

Perioperační zajištění vysoce rizikových kardiokirurgických pomocí Impella 5.5 – Posun indikačního paradigmatu?

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Mixed Cardiogenic-Vasodilatory Shock



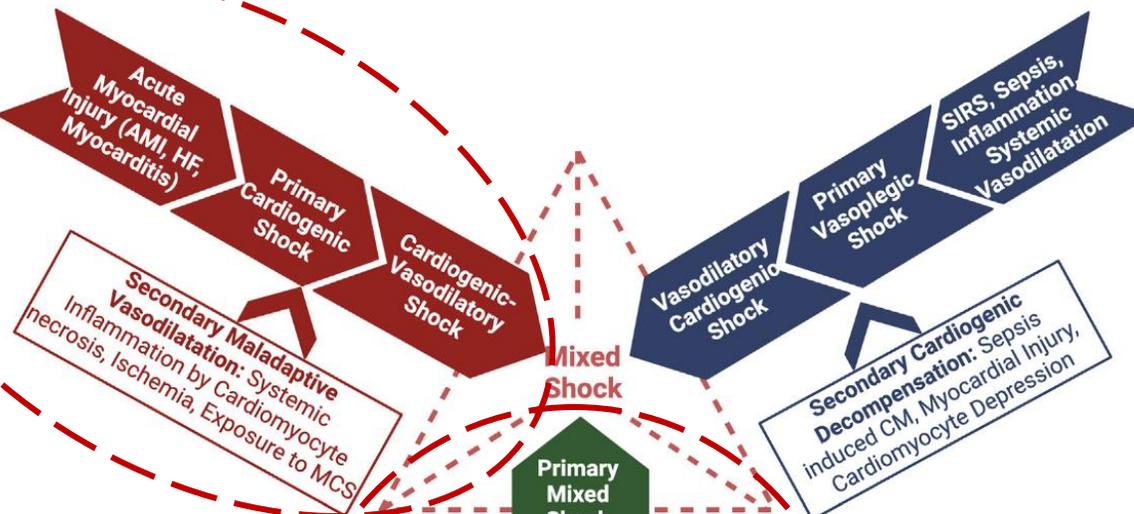
Current Insights and Future Directions

Jacob C. Jentzer, MD,^a David D. Berg, MD, MPH,^b Meshe D. Chonde, MD,^c Garima Dahiya, MD,^d Andrea Elliott, MD,^e Penelope Rampersad, MD,^f Shashank S. Sinha, MD, MSc,^g Alexander G. Truesdell, MD,^g Seife Yohannes, MD,^h Saraschandra Vallabhajosyula, MD, MScⁱ

Jentzer J. et al. JACC 2025

FIGURE 1 Proposed Classification of Mixed Shock

**"Single Hit"
Pathogenesis**



**"Double Hit"
Pathogenesis**

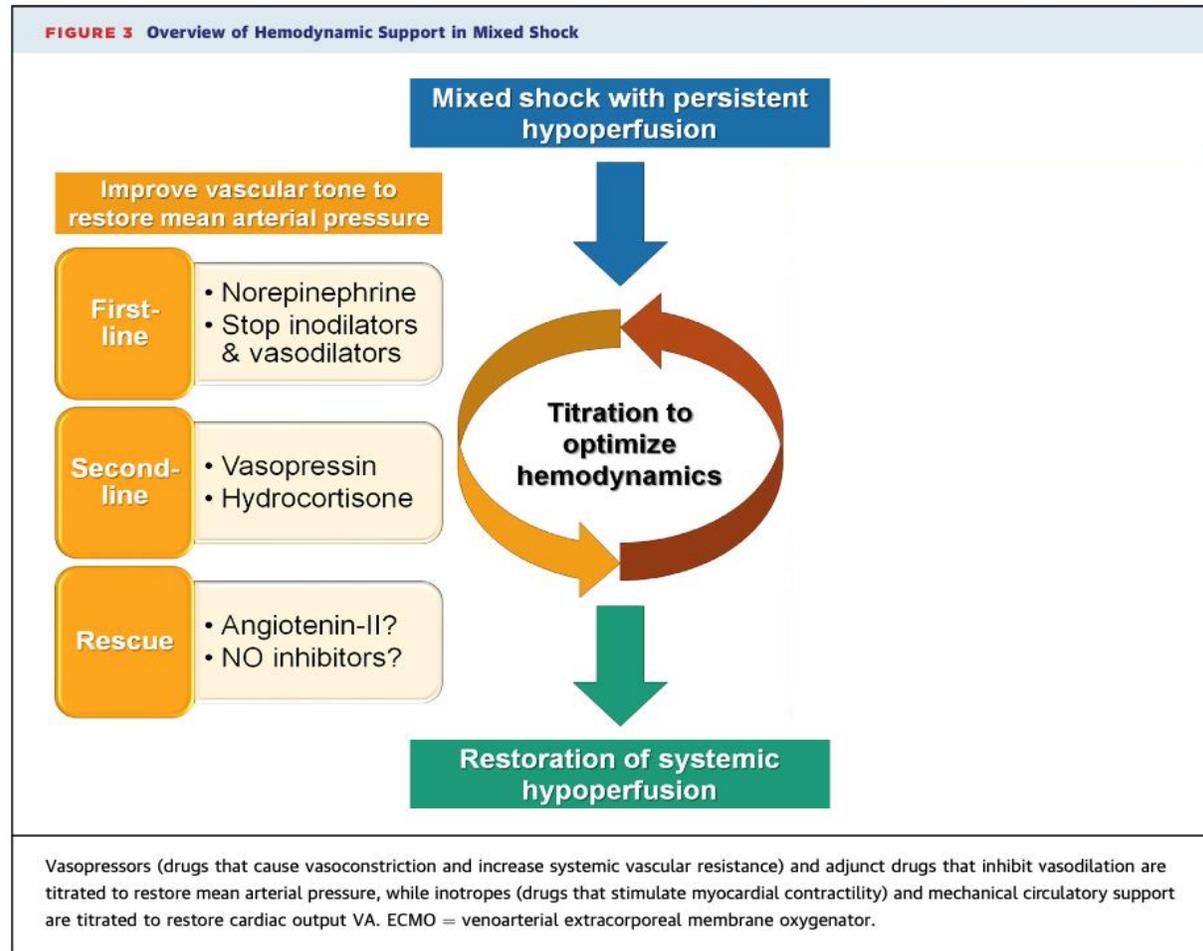
Global Ischemia or Reperfusion Injury: Synchronous Myocardial Depression and Vasoplegia

