

HOT TOPICS IN CARDIOLOGIA 2023

13 e 14 Novembre 2023



OSPEDALE
SAN RAFFAELE
MILANO



Extended Management of AMI-CS Hub Spoke Network

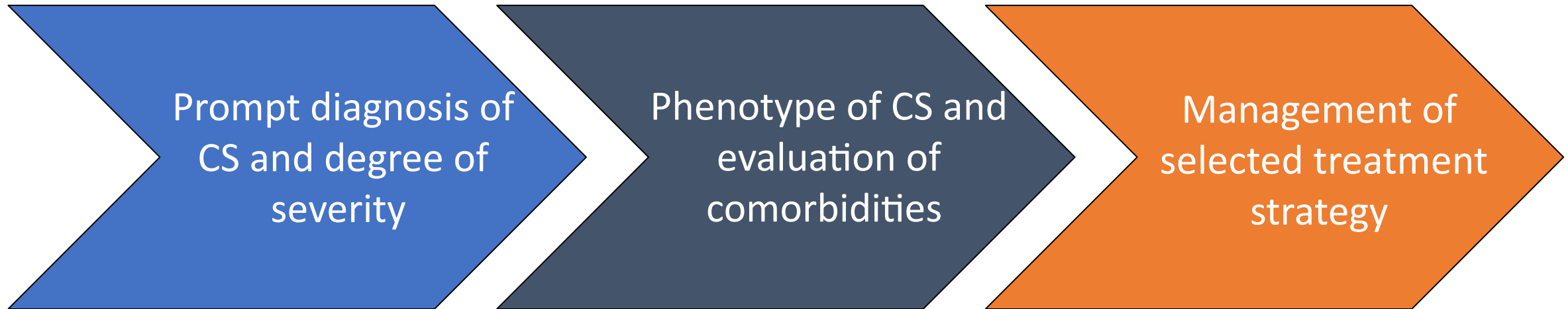
Prof Alaide Chieffo, FESC, FSCAI

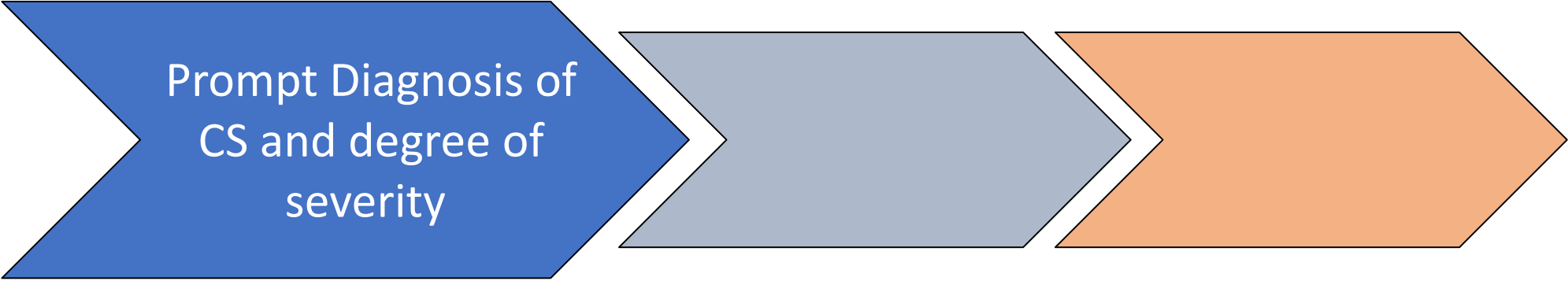
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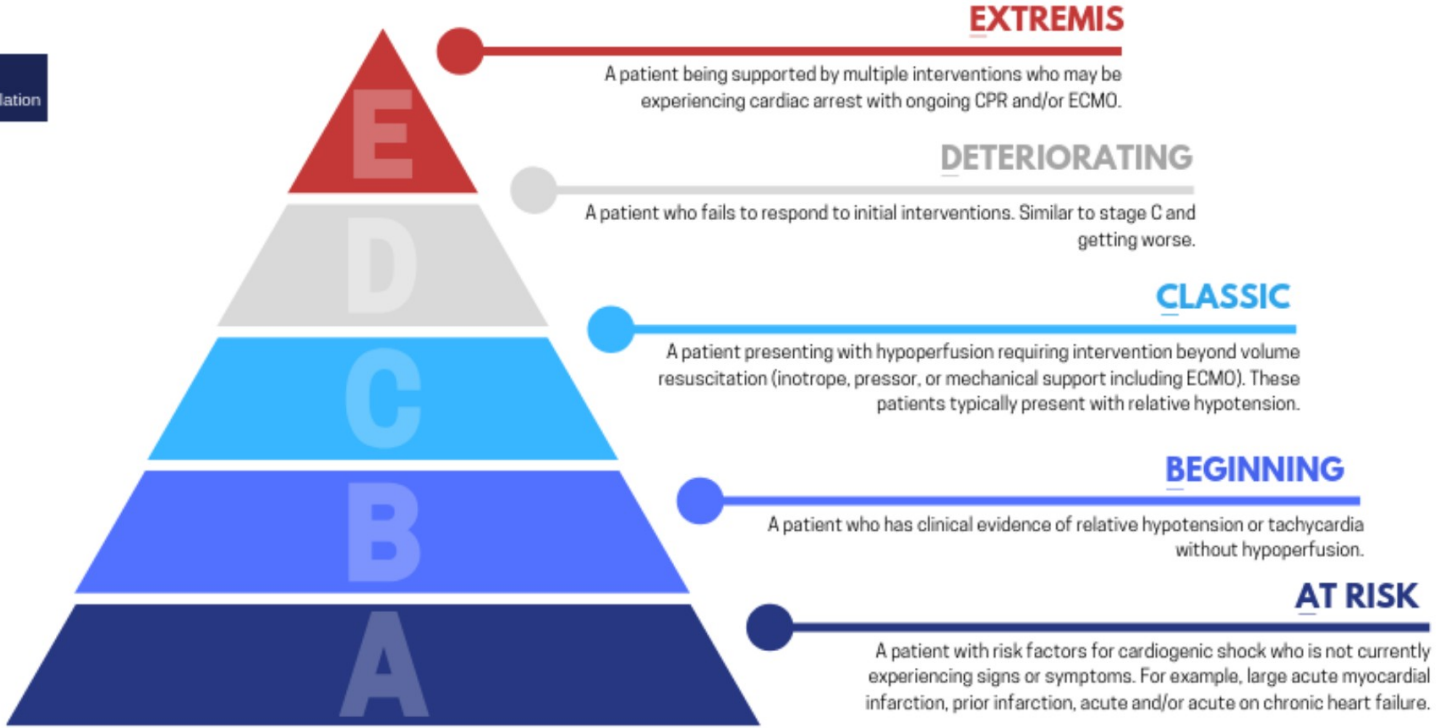
Extended Management of AMI-CS

