Transradial Primary PCI

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Disclosures

☐ Consultant, Honoraria
  ☐ Astra Zeneca, The Medicines Company, Daiichi Sankyo Lilly, Terumo Medical, Zoll

☐ Research funding
  ☐ Ikaria

☐ Off-label uses of drugs/devices may be discussed
Trends in transradial primary PCI in the US

\[N=90,879 \text{ patients undergoing primary PCI}\]
Transradial Primary PCI

- Why
- When
- How
Bleeding in Stable angina, NSTEMI, & STEMI

**NCDR CathPCI Rates**

- **Stable Angina**
  - Overall rate = 2.1%

- **NSTEMI**
  - Overall rate = 4.8%

- **STEMI**
  - Overall rate = 12.7%

*Duke Clinical Research Institute*

*Rao SV, et al., JACC 2010*
Risk for 1 year mortality

N=17393 pts from REPLACE-2, ACUITY, HORIZONS AMI

<table>
<thead>
<tr>
<th></th>
<th>Relative Risk</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unadjusted</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site</td>
<td>2.33 (1.53 - 3.53)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Non-access site</td>
<td>5.40 (4.32 - 6.74)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Adjusted</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site</td>
<td>1.82 (1.17 - 2.83)</td>
<td>0.008</td>
</tr>
<tr>
<td>Non-access site</td>
<td>3.94 (3.07 - 5.15)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

No Bleed

TIMI Major + Minor Bleed

Verheugt JACC Cardio Interv 2011;4:191-7:
# Outcomes stratified by STEMI vs. NSTEACS

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>2N</th>
<th>% Radial</th>
<th>% Femoral</th>
<th>Interaction p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSTE/ACS</td>
<td>5063</td>
<td>3.8</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>1958</td>
<td>3.1</td>
<td>5.2</td>
<td>0.025</td>
</tr>
<tr>
<td><strong>Death, MI or stroke</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSTE/ACS</td>
<td>5063</td>
<td>3.4</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>1958</td>
<td>2.7</td>
<td>4.6</td>
<td>0.011</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSTE/ACS</td>
<td>5063</td>
<td>1.2</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>1958</td>
<td>1.3</td>
<td>3.2</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Non CABG Major Bleed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSTE/ACS</td>
<td>5063</td>
<td>0.6</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>1958</td>
<td>0.8</td>
<td>0.9</td>
<td>0.56</td>
</tr>
<tr>
<td><strong>Major Vascular Complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSTE/ACS</td>
<td>5063</td>
<td>1.4</td>
<td>3.8</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>1958</td>
<td>1.3</td>
<td>3.5</td>
<td>0.89</td>
</tr>
</tbody>
</table>

STEMI Subgroup

A

STEMI

B

NSTEMI

Non-CABG major bleed (secondary outcome)

<table>
<thead>
<tr>
<th>Access site related</th>
<th>1 (0.10)</th>
<th>2 (0.20)</th>
<th>0.53 (0.05–5.84)</th>
<th>0.604</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-access site related</td>
<td>7 (0.74)</td>
<td>7 (0.71)</td>
<td>1.04 (0.36–2.95)</td>
<td>0.948</td>
</tr>
<tr>
<td>ACUITY major bleed</td>
<td>19 (1.99)</td>
<td>41 (4.10)</td>
<td>0.49 (0.28–0.84)</td>
<td>0.009</td>
</tr>
<tr>
<td>Access site related</td>
<td>12 (1.26)</td>
<td>34 (3.39)</td>
<td>0.37 (0.19–0.72)</td>
<td>0.003</td>
</tr>
<tr>
<td>Non-access site related</td>
<td>7 (0.74)</td>
<td>7 (0.71)</td>
<td>1.04 (0.36–2.95)</td>
<td>0.948</td>
</tr>
</tbody>
</table>

Mehta S, JACC 2012
**Design**

- **DESIGN:**
  Prospective, randomized (1:1), parallel group, multi-center trial.

- **INCLUSION CRITERIA:**
  all ST Elevation Acute Coronary Syndrome (STEACS) eligible for primary percutaneous coronary intervention.

- **EXCLUSION CRITERIA:**
  contraindication to any of both percutaneous arterial access.
  international normalized ratio (INR) > 2.0.