Mixed Cardiogenic-Vasodilatory Shock



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VENTING

- Reduce afterload
- Prevent pulmonary complications
- No effective volume displacement
- Inotropes
- IABP
- Septostomy

UNLOADING

- Reducing ventricular pressure & volume
- Enhance CO
- Improve myocardial O_2 consumption/WT/PVA
- Favorable for recovery
- Percutaneous/Surgical VAD

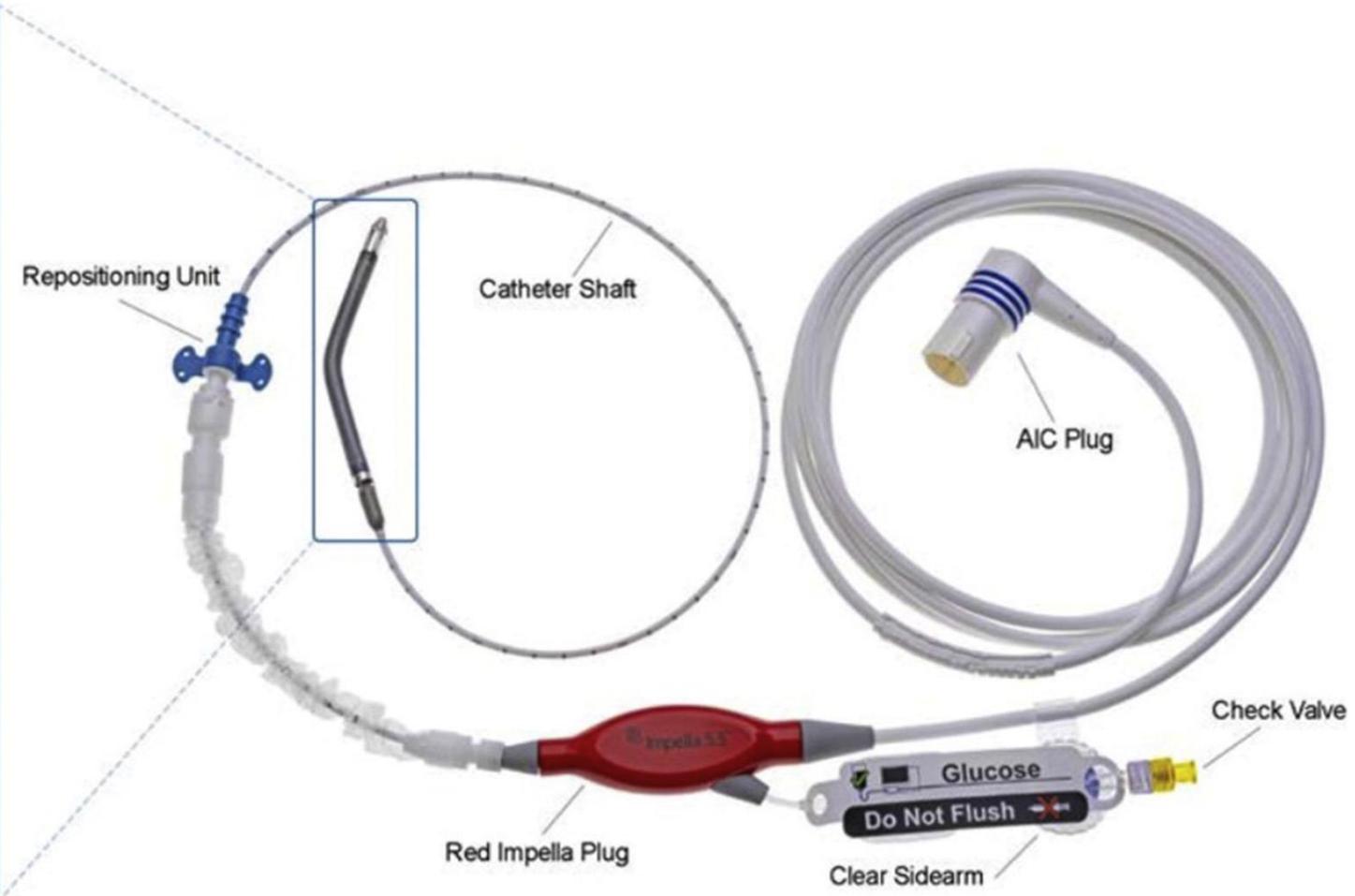
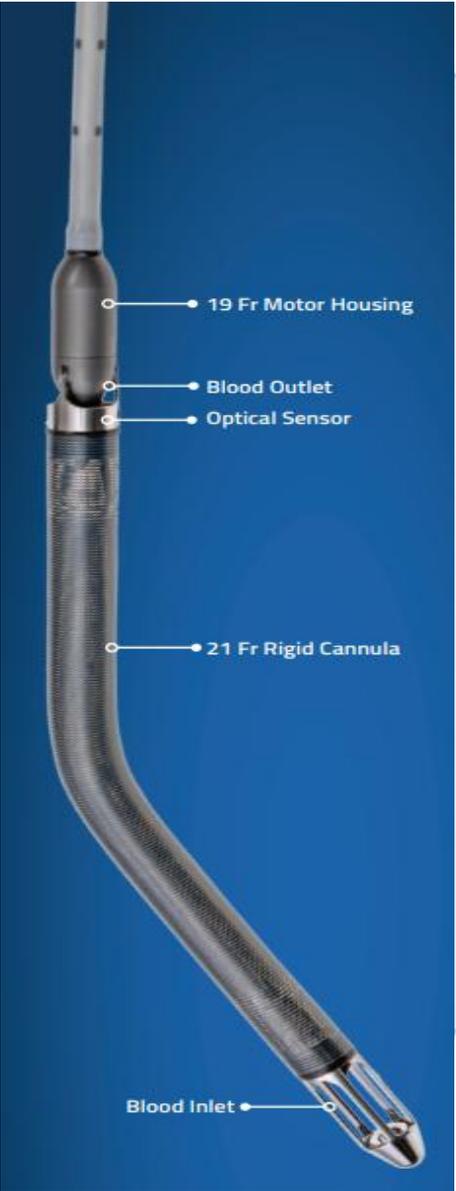
Komparace patofyziologických vlastností MSP

