Bleeding Issues with PCI & Approaches

Saudi Heart ACC
Riyadh, Saudi Arabia
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Mayo Clinic
Rochester, MN
Presenter Disclosure Information

David R. Holmes, Jr., M.D.

“Bleeding Issues with PCI & Approaches”

The following relationships exist related to this presentation:

ACC President-elect
Knowledge

• Randomized clinical trials
• Scientific studies
• Registries
• Meta-analyses
• Expert consensus guidelines
• Appropriate use criteria
Challenge

Knowledge  Delivery to care
American College of Cardiology
60 Years of Quality and Education
1949-2009

Heart House, Washington D.C.
ACC’s Role in Measurement and Improvement

- Define Care Standards ➔ Clinical Guidelines
- Define Data Standards ➔ Data Standards
- Develop Measures ➔ Performance Measures
- Measure Quality ➔ ACC-NCDR
- Improve Quality ➔ CathKIT, etc
- Appropriateness ➔ AUC
Registries Can

• Capture high quality clinical data efficiently
  • Track patients’ longitudinal care
  • Track drugs and devices
  • Be linked to biological and imaging data
• Be used for scientific discovery
• Complement and support randomized clinical trials
• Help drive new evidence into routine practice
Global Interest in Registries

- Development of International Registries
- Implemented in the US, EU, and interest in emerging markets
- IT & Provision of Healthcare
- Benefits of registries
- Quality improvement deliverables
Some last words....

Science tells us what we can do;

Guidelines what we should do;

Registries what we are actually doing.
Bleeding After PCI

- A marker of increased early and late morbidity and mortality after PCI
- Mechanisms are unclear
- Typically under reported (bleeder vs bleedee)
- Strategies to decrease bleeding the subject of intense interest
## Clinical Risk Algorithm for Post PCI Bleeding

### Clinical & Procedural Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Bleeding</th>
<th>Bleeding</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=294,824</td>
<td>n=7,328</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>14.5</td>
<td>30.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>NSTEMI/UA</td>
<td>51.1</td>
<td>48.9</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>34.4</td>
<td>20.5</td>
<td></td>
</tr>
<tr>
<td>Acute MI (&lt;7d)</td>
<td>29.3</td>
<td>25.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>IABP</td>
<td>2.0</td>
<td>10.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>PCI Indication</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Elective</td>
<td>49.2</td>
<td>29.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Urgent</td>
<td>36.3</td>
<td>38.5</td>
<td></td>
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<tr>
<td>Emergency</td>
<td>14.3</td>
<td>31.7</td>
<td></td>
</tr>
<tr>
<td>Salvage</td>
<td>0.2</td>
<td>0.8</td>
<td></td>
</tr>
</tbody>
</table>

### NCDR Bleeding Risk Algorithm

- 302,152 pts undergoing PCI at 440 U.S. hospitals
- Bleeding characterized as:
  1. During or after procedure at entry site
     - Requiring transfusion, prolonged hospital stay, or drop ≥3gm Hgb
  2. Hematoma >10 cm femoral, 5 cm brachial, 2 cm radial
  3. Gastrointestinal or genitourinary

# Clinical Risk Algorithm for Post PCI Bleeding

## Variables Used to Calculate Bleeding Risk Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>10</td>
</tr>
<tr>
<td>NSTEMI/UA</td>
<td>3</td>
</tr>
<tr>
<td>Cardio shock</td>
<td>8</td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
</tr>
<tr>
<td>Previous CHF</td>
<td>5</td>
</tr>
<tr>
<td>No previous PCI</td>
<td>4</td>
</tr>
<tr>
<td>NYHA class IV CHF</td>
<td>4</td>
</tr>
<tr>
<td>PVD</td>
<td>2</td>
</tr>
<tr>
<td>Age (y) 66-75</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>76-85</td>
</tr>
<tr>
<td></td>
<td>≥85</td>
</tr>
<tr>
<td>Estimated GFR</td>
<td>1</td>
</tr>
</tbody>
</table>

## Prevalence of Post-PCI Bleeding

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Bleeding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 7</td>
<td>0.63</td>
</tr>
<tr>
<td>8-17</td>
<td>1.77</td>
</tr>
<tr>
<td>≥ 18</td>
<td>5.08</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Bleeding</th>
<th>Bleeding</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=294,824</td>
<td>n=7,328</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>64.0</td>
<td>70.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>(55.0 to 73.0)</td>
<td>(59.0 to 78.0)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>33.2</td>
<td>53.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>28.7</td>
<td>27.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>(25.5 to 32.9)</td>
<td>(24.4 to 32.3)</td>
<td></td>
</tr>
<tr>
<td>Real light &lt;18.5 (% BMI)</td>
<td>1.2</td>
<td>2.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Real heavy ≥30 (% BMI)</td>
<td>41.1</td>
<td>35.8</td>
<td></td>
</tr>
<tr>
<td>GFR</td>
<td>72.8</td>
<td>63.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>(57.9 to 87.9)</td>
<td>(47.5 to 79.0)</td>
<td></td>
</tr>
<tr>
<td>PVD</td>
<td>11.7</td>
<td>15.2</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Prevalence of Post-PCI Bleeding

Conclusions: This report identifies baseline clinical factors associated with bleeding and proposes a clinically useful algorithm to estimate bleeding risk. This model is potentially actionable in altering therapeutic decision making and improving outcomes in patients undergoing PCI.

Key Words: catheterization ■ hemorrhage ■ risk factors

Bleeding is the most common noncardiac complication in patients undergoing percutaneous coronary intervention (PCI)1 and is associated with increased risk of adverse outcomes including death, myocardial infarction (MI), and stroke, as well as increased length of hospitalization and cost.2-4 Although a variety of individual risk factors have been linked to bleeding after PCI, currently there is no accepted method to categorize patients undergoing PCI by risk of post-PCI bleeding. An algorithm to predict risk of bleeding could be highly actionable, enabling physicians to consider alternative adjunctive PCI care. Using data from the National Cardiovascular Data Registry (NCDR), we identified clinical risk factors for post-PCI bleeding and then developed a clinical algorithm to predict patient risk of bleeding.

Clinical Perspective on p 229

Methods

Study Population
A description of the NCDS has been published.5-7 We used version 3.04 of the CathPCI database, which contains data on PCI procedures performed from January 1, 2004, to March 31, 2006. Initially, data were obtained from 399,351 patients undergoing 317,355 PCI...
Case 1

- 71-year-old female with chest pain
- ECG – inferior STEMI
- Hx of hypertension & smoking
- Referred to the cath lab for primary PCI
Hospital Course

• Coronary angiogram
  • RCA 99% proximal and 70% distal lesions
• DES placement
• Regimen –
  • Aspirin
  • Clopidogrel
  • Heparin
  • Eptifibatide
PCI Clinical Decision Making

• What is her mortality risk?
  • 1 out of 1000

• Bleeding risk?
  • 1-3 to of 100

• Restenosis risk?
  • DES 8-9%
  • BMS 20-25%
What is Her Bleeding Risk?

- STEMI 10
- Age 71 2
- Female 6
- Total 18
- Bleeding risk 5.4%

<table>
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</tbody>
</table>
Hospital Course

- Coronary angiogram
  - RCA 99% proximal and 70% distal lesions
- DES placement
- Regimen –
  - Aspirin
  - Clopidogrel
  - Heparin
  - Eptifibatide
- 6F right femoral sheath pulled
- Developed large right groin hematoma requiring transfusion
Case 2

- 87-year-old female with angina
- Hypertension, hyperlipidemia, peripheral vascular disease (claudication), moderate pulmonary hypertension
- Abnormal stress test with anterior ischemia
- Coronary angiogram performed
Case 2

- Significant LAD and RCA disease
- 2 BMS placed
- Regimen –
  - Aspirin
  - Clopidogrel
  - Heparin
What is Her Bleeding Risk?

