

Clinical Perspective: Enrollment, F/U, and Endpoints

Who to include? How frequent to assess?



Timothy D. Henry MD, FACC, SCAI

Medical Director, The Carl and Edyth Lindner Center for Research and Education

The Carl and Edyth Lindner Family Distinguished Chair in Clinical Research

Director of Programmatic and Network Development



SCAI

Society for Cardiovascular
Angiography & Interventions



The
Christ Hospital[™]
Health Network

Traditional Definition of Cardiogenic Shock

Persistent SBP < 90 mm Hg not responsive to fluid administration alone

Secondary to cardiac dysfunction

Associated with signs of hypoperfusion of a CI < 2.2 L/min/m² and a PCWP > 15 mmg Hg



SCAI

Society for Cardiovascular
Angiography & Interventions

Shock is Variable

IMPRESS Trial

- SBP < 90 for 30 minutes
- Pressors to SBP > 90
- All pts intubated
- 90% cardiac arrest
- 20 minutes to ROSC
- 70-80% induced hypothermia
- Signs of Hypoperfusion
- (Lactate > 7-8, pH 7.1-7.2)

IABP SHOCK II Trial

- SBP < 90 for 30 minutes
- Pressors to SBP > 90
- Pulmonary Congestion
- Signs of Hypoperfusion
- Lactate > 2, Alt mental status or Urine Output < 30/hour

One size does not fit all: Lack of common language has impeded the advancement of research on optimal diagnosis & management of these patients



SCAI

Society for Cardiovascular
Angiography & Interventions

Multidisciplinary Lexicon

Experts with diverse backgrounds engaged in the creation of the SCAI SHOCK system

Endorsed by AHA, ACC, STS, and SCCM

Interventional Cardiology

Heart Failure

Critical Care / Cardiology

Emergency Medicine

Critical Care Nursing

Cardiac Surgery



SCAI

Society for Cardiovascular
Angiography & Interventions

Goals of a New Shock Definition

- Simple and intuitive without the need for calculation
- Adds needed granularity in the severity of shock
- Suitable for rapid assessment at the bedside
- Allows for frequent reassessment and reclassification
- Can be applied to retrospective datasets or prior trials to re-examine outcomes, and future trials to better define the include population
- Provide new lexicon for communication between providers, including facilitating multidisciplinary communication within a hospital and between hospitals (hub and spoke model)
- Prognostic discriminatory potential for morbidity and mortality
- Easy to remember nomenclature (model INTERMACS)