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1001 patients enrolled between January 2009 and July 2011 in 4 clinical sites in Italy

- Femoral arm (N=501)
- Radial arm (N=500)

**access shift**
6.1% (61)

- Femoral arm (N=534)
- Radial arm (N=467)

Clinical follow-up at 1 month in 100%

Intention-to-treat analysis
RIFLE STEACS – results

30-day NACE rate

- Net Adverse Clinical Event (NACE) = MACCE + bleeding
- Major Adverse Cardiac and Cerebrovascular event (MACCE) = composite of cardiac death, myocardial infarction, target lesion revascularization, stroke
- Bleeding Academic Research Consortium (BARC) = bleeding definition adopted
RIFLE STEACS – results

30-day MACCE rate

- Cardiac death: p = 0.020
- Myocardial Infarction: p = 1.000
- Target Lesion Revascularization: p = 0.604
- Cerebrovascular Accident: p = 0.725

<table>
<thead>
<tr>
<th>Event</th>
<th>Overall</th>
<th>Femoral Arm</th>
<th>Radial Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac death</td>
<td>7.2</td>
<td>9.2</td>
<td>5.2</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>1.3</td>
<td>1.4</td>
<td>1.2</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>1.5</td>
<td>1.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Cerebrovascular Accident</td>
<td>0.7</td>
<td>0.6</td>
<td>0.8</td>
</tr>
</tbody>
</table>
RIFLE STEACS – results

BARC definitions*

- **TYPE 1**: bleeding not actionable and does not cause unscheduled studies, treatment or hospitalization
- **TYPE 2**: any overt, actionable sign of hemorrhage that does not fit the criteria for type 3, 4, or 5
- **TYPE 3**:
  - overt bleeding plus Hb drop >3g/dL
  - any transfusion with overt bleeding
  - cardiac tamponade
  - bleeding requiring surgical intervention
  - bleeding requiring intravenous vasoactive agents
- **TYPE 4**: CABG-related bleeding
- **TYPE 5**: fatal bleeding

Access site related bleeding

- 47%
- p = 0.002

Non access site related bleeding

- 53%
- p = 1.000

RIFLE STEACS – results

Hospital stay (days)

- Cumulative hospital stay: Overall - 6.8 days, Femoral arm - 7.2 days, Radial arm - 6.4 days
- Intensive coronary care unit: Overall - 3.8 days, Femoral arm - 4.1 days, Radial arm - 3.6 days
- Cardiology ward: Overall - 3.0 days, Femoral arm - 3.1 days, Radial arm - 2.9 days

Significance levels:
- Cumulative hospital stay: $p = 0.003$
- Intensive coronary care unit: $p = 0.002$
- Cardiology ward: $p = 0.220$
Outcomes associated with transradial primary PCI in the US

Mortality
Mortality, adjusted
Procedure success
Procedure success, adjusted
Bleeding
Bleeding, adjusted

Lower with radial
Higher with radial

Baklanov D, et. al. JACC 2013
Radial vs. Femoral in STEMI

N=3347 pts from randomized, case-control, and cohort studies incl. RIVAL

Pooled odds ratio for Mortality 0.53 (0.33-0.84)

Pooled increase in procedure time 1.76 min (0.59, 2.92)

Joyal D, et. al. AJC 2012
Importance of Rapid Treatment: Effects on Mortality

1.6 lives lost per hour delay to randomization

FTT, Lancet 1994
What about door-to-balloon time?
A Decision Analysis

N = 2 randomized trials comparing radial and femoral for primary PCI

<table>
<thead>
<tr>
<th></th>
<th>Radial</th>
<th>Femoral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access site success</td>
<td>Dead</td>
<td>Dead</td>
</tr>
<tr>
<td></td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>Access site failure</td>
<td>Dead</td>
<td>Alive</td>
</tr>
<tr>
<td></td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td></td>
<td>Crossover rate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radial death rate</td>
<td>Femoral death rate</td>
</tr>
<tr>
<td></td>
<td>(radial delay * DTB-death relationship)</td>
<td>(crossover delay * DTB-death relationship)</td>
</tr>
</tbody>
</table>

Wimmer NJ, et. al. AHJ 2014
D2B Delay and outcome

Favors transfemoral strategy

Favors transradial strategy

RR of mortality with transradial vs. transfemoral approach

Transradial delay (minutes)

Wimmer NJ, et. al. AHJ 2014
Access site crossover rate and outcome

Favors transfemoral strategy

Favors transradial strategy

Transradial delay (minutes)

Crossover rate(%)
Probabilistic sensitivity analysis

N = 1000 Monte Carlo simulations of the base case or elderly pts.