- Age 8
- Female 6
- No previous PCI 4
- PVD 2
- Total 20
- Bleeding risk 7.2%

<table>
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<td>5</td>
</tr>
<tr>
<td>≥85</td>
<td>8</td>
</tr>
</tbody>
</table>
| Estimated GFR               | 1      

Risk Category

- ≤ 7: 0.63
- 8-17: 1.77
- ≥ 18: 5.08
Case 2

- Significant LAD and RCA disease
- 2 BMS placed
- Regimen –
  - Aspirin
  - Clopidogrel
  - Heparin
- Right femoral artery sheath pulled
- Developed large right groin hematoma
- Hgb dropped from 14 to 9 g/dL & received transfusion
### Overall Patient Summary

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=2299 #, %</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>67.1 ± 12.0</td>
</tr>
<tr>
<td>Men</td>
<td>1630 (70.9)</td>
</tr>
<tr>
<td>STEMI</td>
<td>373 (16.2)</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>450 (19.6)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>1238 (53.8)</td>
</tr>
<tr>
<td>Shock</td>
<td>74 (3.2)</td>
</tr>
<tr>
<td>Hx of PVD</td>
<td>278 (12.1)</td>
</tr>
<tr>
<td>Estimated GFR</td>
<td>75.5 ± 24.6</td>
</tr>
</tbody>
</table>
# Bleeding Rates in PCI

Bleeding Report for Cath Lab Overall

## Overall Patient Summary

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=2299</th>
</tr>
</thead>
<tbody>
<tr>
<td>#, %</td>
<td></td>
</tr>
<tr>
<td>Sheath size - 5</td>
<td>95 (4.1)</td>
</tr>
<tr>
<td>6</td>
<td>1398 (60.9)</td>
</tr>
<tr>
<td>7</td>
<td>552 (24.1)</td>
</tr>
<tr>
<td>8</td>
<td>214 (9.3)</td>
</tr>
<tr>
<td>9+</td>
<td>35 (1.5)</td>
</tr>
<tr>
<td>Radial approach</td>
<td>331 (14.4)</td>
</tr>
<tr>
<td>Closure device use</td>
<td>7 (0.3)</td>
</tr>
<tr>
<td>GPIIb/IIIa use</td>
<td>1389 (60.4)</td>
</tr>
<tr>
<td>Bivalirudin use</td>
<td>12 (0.5)</td>
</tr>
<tr>
<td>Expected bleeding from NCDR</td>
<td>57.5 (2.5)</td>
</tr>
<tr>
<td>Observed bleeding complication</td>
<td>95 (4.1)</td>
</tr>
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</table>
Bleeding Rates in PCI
Bleeding Report for Cath Lab Overall

<table>
<thead>
<tr>
<th>Summary by PCI date</th>
<th>2009 Q1 n=342</th>
<th>2009 Q2 n=451</th>
<th>2009 Q3 n=407</th>
<th>2009 Q4 n=375</th>
<th>2010 Q1 n=334</th>
<th>2010 Q2 n=390</th>
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</thead>
<tbody>
<tr>
<td>Variable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected bleeding from NCDR, # (%)</td>
<td>8.2 (2.4)</td>
<td>11.3 (2.5)</td>
<td>9.8 (2.4)</td>
<td>9.4 (2.5)</td>
<td>8.4 (2.5)</td>
<td>9.4 (2.4)</td>
</tr>
<tr>
<td>Observed bleeding complication, # (%)</td>
<td>22 (6.4)</td>
<td>24 (5.3)</td>
<td>16 (3.9)</td>
<td>13 (3.5)</td>
<td>5 (1.5)</td>
<td>15 (3.8)</td>
</tr>
</tbody>
</table>
Bleeding Rates in PCI

Bleeding Report for Cath Lab Overall

Observed/Expected Plots
PCI Clinical Decision Making

- What is her mortality risk?
  - 1 out of 1000
- Bleeding risk?
  - 1-3 to of 100
- Restenosis risk?
  - DES 8-9%
  - BMS 20-25%
Bleeding Rates in PCI
Bleeding Report for Cath Lab Overall

Observed/Expected Plots

Overall O/E ratio: 1.7
**Bleeding Rates in PCI**

**Bleeding Report for Holmes**

### Overall Patient Summary

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=143 #, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>67.1 ± 12.3</td>
</tr>
<tr>
<td>Men</td>
<td>100 (69.9)</td>
</tr>
<tr>
<td>STEMI</td>
<td>15 (10.5)</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>21 (14.7)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>73 (51.0)</td>
</tr>
<tr>
<td>Shock</td>
<td>6 (4.2)</td>
</tr>
<tr>
<td>Hx of PVD</td>
<td>24 (16.8)</td>
</tr>
<tr>
<td>Estimated GFR</td>
<td>74.4 ± 24.9</td>
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</table>
## Bleeding Rates in PCI

### Bleeding Report for Holmes

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=143</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#, %</td>
</tr>
<tr>
<td>Sheath size - 6</td>
<td>43 (30.1)</td>
</tr>
<tr>
<td>7</td>
<td>50 (35.0)</td>
</tr>
<tr>
<td>8</td>
<td>45 (31.5)</td>
</tr>
<tr>
<td>9+</td>
<td>5 (3.5)</td>
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<tr>
<td>Radial approach</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Closure device use</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>GPIIb/IIla use</td>
<td>84 (58.7)</td>
</tr>
<tr>
<td>Bivalirudin use</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Expected bleeding from NCDR</td>
<td>3.4 (2.4)</td>
</tr>
<tr>
<td>Observed bleeding complication</td>
<td>4 (2.8)</td>
</tr>
</tbody>
</table>
# Bleeding Rates in PCI

## Bleeding Report for Holmes

### Summary by PCI date

<table>
<thead>
<tr>
<th>Variable</th>
<th>2009 Q1 n=16</th>
<th>2009 Q2 n=23</th>
<th>2009 Q3 n=36</th>
<th>2009 Q4 n=20</th>
<th>2010 Q1 n=24</th>
<th>2010 Q2 n=24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected bleeding from NCDR, # (%)</td>
<td>0.5 (3.2)</td>
<td>0.6 (2.4)</td>
<td>0.9 (2.6)</td>
<td>0.4 (1.8)</td>
<td>0.6 (2.3)</td>
<td>0.5 (2.0)</td>
</tr>
<tr>
<td>Observed bleeding complication, # (%)</td>
<td>1 (6.3)</td>
<td>2 (8.7)</td>
<td>0 (0.0)</td>
<td>1 (5.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>
Bleeding Rates in PCI
Bleeding Report for Holmes

Observed/Expected Plots
Bleeding Rates in PCI
Bleeding Report for Holmes

Observed/Expected Plots

Overall O/E ratio: 1.2
Approaches to Bleeding

- Meticulous access site management
- Radial approach
- Vascular closure devices
- Bivalirudin
- Minimize GPIIb/IIIa
Use of Bleeding Avoidance Strategies Among Patients Undergoing PCI


M = Manual comp
C = Closure only
B = Bival only
BC = Bival + closure
The Problem a la Healthcare

- Information explosion
- Unconnected environments
- Workus Interruptus
- Rare or inconsistent users’ manuals
- Perverse incentives
- Delayed and incomplete dissemination
Science and Quality

- Science and Clinical Policy
- Best Practices and Implementation
- CardioSource and CardioSmart
- PINNACLE Network and Registry
- National Cardiovascular Data Registries
Lessons Learned

- Guidelines are not easily applied in practice
- Performance is difficult to measure
- Data by itself does not improve quality
- Guidelines, performance measures, and data standards need to be coordinated
- Clinician champions are critical to success
- Health care needs a culture of quality
Best Practice and Quality Improvement Solutions

Goal
To enable and equip the cardiovascular professional with the best practice strategies and tools they need to provide high quality patient care

• Targeting large integrated health systems
• Targeting regions with the most variation/gaps
• Collaborating with ACC chapters
Clinical Best Practice Tool Kits

Data and members tell us which tool kits to develop:

• Most variation/gaps
• Most easily improved
• Of greatest value to patient outcomes
• Metrics tied to opportunities for reimbursement

Tools Kits for 2011
Systems that Work

• Knowledge: fresh, accessible, and contextualized
• Team with complementary roles and skills
• Script, tips, and tools
• Measurement and timely feedback
• Evaluation and refinement
• Community to road-test, disseminate, ring alarms, and direct traffic
Where we need to get to....
Subject: NCDR Bleeding Risk-Mehta

Background: BU3
Banner/brdr: 0-40-159/BU41
Side title: YW105
• /colhdgs: YW105
Text: WT/BK
Highlight: Y0114
Subdue: BU31
Footnotes: BU41

PPT shooting instructions
PPT File to Server (3 images)
Artist: DV  Due Date: 2-17-2011

COLOR REFERENCE ONLY
Match: Mayo2bu-2002 (CP1111378)
“In the final analysis, medicine, science and music stem from a common source—that of the search for the unknown, and the respect for the awesome presence behind the curtain.”