TABLE 1. Hemodynamic effects of drugs and devices used in the treatment of low cardiac output syndrome

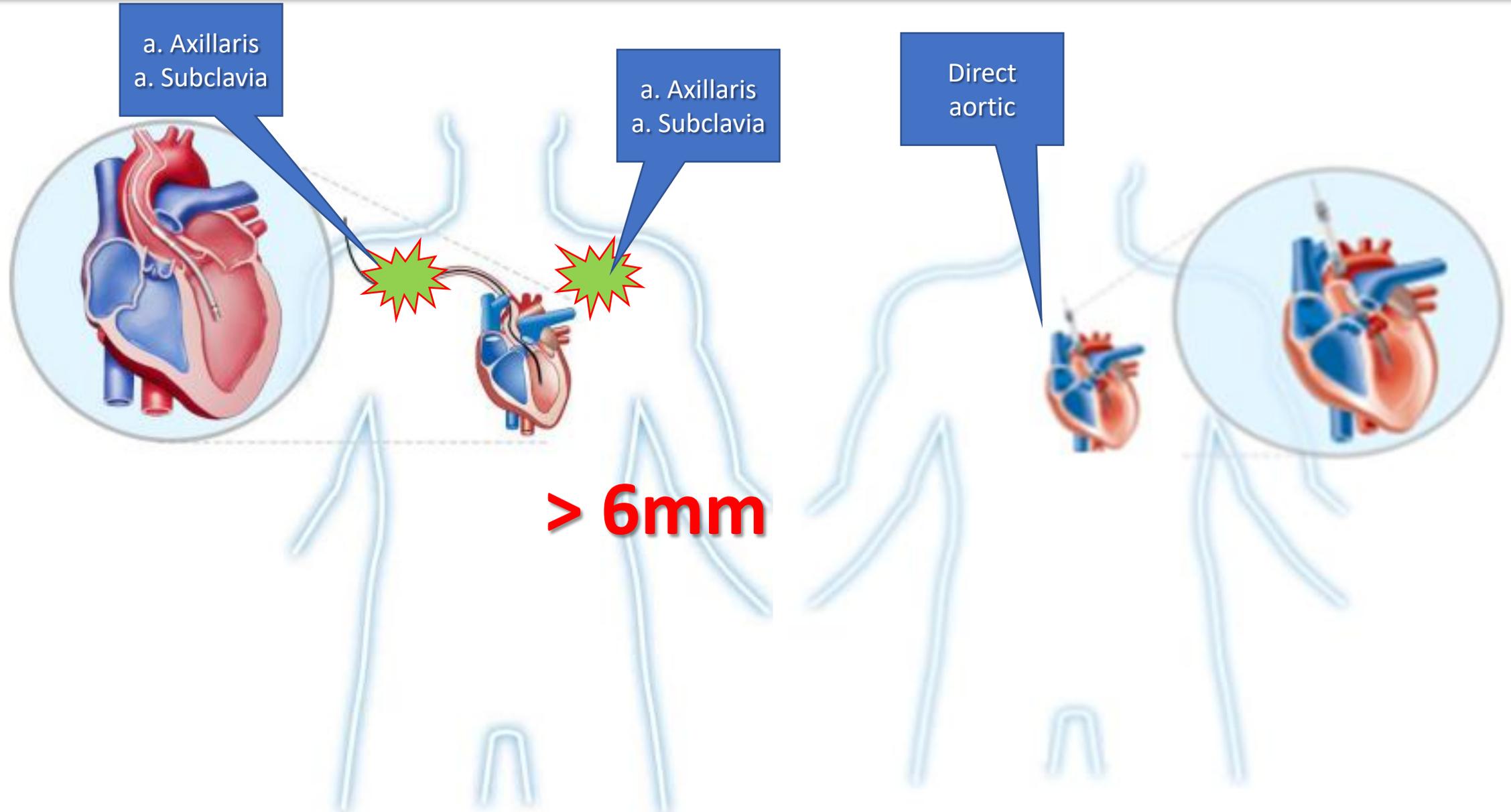
	Afterload	Cardiac output	LV unloading	Myocardial oxygen consumption
Vasoactive agents				
Inotropes	↓	↑	↔	↑
Pressors	↑	↓	↔	↑
Mechanical devices				
IABP	↓	↔ to mild ↑	↔	↓
Venoarterial ECMO	↑↑	↑↑	↓	↑
TandemHeart	mild ↑	↑	↑	moderate ↓
Impella	↓	↑↑	↑↑	↓↓

