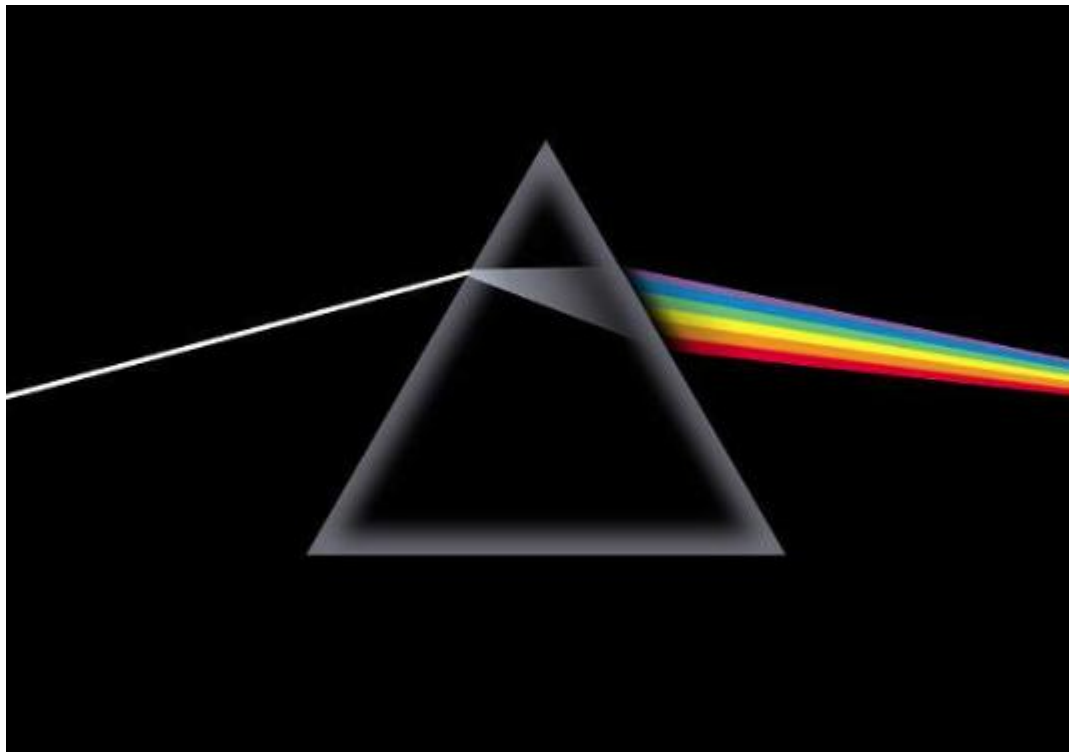
Podpory oběhu - IMPELLA



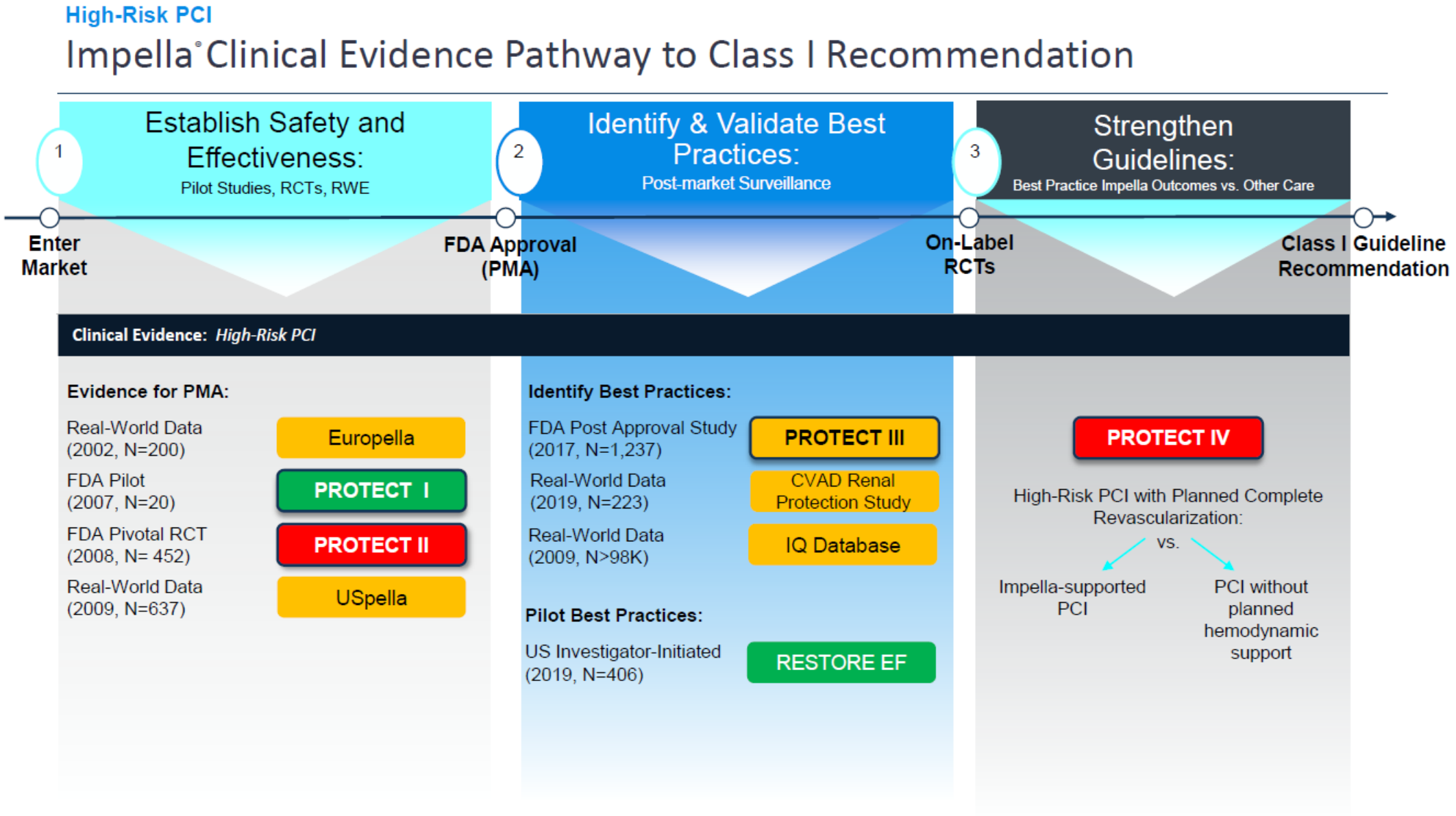
Michael Želízko

Klinické scénáře

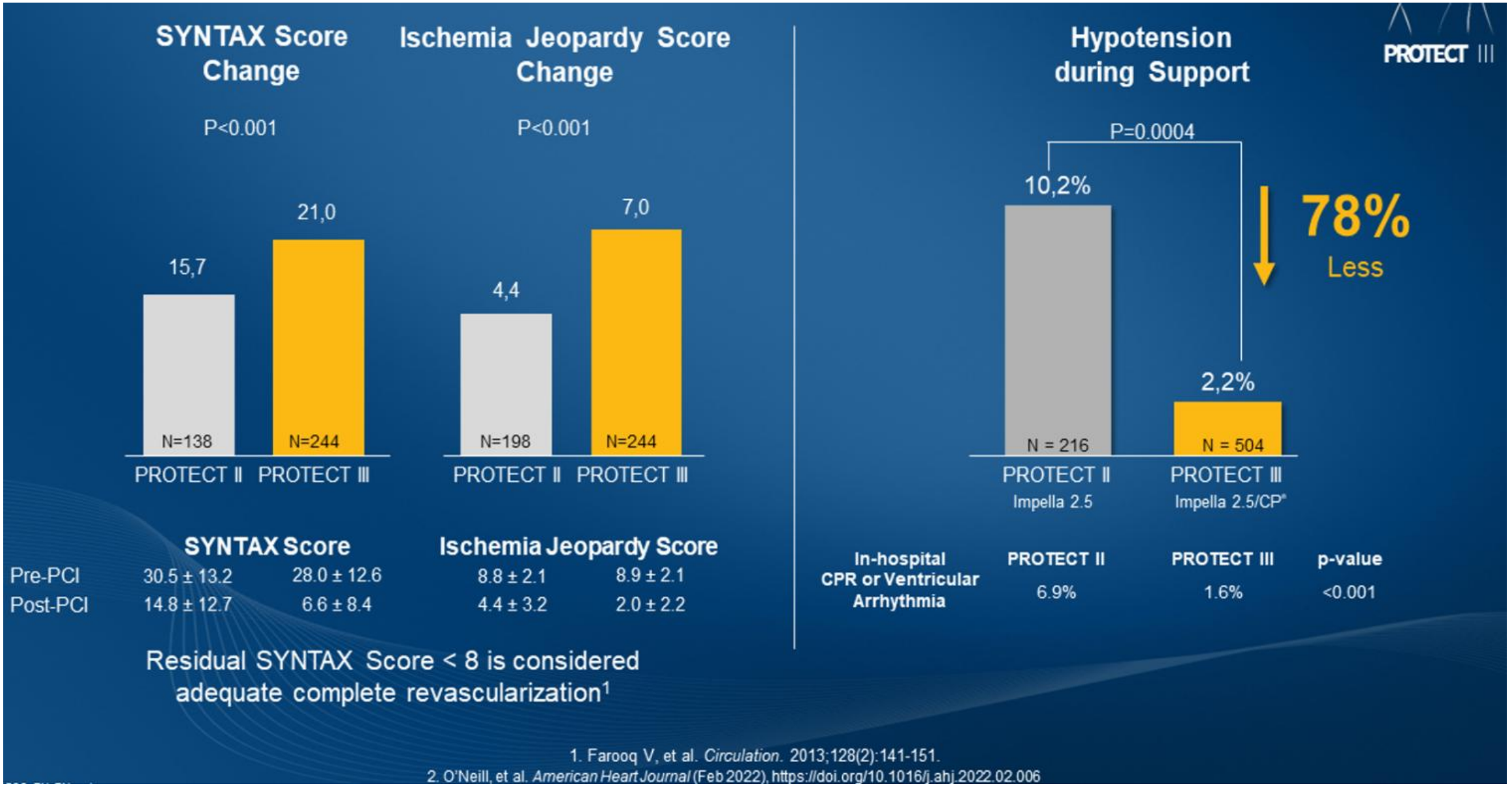
- **High-risk PCI**
- Kardiogenní šok v akutní fázi infarktu myokardu (AMICS)
- Unloading a restaurace funkce LK u rozsáhlého STEMI
- Kardiogenní šok u chronického srdečního selhání

- Kardiochirurgické indikace (Impella 5,5; Impella RP)