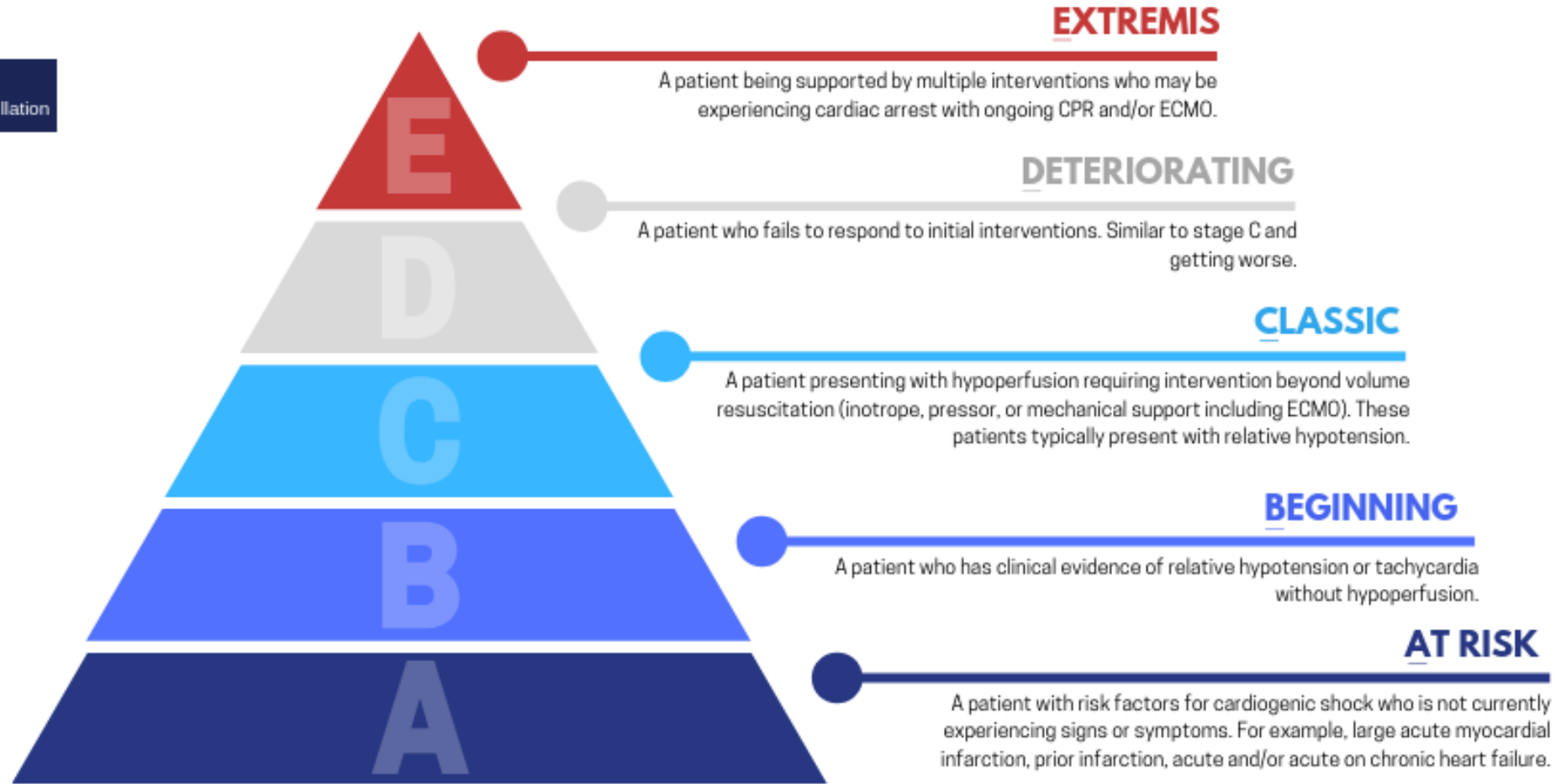
SCAI

Society for Cardiovascular
Angiography & Interventions

SCAI Stages of Cardiogenic Shock

Adapted from the SCAI Clinical Expert Consensus Statement on the Classification of Cardiogenic Shock
Endorsed by ACC, AHA, SCCM, and STS

Arrest (A) Modifier:
CPR, including defibrillation



Baran DA, Grines CL, Bailey S, et al. SCAI clinical expert consensus statement on the classification of cardiogenic shock. Catheter Cardiovasc Interv. 2019;1-9. <https://doi.org/10.1002/ccd.28329>
For more information, please visit: www.scai.org/shockdefinition

Risk Modifier for Cardiac Arrest

- Any cardiac arrest however brief (Defib or CPR)
 - **SCAI SHOCK B(A)** = A patient with relative hypotension or tachycardia *without* hypoperfusion who suffers a witnessed VF successfully defibrillated and remains without signs of hypoperfusion
 - If signs of hypoperfusion develop after the arrest, this patient would be **SCAI SHOCK C(A)**, and in need of *initial* efforts to improve perfusion; if those efforts do not work, the patient is now **SCAI SHOCK D(A)**



SCAI

Society for Cardiovascular
Angiography & Interventions

Interaction of Cardiac Arrest and Cardiogenic Shock

	Cardiogenic Shock (+)	Cardiogenic Shock (-)
Cardiac Arrest (+)	184 Patients In-hospital Mortality: 47.3% 1 – Year Mortality: 51.6%	317 Patients In-hospital Mortality: 20.2% 1 – Year Mortality: 22.7%
Cardiac Arrest (-)	259 Patients In-hospital Mortality: 25.1% 1 – Year Mortality: 33.6%	4157 Patients In-hospital Mortality: 1.7% 1 – Year Mortality: 5.5%