Richard Bing, M.D.
10-12-1909 to 11-08-2010
HAS-BLED Score

- 7,329 patients with atrial fibrillation in the SPORTIF III and IV trials
- Patients anticoagulated with adjusted dose warfarin
  - INR 2-3 on ximelagatran 36 mgm bid
- Major bleeding centrally adjudicated
  - Aspirin allowed clinically for CAD

## HAS-BLED Score
### Baseline Characteristics of AFib Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bleeding Event (n=234)</th>
<th>No Bleed (n=7,095)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>73.9 (8.6)</td>
<td>70.9 (8.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&gt;65</td>
<td>196 (84)</td>
<td>5,349 (75)</td>
<td>0.0031</td>
</tr>
<tr>
<td>≥75</td>
<td>125 (53)</td>
<td>2,679 (38)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Female</td>
<td>73 (31)</td>
<td>2,184 (31)</td>
<td>0.89</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>28.7 (6.6)</td>
<td>29.0 (5.8)</td>
<td>0.50</td>
</tr>
<tr>
<td>AF type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>26 (11)</td>
<td>810 (12)</td>
<td>1.00</td>
</tr>
<tr>
<td>Persistent/permanent</td>
<td>208 (89)</td>
<td>6,282 (88)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

## HAS-BLED Score

**Baseline Characteristics of AFib Patients**

<table>
<thead>
<tr>
<th>Medical History</th>
<th>Bleeding Event (n=234)</th>
<th>No Bleed (n=7,095)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>180 (77)</td>
<td>5,445 (77)</td>
<td>1.00</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>67 (29)</td>
<td>1,658 (23)</td>
<td>0.071</td>
</tr>
<tr>
<td>CAD</td>
<td>117 (50)</td>
<td>3,162 (45)</td>
<td>0.11</td>
</tr>
<tr>
<td>LV dysfunction</td>
<td>102 (44)</td>
<td>2,579 (36)</td>
<td>0.027</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>61 (26)</td>
<td>1,478 (21)</td>
<td>0.060</td>
</tr>
<tr>
<td>Systemic embolic events</td>
<td>8 (3)</td>
<td>320 (5)</td>
<td>0.52</td>
</tr>
<tr>
<td><strong>CHADS$_2$ Score</strong></td>
<td><strong>2.6 (1.2)</strong></td>
<td><strong>2.2 (1.2)</strong></td>
<td><strong>&lt;0.0001</strong></td>
</tr>
</tbody>
</table>

## HAS-BLED Score

### Baseline Characteristics of AFib Patients

<table>
<thead>
<tr>
<th>Bleeding Risk Factors</th>
<th>Bleeding Event (n=234)</th>
<th>No Bleed (n=7,095)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous clinically significant bleed</td>
<td>19 (8)</td>
<td>441 (6)</td>
<td>0.22</td>
</tr>
<tr>
<td>Systolic BP at entry, mean (SD)</td>
<td>136 (19)</td>
<td>135 (18)</td>
<td>0.48</td>
</tr>
<tr>
<td>CrCl &lt; 50 ml/min</td>
<td>57 (24)</td>
<td>885 (13)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>97 (41)</td>
<td>3,230 (46)</td>
<td>0.23</td>
</tr>
<tr>
<td>Smoking</td>
<td>11 (5)</td>
<td>667 (9)</td>
<td>0.011</td>
</tr>
</tbody>
</table>

# HAS-BLED Score
## Risk Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Event Rate (%/Pt-Yr)</th>
<th>Multivariate Analyses</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Risk Factor Present</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Aspirin use</td>
<td>3.94</td>
<td>1.94</td>
<td>1.92 (1.40-2.51)</td>
</tr>
<tr>
<td>CrCl &lt;50 ml/min</td>
<td>4.91</td>
<td>2.01</td>
<td>1.90 (1.38-2.62)</td>
</tr>
<tr>
<td>Age ≥75 yrs</td>
<td>3.42</td>
<td>1.73</td>
<td>1.71 (1.30-2.25)</td>
</tr>
<tr>
<td>DM</td>
<td>2.95</td>
<td>2.17</td>
<td>1.36 (1.03-1.81)</td>
</tr>
<tr>
<td>LV dysfunction</td>
<td>2.85</td>
<td>2.07</td>
<td>1.31 (1.01-1.70)</td>
</tr>
<tr>
<td>Smoking</td>
<td>1.20</td>
<td>2.47</td>
<td></td>
</tr>
<tr>
<td>Prev. stroke or TIA</td>
<td>3.05</td>
<td>2.18</td>
<td></td>
</tr>
<tr>
<td>CAD</td>
<td>2.65</td>
<td>2.11</td>
<td></td>
</tr>
<tr>
<td>Clinically significant bleeding</td>
<td>3.15</td>
<td>2.30</td>
<td></td>
</tr>
<tr>
<td>Alcohol abuse</td>
<td>2.14</td>
<td>2.53</td>
<td></td>
</tr>
<tr>
<td>Statin use</td>
<td>2.08</td>
<td>2.48</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2.41</td>
<td>2.32</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>2.36</td>
<td>2.33</td>
<td></td>
</tr>
</tbody>
</table>
HAS-BLED Score

- Labile INR
- Concomitant ASA/nonsteroidal
- Older than 75 years

### HAS-BLED Score

- Bleeders (n=217, ___%)  
- More often elderly  
- Non-smokers  
- Diabetes  
- Prior stroke/TIA  
- Worse renal function

## Major Bleeding Rates by HAS-BLED Score & Those Taking Warfarin Only

<table>
<thead>
<tr>
<th>HAS-BLED Score</th>
<th>Major Bleeding Events n= 7,329</th>
<th>Major Bleeding Events (Warfarin Only) n=3,665</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>21 (1.2)</td>
<td>7 (0.9)</td>
</tr>
<tr>
<td>1</td>
<td>75 (2.8)</td>
<td>44 (3.4)</td>
</tr>
<tr>
<td>2</td>
<td>63 (3.6)</td>
<td>39 (4.1)</td>
</tr>
<tr>
<td>3</td>
<td>50 (6.0)</td>
<td>28 (5.8)</td>
</tr>
<tr>
<td>4</td>
<td>23 (9.5)</td>
<td>16 (8.9)</td>
</tr>
<tr>
<td>5</td>
<td>2 (7.4)</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusions: This analysis identifies diabetes and heart failure or left ventricular dysfunction as potential risk factors for bleeding in AF beyond those previously recognized. Of the contemporary bleeding risk stratification schemas, the new HAS-BLED scheme offers useful predictive capacity for bleeding over previously published schemas and may be simpler to apply.
CRUSADE Bleeding Score

- Baseline HCT
- CR clearance
- Heart rate
- Sex
- CHF
- Systemic BP
- Prior vascular disease
- Diabetes
NCDR Bleeding
NSTEMI and STEMI

Jan. 2007 – June 2009

STEMI
N=48,943

UFH  Bivalirudin  LMWH
66  14  8

NSTEMI
N=72,699

UFH  Bivalirudin  LMWH
42  13  27

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Usage of Anticoagulant Regimens

**STEMI**
N=48,943

- UFH 66%
n=32,214
- LMWH 8%
n=4,044
- Bivalirudin 14%
n=6,945
- UFH + LMWH 6%
n=2,946
- None 6%
n=2,794

**NSTEMI**
N=72,699

- UFH 42%
n=30,611
- LMWH 27%
n=19,425
- UFH + LMWH 10%
n=19,425
- None 9%
n=6,420
- Bivalirudin 13%
n=9,286

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Anticoagulant Use According to Therapeutic Strategy

STEMI - PCI
N=32,455

- UFH 68%
- Bivalirudin 17%
- UFH + LMWH 5%
- LMWH 5%
- None 5%

STEMI – Fibrinolytics only
N=5,123

- UFH 62%
- Bivalirudin 12%
- UFH + LMWH 9%
- LMWH 14%
- None 3%

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Anticoagulant Use According to Therapeutic Strategy

NSTEMI – Invasive Strategy
N=46,012

- UFH 46%
- LMWH 21%
- UFH + LMWH 11%
- Bivalirudin 17%
- None 6%

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010

NSTEMI – Conservative Strategy
N=15,631

- UFH 35%
- LMWH 35%
- UFH + LMWH 9%
- Bivalirudin 9%
- None 12%
## Bleeding Risk Scores

<table>
<thead>
<tr>
<th>CRUSADE Bleeding Score</th>
<th>STEMI (n=42,918)</th>
<th>N (%)</th>
<th>Major Bleeding Events (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\leq 20)</td>
<td>19,050 (44.4)</td>
<td>1,036 (5.4)</td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>9,864 (23.0)</td>
<td>1,002 (10.2)</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>6,565 (15.3)</td>
<td>956 (14.6)</td>
<td></td>
</tr>
<tr>
<td>41-50</td>
<td>4,250 (9.9)</td>
<td>857 (20.2)</td>
<td></td>
</tr>
<tr>
<td>(&gt;50)</td>
<td>3,189 (7.4)</td>
<td>928 (29.1)</td>
<td></td>
</tr>
</tbody>
</table>