HIGH-RISK PCI

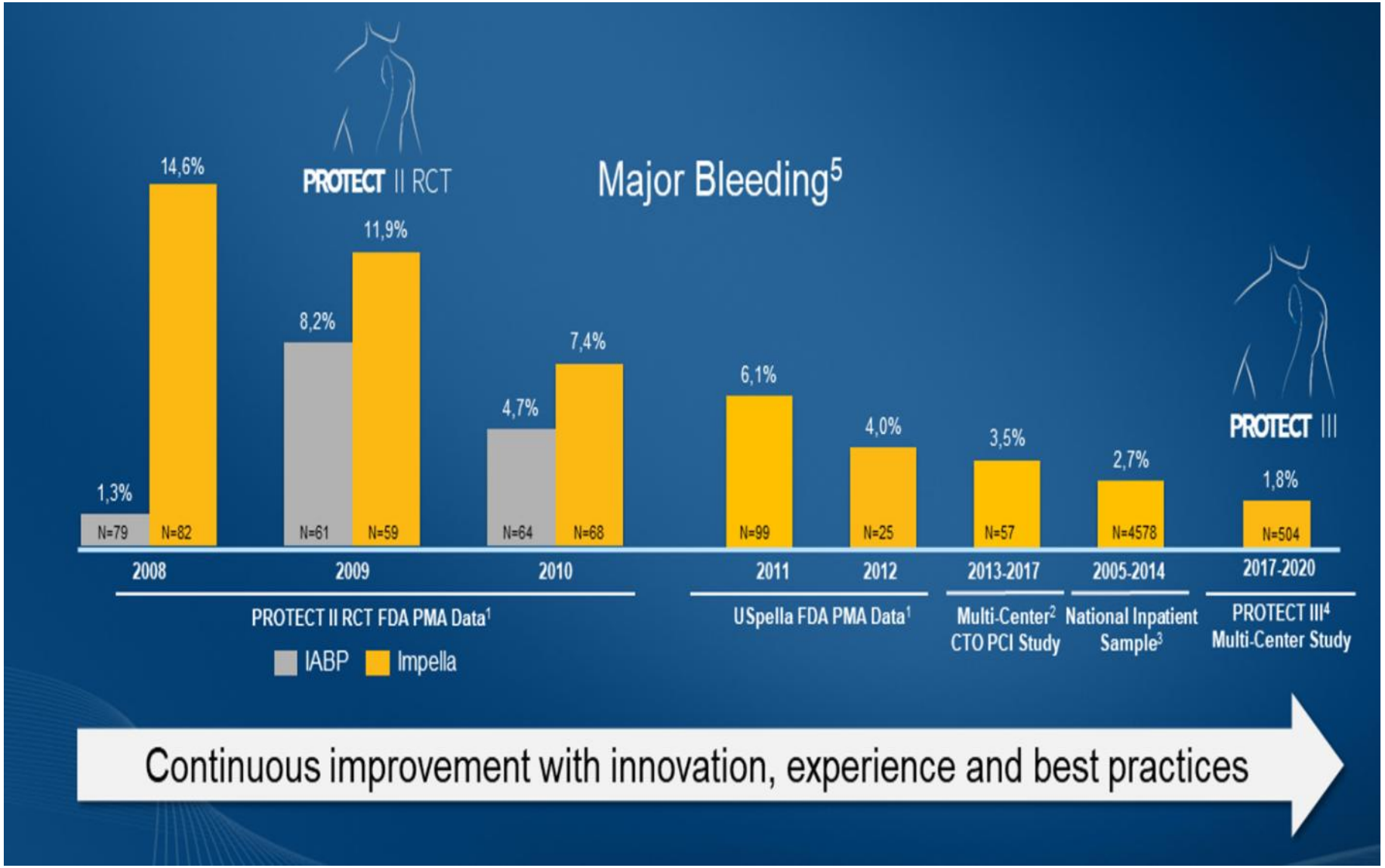


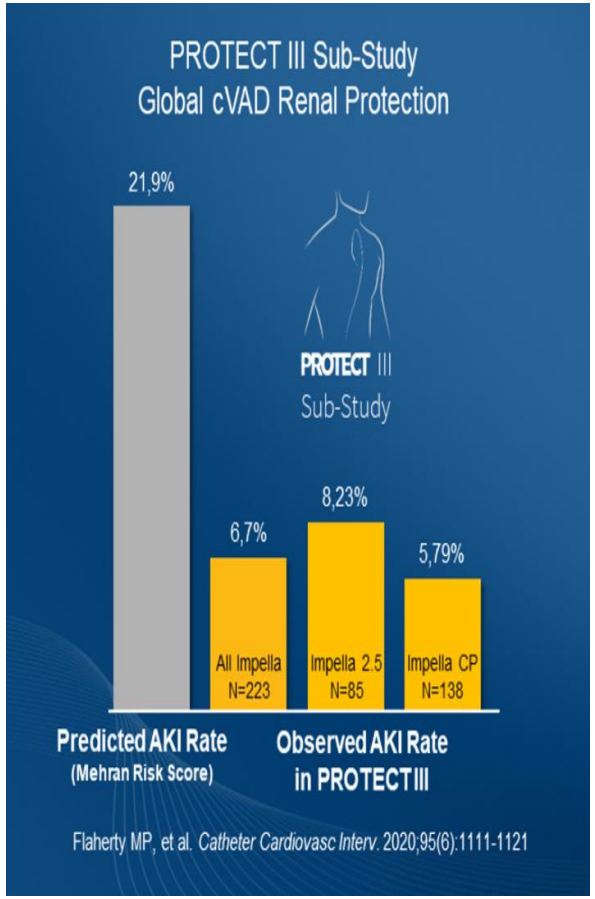
Protect III – komplexnost výkonu



William W. O'Neill, Mark Anderson, Daniel, American Heart Journal, Volume 248, 2022, https://doi.org/10.1016/j.ahj.2022.02.006

High-risk PCI – nerandomizovaná data





PROTECT IV

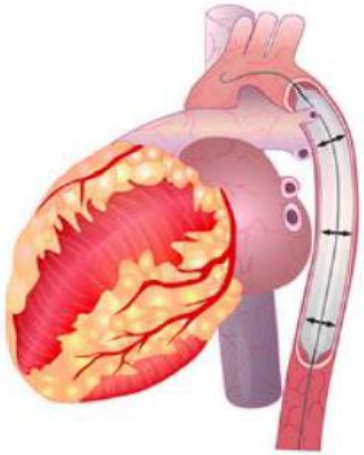
randomizovaná studie

Impella + PCI vs PCI

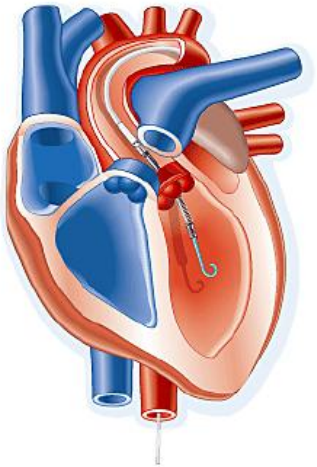
Klinické scénáře

- High-risk PCI
- **Kardiogenní šok v akutní fázi infarktu myokardu (AMICS)**
- Unloading a restaurace funkce LK u rozsáhlého STEMI
- Kardiogenní šok u chronického srdečního selhání
- Kardiochirurgické indikace

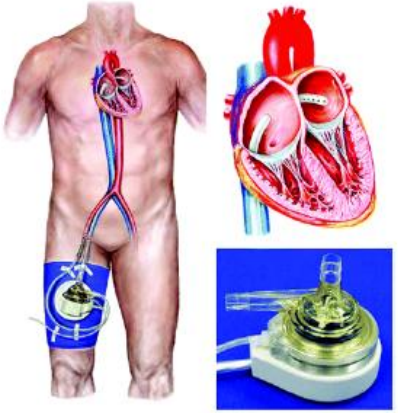
Kardiogenní šok a Impella



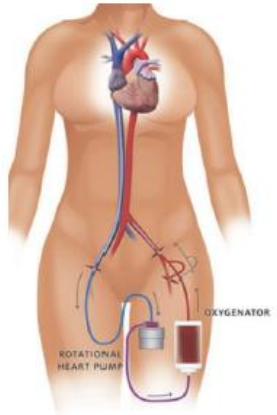
IABP



Impella family



Tandem family



ECMO

CentriMag

