Cohorts to Study: Defining a “Population of Intended Use”

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Disclosures

- Consultant/ Speakers Bureau, Abiomed
  - Site PI, SHIELD II Trial, Abbott
  - Site PI, INOVA-SHOCK Registry
  - Site Co-PI, National CS Initiative
Table 1. Pragmatic and Clinical Trial Definitions of CS

<table>
<thead>
<tr>
<th>Clinical Definition</th>
<th>SHOCK Trial*</th>
<th>IABP-SHOCK II†</th>
<th>ESC HF Guidelines‡</th>
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<tbody>
<tr>
<td>Cardiac disorder that results in both clinical and biochemical evidence of tissue hypoperfusion</td>
<td>Clinical criteria: SBP &lt;90 mm Hg for ≥30 min OR Support to maintain SBP ≥90 mm Hg AND End-organ hypoperfusion (urine output &lt;30 ml/h or cool extremities) Hemodynamic criteria: CI of ≤2.2 L·m⁻¹·min⁻¹ AND PCWP ≥15 mm Hg</td>
<td>Clinical criteria: SBP &lt;90 mm Hg for ≥30 min OR Catecholamines to maintain SBP &gt;90 mm Hg AND Clinical pulmonary congestion AND Impaired end-organ perfusion (altered mental status, cold clammy skin and extremities, urine output &lt;30 ml/h, or lactate &gt;2.0 mmol/l)</td>
<td>SBP &lt;90 mm Hg with adequate volume and clinical or laboratory signs of hypoperfusion Clinical hypoperfusion: Cold extremities, oliguria, mental confusion, dizziness, narrow pulse pressure Laboratory hypoperfusion: Metabolic acidosis, elevated serum lactate, elevated serum creatinine</td>
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CI indicates cardiac index; CS, cardiogenic shock; ESC, European Society of Cardiology; HF, heart failure; IABP-SHOCK II, Intraaortic Balloon Pump in Cardiogenic Shock II; LV, left ventricular; MI, myocardial infarction; PCWP, pulmonary capillary wedge pressure; SBP, systolic blood pressure; and SHOCK, Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock.

*In setting of MI complicated by predominantly LV dysfunction in setting of acute MI.

Maintain high index of suspicion and act early

Who is in Shock?

- “Pre” Shock
- Shock
- “Refractory” Shock
- “Hemo-metabolic” Shock
- “Terminal” Shock...
  - AMI vs. ADHF
  - CS vs. “Mixed”
  - LV vs. RV vs. BiV
- Clinical, Laboratory, Hemodynamic...
  - Pathophysiology, prognosis, treatment...
• Multiple specialties, multiple therapies/devices

• Hemodynamic classification/guidance, protocolized/standardized care, “unblinking eye”

• Different patients have different needs at different times (re-stage)...

Truesdell et al Interv Cardiol 2018
Tehrani et al JMIR Res Protoc 2018
- Clinical, imaging, hemodynamic, laboratory ("non-standard") biomarkers, time variables?

- "Boutique" Identification and categorization scores: dichotomous variables vs. continuous variables?
Our Experience

- Multidisciplinary team-based care
- Rapid identification of the shock state
- Early employment of (LV and RV) MCS (as appropriate)
- Hemodynamic assessment and guidance
  - Minimize inotropes and vasopressors
- After-action reviews (QI)
- Now > 240 pts (all-comers)
- Updates coming at TCT 2018...

Truesdell et al. Interv Cardiol 2018
Tehrani et al. JMIR Res Protoc 2018
Summary

• Early diagnosis, early treatment
• Standardized consensus clinical, laboratory, hemodynamic definitions
  • Subgroup analysis (etiology [AMI vs. ADHF] and “stage“)
    • When, how, how often to “re-stage“
  • Large-scale multicenter collaborative data collection
• Predictive models, variables, biomarkers for evolving “pre“-shock
  • Continuous monitoring: laboratory, hemodynamic
    • After action reviews ("evolving" trials)
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