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
## Bleeding Risk Scores

<table>
<thead>
<tr>
<th>NSTEMI n=61,540</th>
<th>CRUSADE Bleeding Score</th>
<th>N (%)</th>
<th>Major Bleeding Events (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤20</td>
<td>19,803 (32.2)</td>
<td>605 (3.1)</td>
</tr>
<tr>
<td></td>
<td>21-30</td>
<td>11,134 (18.1)</td>
<td>670 (6.0)</td>
</tr>
<tr>
<td></td>
<td>31-40</td>
<td>9,831 (16.0)</td>
<td>822 (8.4)</td>
</tr>
<tr>
<td></td>
<td>41-50</td>
<td>8,944 (14.5)</td>
<td>1,099 (12.3)</td>
</tr>
<tr>
<td></td>
<td>&gt;50</td>
<td>11,828 (19.2)</td>
<td>2,314 (19.6)</td>
</tr>
</tbody>
</table>

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Anticoagulant Regimens in STEMI

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Anticoagulant Regimens in NSTEMI

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Anticoagulant Strategy in NSTE MI

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Rate of Major Bleeding by CRUSADE Bleeding Score – STEMI

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
Rate of Major Bleeding by CRUSADE Bleeding Score – NSTEMI

Kadakia MB et al: J AM Coll Cardiol Intv 3:1166-77, 2010
This decision-analytic modeling study demonstrates that for patients undergoing PCI, substitution of bivalirudin for unfractionated heparin monotherapy is projected to increase costs for virtually all patients and would be considered cost-effective for only a minority of patients with a high bleeding risk. From a policy standpoint, studies such as this, aimed at identifying the appropriate risk threshold for initiating treatment, may help in the development of informed guidelines for the use of expensive therapies.
The National Cardiovascular Data Registry: A Partnership between the Kingdom of Saudi Arabia and the American College of Cardiology

Presentation to H.E Dr. Abdullah bin Abdul Aziz Al-Rabeeah, the Honorable Minister of Health for the Kingdom of Saudi Arabia

by

Dr. Ralph Brindis, Dr. Alfred Bove, Dr. Douglas Weaver and Dr. Janet Wright
The ACC is the primary professional organization for cardiologists worldwide with:

- Over 37,000 members, > 90% of US Cardiologists and > 4,000 International members
- Over 7,000 manuscripts submitted / year
- Over 20,000 live-event attendees every year
- Over 40,000 CME recipients / year
- Nearly 10 million patient records in NCDR
The ACC’s International Strategy

- **Education**
  - Increase International Knowledge Exchange & Global Participation in Educational Activities
  - Put knowledge in the hands of every clinician
  - Middle Eastern Cardiovascular Conference

- **Quality Care**
  - Increase International Participation in Practice Standards
  - Define quality for CV care and improve care for patients
What is the NCDR?

• Suite of Hospital and Office-Based Quality Improvement Programs
  • Measure, quantify and benchmark outcomes
    • Risk-adjusted
    • Identify gaps in the delivery of quality cardiovascular patient care

• Our Mission is to:
  • Improve patient care
  • Provide knowledge and tools
  • Implement quality initiatives
  • Support research
NCDR Registry Services

- Site training and orientation
  - Web-based training
  - Conference calls
  - Annual User Group meeting
  - On site training if requested
- Quarterly benchmarked Outcome Reports
  - Facility level reports
  - System level / country level if requested
  - Benchmarked to US aggregate
- QI tools
- Audit if requested
- Analytics if requested
NCDR Research

• Effectiveness
  • Diffusion of new technologies

• Post Market Surveillance
  • Adverse/sentinel events
  • Inappropriate off-label use

• Quality Improvement and Translational Research
  • Guideline adherence, Appropriateness, Benchmarked Outcomes
  • Performance measure development, implementation, validation

• Informing Public policy
  • Evidence-based reimbursement

• Intense interest in assessing efficiency, return on investment
Cath PCI Registry

- First NCDR registry program established 1998
- Provides a system to assess treatment and outcomes of patients who undergo cardiac catheterization procedures including PCI
- Optimize the outcomes and management of patients through implementation of evidence-based guideline recommendations in clinical practice
- Facilitate efforts to improve the quality and safety of patient care
- Provide a risk-adjusted assessment of patients for comparison
Cath PCI Registry

- Registry partner - Society for Cardiovascular Angiography and Intervention (SCAI)
- Currently 1237 participating US sites
- Approaching 10 million patient records
- Experienced support personnel
- Periodic benchmark and comparison reports
- Conferences and workshops
- Tools and programs to advance quality improvement
<table>
<thead>
<tr>
<th>Data Collected in Cath PCI Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient demographics</td>
</tr>
<tr>
<td>• Episode of care</td>
</tr>
<tr>
<td>• History and risk factors</td>
</tr>
<tr>
<td>• Clinical evaluation leading to procedure</td>
</tr>
<tr>
<td>• Diagnostic cath information</td>
</tr>
<tr>
<td>• Coronary anatomy</td>
</tr>
<tr>
<td>• PCI procedure information</td>
</tr>
<tr>
<td>• Lesions/devices</td>
</tr>
<tr>
<td>• Labs and medications</td>
</tr>
<tr>
<td>• Adverse outcomes</td>
</tr>
<tr>
<td>• Discharge status</td>
</tr>
</tbody>
</table>
CathPCI Registry

A. DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSN</td>
<td>Patient ID</td>
<td>Other ID</td>
</tr>
<tr>
<td>Birth Date</td>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Race:</td>
<td>Hispanic or Latino Ethnicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O Male O Female</td>
</tr>
</tbody>
</table>

B. EPISODE OF CARE

<table>
<thead>
<tr>
<th>Arrival Date/Time</th>
<th>Patient Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admit Source</td>
<td>Zip Code N/A</td>
</tr>
<tr>
<td>Insurance Payors:</td>
<td></td>
</tr>
</tbody>
</table>

C. HISTORY AND RISK FACTORS (On arrival to CathPCI facility)

<table>
<thead>
<tr>
<th>Current/Recent Smoker</th>
<th>Height</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently On Dialysis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PCI Quality Measures

1. Proportion of STEMI Pts with DBT $\leq$ 90"
   My Hospital: 65.5% (Rank: 87 of 389, Rank Percentile: 78)
   The proportion of primary PCI patients with DBT (door to balloon time) $\leq$ 90 minutes. The goal is to have a DBT of $\leq$ 90 minutes for all non-transferred patients pts having an ST elevated MI and having primary PCI. [Detail Line: 1767]

2. Risk Adjusted Mortality
   My Hospital: 1.02% (Rank: 118 of 366, Rank Percentile: 68)
   Your hospital’s PCI mortality rate adjusted using the ACC-NCDR® risk adjustment model [Detail Line: 1732]

3. Incidence of Vascular Complications
   My Hospital: 2.7% (Rank: 286 of 401, Rank Percentile: 30)
   Includes procedures with at least one vascular complication. [Detail Line: 2029]
Data Collection Options

- Web-Based Data Capture
  - Secure, password-protected data entry system

- Vendor-Based Data Capture
  - Data submitted via encrypted, password-protected file
  - Interface with hospital EHR systems (where applicable)
  - Certified vendors include
    - LUMEDX
    - Quantros
    - Others
Web-Based Data Capture

- ACC Developed Cath PCI Registry for Saudi
- Data elements identical to Cath PCI Registry
  - Modification for demographic variance
  - Modification for international units of measure
  - Modification for specific device and medication list
- Metrics and algorithms identical to US version
- Facility level quarterly outcome report
- Country specific aggregation
  - Country comparison
  - US national benchmark comparison
Vendor Data Capture

- NCDR certified commercial software vendor
- Data elements identical to Cath PCI Registry
  - Any modifications would be negotiated with vendor
- Metrics and algorithms identical to US version
- Facility level quarterly outcome report
- Country specific aggregation
  - Country comparison
  - US national benchmark comparison
Implementation Timeline

- ACC Model Timeline
  - Approximately 6 months for complete development
- Vendor Timeline
  - Approximately 4-5 months for modification of the Outcome Reports
Next Steps

- Identification of Contact Points
- Meeting at ACC 10
- Choice of data collection option
- Determine implementation plan
Future Considerations

- Participation in other NCDR registry programs
  - PINNACLE Registry (ambulatory)
  - IMPACT Registry
  - ACTION Registry-GWTG
  - ICD Registry
  - CARE Registry
- Collaborative research opportunities
- Educational opportunities
Shukran! - Thank You!
ACC Leadership Forum

Division of Science and Quality

January 28, 2011
Janet Wright MD FACC
ACC: Who Are We?