Device strategy: kombinace podpor

Circulation: Heart Failure
Volume 13, Issue 9, September 2020
https://doi.org/10.1161/CIRCHEARTFAILURE.120.007099

ORIGINAL ARTICLE

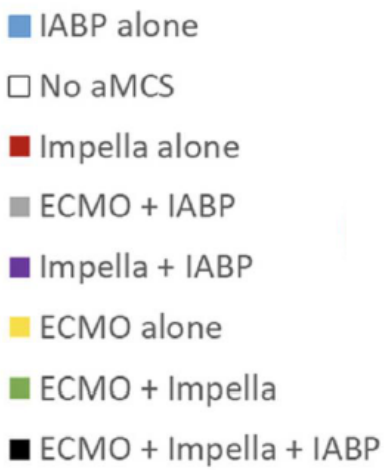
Invasive Hemodynamic Assessment and Classification of In-Hospital Mortality Risk Among Patients With Cardiogenic Shock

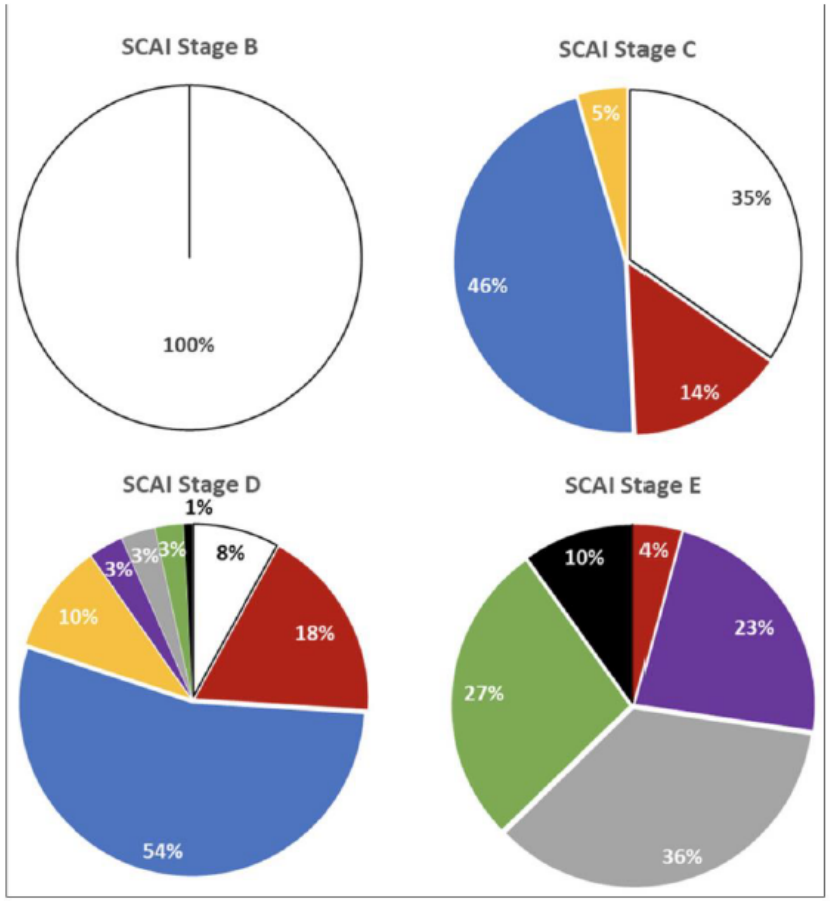
See Editorial by Jentzer

Katherine L. Thayer, MPH, Elric Zweck, Mohyee Ayouty, MS, A. Reshad Garan, MD, Jaime Hernandez-Montfort, MD, MPH, Claudius Mahr, DO, Kevin J. Morine, MD, Sarah Newman, BS, Lena Jorde, BS, Jillian L. Haywood, MS, Neil M. Harwani, MS, Michele L. Esposito, MD, Carlos D. Davila, MD, Detlef Wencker, MD, Shashank S. Sinha, MD, MSc, Esther Vorovich, MD, Jacob Abraham, MD, William O'Neill, MD, James Udelson, MD, Daniel Burkhoff, MD, PhD, and Navin K. Kapur, MD