30 days use CE
Mark

Impella 5.5

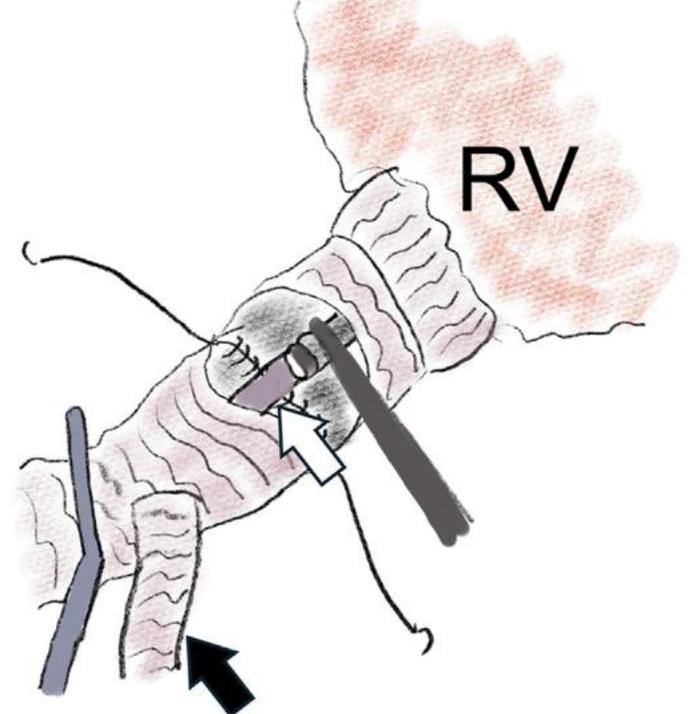
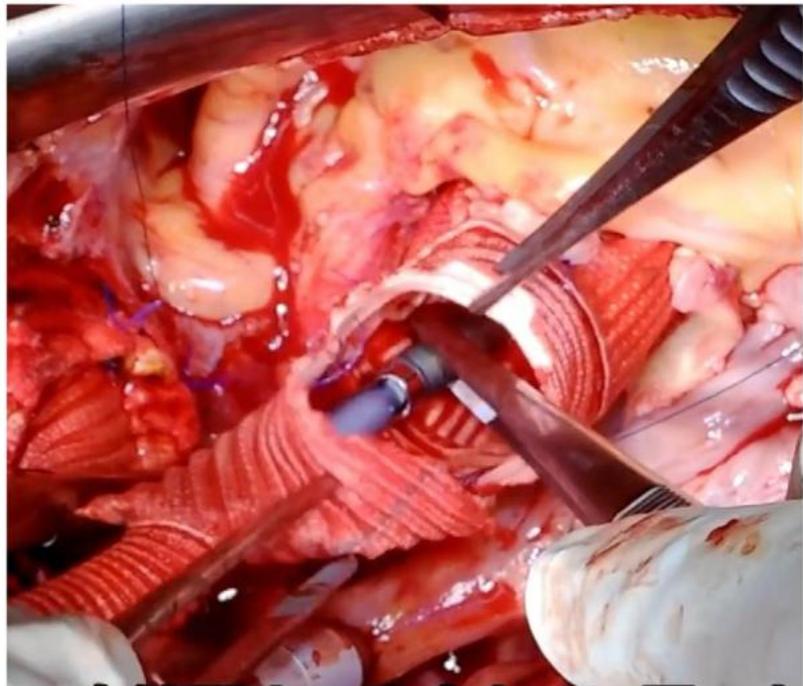
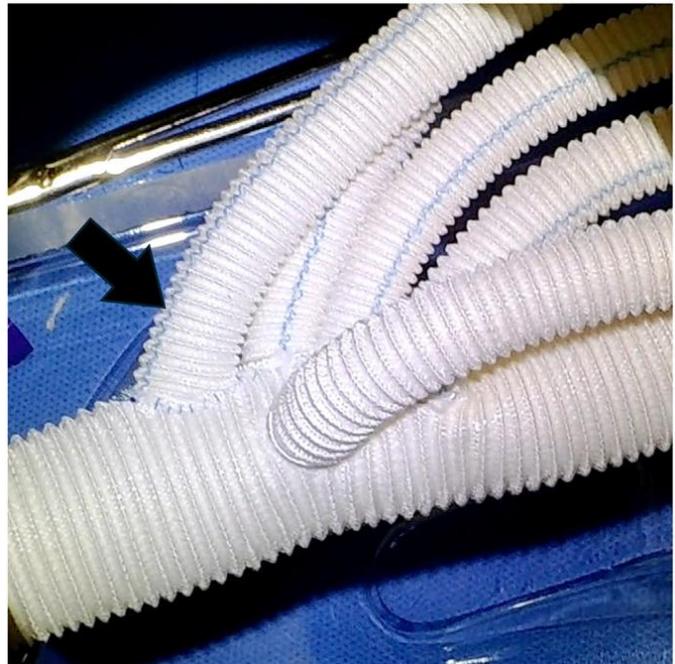
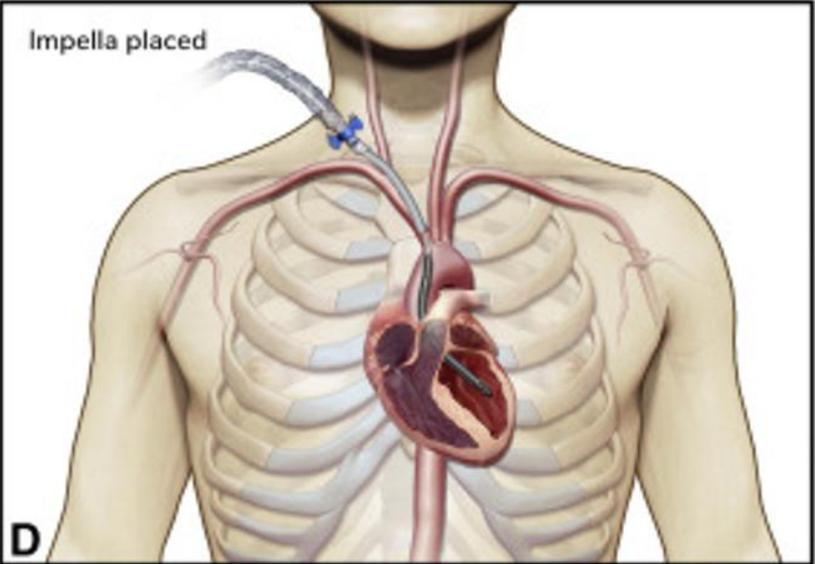


Impella 5.5 – versatilita implantace



Preemptive Direct Aortic Insertion of Impella 5.5 in Patients Undergoing Cardiac or Aortic Surgery

Masaaki Ryomoto, MD, PhD,¹ Masaru Ishida, MD, PhD,¹ Kanji Ishizu, MD,¹ and Toshihiro Funatsu, MD, PhD¹



Indikace vysoce rizikových výkonů + Impella 5.5

- **Aortokoronární bypass**
- **Intervence na mitrální chlopní (MR)**
- **Intervence na aortální chlopní (AR)**
- **Defekt komorového septa**
- **Resekce aneurysmatu LK**

HFrEF Guidelines



Recommendations	Class ^a	Level ^b
In patients with severe LV systolic dysfunction and coronary artery disease suitable for intervention, myocardial revascularization is recommended. ^{81,250}	I	B
CABG is recommended as the first revascularization strategy choice in patients with multivessel disease and acceptable surgical risk. ^{68,81,248,255}	I	B