The primary professional organization for cardiologists world wide

- Over 39,000 members, more than 90% of US cardiologists
- Over 7,000 manuscripts submitted
- Over 20,000 live-event attendees
- Over 40,000 CME recipients
- Over 11 million patient records in NCDR
- Over 100,000,000 patients visits per year
ACC: What Do We Do?
Transform CV Care and Improve Heart Health

- **Quality**: Define it for CV care and improve it for patients
- **Education**: Put knowledge in the hands of every clinician
- **Advocacy**: Ensure value, reward quality, and preserve access
Science and Quality
Aligning the Incentives

- Patient Outcomes
- Performance Improvement
- Professional Vitality
Science and Quality 2011 +
Aligning the Incentives

- ACC members become experts in “the how”
  - Practical, data-driven QI
  - Use of multiple streams of data for QI, PI, efficiency, workforce, patient activation, etc
  - Behavior change

- Registry collaboration beyond cardiology
- Linkage of QI, PI to MOC and CME
Clinical Quality Committee

- 14 members; Chaired by Joseph Drozda
- Science and Clinical Policy
- Quality Implementation and Innovations
- CardioSource, Science and Quality
- Partners in Quality
- Best Practices/Quality Improvement
- Multiple Work Groups
Science and Quality

- Science and Clinical Policy
  - Guidelines, Performance Measures, Data Standards
- FOCUS and Appropriate Use Criteria
- Quality Improvement Programs
  - H2H, D2B, CPIP
- PINNACLE Registry and Network
- National Cardiovascular Data Registry
FOCUS: CV Imaging Strategies

New ACC product for health plans focuses on appropriate patient selection through

- Physician-developed Appropriate Use Criteria
- Point of order clinical decision support
- Benchmarking to target education and quality improvement
FOCUS: CV Imaging Strategies

Benefits

- Reduces hassles for doctors and costs for plans
- Optimizes utilization by sticking to the evidence
- Nationally recognized standards from trusted source
- Fulfills MOC Part IV and lab accreditation requirements
FOCUS: CV Imaging Strategies

Why Now?

• Profession can define, document, and improve quality
• Gain insights into ordering patterns for practice and referring doctors
• Escape from the Land of Denial
• More efficient than RBM alternative
• DE Chapter first state to implement with BCBS
Best Practice and Quality Improvement Solutions

Goal

To enable and equip the cardiovascular professional with the best practice strategies and tools they need to provide high quality patient care

• Targeting large integrated health systems
• Targeting regions with the most variation/gaps
• Collaborating with ACC chapters
Clinical Best Practice Tool Kits

Data and members tell us which tool kits to develop:

• Most variation/gaps
• Most easily improved
• Most intensely scrutinized by the public
• Metrics tied to opportunities for reimbursement

Tools Kits for 2011

Quality Improvement Tool Kit
Heart Failure Tool Kit (focus on transitions)
Atrial Fibrillation Tool Kit
Goal
To reduce 30 day, all-cause, risk standardized readmission rates for patients discharged with cardiac conditions by 20% by Dec 2012

Core Concept Areas
• Post-discharge med mgmt
• Follow-up within 1 week of discharge
• Symptom management

Community Reach 2010
• 937 Organizations
• 1500 Participants
• 34 Partners, 25 QIOs
• $70K grants

Key Activities 2010
• 25+ presentations nationwide
• 3+ listserv topics/month
• 8 best practice webinars
• 900 participants per webinar
H2H Challenges in 2011

Challenge #1: strategies to improve early follow-up of patients within 1 week of discharge

Components: Each challenge consists of 1 tool kit, 3 webinars, and 2 surveys

Timeline: Challenge #1 is Feb-Jun 2011
Cardiology Practice Improvement Pathway (CPIP):

- Practice-level performance improvement program housed on cardiosource.org
- Approved by ABIM for Part IV MOC
- Practices can choose to apply for “recognition” by submitting their CPIP data to a performance assessment organization for evaluation against established thresholds

Cardiology Practice Recognition

Recognition “status” is awarded by Bridges to Excellence to cardiology practices that achieve the performance thresholds for recognition established jointly by the ACC and BTE
<table>
<thead>
<tr>
<th>Why CPIP?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal Value</strong></td>
</tr>
<tr>
<td>✓ Understand your practice’s achievement of quality goals</td>
</tr>
<tr>
<td>✓ Step-by-step Practice-level performance improvement program</td>
</tr>
<tr>
<td>✓ Immediate feedback on performance and tools to improve and then reassess performance in targeted areas</td>
</tr>
<tr>
<td><strong>External Value</strong></td>
</tr>
<tr>
<td>✓ Consistency in market by standardizing the methodology for CV practice assessment and recognition</td>
</tr>
<tr>
<td>✓ Demonstrate your commitment to CQI and achievement of established quality thresholds</td>
</tr>
<tr>
<td>✓ Foundation for practices to participate in value-based payment programs</td>
</tr>
</tbody>
</table>
Certificate of Recognition

AWARDED TO:

Practice Name

ON ACHIEVEMENT OF RECOGNITION FOR EXCELLENCE IN THE DELIVERY OF QUALITY CARDIOVASCULAR CARE

AWARDED ON*: October 1, 2010

BY: IPRO

FRANCOIS DE BRANTES
CEO, BRIDGES TO EXCELLENCE

JACK LIWIN, M.D.
CEO, AMERICAN COLLEGE OF CARDIOLOGY

* Recognition duration is two years from the date recognition is awarded. Bridges to Excellence Recognition assessment is performed by.
What is PINNACLE Network?

- Community of CV professionals who share a commitment to the delivery of coordinated, efficient, safe, and effective care
- Set of resources to systematically measure, review and improve performance, continuously learn and teach, design or redesign care to meet needs of patients
- Data => action => high performance => reward
### PINNACLE Network Portfolio

**Streamlined access to ACC Programs, Products, Services**
- FOCUS program
- Practice Management
- Cardiology Practice Improvement Pathway
- Education—PI-CME
- PQRI—Registry or PQRI wizard tool
- Advocacy
- Risk Management Institute

**New or enhanced programs, products and services**
- QI 101 Toolkit
- Clinical QI Tools—AF, HF
- Primers in performance measures, AUC, QI, EHR
- Finance primers
- Legal briefs
- Monthly webinars
- Case studies
- Live programs (non CME)
<table>
<thead>
<tr>
<th>Members of PINNACLE Network Work Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cathie Biga, CCA</td>
</tr>
<tr>
<td>• Blair Erb, FACC, Chair</td>
</tr>
<tr>
<td>• David Clardy, FACC</td>
</tr>
<tr>
<td>• David May, FACC</td>
</tr>
<tr>
<td>• Ganpat Thakker, FACC</td>
</tr>
<tr>
<td>• Howard Rosman, FACC</td>
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<tr>
<td>• James Jollis, FACC</td>
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<tr>
<td>• John Doherty, FACC</td>
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<tr>
<td>• John Harold, FACC</td>
</tr>
<tr>
<td>• Michael Ring, FACC</td>
</tr>
<tr>
<td>• William Oetgen, FACC</td>
</tr>
<tr>
<td>• Oscar Jenkins, FACC</td>
</tr>
<tr>
<td>• Richard Kovacs, MD</td>
</tr>
<tr>
<td>• Suzette Jaskie, CCA</td>
</tr>
<tr>
<td>• Uma Valetti, FACC</td>
</tr>
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</table>

2/22/2011
<table>
<thead>
<tr>
<th>Month</th>
<th>Highlights</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>website launch; PQRI webinar</td>
</tr>
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<td>Business Plan; QI 101 webinar; Med Axiom Service Line Mgt. Program</td>
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<td>Begin search for patient experience tool; webinar on EHR implementation</td>
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Highlights for 2011, cont.