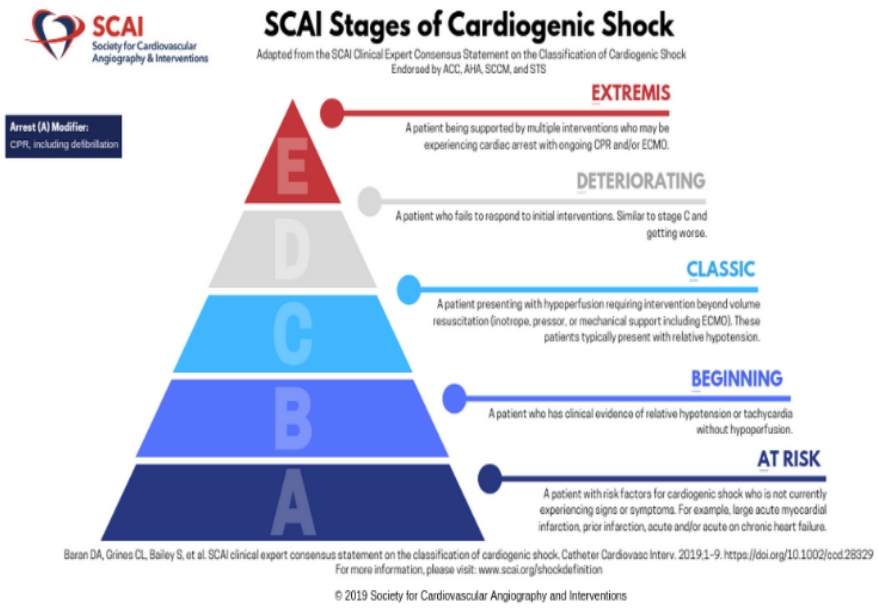
- 1414 shock patients
- 8 centers
- Decompensated HF 50%
  Acute MI 35%
- Classification from SCAI B to E

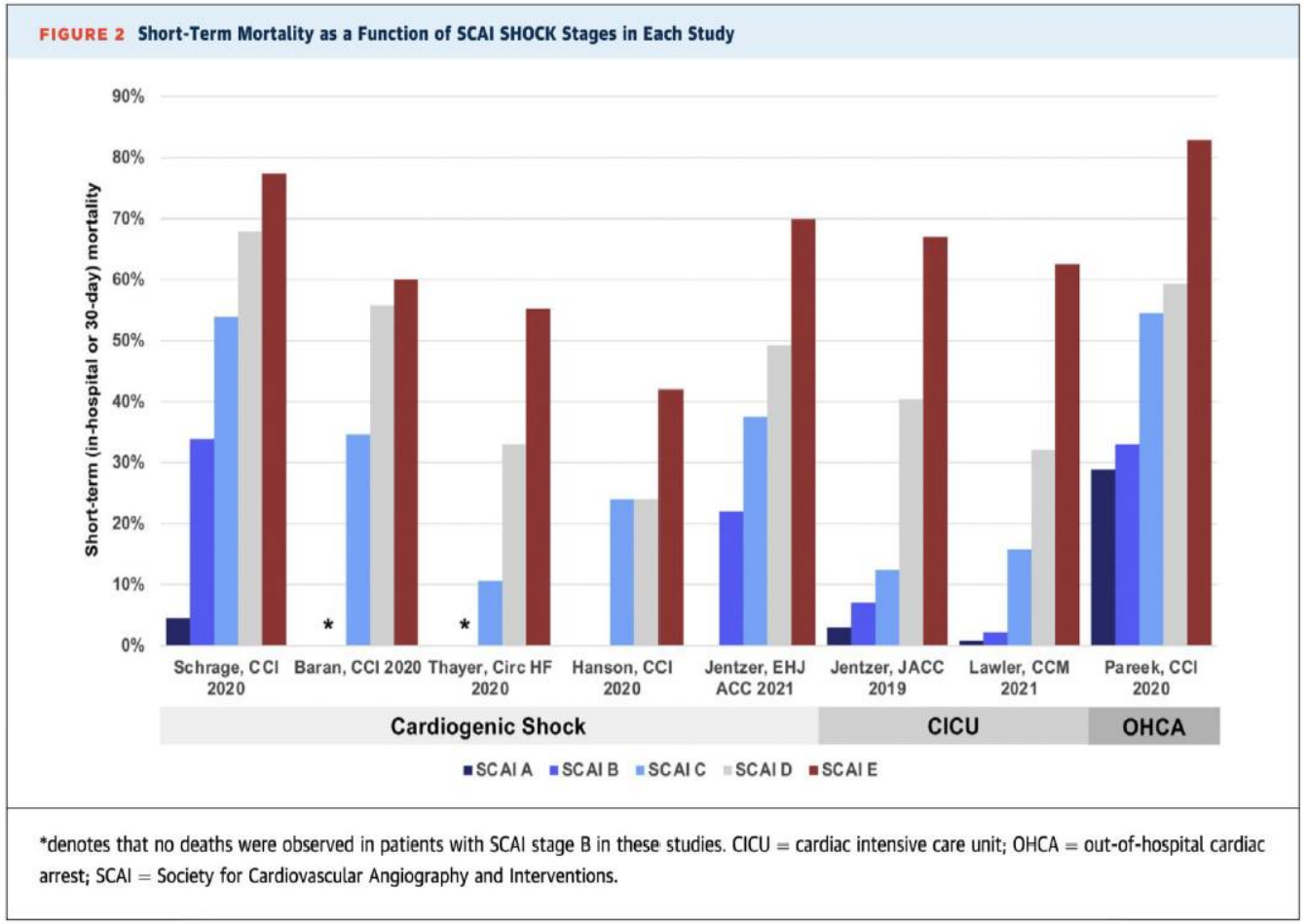
- Device usage by SCAI stage





Mortalita kardiogenního šoku





IABP-SHOCK II: žádný benefit IABP

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 4, 2012 VOL. 367 NO. 14

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebelt, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D., for the IABP-SHOCK II Trial Investigators*

- Randomized, prospective, open-label trial
- 600 patients with AMI and CS
- Patients underwent early revascularization
- No difference in 30 day all cause mortality
- No difference in major bleeding, peripheral ischemic complications, CVA, sepsis

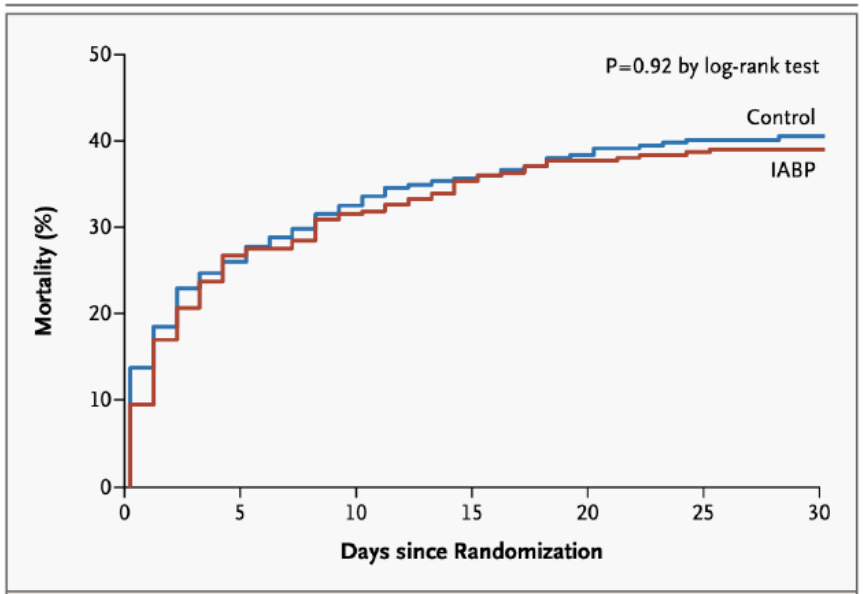


Figure 1. Time-to-Event Curves for the Primary End Point.

Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan–Meier estimates.

RANDOMIZATION IN CARDIOGENIC SHOCK IS CHALLENGING

Attempted Randomized Impella Trials In Emergent Settings

Study	Trial ID	Condition	N planned	N enrolled	Duration (months)	Status	Discontinuation Reason/ comment
FRENCH TRIAL (2006)	NCT00314847	AMI CS	200	19	52	Discontinued	Low enrollment
ISAR-SHOCK (2006)	NCT00417378	AMI CS	26	26	19	Completed	Non-randomized execution; cardiac output study
IMPRESS in STEMI (2007)	NTR1079 trialregister.nl	STEMI Pre-CS	130	18	22	Discontinued	Low enrollment
RECOVER I FDA (2008)	NCT00596726	PCCS	Up to 20	17	28	Completed	Feasibility study
RECOVER II FDA (2009)	NCT00972270	AMI CS	384	1	18	Discontinued	Low enrollment; 50 IRBs approved
RELIEF I (2010)	NCT01185691	ADHF	20	1	33	Discontinued	Low enrollment
IMPRESS in CA (2016)	NTR3450	Cardiac arrest Mechanical ventilation	>100	48	52	Discontinued	Low enrollment; Non-randomized execution
DanGer SHOCK (2012)	NCT01633502	AMI CS	360	>340	~114!	Enrolling	ABMD funded, ongoing

DanGer Shock

Danish German Cardiogenic Shock trial

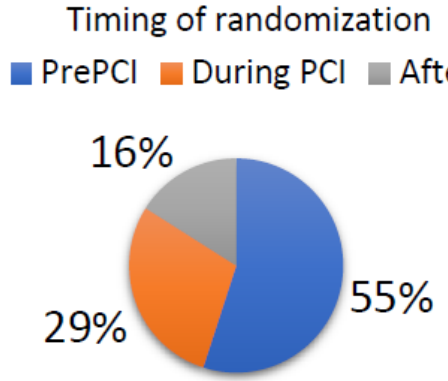
Hypothesis	**MCS with a transvalvular axial flow pump can improve survival in STEMI - CS**
Design	Randomized 1:1 open label
Key inclusion criteria	STEMI <36 hrs; Shock with lactate >2.5 mmol/l or SvO_2 <55%; LVEF <45%
Key exclusion criteria	Shock >24 hrs Ongoing CPR Comatose OHCA Severe RV failure
Device	Impella CP vs control (no IABP)
Primary endpoint	All-cause death at 180 days
Sample size and power	360 pts has 80% power to show reduction from 60% to 42% (30%↓)
Timing of rand. and device placement	When shock is recognized (pre, during or up to 12 hours post PCI)

Udesen NJ et al. Am Heart J 2019;214:60-8

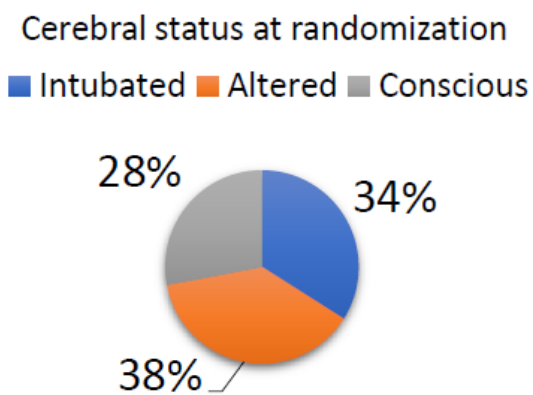
Danish (and German) law allows **research without formal informed consent** in situation where the following criteria are met:

- The research can only be conducted in the given acute situation
- The patient is incapable of providing informed consent
- Consent cannot be obtained from a surrogate given the urgency of the intervention
- The research specifically involves the patient's current condition
- There is a possibility of benefit to the patient

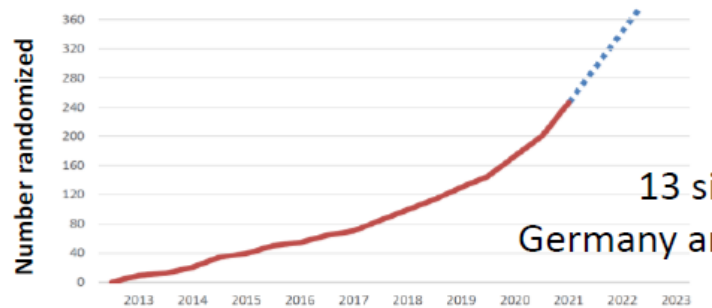
Timing of randomization



Cerebral status at randomization



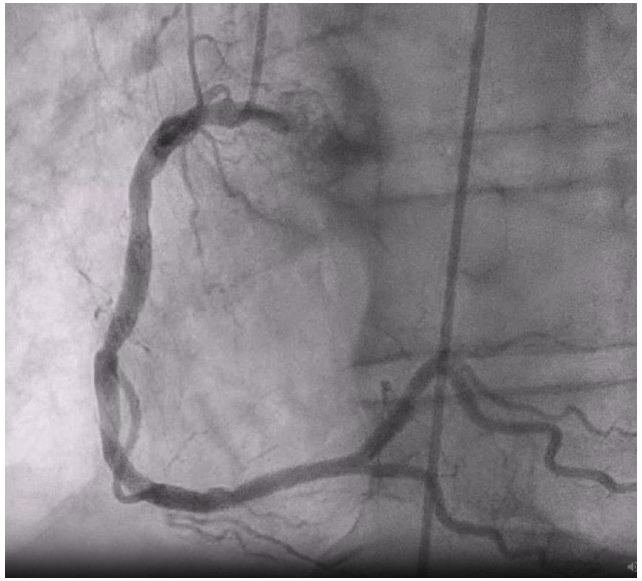
Status – 341 patients randomized (2013 - 2023)