In-depth characterization and patient-tailored approach

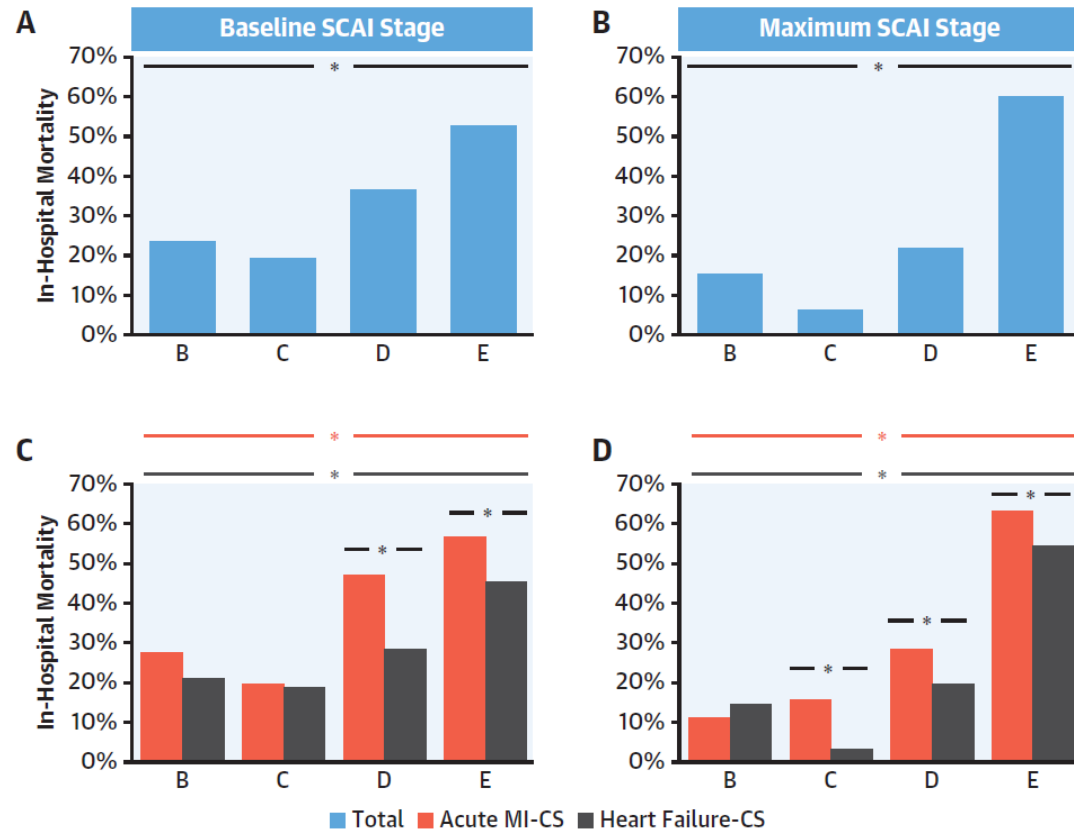




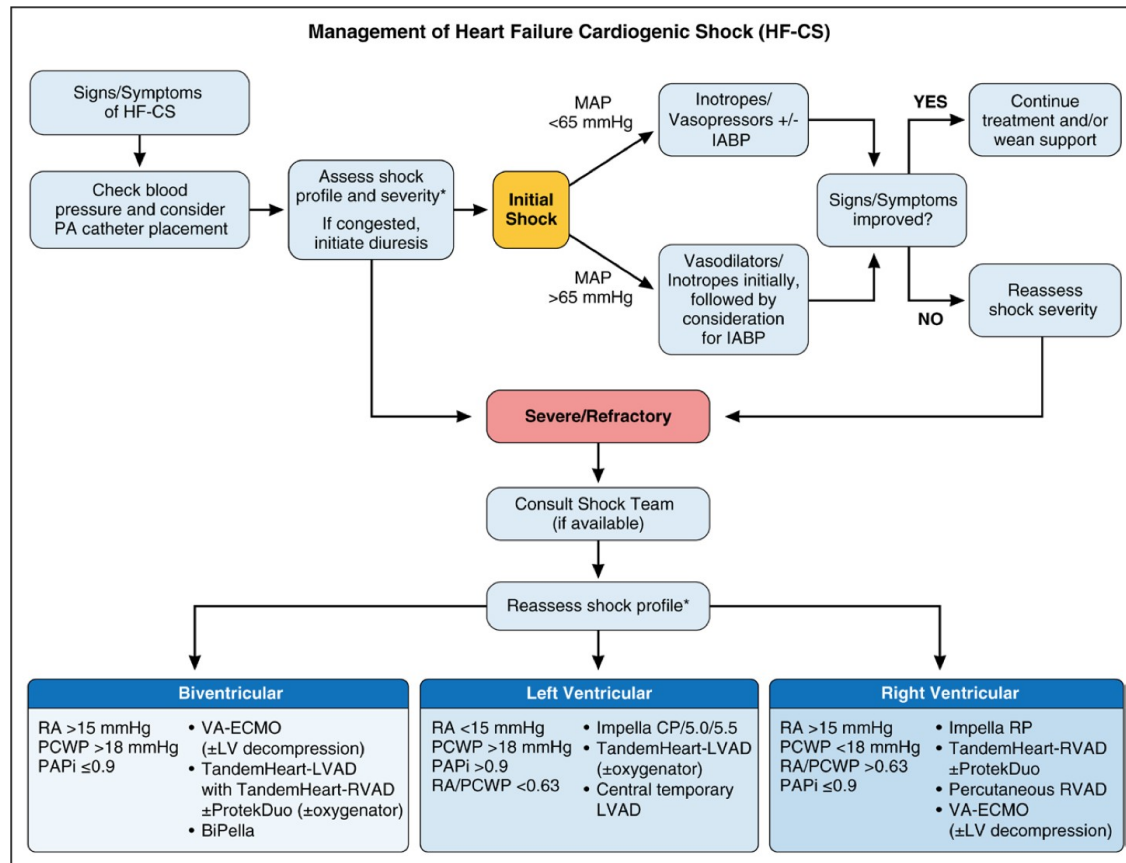
Arrest (A) Modifier:
CPR, including defibrillation