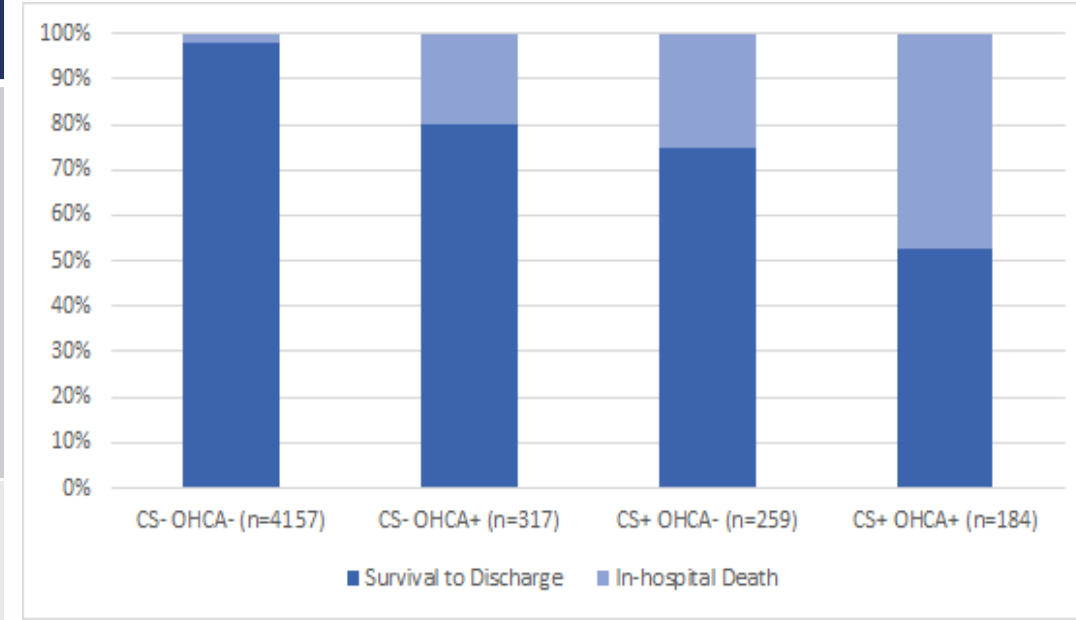


Figure 2: Relationship of CS and OHCA status on presentation, in-hospital mortality and 1-year mortality.



SCAI

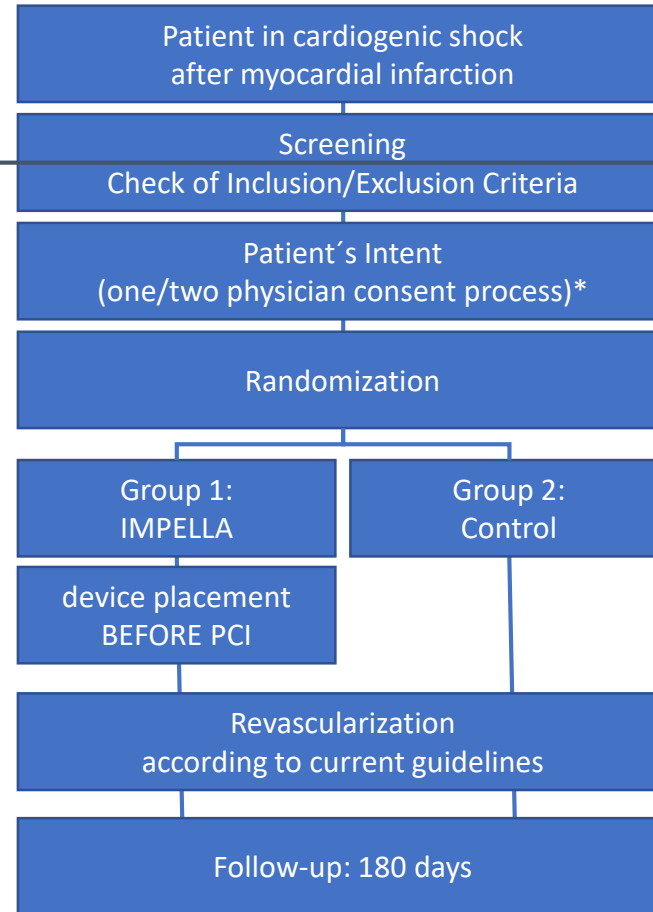
Society for Cardiovascular
Angiography & Interventions

Trial Protocol

Inclusion:

1. **STEMI** of <36 hrs (ECG, Angio)
2. **CGS** <24 hrs
lactate >2.5 &/or SvO₂ <55%
(at normal PaO₂) and
SBP < 100 mmHg or vasopressors
3. **LVEF <45%**

additional inclusion (same criteria) if shock is developed within 12 hrs of procedure



Exclusion:

- other cause of shock (hypovolemia, sepsis, embolism, anaphylaxis)
- cardiac mechanical complications (papillary muscle rupture, VSD, rupture of free wall)
- severe aortic valve regurgitation / stenosis / mechanical valve
- severe RV failure (e.g. TAPSE <1cm)
- OOH cardiac arrest with GCS <8 after ROSC
- shock >24 hrs
- already established MCS
- DNR / severe comorbidity
- known intolerance to Heparine, Aspirin, ADPr/P2Y12 inhibitors, (e.g. clopidogrel) contrast media

Primary Endpoint: Death from all causes through 180 days

Secondary Endpoints:

- Composite cardiovascular events (survival with native heart: need for additional MCS, cardiac transplantation, death of all causes)
- hemodynamics (CPO, Lactate clearance, PAP)
- sequential organ failure assessment (SOFA) score @ 24, 48, 72 hrs after randomization
- use and dosage of vasopressor and inotropes @ 24, 48, 72 hrs after randomization
- renal function
- LV function @ 180 days

* patient / proxy consent as soon as safe and feasible

Where do we go from here?

