, be comfortable in leaving a smaller sized sheath and pulling it later
- Consider alternate access sites such as axillary or transcaval (if that expertise is available)
- Familiarity with crossover/endovascular rescue techniques
Bleeding Complications after Large-Bore Access

17,672 pts from NIS undergoing EVAR (12.6K), TAVR (3.2K), pVAD (1.8K)

Bleeding was associated with increased costs and mortality.
## Contemporary Outcomes in MCS/PLVAD devices

<table>
<thead>
<tr>
<th>Trials</th>
<th>Indication</th>
<th>Number of patients</th>
<th>IABP</th>
<th>Devices</th>
<th>Survival @ 30 days</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kar et al</td>
<td>Severe CS</td>
<td>117</td>
<td>Refractory</td>
<td>Tandem Heart</td>
<td>60 %</td>
<td>Severe bleeding</td>
</tr>
<tr>
<td>Seyfarth et al</td>
<td>Severe CS</td>
<td>25</td>
<td>Refractory</td>
<td>Impella</td>
<td>54%</td>
<td>Hemolysis</td>
</tr>
<tr>
<td>USPella</td>
<td>Prophylactic HR-PCI</td>
<td></td>
<td></td>
<td>Impella</td>
<td>88%</td>
<td>MACE: 8%</td>
</tr>
<tr>
<td>PROTECT-2</td>
<td>HR-PCI</td>
<td>452</td>
<td>226</td>
<td>IMPPELLA</td>
<td>22%</td>
<td>MACCE: 22% IABP 31%</td>
</tr>
<tr>
<td>Ally et al</td>
<td>Prophylactic HR-PCI</td>
<td>54</td>
<td></td>
<td>Tandem Heart</td>
<td>87%</td>
<td>13% vascular</td>
</tr>
<tr>
<td>Nichol et al</td>
<td>Cardiogenic Shock or Cardiac arrest</td>
<td>84</td>
<td></td>
<td>ECMO</td>
<td>50%</td>
<td>Vascular &amp; Acute lung Injury</td>
</tr>
<tr>
<td>ECMO registry</td>
<td>Cardiac arrest</td>
<td>2,633</td>
<td></td>
<td>ECMO</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>Takyama et al</td>
<td>Cardiogenic Shock (CS)</td>
<td>143</td>
<td></td>
<td>ECMO</td>
<td>49%</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusions:** Improved outcomes if these devices are placed prophylactically EARLY rather than LATE. Average 60% survival with Impella, Tandem Heart and ECMO vs IABP.
Radiation safety for the patient and operator

1. Minimize cine. Fluoro save has <10% radiation exposure of cine


3. Minimize magnification modes. Utilize “Live Zoom” feature without significant degradation of the image. For example in lieu of magnification, in an 8 inch field of view with a zoom factor of 1.2 results in a 6.7 inch field of view, without added radiation.

4. Minimize frame rate of fluoroscopy and cine. Long cases should be performed on 7.5 frames/sec fluoroscopy setting. Reduction of fluoroscopic pulse rate from 15 frames/sec to 7.5 frames/sec reduces radiation exposure by half

5. Keep the image detector close to the patient (low subject-image distance). Utilize collimation to the fullest extent possible

   **Maximum allowable: 5 Gy**
Correlation of Contrast Volume with AKI

CathPCI study of 1.3 million PCIs

Amin et al JAMA Cardiology 2017
Contrast Preservation

• Estimation of maximal contrast volume to be used:

  \[ 5 \text{ml} \times \text{body weight (in kg)} \]

  \[ \text{Serum Creatinine (mg/dl)} \]

• Small manifold syringes (8 cc)
• Iso osmolar contrast
• 50:50 diluted contrast
• Biplane imaging
• Intravascular ultrasound (IVUS) in optimizing device placement and PCI outcomes
• Marker wires for lesion length and device position
• Mechanized contrast injectors delivering prefixed contrast amount
• Using contrast savers