- **July**: Webinar on payment models; identification of critical partners
- **August**: Webinar on ICD-10 coding update; clinical QI Toolkit for Atrial Fibrillation
- **September**: Live program on Service Line Management, physician payment models
- **October**: Case study #3; webinar on hospital employer contracting
- **November**: Webinar on Final Rule
- **December**: Webinar on team based care; contracts with partners completed
NCDR Management Board

- John Rumsfeld
- Fred Masoudi
- Chuck McKay
- Skip Anderson
- Martha Radford
- Steve Hammill

- Greg Dehmer
- Bill Weintraub
- Mike Mirro
- Fred Grover
- Joe Drozda
- Joe Cacchione
Translating Clinical Guidelines into Clinical Care

9th Annual Parkview Research Symposium
February 5, 2011

Janet Wright MD FACC SVP, Science and Quality
Today

- ACC
- Division of Science and Quality at ACC
- The Problem a la Mirro
- “Solutions” that are very much works in progress
<table>
<thead>
<tr>
<th>Who We Are....</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 40,000 cardiologists, nurses, nurse practitioners, physician assistants, pharmacologists, administrators, and surgeons</td>
</tr>
<tr>
<td>- 7,000 manuscripts submitted</td>
</tr>
<tr>
<td>- 35,000 recipients of CME</td>
</tr>
<tr>
<td>- More than 1 million CardioSource page views</td>
</tr>
<tr>
<td>- Over 11 million patient records in NCDR</td>
</tr>
<tr>
<td>- Over 100,000,000 patients visits each year</td>
</tr>
</tbody>
</table>
What We Do…

- **Quality**: Define quality care for the CV community
- **Education**: Provide CV knowledge for every clinician
- **Advocacy**: Attest to value and ensure access to care

Working to transform CV care and improve heart health
National Cardiovascular Data Registry

Number of sites and patients records

- IMPACT Registry
  - >1.3M

- PINNACLE Registry
  - >1.3M

- Afib Ablation Registry
  - 1575, >250K

- CARE Registry
  - 170, >9K

- ACTION-GWTG Registry
  - 702, >120K

- HF Registry

- CathPCI
  - 1376, 11M

- ICD
  - 1575, >250K

- 1998…2004

- 2005

- 2006

- 2007

- 2008

- beyond
Beyond publishing and building registries

Pull all the levers to reward: satisfaction, hassle reduction, recognition, financial

Become experts in “the how”
- Practical, data-driven QI
- Use of multiple streams of data for QI, PI, efficiency, workforce, patient activation, and more
- Behavior change for patients, ourselves, systems
Aligning Incentives for Better Health, Better Care, and Lower Cost

- Patient Outcomes
- Performance Improvement
- Professional Vitality
The Problem a la Mirro

- Stimulus
- Transmission
- Activation
- Improved function, sustained over time
- Complications rapidly identified, corrected
Systems that Work

- Knowledge: fresh, accessible, and contextualized
- Team with complementary roles and skills
- Script, tips, and tools
- Measurement and timely feedback
- Evaluation and refinement
- Community to road-test, disseminate, ring alarms, and direct traffic
Systems that Don’t
D2B Strategies
Reduce MI Deaths

- **D2B** is designed to save time, cost and lives by reducing the door-to-balloon times in hospitals performing primary PCI

- **75%** of participating hospitals in the Door-to-Balloon Alliance were able to treat ST-segment elevation myocardial infarction patients within 90 minutes

- The way heart attack care is delivered can make a life or death difference

For more on the study, view the December 15 – 22, 2009 issue of JACC
Quality and Cost Alignment

Emergency Dept Activation of Cath Lab and Immediate Transfer

Door-to-balloon time ↓ from 113 to 75 minutes
Transfer time ↓ from 147 to 85 minutes
Infarct size ↓ (creatinine kinase)
Hospital stays ↓ by 2-3 days
Cost ↓ by over 30 percent

U. M. Khot et al, Circulation. 2007; 116
• Performance in care for patients with Coronary artery disease, Hypertension, Atrial fib, and Heart Failure
• 1.3 Million patient encounters
• Issued first practice outcomes report
• In process of switching to dashboard
• PQRI participants -2009
  • 14 practices in 14 states, 172 providers
  • AL, AR, FL, IL, MD, MO, NC, NE, NJ, NY, SC, TX, VA, WA
  • 100% received PQRI payments
  • 13 practices, 171 providers reported results to ACC
Geographic Distribution of PINNACLE Registry Practices – January 2011

Key: (Practices; providers)
States = 26
Practices = 43
Providers = 516
Pinnacle Registry Practice Sizes

Providers per Practice

# of Practices

0 1 2 3 5 6 7 8 9 10 11 14 16 17 22 23 24 26 28 29 50 82

Pinnacle Registry

Timely Feedback of Measurement

Current Quarterly Report

The PINNACLE Dashboard

- Ability to push survey questions or additional data collection to physicians
- Individual patient record audit trail and corrections
- Fully functional web-based data entry tool
Running on......
• Nextgen
• GE Centricity
• GE Logician
• GEMMS
• Allscripts
• Greenway Medical
• Misys
• Medisoft Clinical
• MIE
• Soapware
• gMed
• Amazing Charts
• Universal EMR
• PrimeSuite

Mapping in progress
• MDrec
• NextTech
• eMD
• MyWay
• EPIC
• Pronto EMR
• eClinical Works
• Med Informatics
• Cerner
• Infinity
• Alteer Visionary Health Care
• Springcharts
• DigiDMS
• Athena
• Intergy / Sage
PINNACLE Registry can capture 75% - 80% of the required data for calculation of 27 performance measures for most EHRs.

Permits calculation of 75%-80% of performance measures.

- **Before PINNACLE, zero** performance measures were being calculated and reported back to practices.
Streamlined access to Programs, Products, Services

- FOCUS program
- Practice Management
- Cardiology Practice Improvement Pathway
- Education—PI-CME
- PQRI—Registry or PQRI wizard tool
- Advocacy
- Risk Management Institute

New or enhanced programs, products and services

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PINNACLE Network will make a difference

**Problem**
Where does it hurt?
- Lack of measurement
- Unfocused learning
- Disconnected from performance
- Not rewarded by payment

**Solution**
What are my peers doing better? Who are the positive deviants? What are practices like mine doing right?
- Measurement
  - PINNACLE Registry
  - NCDR
- Learning
  - Workflow Redesign
  - Life Long Learning
  - MOC
  - CLI
  - Online Communities

**Results**
How has ACC improved my professional life?
- Deeper understanding of my practice
- Customized learning and credit earned
- “Top of My Game” performance
- Better payment
- Stronger negotiating position
Aligned Incentives

- Satisfaction due to success, excellence, security
  - Revitalized patient-professional communication
  - Mastery = no sweat MOC, MOL; control of condition and best health
- Recognition
- Hassle Reduction
- Med Mal advantages
- Financial: PQRS, e-Prescribing, P4P, contracting ammunition; health costs less!
Aligned.....
We are positioned to reduce variation, disparities, and waste
• Percutaneous coronary intervention (PCI) is performed approximately 1 million times annually in the United States
• The safety of PCI continues to be excellent with very low rates of death, myocardial infarction (MI), and need for urgent revascularization
• PCI-related bleeding occurs in approximately 2-6% of patients in national PCI databases; marked institutional variability in rates exists
• Bleeding complications are associated with increased length of stay, hospital costs, and important clinical complications such as death and MI
Candidate Bleeding Avoidance Strategies

- Bivalirudin
- Vascular closure devices
- Both therapies (bivalirudin + vascular closure)
Bleeding Risk Strata

- Bleeding risk score calculated for each patient using NCDR bleeding risk model\textsuperscript{1}
- Clinical elements used to calculate bleeding risk score
  - STEMI/non-STEMI
  - Female sex
  - Previous CHF
  - No previous PCI
  - NYHA/CCS Class IV CHF
  - PVD
  - Age
  - Estimated glomerular filtration rate

\textsuperscript{1} Mehta et al: Circ Cardiovasc Intervent 2:222, 2009

Marso et al: JAMA 303:2156, 2010
Study Outcomes

In-hospital bleeding according to NCDR data definition

- Requiring transfusion and/or
- Prolonged hospital stay and/or
- Decrease in hemoglobin >3 g/dL

Marso et al: JAMA 303:2156, 2010
Statistical Analysis

- Patients categorized into 3 groups of bleeding risk based on NCDR bleeding risk score
  - Low (<1%)
  - Intermediate (1-3%)
  - High (>3%)
- Propensity score matching with site adjustment using 26 clinical variables for each bleeding avoidance strategy performed to minimize confounding
- Population was well matched (standard difference plot on next slide)