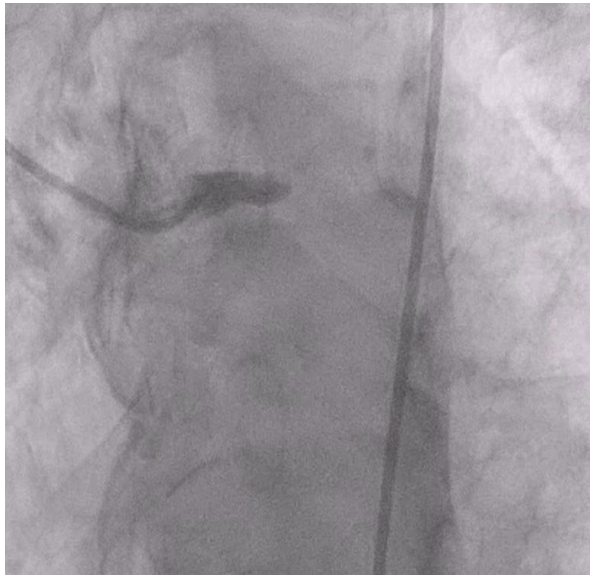


13 sites in Germany and Denmark

Data courtesy of Jacob Møller

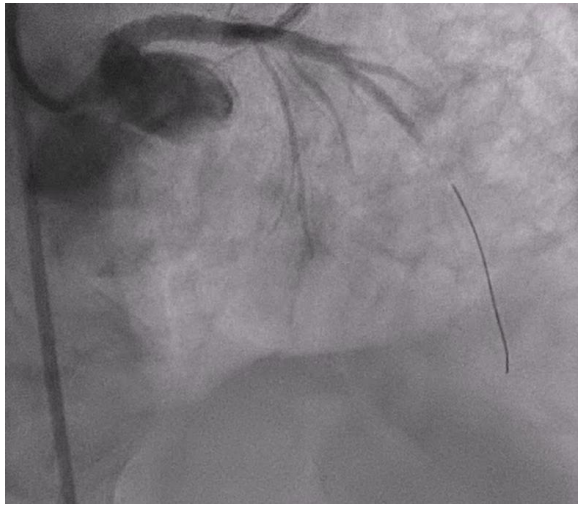
Kasuistika

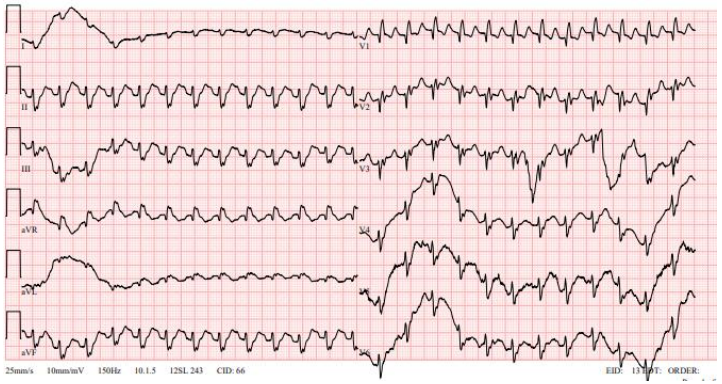




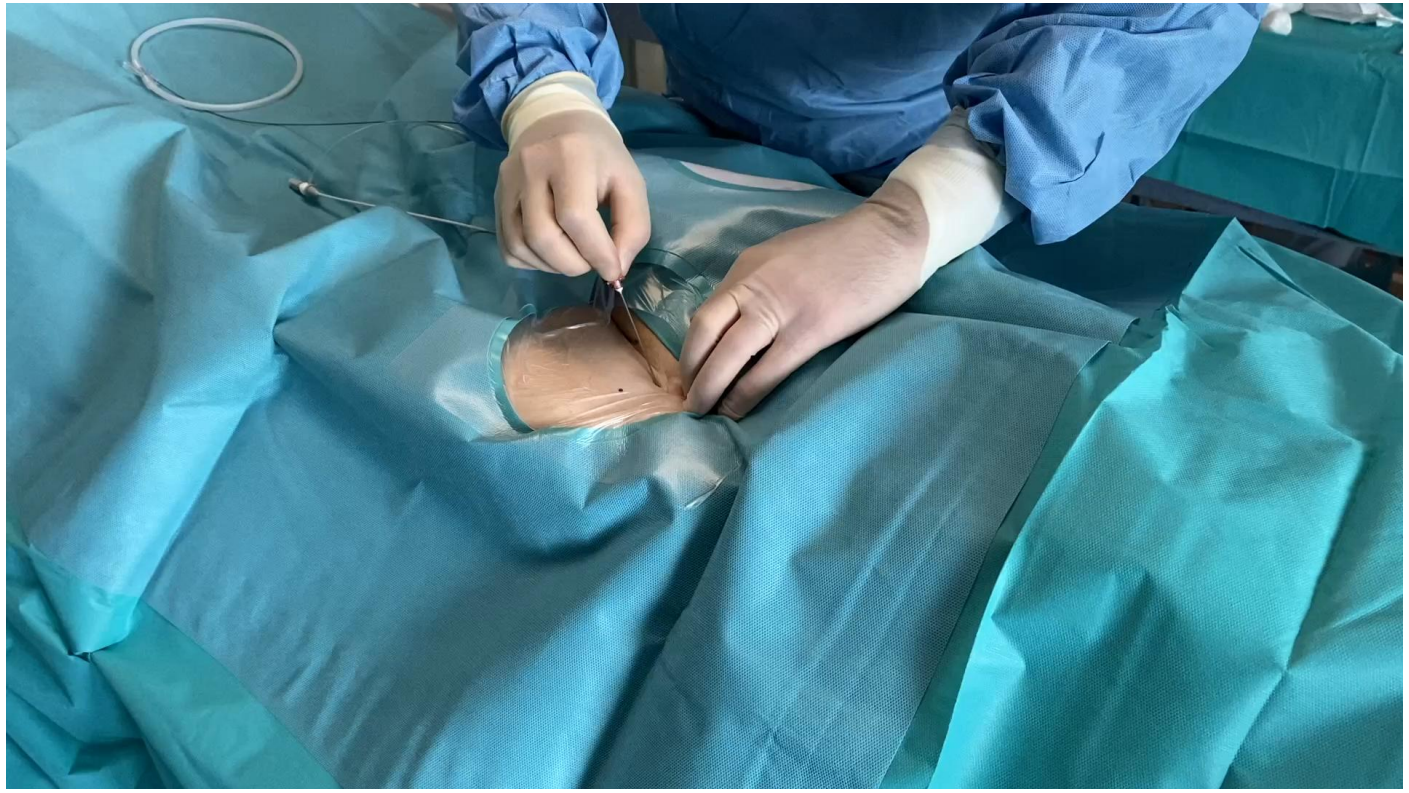
- Muž, 76 let
- 30 minut trvající stenokardie
- 16.5. ve 23:30 Regionální kardiocentrum
- Vstupně kardiogenní šok, trombotický uzávěr kmene ACS, PCI+ DES, IABP 1:1, TTE EF LK 20-25%
- NA 1,35ug/min, Simdax 0,1 ug/kg/min, Integrilin kont.
- Pro progresi oběhové nestability referován k upgrade MSP, TK 80/50, SF 150, spO2 93%

- hsTnT 91 050, AST 38,4, krea 253, laktát 14,1, pH 6,92
- 17.5. v 12:11 cathlab IKEM, po příjezdu na sál KPCR pro hypo/asystolii
- 12:50 re-SKG + Impella CP





Kasuistika



- Muž, 76 let
- 30 minut trvající stenokardie
- 16.5. ve 23:30 spádové kardiocentrum
- Vstupně kardiogenní šok, trombotický uzávěr kmene ACS, PCI+ DES, IABP 1:1, TTE EF LK 20-25%
- NA 1,35ug/min, Simdax 0,1 ug/kg/min, Integrilin kont.
- Pro progresi oběhové nestability referován k upgrade MSP, TK 80/50, SF 150, spO2 93%
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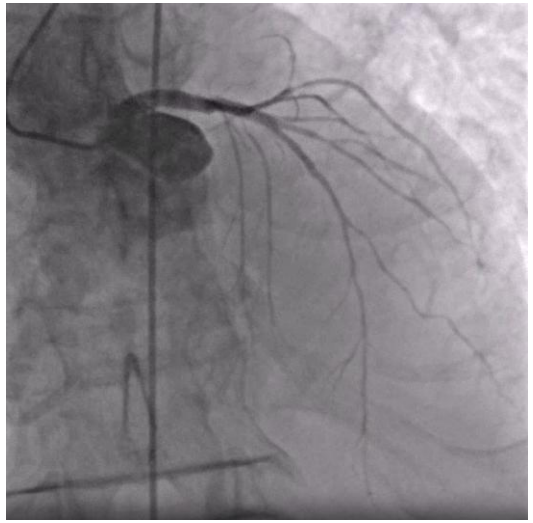
- 17.5. v 12:11 cathlab IKEM, po příjezdu na sál KPCR pro hypo/asystolii
- 12:50 re-SKG + Impella CP
- 14:20 ……. ???