2018 ESC/EACTS Guidelines on myocardial revascularization European Heart Journal



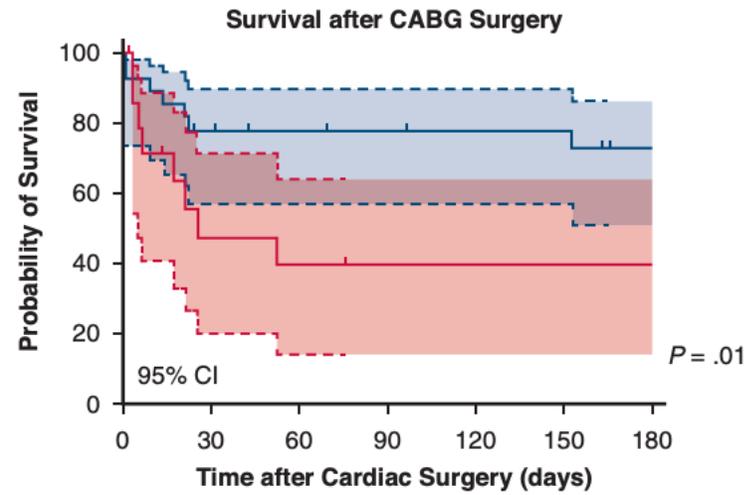
1	A	1. In patients with CCD and lifestyle-limiting angina despite GDMT and with significant coronary artery stenoses amenable to revascularization, revascularization is recommended to improve symptoms.* ¹⁻⁷
1	B-R	2. In patients with CCD who have significant left main disease or multivessel disease with severe LV dysfunction (LVEF ≤ 35%), CABG in addition to medical therapy is recommended over medical therapy alone to improve survival.* ⁸⁻¹¹

1	B-R	1. In patients with CCD who require revascularization for significant left main involvement associated with high-complexity CAD, CABG is recommended in preference to PCI to improve survival.* ^{1,2}
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2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease, Circulation 2023

Temporary circulatory support with surgically implanted microaxial pumps in postcardiotomy cardiogenic shock following coronary artery bypass surgery

Wiebke Sommer ¹, Rawa Arif ¹, Jamila Kremer ¹, Sameer Al Maisary ¹, Markus Verch ¹, Ursula Tochtermann ¹, Matthias Karck ¹, Anna L Meyer ¹, Gregor Warnecke ¹



At risk	0	30	60	90	120	150	180
Simultaneous:	27	21	19	18	17	17	14
Delayed:	15	7	6	5	5	5	5

— Simultaneous Impella Implantation (n = 27)
— Delayed Impella Implantation (n = 15)

TABLE 3. Postoperative characteristics

	Simultaneous Impella implantation (n = 27)	Delayed Impella implantation (n = 15)	P value
ICU stay, d (median; IQR)	13 (8; 23)	17 (6; 26)	.92
Mechanical ventilation, d (median; IQR)	3.7 (0.8; 14.9)	9.9 (3.9; 17.7)	.09
Total hospital stay, d (median; IQR)	20 (13; 24)	18 (8; 28)	.96
Renal-replacement therapy, n; %	12; 44.4	8; 53.3	.75
Bilirubin, max, mg/dL, mean ± SD	6.3 ± 7.6	8.3 ± 5.3	.02
Tracheostomy, n; %	7; 25.9	5; 33.3	.73
Re-sternotomy for bleeding, n; %	6; 22.2	1; 6.7	.39
Cerebrovascular event	3; 11.1	1; 6.7	>.99
Duration of Impella support, d (median; IQR)	9 (6; 16)	14 (5; 16)	.66
30-d survival, %	77.8	47.6	.04
6-mo survival, %	72.9	39.7	.06
1-y survival, %	72.9	29.8	.03

Mann-Whitney *U* test for categorical and continuous values, log-rank test for survival analysis. *ICU*, Intensive care unit; *IQR*, interquartile range; *SD*, standard deviation.

