Devilish Definitions: Professional Society View

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Deconstructing Definitions: Importance of data elements

Bleeding definition

Data Elements

Clinical
- ICH
- Hematoma

Laboratory
- Hgb decrease

Consequences
- Hemodynamic compromise
- Transfusion
- Fatal

Severity Classification
## “Major” Bleeding Data Elements

<table>
<thead>
<tr>
<th>Definition</th>
<th>TIMI¹</th>
<th>GUSTO¹</th>
<th>CURE²</th>
<th>PLATO³</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial</strong></td>
<td>TRITON</td>
<td>CHARISMA</td>
<td>CURE</td>
<td>PLATO</td>
</tr>
<tr>
<td>Fatal / life threatening (related to instrumentation, spontaneous, trauma), ICH, Hb &gt;5 g/dL, or absolute HCT &gt;15%</td>
<td>Fatal, ICH, or causes haemodynamic compromise and requires intervention</td>
<td>Fatal / Life threatening</td>
<td>Fatal, ICH, requires surgery, hypotension requiring inotropes, Hb &gt;5 g/dL, or transfusion 4 U</td>
<td>Fatal / Life threatening</td>
</tr>
<tr>
<td>Fatal / Life threatening</td>
<td></td>
<td>Other major</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disabling, intraocular with vision loss, or transfusion 2-3 U</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other major</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

ICH = intracranial haemorrhage; PLATO = Platelet Inhibition and Patient Outcomes.

Effect of Bleeding Definition on the Association of Bleeding and Death/MI

N=15,858 ACS patients from PURSUIT & PARAGON B

30-day death/MI

<table>
<thead>
<tr>
<th>Bleeding Definition</th>
<th>30-day death/MI Hazard Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUSTO Mild</td>
<td>1.19 (1.01, 1.41)</td>
</tr>
<tr>
<td>GUSTO Moderate</td>
<td>1.92 (1.58, 2.34)</td>
</tr>
<tr>
<td>GUSTO Severe</td>
<td>3.48 (2.56, 4.73)</td>
</tr>
<tr>
<td>TIMI Minimal</td>
<td>1.13 (0.97, 1.33)</td>
</tr>
<tr>
<td>TIMI Minor</td>
<td>1.08 (0.85, 1.36)</td>
</tr>
<tr>
<td>TIMI Major</td>
<td>1.00 (0.85, 1.20)</td>
</tr>
</tbody>
</table>

Decreased Risk .00 Increased Risk

# Major bleeding data elements and outcomes:

*N=22,000 pts from REPLACE-2, ACUITY, HORIZONS-AMI*

<table>
<thead>
<tr>
<th>Event</th>
<th>Hazard ratio (95% CI)</th>
<th>Deaths within 1 y, n</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIMI major bleed</td>
<td>4.85 (3.56–6.60)</td>
<td>53</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non-TIMI major bleed with transfusion</td>
<td>2.98 (2.10–4.24)</td>
<td>40</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non-TIMI major bleed without transfusion</td>
<td>1.79 (1.09–2.93)</td>
<td>17</td>
<td>0.021</td>
</tr>
<tr>
<td>Large (≥5 cm) hematoma only</td>
<td>1.30 (0.58–2.92)</td>
<td>6</td>
<td>0.53</td>
</tr>
</tbody>
</table>
Hematomas and outcomes: 
N=3342 pts from STEEPLE

Hematomas ≥5 cm

Incidence of 30-day composite ischemic end point in patients with and without hematomas ≥5 cm.

Mortality, non fatal MI, urgent target vessel revascularization (%)

- 6/103 Patients with hematomas ≥5 cm (5.8%)
- 190/3,239 Patients with no hematomas ≥5 cm (5.9%)

1 Year mortality (%)

- 0/103 Patients with hematomas ≥5 cm (0.0%)
- 55/3,239 Patients with no hematomas ≥5 cm (1.7%)

Incidence of all-cause 1-year mortality in patients with and without hematomas ≥5 cm.

P = .98
# NCDR CathPCI bleeding (version 3.04)

## J. Adverse Outcomes:
(Complete this section for each Lab Visit)

### General Complications:
- **Periprocedural MI**: Yes; No
- **Cardiogenic Shock**: Yes; No
- **CHF**: Yes; No
- **CVA/Stroke**: Yes; No
- **Tamponade**: Yes; No
- **Thrombocytopenia**: Yes; No
- **Contrast Reaction**: Yes; No
- **Renal Failure**: Yes; No
- **Emergency PCI**: Yes; No

### Vascular/Bleeding Complications:
- **Bleeding at Pecutaneous Entry Site**: Yes; No
- **Retroperitoneal Bleeding**: Yes; No
- **Gastrointestinal Bleeding**: Yes; No
- **Genital-Urinary Bleeding**: Yes; No
- **Bleeding - Other/Unknown Cause**: Yes; No
- **Access Site Occlusion**: Yes; No
- **Peripheral Embolization**: Yes; No
- **Dissection**: Yes; No
- **Pseudoaneurysm**: Yes; No

→ If Yes **Treatment**: None; Pressure; Fibrin Injection; Surgery

**AV Fistula**: Yes; No
To qualify a bleeding event should require a transfusion, and/or prolong hospital stay, and/or cause a drop in hgb > 3.0 g/dl

Percutaneous entry site
- External
- Hematoma > 10 cm for femoral, > 2 cm for radial access, > 5 cm brachial
Considerations for TREAT

- Prospective data collection
  - Surveillance for bleeding rather than chart review
  - Collection of additional data elements
  - Complications:
    - Arterial occlusion
    - Hematomas not leading to prolonged hosp or decreasing hgb