Prompt Diagnosis of CS and degree of severity



Phenotype of CS and Evaluation of Comorbidities

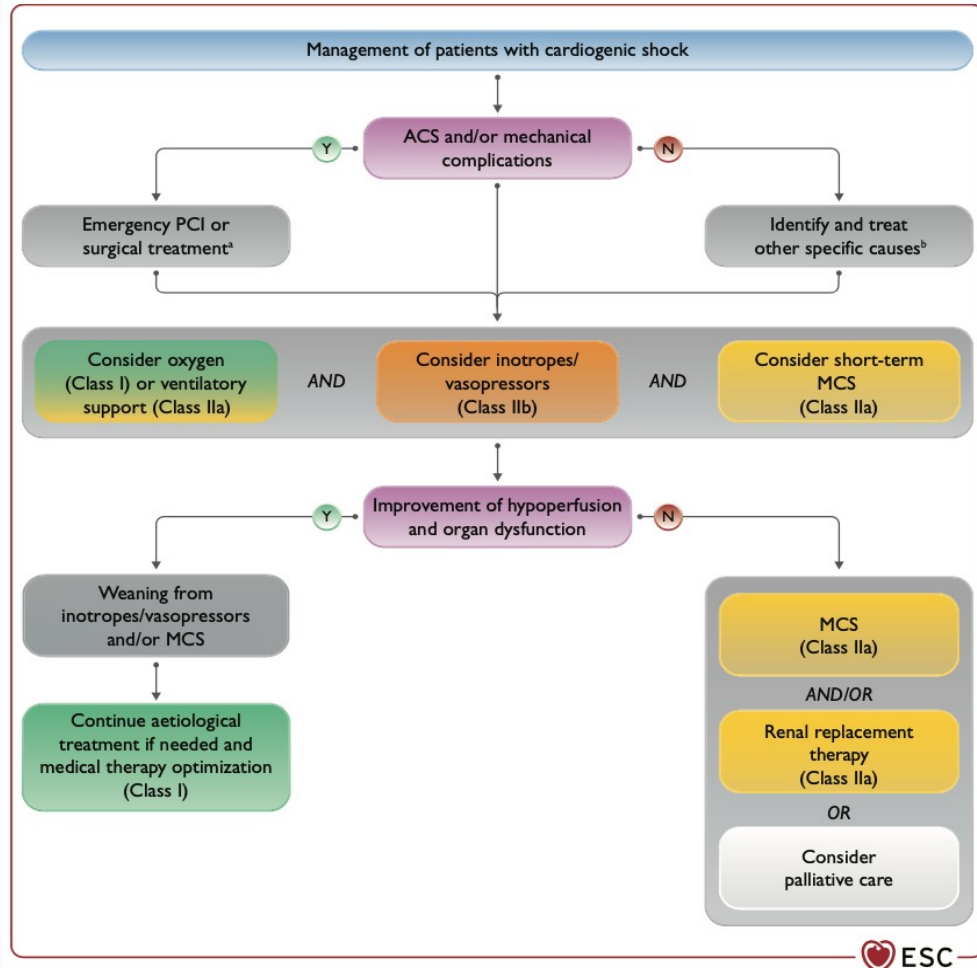


Consider the Phenotype of CS Will the patient need LV unloading?
Consider pre-emptive placement over bailout



Consider the Clinical Picture: Right heart failure biventricular failure, cardiac arrest, SCAI class (SCAI C, D, E)?

Management of selected treatment strategy



Recommendations for cardiogenic shock



Recommendations

Immediate coronary angiography and PCI of the IRA (if indicated) is recommended in patients with CS complicating ACS.

Emergency CABG is recommended for ACS-related CS if PCI of the IRA is not feasible/unsuccessful.

In cases of haemodynamic instability, emergency surgical/catheter-based repair of mechanical complications of ACS is recommended, based on Heart Team discussion.

Fibrinolysis should be considered in STEMI patients presenting with CS if a PPCI strategy is not available within 120 min from the time of STEMI diagnosis and mechanical complications have been ruled out.

In patients with ACS and severe/refractory CS, short-term mechanical circulatory support may be considered.

The routine use of an IABP in ACS patients with CS and without mechanical complications is not recommended.