The dilemma of LVEF in severe MI

Forward Ejection Fraction in Mitral Regurgitation *Dupuis et al*

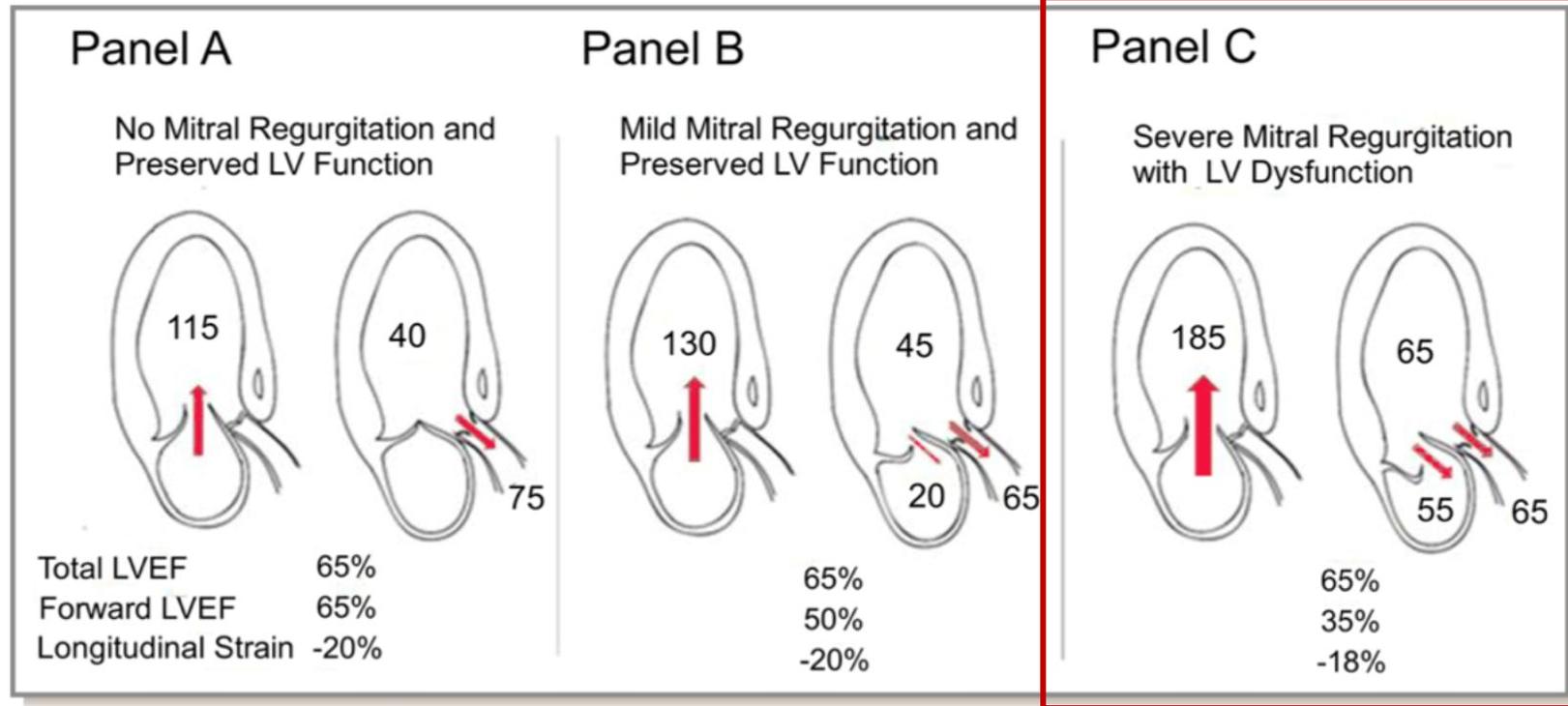
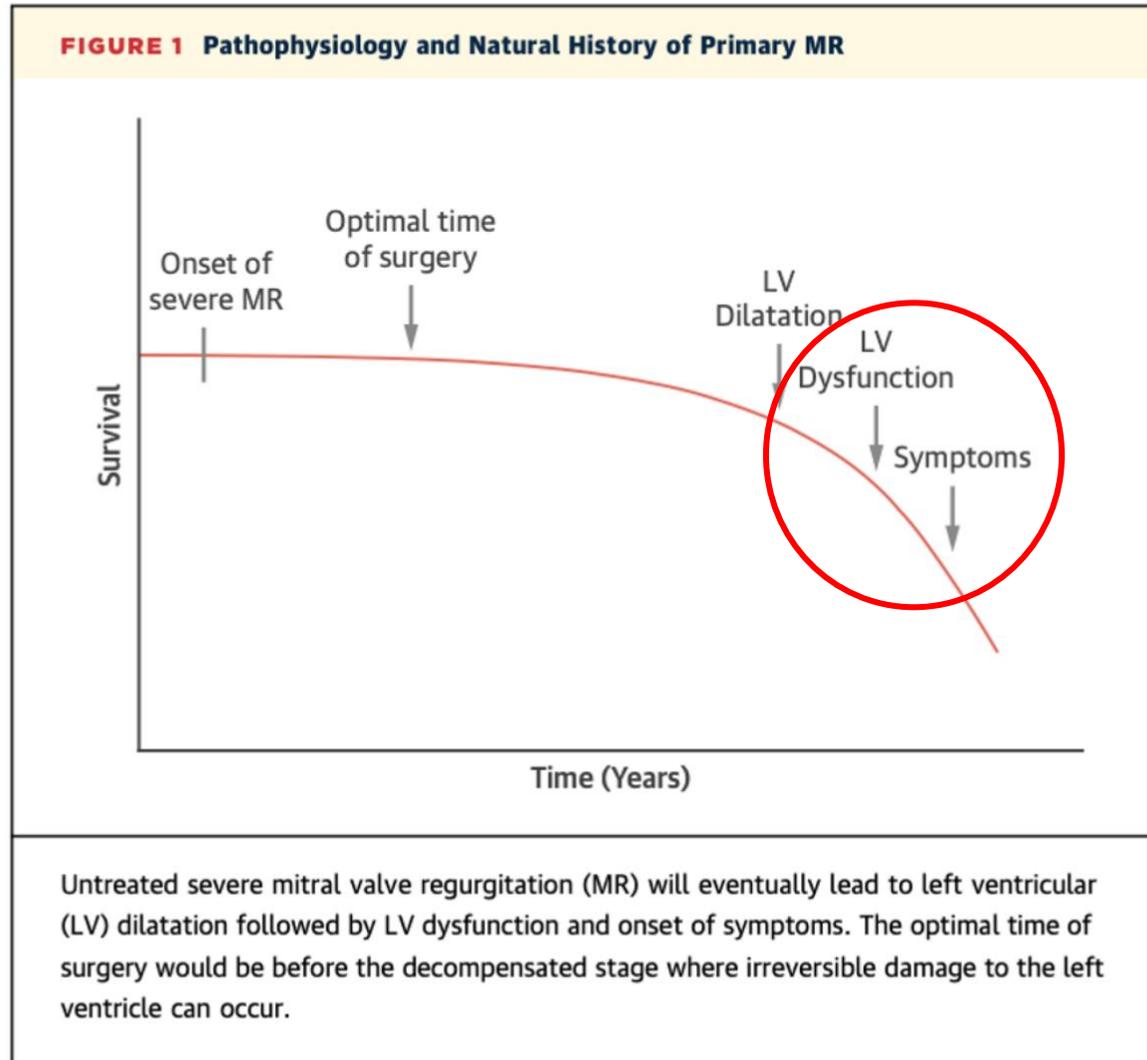


Figure 4. Comparison between total LVEF, forward LVEF and global longitudinal strain according to MR severity and associated LV dysfunction. This figure shows the comparison of Total LVEF, Forward LVEF and Global Longitudinal Strain when there is no mitral regurgitation (A), a mild mitral regurgitation with preserved LV systolic function (B), and a severe mitral regurgitation with a LV systolic dysfunction (C). LV indicates left ventricular; LVEF, left ventricular ejection fraction; MR, mitral regurgitation.

Timing of Mitral Valve Surgery



Short-term mechanical support with the Impella 5.x for mitral valve surgery in advanced heart failure—protected cardiac surgery

Anja Osswald^{1*}, Sharaf-Eldin Shehada¹, Alina Zubarevich¹, Markus Kamler¹, Matthias Thielmann¹, Wiebke Sommer², Alexander Weymann^{1,3}, Arjang Ruhparwar^{1,3}, Mohamed El Gabry^{1†} and Bastian Schmack^{1,3†}

Introduction: Surgical treatment of patients with mitral valve regurgitation and advanced heart failure remains challenging. In order to avoid peri-operative low cardiac output, Impella 5.0 or 5.5 (5.x), implanted electively in a one-stage procedure, may serve as a peri-operative short-term mechanical circulatory support system (st-MCS) in patients undergoing mitral valve surgery.