Wimmer NJ, et. al. AHJ 2014
Transradial Primary PCI

- Why
- When
- How
Issues unique to Primary PCI

- Most important – the team MUST have experience with radial diagnostic and interventional cases

- **Success of transradial primary PCI is dependent almost entirely on the cath lab staff**
  - The set-up is the rate-limiting factor

- Starting a transradial primary PCI program is reasonable when:
  - 1 year of experience with “radial first” elective PCI
  - OR
  - 100 elective PCI cases AND
  - Femoral crossover rate ≤ 4%

Transradial Primary PCI

- Why
- When
- How
I hate it when this happens…
Mechanisms of TRI failure

N=2100 TRI cases 2002-2006; 4.6% failure rate

- 14 operators
- TRI in 8-42% of annual volume across operators

Causes of TRI failure

<table>
<thead>
<tr>
<th>Cause</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure of access</td>
<td></td>
</tr>
<tr>
<td>Inadequate puncture</td>
<td>13%</td>
</tr>
<tr>
<td>Failure to reach ascending aorta with guide</td>
<td></td>
</tr>
<tr>
<td>Radial artery spasm</td>
<td>34%</td>
</tr>
<tr>
<td>Radial artery dissection</td>
<td>10%</td>
</tr>
<tr>
<td>Radial loop/tortuosity</td>
<td>6%</td>
</tr>
<tr>
<td>Radial artery stenosis</td>
<td>1%</td>
</tr>
<tr>
<td>Lack of guide support</td>
<td></td>
</tr>
<tr>
<td>Subclavian tortuosity</td>
<td>18%</td>
</tr>
<tr>
<td>Inadequate back-up</td>
<td>17%</td>
</tr>
</tbody>
</table>

Multivariate predictors of TRI Failure

- Age > 75: OR (95% CI) = 3.86 (2.33, 6.40)
- Prior CABG: OR (95% CI) = 7.48 (3.45, 16.19)
- Height, cm: OR (95% CI) = 0.97 (0.95, 0.99)
Patient height predicts TRI failure

- Pt less than 5’ 5” had a greater than 6% failure rate
- Pts. taller than 5’ 9” had a less than 3% failure rate
- Short Aorta/Subclavian disease likely the cause

Figure 3. TR-PCI Failure Stratified by Patient Height
Data shown as quartiles. The transradial approach percutaneous coronary intervention (TR-PCI) failure rate was highest in patients with height <165 cm and lowest in patients with height >175 cm.
Systematic use of LRA in Primary PCI
Lahey Clinic as a case study

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**Arterial Access for Primary PCI**

- **Right Radial**
  - Default access

- **Femoral**
  - Shock: IABP/PVAD support
  - Negative Allen’s Test
  - Non-radial Interventionalist

- **Left Radial**
  - Older (>65 years)
  - Female
  - Shorter stature
  - Lower weight/BMI
  - Previous CABG

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*Slide courtesy of Chris Pyne MD*
Systematic use of LRA in Primary PCI
Lahey Clinic as a case study

- No left side procedure failures
- 2 failures from the right side (n=85)
- Procedure and fluoro times similar

Figure 1. Procedural Times

- No left side procedure failures
- 2 failures from the right side (n=85)
- Procedure and fluoro times similar

Slide courtesy of Chris Pyne MD
Duke Clinical Research Institute
Larsen P, et. al. CCI 2010
Algorithm for transradial primary PCI

Patient presents with STEMI

- Administration of dual antiplatelet therapy
- Administration of parenteral anti-thrombin therapy

Arrival to cath lab

Radial access

- Consider Left Radial Approach if prior CABG, age ≥ 70 years, height ≤ 55

Diagnostic angiography of non-IRA

Guiding catheter to IRA

PCI of IRA

Transradial Primary PCI

Summary

- Start transradial primary PCI for STEMI only after significant experience with elective cases

- Success in transradial primary PCI is a systems change – dependent on cath lab staff

- Data emerging on best approaches – LRA for older and shorter patients

- Use common sense – the clock is ticking and the myocardium is dying!
Questions

☐ Thank you!