Marso et al: JAMA 303:2156, 2010
Marso et al: JAMA 303:2156, 2010

Standardized Difference Before and After Propensity Matching

- STEMI
- NYHA Class III/IV
- Previous PCI
- Hypocholesterolemia
- Hypertension
- Hx of smoking
- Age
- BMI
- PVD
- Previous MI
- Previous CABG
- Diabetes
- Renal failure
- CHF
- White race
- Family Hx of CAD
- Gender
- Previous CHF
- Cerebrovascular disease
- Previous cardiac transplant
- Previous valve surgery
- Chronic lung disease

Before match
After match

Standardized difference
Standardized Difference Before and After Propensity Matching

1,759,408 records from NCDR version 3.04
2004-2008

Exclusions: 236,473 (15%)
- >1 in-hospital PCI procedure: 91,874 (5%)
- Data incomplete for calculation of expected bleeding rate: 69,247 (4%)
- PCI of a radial or non-femoral artery; 35,951 (2%)
- Cardiogenic shock: 34,842 (2%)
- Missing device data: 3,384 (<1%)
- Death in catheterization lab: 1,111 (<1%)
- Bleeding event unknown: 64 (,1%)

Final study population: n=1,522,935

Manual compression
n=529,247 (35%)
Low risk: 146,557 (28%)
Intermediate risk: 261,363 (49%)
High risk: 121,327 (23%)

Vascular closure device
n=363,583 (24%)
Low risk: 115,510 (32%)
Intermediate risk: 178,200 (49%)
High risk: 69,873 (19%)

Bivalirudin
n=353,769 (23%)
Low risk: 113,118 (32%)
Intermediate risk: 174,131 (49%)
High risk: 66,520 (19%)

Both strategies
n=276,336 (18%)
Low risk: 99,967 (36%)
Intermediate risk: 133,033 (48%)
High risk: 43,336 (16%)

Marso et al: JAMA 303:2156, 2010
## Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total (n=1,522,935)</th>
<th>Manual compression (n=529,247)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All P&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age, mean (SD) (yr)</strong></td>
<td>64.3 (12.1)</td>
<td>63.87 (12.33)</td>
</tr>
<tr>
<td><strong>Male, no. (%)</strong></td>
<td>1,011,992 (66.5)</td>
<td>350,424 (66.21)</td>
</tr>
<tr>
<td><strong>Weight, mean, SD (kg)</strong></td>
<td>87.71 (20.45)</td>
<td>87.25 (20.42)</td>
</tr>
<tr>
<td><strong>BMI, mean, SD (kg/m2)</strong></td>
<td>29.8 (6.3)</td>
<td>29.7 (6.3)</td>
</tr>
<tr>
<td><strong>Obesity, no. (%)</strong></td>
<td>643,500 (42.25)</td>
<td>219,470 (41.47)</td>
</tr>
<tr>
<td><strong>NYHA class, no. (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>480,785 (31.57)</td>
<td>160,016 (30.24)</td>
</tr>
<tr>
<td>II</td>
<td>355,937 (23.37)</td>
<td>107,093 (20.24)</td>
</tr>
<tr>
<td>III</td>
<td>415,651 (27.30)</td>
<td>146,439 (27.67)</td>
</tr>
<tr>
<td>IV</td>
<td>270,376 (17.76)</td>
<td>115,629 (21.85)</td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
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</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) (yr)</td>
<td>63.34 (12.26)</td>
<td>65.43 (11.86)</td>
<td>64.77 (11.80)</td>
<td></td>
</tr>
<tr>
<td>Male, no. (%)</td>
<td>250,753 (68.97)</td>
<td>225,235 (63.67)</td>
<td>185,580 (67.16)</td>
<td></td>
</tr>
<tr>
<td>Weight, mean, SD (kg)</td>
<td>88.22 (20.28)</td>
<td>87.29 (20.71)</td>
<td>88.47 (20.40)</td>
<td></td>
</tr>
<tr>
<td>BMI, mean, SD (kg/m2)</td>
<td>29.8 (6.2)</td>
<td>29.8 (6.4)</td>
<td>30.0 (6.3)</td>
<td></td>
</tr>
<tr>
<td>Obesity, no. (%)</td>
<td>153,233 (42.15)</td>
<td>150,813 (42.63)</td>
<td>119,984 (43.42)</td>
<td></td>
</tr>
<tr>
<td>NYHA class, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>125,209 (34.44)</td>
<td>107,678 (30.44)</td>
<td>87,882 (31.81)</td>
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<tr>
<td>II</td>
<td>79,475 (21.86)</td>
<td>90,682 (25.64)</td>
<td>78,687 (28.48)</td>
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<tr>
<td>III</td>
<td>87,352 (24.03)</td>
<td>107,952 (30.52)</td>
<td>73,908 (26.75)</td>
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<tr>
<td>IV</td>
<td>71,508 (19.67)</td>
<td>47,412 (13.40)</td>
<td>35,827 (12.97)</td>
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Marso et al: JAMA 303:2156, 2010
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<tr>
<td>All P&lt;0.001</td>
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</tr>
<tr>
<td>Diabetes</td>
<td>509,455 (33.45)</td>
<td>173,024 (32.69)</td>
</tr>
<tr>
<td>Estimated GFR, mean (SD)</td>
<td>73.77 (29.62)</td>
<td>73.60 (29.88)</td>
</tr>
<tr>
<td>Coronary artery disease Hx, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>576,207 (37.84)</td>
<td>182,518 (34.49)</td>
</tr>
<tr>
<td>CABG</td>
<td>291,773 (19.16)</td>
<td>98,038 (18.52)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>427,655 928.08)</td>
<td>144,381 927.28)</td>
</tr>
<tr>
<td>CHF</td>
<td>136,483 (8.96)</td>
<td>54,661 (10.33)</td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
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<tr>
<th>Patient Characteristics</th>
<th>VCD (n=363,583)</th>
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<td>All P&lt;0.001</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Diabetes</td>
<td>113,130 (31.12)</td>
<td>129,335 (36.56)</td>
<td>93,966 (34.00)</td>
</tr>
<tr>
<td>Estimated GFR, mean (SD)</td>
<td>75.02 (30.48)</td>
<td>72.46 (29.06)</td>
<td>74.09 (28.61)</td>
</tr>
<tr>
<td>Coronary artery disease Hx, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>125,649 (34.56)</td>
<td>151,835 (42.92)</td>
<td>116,205 (42.05)</td>
</tr>
<tr>
<td>CABG</td>
<td>59,980 (16.50)</td>
<td>79,189 (22.39)</td>
<td>54,566 (19.75)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>96,191 (26.46)</td>
<td>105,403 (30.08)</td>
<td>80,690 (29.20)</td>
</tr>
<tr>
<td>CHF</td>
<td>32,255 (8.87)</td>
<td>43,082 (12.18)</td>
<td>28,751 (10.40)</td>
</tr>
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</table>

Marso et al: JAMA 303:2156, 2010
## Admission Characteristics

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<td><strong>All P&lt;0.001</strong></td>
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<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>527,624 (34.65)</td>
<td>168,813 (31.90)</td>
</tr>
<tr>
<td>Non-STEMI</td>
<td>238,305 (15.65)</td>
<td>98,866 (18.68)</td>
</tr>
<tr>
<td>STEMI</td>
<td>186,810 (12.27)</td>
<td>99,900 (18.88)</td>
</tr>
<tr>
<td><strong>PCI type</strong></td>
<td></td>
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</tr>
<tr>
<td>Elective</td>
<td>758,110 (49.79)</td>
<td>220,576 (41.68)</td>
</tr>
<tr>
<td>Urgent</td>
<td>553,524 (36.35)</td>
<td>196,634 (37.16)</td>
</tr>
<tr>
<td>Emergency</td>
<td>209,465 (13.76)</td>
<td>110,990 (20.97)</td>
</tr>
<tr>
<td>Salvage</td>
<td>1,662 (0.11)</td>
<td>968 (0.18)</td>
</tr>
</tbody>
</table>

All data are no. (%)  

Marso et al: JAMA 303:2156, 2010
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All</td>
<td>113,413 (31.19)</td>
<td>142,473 (40.27)</td>
<td>102,925 (37.25)</td>
</tr>
<tr>
<td></td>
<td>Non</td>
<td>142,473 (40.27)</td>
<td>102,925 (37.25)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STEMI</td>
<td>102,925 (37.25)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>PCI type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Elective</td>
<td>157,348 (43.28)</td>
<td>212,562 (60.09)</td>
<td>167,624 (60.67)</td>
</tr>
<tr>
<td></td>
<td>Urgent</td>
<td>140,023 (38.52)</td>
<td>121,995 (34.49)</td>
<td>94,872 (34.34)</td>
</tr>
<tr>
<td></td>
<td>Emergency</td>
<td>64,758 (18.09)</td>
<td>19,011 (5.37)</td>
<td>13,706 (4.96)</td>
</tr>
<tr>
<td></td>
<td>Salvage</td>
<td>422 (0.12)</td>
<td>172 (0.05)</td>
<td>100 (0.04)</td>
</tr>
<tr>
<td><strong>All data are no. (%)</strong></td>
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</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
## Hospital Characteristics