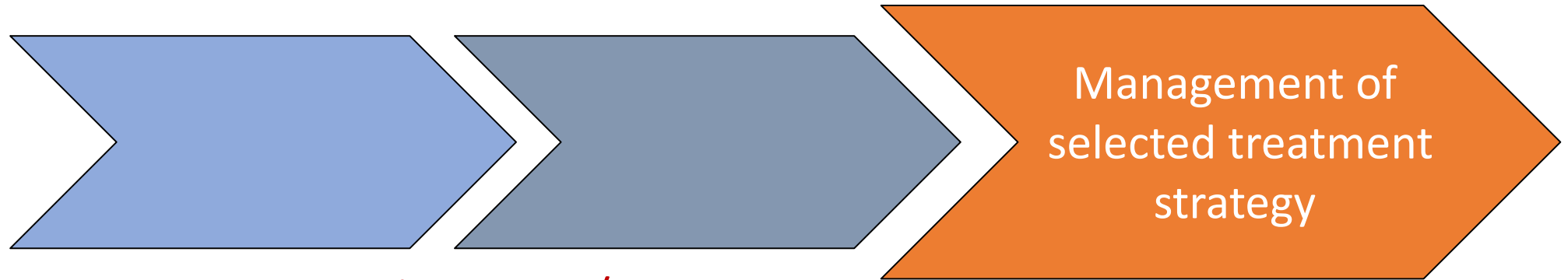
| Recommendations | Class | Level |
|--|-------|-------|
| Immediate coronary angiography and PCI of the IRA (if indicated) is recommended in patients with CS complicating ACS. | I | B |
| Emergency CABG is recommended for ACS-related CS if PCI of the IRA is not feasible/unsuccessful. | I | B |
| In cases of haemodynamic instability, emergency surgical/catheter-based repair of mechanical complications of ACS is recommended, based on Heart Team discussion. | I | C |
| Fibrinolysis should be considered in STEMI patients presenting with CS if a PPCI strategy is not available within 120 min from the time of STEMI diagnosis and mechanical complications have been ruled out. | IIa | C |
| In patients with ACS and severe/refractory CS, short-term mechanical circulatory support may be considered. | IIb | C |
| The routine use of an IABP in ACS patients with CS and without mechanical complications is not recommended. | III | B |

www.escardio.org/guidelines

2023 ESC Guidelines for the management of acute coronary syndromes (European Heart Journal; 2023 – doi:10.1093/eurheartj/ehad191)

* McDonagh T. A, Metra M et al European Heart Journal (2021)

lib LOE C ACS 2023 ESC GUIDELINES



Joint EAPCI /ACVC Expert Consensus Document

| Device | Indication |
|---------|--|
| IABP | Routine use is not recommended ²³ ; may be used in patients with mechanical complications post-AMI or in non-AMI related shock |
| AFP | Impella CP may be used as a short-term therapy in CS, ^a stage C and D with potentially reversible underlying cause/transplant/VAD candidates |
| VA-ECMO | May be used as a short-term therapy in CS stage C, D, and E, particular in patients with combined respiratory insufficiency with potentially reversible underlying cause/transplant/VAD candidates May be used for selected patients in refractory cardiac arrest |

Biventricular CS

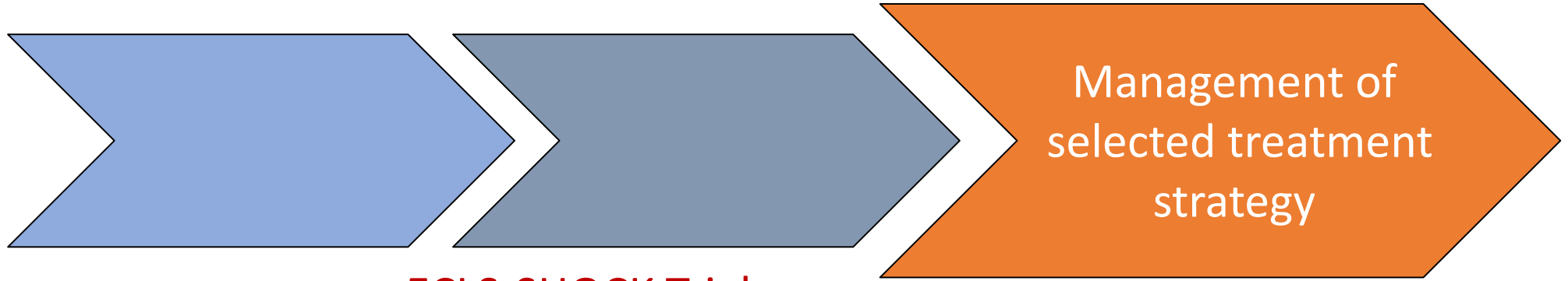
VA-ECMO

May be used in case of:

- Combined left and right ventricular failure
- Combined left ventricular and ventilation/oxygenation failure
- Combined ventilation/oxygenation and right ventricular failure
- Refractory cardiac arrest