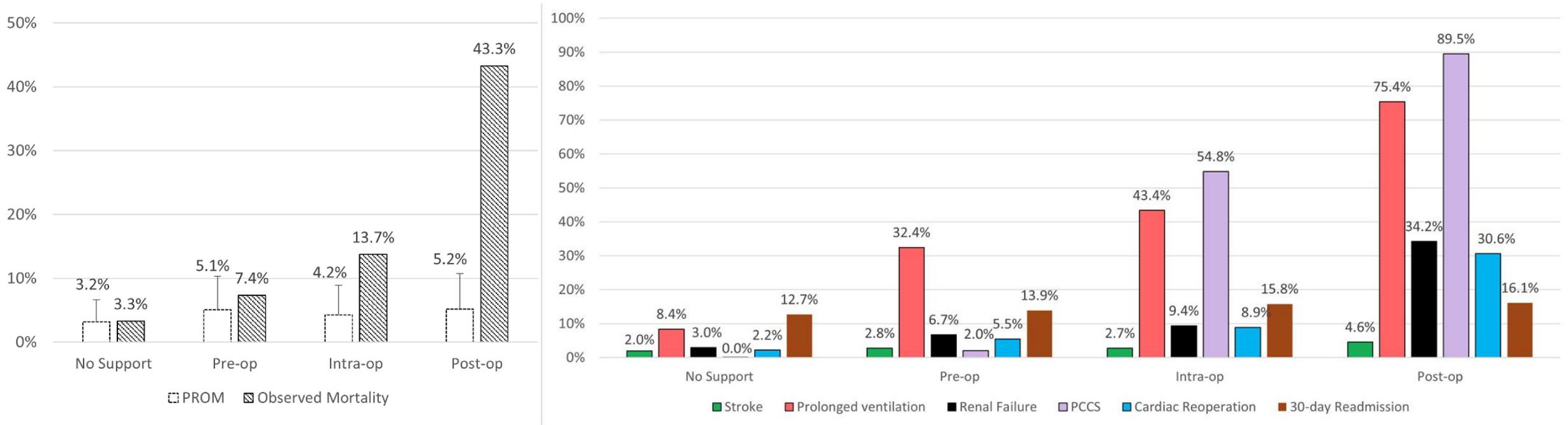
Methods: Between July 2017 and April 2022, 11 consecutive patients underwent high-risk mitral valve surgery for mitral regurgitation supported with an Impella 5.x system (Abiomed, Inc. Danvers, MA). All patients were discussed in the heart team and were either not eligible for transcatheter edge-to-edge repair (TEER) or surgery was considered favorable. In all cases, the indication for Impella 5.x implantation was made during the preoperative planning phase.

Results: The mean age at the time of surgery was 61.6 ± 7.7 years. All patients presented with mitral regurgitation due to either ischemic ($n = 5$) or dilatative ($n = 6$) cardiomyopathy with a mean ejection fraction of $21 \pm 4\%$ (EuroScore II 6.1 ± 2.5). Uneventful mitral valve repair ($n = 8$) or replacement ($n = 3$) was performed via median sternotomy ($n = 8$) or right lateral mini thoracotomy ($n = 3$). In six patients, concomitant procedures, either tricuspid valve repair, aortic valve replacement or CABG were necessary. The mean duration on Impella support was 8 ± 5 days. All, but one patient, were successfully weaned from st-MCS, with no Impella-related complications. 30-day survival was 90.9%.

Conclusion: Protected cardiac surgery with st-MCS using the Impella 5.x is safe and feasible when applied in high-risk mitral valve surgery without st-MCS-related complications, resulting in excellent outcomes. This strategy might offer an alternative and comprehensive approach for the treatment of patients with mitral regurgitation in advanced heart failure, deemed ineligible for TEER or with need of concomitant surgery.

30-Day Mortality and Adverse Events in CABG or CABG/MVS with EF ≤ 35% (n=35,649)

Stratified by TIMING of tMCS Use



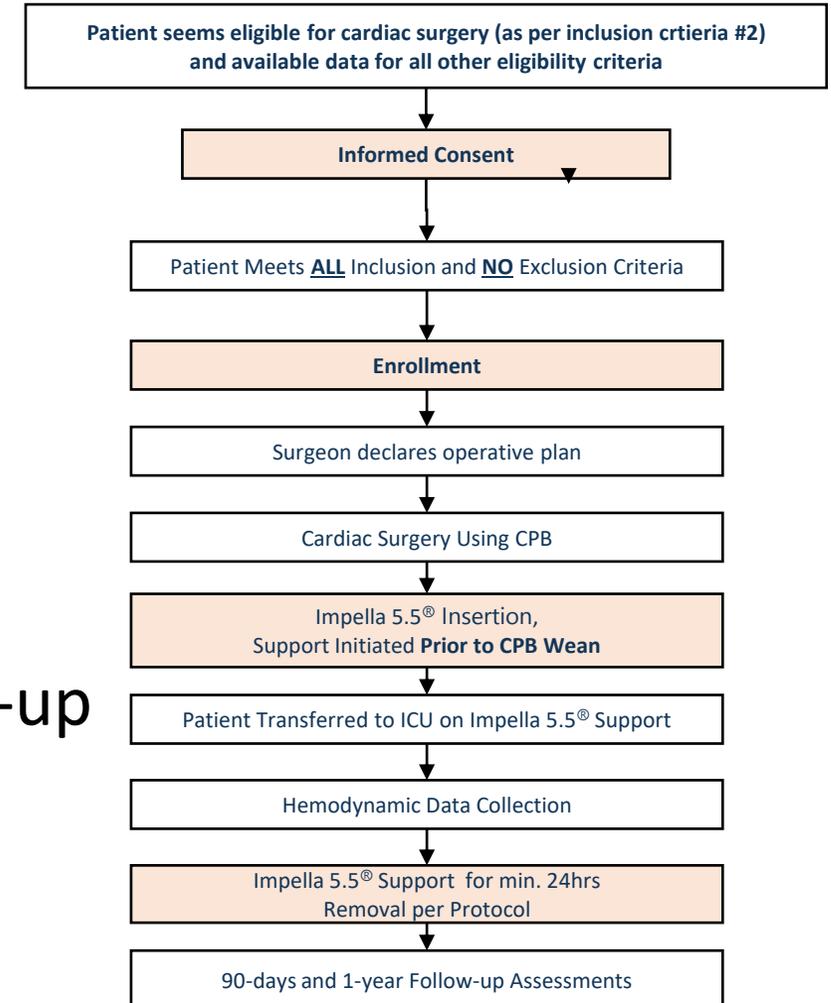
Soltesz E, Goldstein D. (submitted)