<table>
<thead>
<tr>
<th>Community type, no. (%)</th>
<th>Total (n=1,522,935)</th>
<th>Manual compression (n =529,247)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural</td>
<td>177,441 (15.92)</td>
<td>59,727 (15.44)</td>
</tr>
<tr>
<td>Urban</td>
<td>937,476 (84.08)</td>
<td>327,222 (84.56)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reimbursement type, no. (%)</th>
<th>Total (n=1,522,935)</th>
<th>Manual compression (n =529,247)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>23,838 (1.57)</td>
<td>7,895 (1.49)</td>
</tr>
<tr>
<td>Private/Community</td>
<td>1,356,756 (89.09)</td>
<td>465,238 (87.91)</td>
</tr>
<tr>
<td>University</td>
<td>142,341 (9.35)</td>
<td>56,114 (10.60)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Annual PCI volume, mean (SD)</th>
<th>Total (n=1,522,935)</th>
<th>Manual compression (n =529,247)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1,095.81 (795.18)</td>
<td>1,058.04 (704.88)</td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
# Hospital Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All P&lt;0.001</th>
<th>VCD (n=363,583)</th>
<th>Bivalirudin (n=353,769)</th>
<th>Both (n=276,336)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Community type, no. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>54,008 (21.02)</td>
<td>31,542 (11.48)</td>
<td>32,164 (16.38)</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>202,931 (78.98)</td>
<td>243,165 (88.52)</td>
<td>164,158 (83.62)</td>
<td></td>
</tr>
<tr>
<td><strong>Reimbursement type, no. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>4,948 (1.36)</td>
<td>5,988 (1.69)</td>
<td>5,007 (1.81)</td>
<td></td>
</tr>
<tr>
<td>Private/Community</td>
<td>319,915 (87.99)</td>
<td>318,550 (90.04)</td>
<td>253,053 (91.57)</td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>38,720 (10.65)</td>
<td>29,231 (8.26)</td>
<td>18,276 (6.61)</td>
<td></td>
</tr>
<tr>
<td><strong>Annual PCI volume, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>981.16 (732.27)</td>
<td>1,303.62 (782.65)</td>
<td>1,052.94 (678.44)</td>
<td></td>
</tr>
</tbody>
</table>

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**Bleeding Rates**

*Overall bleeding = 30,429 (2%)*

P<0.001 all intra-risk group comparisons


M = Manual comp
C = Closure only
B = Bival only
BC = Bival + closure

*NCDR bleeding risk <1%*
†NCDR bleeding risk 1-3%
‡NCDR bleeding risk ≥3%
## Estimated Bleeding Reductions – All Patients (Propensity Adjusted)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Treatment (no.)</th>
<th>Bleeding no. (%)</th>
<th>Odds ratio (95% CI)</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual compression</td>
<td>508,455</td>
<td>13,597 (2.7)</td>
<td>1 [reference]</td>
<td></td>
</tr>
<tr>
<td>VCD</td>
<td>205,606</td>
<td>5,050 (2.5)</td>
<td>0.77 (0.73-0.80)</td>
<td>148 (130-175)</td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>172,471</td>
<td>3,224 (1.9)</td>
<td>0.67 (0.63-0.70)</td>
<td>118 (107-132)</td>
</tr>
<tr>
<td>Both</td>
<td>130,378</td>
<td>1,361 (1.0)</td>
<td>0.38 (0.35-0.42)</td>
<td>70 (68-74)</td>
</tr>
<tr>
<td>Total</td>
<td>1,016,910</td>
<td>23,232 (2.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
## Estimated Bleeding Reductions (Propensity Adjusted)

<table>
<thead>
<tr>
<th>Treatment (no.)</th>
<th>Bleeding no. (%)</th>
<th>Odds ratio (95% CI)</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low risk (&lt;1%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual compression</td>
<td>144,594</td>
<td>1,320 (0.9)</td>
<td>1 [reference]</td>
</tr>
<tr>
<td>VCD</td>
<td>54,217</td>
<td>532 (1.0)</td>
<td>1.07 (0.93-122)</td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>48,378</td>
<td>296 (0.6)</td>
<td>0.65 (0.56-0.77)</td>
</tr>
<tr>
<td>Both</td>
<td>41,999</td>
<td>166 (0.4)</td>
<td>0.42 (0.34-0.51)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>289,188</td>
<td>2,314 (0.8)</td>
<td></td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
## Estimated Bleeding Reductions (Propensity Adjusted)

<table>
<thead>
<tr>
<th></th>
<th>Treatment (no.)</th>
<th>Bleeding no. (%)</th>
<th>Odds ratio (95% CI)</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intermediate risk (1-3%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual compression</td>
<td>252,898</td>
<td>5,722 (2.3)</td>
<td>1 [reference]</td>
<td></td>
</tr>
<tr>
<td>VCD</td>
<td>103,095</td>
<td>2,077 (2.0)</td>
<td>0.76 (0.71-0.81)</td>
<td>169 (141-217)</td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>85,800</td>
<td>1,311 (1.5)</td>
<td>0.69 (0.63-0.74)</td>
<td>153 (131-187)</td>
</tr>
<tr>
<td>Both</td>
<td>64,003</td>
<td>573 (0.9)</td>
<td>0.39 (0.35-0.44)</td>
<td>80 (75-86)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>505,796</td>
<td>9,683 (1.9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
## Estimated Bleeding Reductions (Propensity Adjusted)

<table>
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<tr>
<th>Treatment</th>
<th>Treatment (no.)</th>
<th>Bleeding no. (%)</th>
<th>Odds ratio (95% CI)</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual compression</td>
<td>110,963</td>
<td>6,555 (5.9)</td>
<td>1 [reference]</td>
<td></td>
</tr>
<tr>
<td>VCD</td>
<td>48,294</td>
<td>2,441 (5.1)</td>
<td>0.79 (0.75-0.82)</td>
<td>81 (66-109)</td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>38,293</td>
<td>1,617 (4.2)</td>
<td>0.67 (0.62-0.73)</td>
<td>56 (49-66)</td>
</tr>
<tr>
<td>Both</td>
<td>24,376</td>
<td>622 (2.6)</td>
<td>0.42 (0.38-0.47)</td>
<td>33 (31-36)</td>
</tr>
<tr>
<td>Total</td>
<td>221,926</td>
<td>11,235 (5.1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Marso et al: JAMA 303:2156, 2010
Bleeding Avoidance Strategy use by Pre-PCI Bleeding Risk

Risk-Treatment Paradox

P<0.001 all intra-risk group comparisons

M = Manual comp
C = Closure only
B = Bival only
BC = Bival + closure

* NCDR bleeding risk <1%
† NCDR bleeding risk 1-3%
‡ NCDR bleeding risk ≥3%
Conclusions

In 1.5 million PCI patients in the NCDR

- Post-PCI bleeding occurred in 2%
- Use of bivalirudin plus vascular closure devices was associated with an absolute 3.8% lower rate in PCI related bleeding in high risk patients
- To prevent 1 bleeding event in high risk patients would require treating 33 patients with both therapies
- High risk patients were least likely to receive both strategies (risk-treatment paradox)
Importance of Registries

Registries are important for introducing really good things
“Double Counting” PCI Procedures
AHA Annual CV Statistics

- **“Double Counted” PCI Procedures (AHA Statistics):** 1,300,000
- **Actual PCI Procedures (confirmed by AHRQ):** 600,000
Calibration Plots

Overall

- n=60,640
- Brier score: 0.0223
- C-index=0.72

NSTEMI/UA

- n=30,872
- C-index=0.70

STEMI

- n=9,130
- C-index=0.68

Non-ACS

- n=20,638
- C-index=0.68

About the American College of Cardiology

• The College is a global leader in the formulation of health policy, standards and guidelines.

• The ACC uses these guidelines to help improve cardiovascular care and practice through the use of products, programs and services.

• The ACC provides information and tools to cardiologists, general practitioners and internists to improve cardiovascular health in the general population and equip practitioners with the information and informational tools needed to effectively address prevention of cardiovascular disease.

• The College has 37,000 members throughout the world