ECPella

VA-ECMO and left ventricular unloading

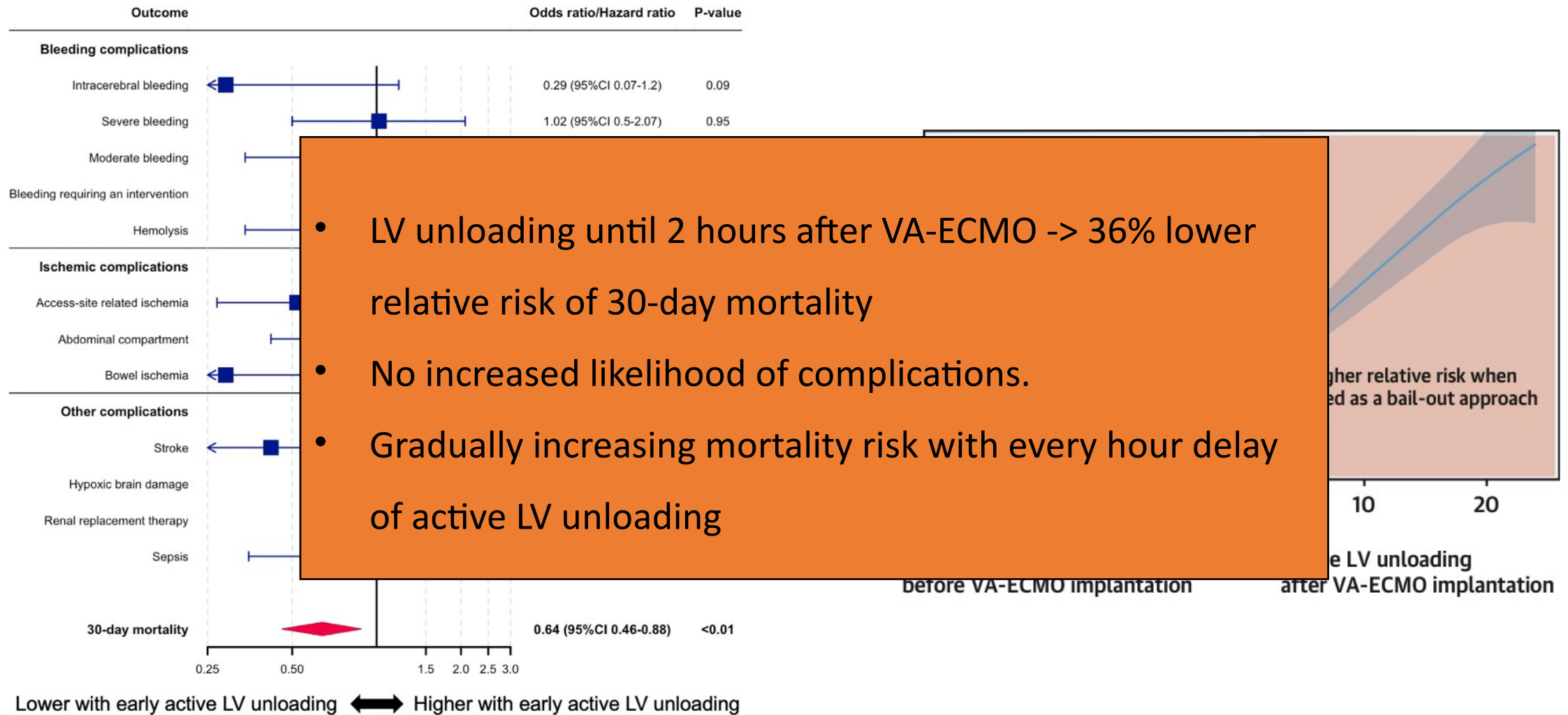


ECLS-SHOCK Trial

| | ECLS (n=209) | Control (n=208) |
|--|-----------------|-----------------|
| ECLS therapy; n/total (%) | 192/209 (91.8) | 26/208 (12.5) |
| Initiation in catheterization laboratory | | |
| Prior revascularization | 42/192 (21.9) | 4/26 (15.4) |
| During revascularization | 50/192 (26.0) | 8/26 (30.8) |
| After revascularization | 100/192 (52.1) | 7/26 (26.9) |
| Duration ECLS therapy (days) median (IQR) | 2.7 (1.5 - 4.8) | 2.7 (2.2 - 3.8) |
| Active left ventricular unloading in ECLS; n/total (%) | 11/191 (5.8) | 6/19 (31.6) |
| Other MCS in patients without ECLS | 0/1 | 28/182 (15.4) |