- Present, publish, and spread the word to the wider cardiovascular and critical care communities
- Validate the classification by evaluating its prognostic power and ease-of-use in databases
- Drive earlier recognition of shock and the more precise stage, to guide appropriate and timely escalation of care including transfer to centers more fully equipped
- Utilize the stages to better define prospectively the value of MCS/ECMO and other therapies
- Perhaps future trials looking at similar patients will finally reduce the mortality of cardiogenic shock



SCAI

Society for Cardiovascular
Angiography & Interventions

Key Factors

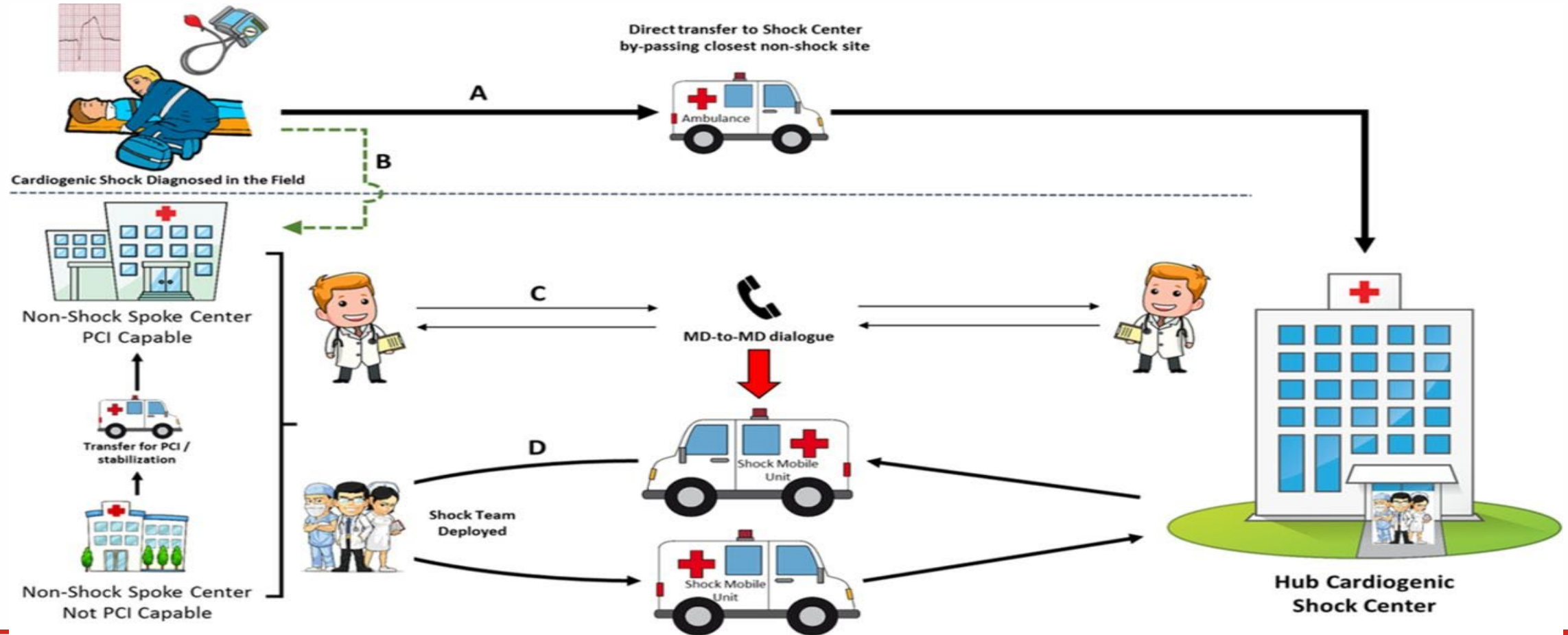
- Define the Pt population:
 - STEMI vs ACS, Advanced HF, Structural, Post CABG...
 - Shock Stage
 - Cardiac Arrest Modifier (sufficient detail and treatment algorithms)
- End Points
 - Mortality with detail about cause
 - Hospitalization and Rehosp
 - Recurrent Events
 - Stroke and Neurologic status
- Time Points
 - In Hospital
 - 30 days
 - 1 year



SCAI

Society for Cardiovascular
Angiography & Interventions

AHA Scientific Statement
Contemporary Management of Cardiogenic Shock
A Scientific Statement from the American Heart Institution



SCAI

Society for Cardiovascular
Angiography & Interventions

Shock Centers

- Committed to standardized protocols
- Committed to Comprehensive Registries
- Committed to Randomized Trials
- Committed to Transparent Quality reporting



SCAI

Society for Cardiovascular
Angiography & Interventions

Simple easy to remember:
the intermacros of shock

Cardiogenic Shock Classification A through E



Designed by Freepik from www.flaticon.com



SCAI

Society for Cardiovascular
Angiography & Interventions



SCAI

Society for Cardiovascular
Angiography & Interventions