14:20 – tj. 13 hodin od vzniku STEMI exitus letalis

Klinické scénáře

- High-risk PCI
- Kardiogenní šok v akutní fázi infarktu myokardu (AMICS)
- **Unloading a restaurace funkce LK u rozsáhlého STEMI**
- Kardiogenní šok u chronického srdečního selhání
- Kardiochirurgické indikace

RECOVER IV: OVERVIEW

- **Objective:** To demonstrate the effectiveness of Impella using a pre-specified treatment algorithm in reducing mortality in patients with AMI-CGS
- **Hypothesis:** By providing effective LV ± RV hemodynamic support prior to and during PCI and enabling reduction in inotropes in patients with AMI-CGS undergoing PCI, an Impella-based treatment protocol will enhance myocardial recovery and reduce early and late mortality compared to standard of care (PCI alone or with IABP)
- **Design:** Large-scale, multicenter, randomized, controlled, open-label, two-arm trial

ClinicalTrials.gov Identifier: NCT05506449

Co-PI's: Navin Kapur, Jacob Møller, Bill O'Neill. **Study Chair:** Gregg W. Stone. **Sponsor:** Abiomed
Protocol planning committee: Mark Anderson, Dan Burkhoff, Navin Kapur, Jacob Møller, William O'Neill, Gregg W. Stone

RECOVER IV TRIAL DESIGN: CORE CONCEPTS

Critical elements

- **560 pts,** STEMI only, with cardiogenic shock before planned PCI
- Recruitment by **EFIC** – Exception From Informed Consent
- Exclusion of patients unlikely to benefit (especially uncertain neurologic status)
- Randomization of MCS vs. control treatment pre-PCI
- Invasive hemodynamic monitoring (RHC) to guide Rx and weaning
- Rapid down-titration of pressors and inotropes with Impella
- Protocol-driven recognition of RV failure and use of RV support
- Protocol-driven MCS escalation strategies

ClinicalTrials.gov Identifier: NCT05506449

Co-PI's: Navin Kapur, Jacob Møller, Bill O'Neill. **Study Chair:** Gregg W. Stone. **Sponsor:** Abiomed
Protocol planning committee: Mark Anderson, Dan Burkhoff, Navin Kapur, Jacob Møller, William O'Neill, Gregg W. Stone

RECOVER IV TRIAL DESIGN: POWERED OUTCOMES

DRAFT

Primary endpoint:

- All-cause mortality at 30 days → 90% power to detect a reduction in 30-day all-cause mortality from 40% to 26.5% (34% RRR, 13.5% ARR, NNT 7.4)

Secondary endpoints (hierarchical testing):

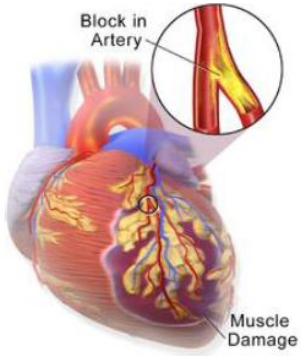
1. MACCE at 30 days
2. Days alive out-of-hospital at 6 months
3. KCCQ-OS at 1 year

Co-PI's: Navin Kapur, Jacob Møller, Bill O'Neill. **Study Chair:** Gregg W. Stone. **Sponsor:** Abiomed
Protocol planning committee: Mark Anderson, Dan Burkhoff, Navin Kapur, Jacob Møller, William O'Neill, Gregg W. Stone

Klinické scénáře

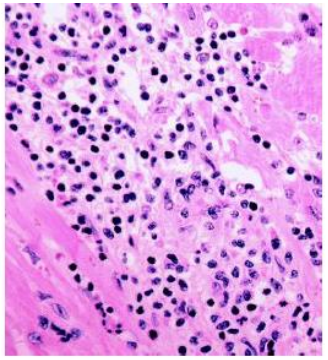
- High-risk PCI
- Kardiogenní šok v akutní fázi infarktu myokardu (AMICS)
- Unloading a restaurace funkce LK u rozsáhlého STEMI
- **Kardiogenní šok u chronického srdečního selhání**