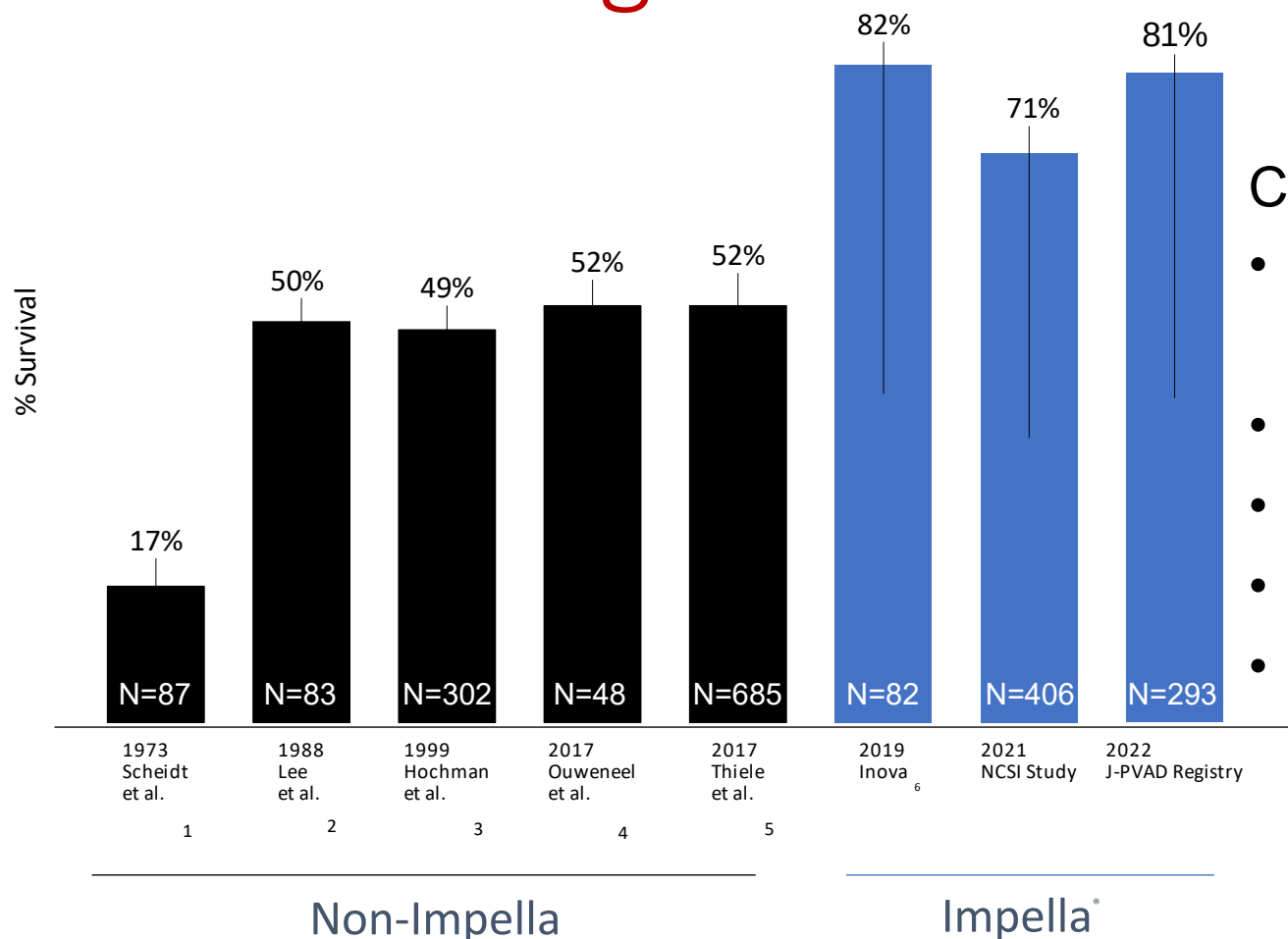
**25.9%
received
at least 1
MCS**

Timing of Active LV Unloading during ECMO



- LV unloading until 2 hours after VA-ECMO -> 36% lower relative risk of 30-day mortality
- No increased likelihood of complications.
- Gradually increasing mortality risk with every hour delay of active LV unloading

Investigator-Led AMI-CS Studies



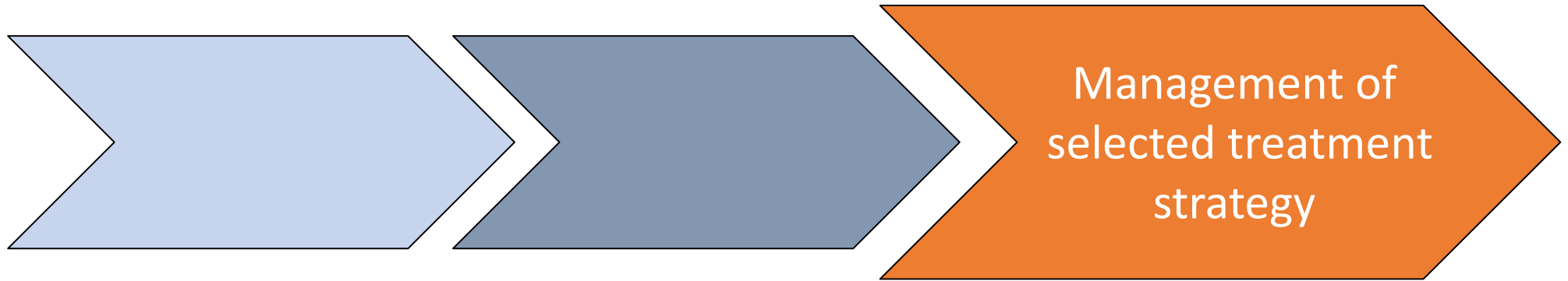
Characteristics of Best Practice Protocols⁶⁻⁹

- Identify CS early and Impella[®] pre-PCI < 90 mins
- Aggressive down-titration of inotropes
- Identify RV dysfunction early and support
- Identify inadequate LV support and escalate
- Systematic use of RHC to guide therapy

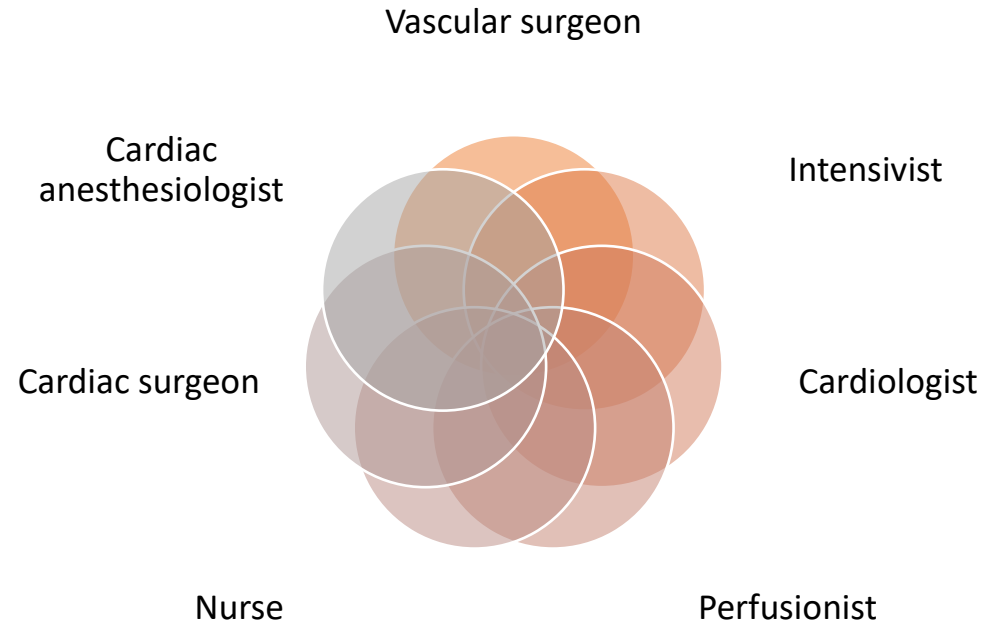
The J-PVAD Registry is a registry of ALL Impella patients in Japan, conducted by 10 Japanese professional societies, including the Japanese Circulation Society (JCS).