Různorodá etiologie kardiogenního šoku

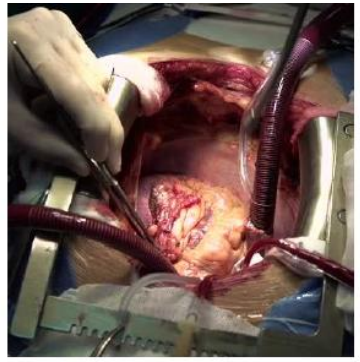


Acute MI and mechanical complications

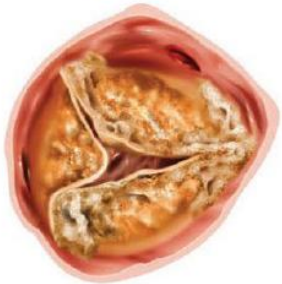
Acute decompensated HF



Myocarditis

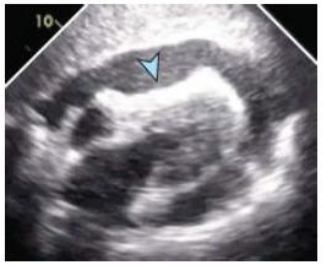


Postcardiotomy

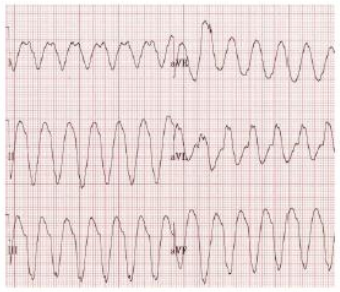


Valvular

Postpartum Cardiomyopathy



Cardiac Tamponade

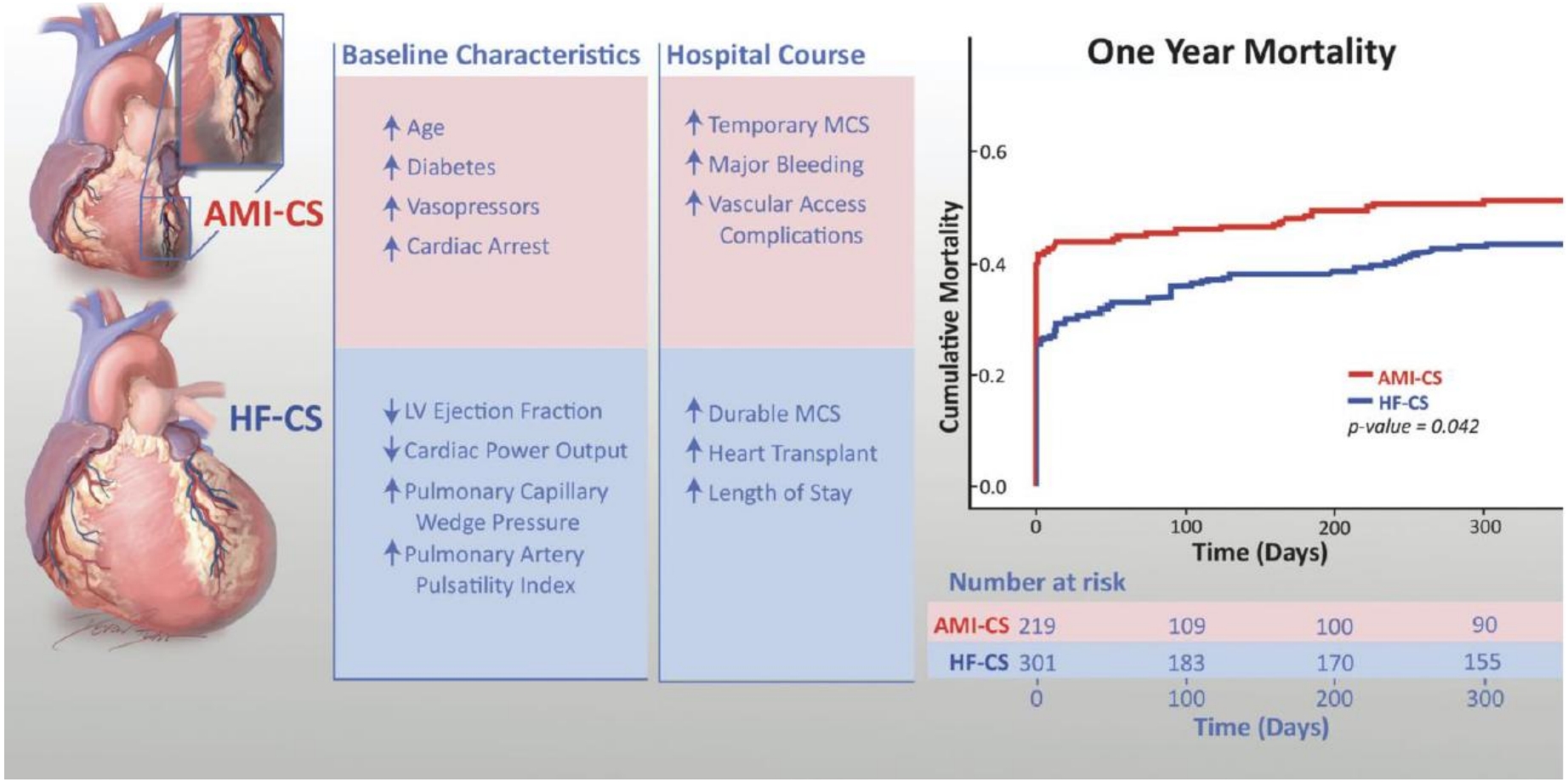


Arrhythmias

Kar B, et al. *Circulation*.2012;125:1809.

Weill Cornell Medicine | NewYork-Presbyterian | Columbia

Prognóza kardiogenního šoku



Dekompenzovaní srdeční selhání/šok + IABP

ELSEVIER

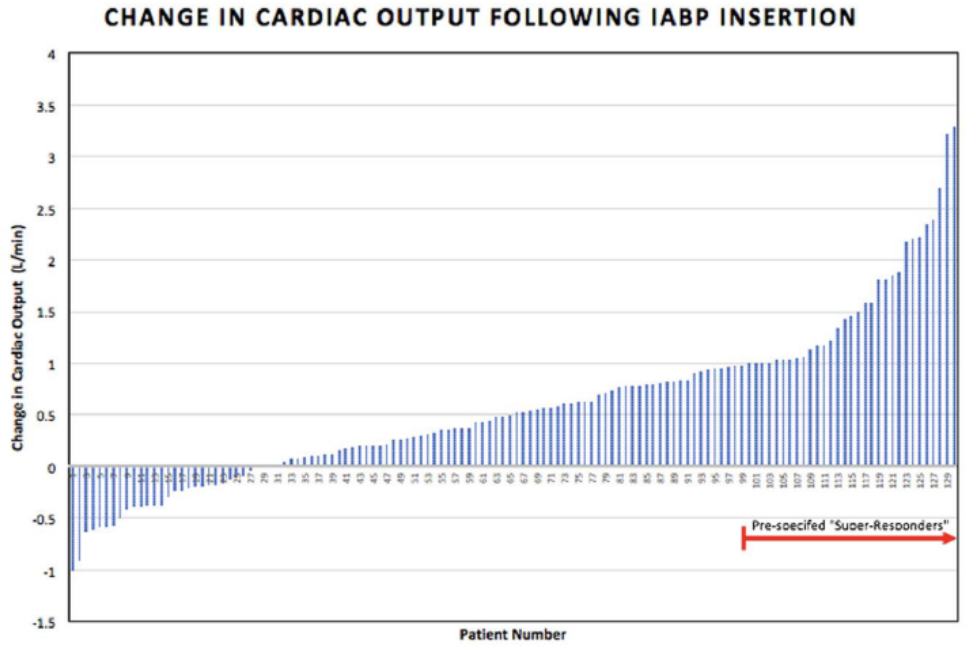
The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

Clinical and hemodynamic effects of intra-aortic balloon pump therapy in chronic heart failure patients with cardiogenic shock

Justin A. Fried, MD,[a] Abhinav Nair, MD,[a] Koji Takeda, MD, PhD,[b] Kevin Clerkin, MD, MSc,[a] Veli K. Topkara, MD,[b] Amirali Masoumi, MD,[a] Melana Yuzefpolskaya, MD,[a] Hiroo Takayama, MD, PhD,[b] Yoshifumi Naka, MD, PhD,[b] Daniel Burkhoff, MD, PhD,[a] Ajay Kirtane, MD, SM,[a] Dimitrios Karmpaliotis, MD,[a] Jeffrey Moses, MD,[a] Paolo C. Colombo, MD,[a] and A. Reshad Garan, MD[a]

- 132 shock patients from chronic HF
- IABP initial treatment
- 84% survive,
- 78% bridge to heart replacement therapies or recovery
- 2% major complications rate

There were super-responders whose CO increased by ≥0.98 liter/min



IKEM

Využití krátkodobé mechanické srdeční podpory Impella v klinické praxi u 122 pacientů

Martina Podolec[1], Michael Želízko[1], Bronislav Janek[1], Marek Šramko[1], Ivan Netuka[2], Jiří Malý[2], Josef Kautzner[1]
[1]Kardiologická klinika Institutu klinické a experimentální medicíny-IKEM, Praha, Česká republika
[2]Klinika kardiovaskulární chirurgie, Institut klinické a experimentální medicíny-IKEM, Praha, Česká republika

128 implantací u 122 pacientů

- Impella CP – 90x
- Impella 5,0 – 35x

30-denní mortalita = 35%

Jednoletá mortalita = 46%

eskalace na MSP = 34%

WL Tx srdce = 13,3%

Charakteristika	Impella 5.0 [možná po Impella CP implantaci], n=35	Jen Impella CP, n=85
Impella CP	5 (14%)	85 (100%)
SCAI skóre		
A	0 (0%)	20 (24%)
B	2 (5,7%)	15 (18%)
C	11 (31%)	16 (19%)
D	4 (11%)	7 (8,2%)
E	18 (51%)	27 (32%)
MSP Heartmate	21 (60%)	9 (11%)
Srdeční transplantace	2 (5,7%)	2 (2,4%)
Čekací listina na transplantaci srdce	7 (20%)	4 (4,7%)
Důvod		
1 – sub/akutní IM	9 (26%)	51 (60%)
2 – chráněná RF ablace	0 (0%)	3 (3,5%)
3 – postkardiotomický KŠ	5 (14%)	4 (4,7%)
4 – chráněná PCI	0 (0%)	15 (18%)
5 – myokarditida	4 (11%)	4 (4,7%)
6 – Tako Tsubo kardiomyopatie	0 (0%)	3 (3,5%)
7 – infekční endokarditida	0 (0%)	1 (1,2%)
8 – malfunkce MSP Heartmate	0 (0%)	1 (1,2%)
9 – dekompenzované chronické srdeční selhání	17 (49%)	3 (3,5%)

Potenciální klinické strategie

Shock from chronic HF

- IABP insertion
- Re-assess hemodynamics, u/o, lactate trend
- If deteriorated/no improve,
  switch to axillary Impella 5.5 (OR/time allows) or
  add femoral ECMO at bedside
- Work up for VAD/Transplant

Shock from Acute MI

- Send to cath lab
- Impella CP insertion
  2nd look of coronary
- Re-assess hemodynamics, u/o, lactate trend
- If deteriorated/no improve, add femoral ECMO
- Recovery, VAD/Transplant
  Consider switch CP/ECMO to 5.5

Žádná klinická strategie nemá validní randomizovanou studii pro rutinní požití systému Impella