1. Scheidt, S. et al. (1973). *N Engl J Med*, 288(19), 979-984
 2. Lee, L. et al. (1988). *Circulation*, 78(6), 1345-1351
 3. Hochman, J. et al. (1999). *N Engl J Med*, 341(9), 625-634
 4. Ouweneel, D. et al. (2017). *J Am Coll Cardiol*, 69(3), 278-287
 IMPRESS in Severe Shock/Cardiac Arrest. ~10% Impella pre-PCI.

5. Thiele, H. et al. (2017). *N Engl J Med*, 377(25), 2419-2432. ~5% with Impella
 6. Tehrani, B. et al. (2019). *J Am Coll Cardiol*, 73(13), 1659-1669
 7. O'Neill, W. et al. (2020). *TCT Connect*
 8. Basir, B. et al. (2021). *SCAI Scientific Sessions*
 9. Ako, J. (2022). *TCT. AMICS with Impella-only Support*

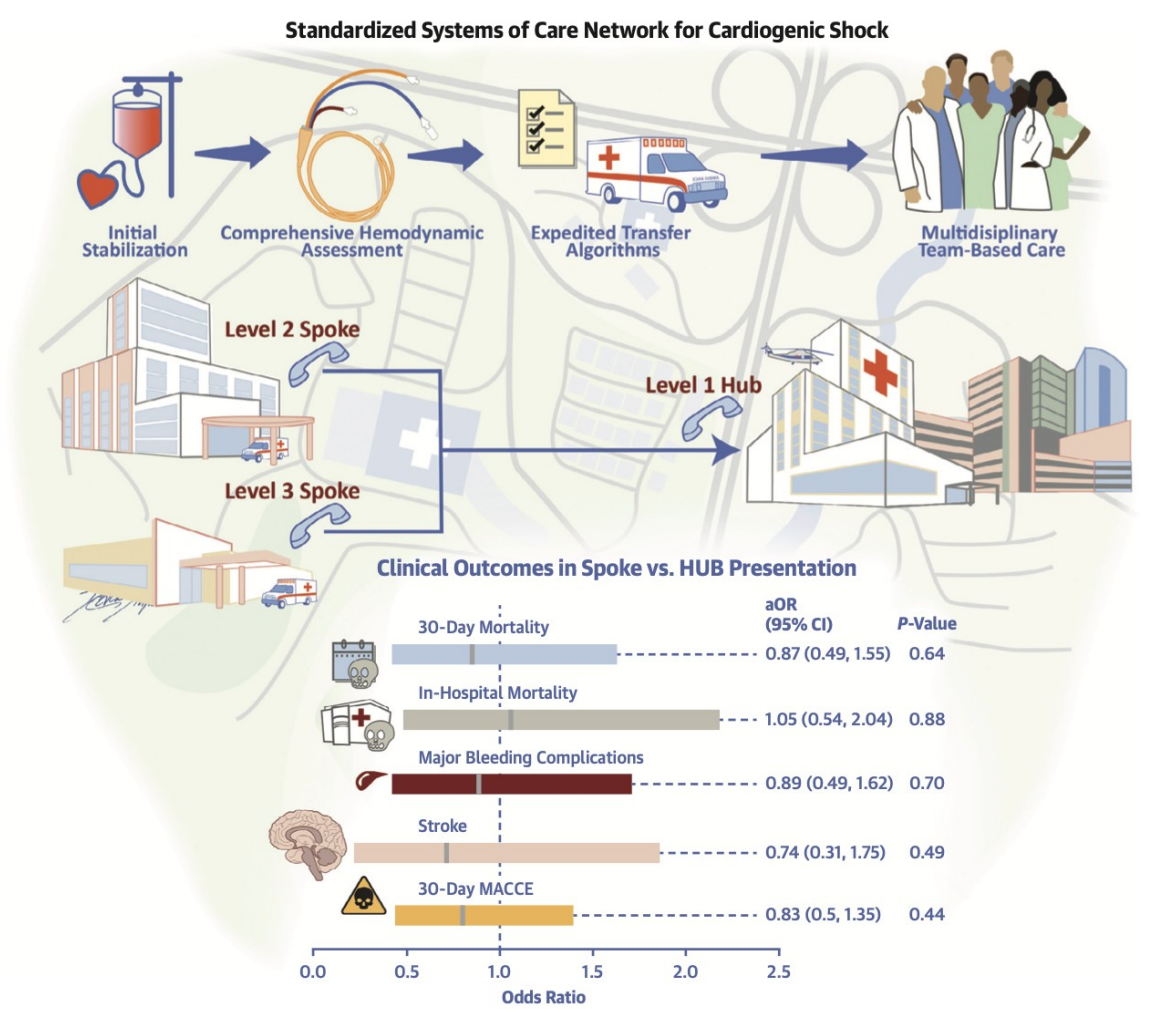


Shock team



HUB SPOKE NETWORK

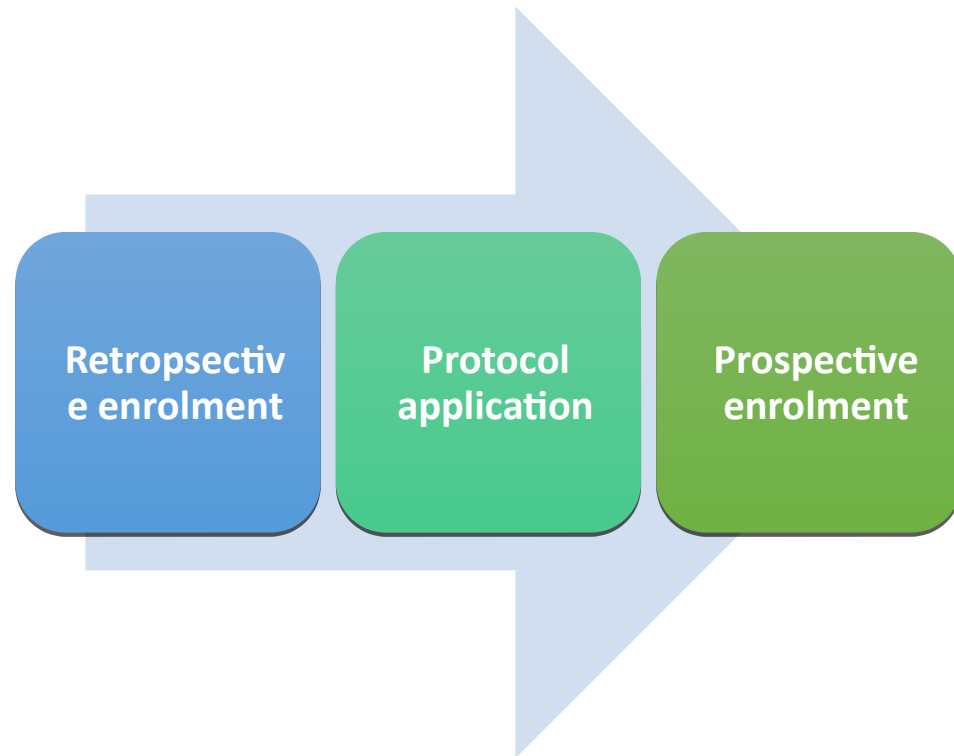
Standardized Systems of Care Network for CS



Tehrani BN, et al. J Am Coll Cardiol HF. 2022; (■): ■-■.



- Observational, single-arm trial, allocating patients referred for advanced shock treatment from a spoke-to hub center.
- The patients that will fulfil the inclusion criteria will be enrolled retrospectively from 2016 to 2019, while prospectively from 2023 to 2025.



Inclusion Criteria

Patients with cardiogenic shock within 24h from the cardiogenic shock diagnosis SCAI B to D.

The SCAI shock stage will be defined (i) at hospital admission, (ii) at 24h from admission, and (iii) at any change in the clinical scenario.

Exclusion Criteria

- Cardiac arrest with no quantifiable or longer than 10 minutes "no-flow" time or with refractory cardiac arrest (as defined by CPR prolonging for more than 20') or those failing to respond to verbal commands and/or who have a Glasgow Coma Scale of <9 after cardiac arrest (Class A modifier in SCAI shock classification).
- Absolute contraindication to support devices
- CS due to other etiology apart from the ones in inclusion criteria as well as SCAI A and E before device positioning.
- Age greater than 75-year-old
- Life expectancy < 1 year due to other reasons than cardiogenic shock

HUB and SPOKE Centers Study Definitions

Hub center

The Hub center is frequently a 3rd level Hospital where there is the availability of:

- CS team 24/7
- PCI service 24/7
- Dedicated CCU
- pMCS availability and extensive expertise in management
- Cardiac surgery back-up +/- LVAD capability
- Cardiac Shock team

Spoke center

The spoke center is frequently:

- 1st level Hospital without PCI service 24/7
- 2nd level Hospital with PCI service 24/7 and dedicated CCU but without pMCS expertise other than IABP

Study Protocol: Spoke Center

SCAI B

Evaluate the clinical risk of rapid worsening to SCAI C-D); Clinical, labs and echo reassessment every 2 hours: Heart rate > 100 bpm, systolic and mean blood pressure < 65 mmHg, hypoperfusion signs (urinary output), ABG (lactate > 2 mmol/L), SvO₂ < 55%, echo evaluation (aortic VTI, estimated CO).
In absence of clinical or labs hypoperfusion criteria the first approach: wait and see. If valid clinical or labs hypoperfusion criteria are present → alert hub center to discuss rapid/delayed transfer

SCAI C

Initiate vasopressor/ inotrope support according to institutional protocols (+/- IABP). Clinical, labs and echo reassessment every 2 hours: Heart rate > 100 bpm, systolic and mean blood pressure < 65 mmHg, hypoperfusion signs (urinary output), ABG (lactate > 2 mmol/L), SvO₂ < 55%, echo evaluation (aortic VTI, estimated CO): Patient improving on at least 2 consecutive evaluations → call the hub center to inform and discuss the management. Patient stable/worsening on at least 2 consecutive evaluations → alert hub center to discuss transfer for pMCS

SCAI D

Evaluate the presence of important comorbidities that could prevent successful interventions;
Evaluate feasibility of a safe and rapid transfer to hub center (is the patient stable enough for the transfer? Would the patient benefit from the transfer?)
Alert hub center to discuss transfer for pMCS considering the age of the patient,

Hub center activation

Study Protocol: Hub Center

SCAI B

wait and see strategy: both the spoke and hub cardiologist agree on this strategy or hub cardiologist refuse to accept the patient as not deemed at risk of worsening to SCAI C-D;
transfer consensus: both the spoke and hub cardiologist agree on this strategy

SCAI C

Disagreement on stable/worsening on at least 2 consecutive evaluations → wait and see
Agreement on stable/worsening on at least 2 consecutive evaluations → transfer
Transfer consensus: both the spoke and hub cardiologist agree on this strategy

SCAI D

Transfer rejection: futility in escalating care
transfer consensus: both the spoke and hub cardiologist agree on this strategy especially for young patients

Conclusions



The Heart is not only the LV; CS is not only about the Heart; extreme CS

- Shock severity and adequate classification
- Shock phenotype and clinical picture



Paradigm shift in Clinical Trials: from one device - one strategy to a **multistrategic** approach

- One device does not fit all
- One device might not be enough



The management of AMI-CS is **Multidisciplinary**

- **Shock team and Shock Network**
- High expertise for optimal MCS outcomes



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Thank you for your kind attention



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