The IMPACT Trial Rationale

- New paradigm of pre-emptive LV unloading
 - Increased possibility of reparative surgery in high risk patients (HFrEF)
- Vasopresors reduction
 - Reduce splanchnic and peripheral vasoconstriction
- Systemic output augmentation
 - Better end-organ perfusion
- Recovery from the CPB

The IMPACT Trial arms

- Impella Support to facilitate weaning in cardiac surgical high-risk population
- A multi-center, multi-national (US and Europe), prospective, single-arm trial.
 - US: investigational device exemption
 - In Europe: post market clinical follow-up



IMPACT-EU: 13 Sites Active

■ Germany

- University Hospital Aachen
- Universitäres Herzzentrum Hamburg GmbH (UHZ)
- Universität von Halle-Wittenberg
- Universitätsklinikum Heidelberg
- Universitätsklinikum Schleswig Holstein
- German Heart Centre Charité
- West German Heart Center Essen
- Universitätsmedizin Mainz
- Cardiology Düsseldorf
- Medizinische Hochschule Hannover
- University Hospital Giessen
- Krankenhaus der Barmherzigen Brüder Trier

■ Czech Republic

- IKEM Prague



The IMPACT Trial Inclusion Criteria

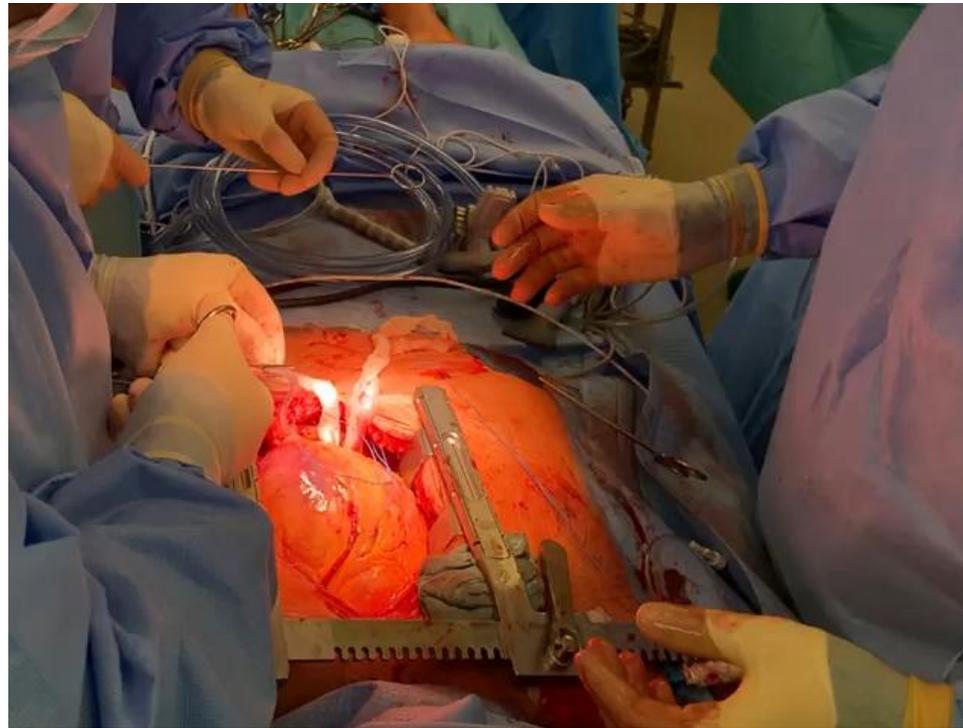
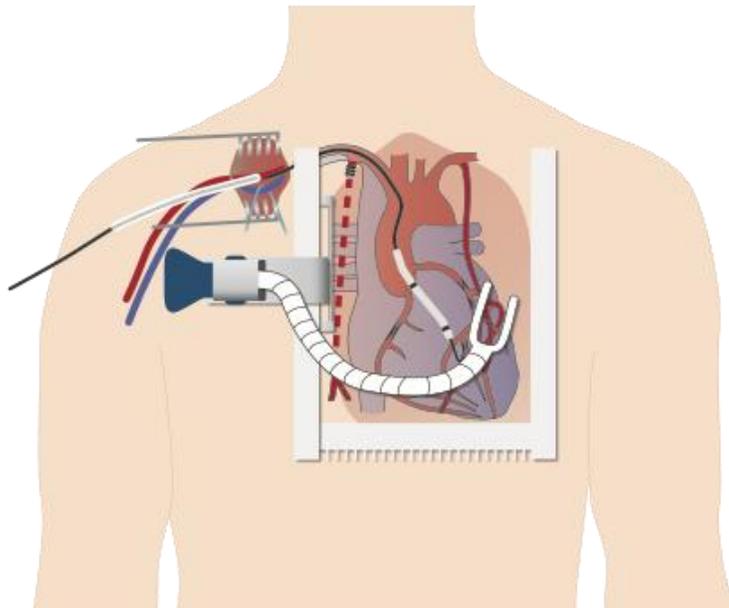
- Hemodynamically stable patient undergoing planned procedure on CPB, aortic cross-clamping and cardioplegic arrest
 - Isolated CABG, MVP/MVR, Aortic valve repair/AVR
 - Combination with TVP/TVR
 - Permitted concomitant procedures: ASD, PFO repair, MAZE
- **LVEF < 25%**
- **LVEF < 35% with significant mitral insufficiency** towards planned MVP/MVR

Protected Off-Pump Coronary Artery Bypass Grafting

Stable chronic ischemic cardiomyopathy

Viabile myocardium in MRI scan

EF<30%



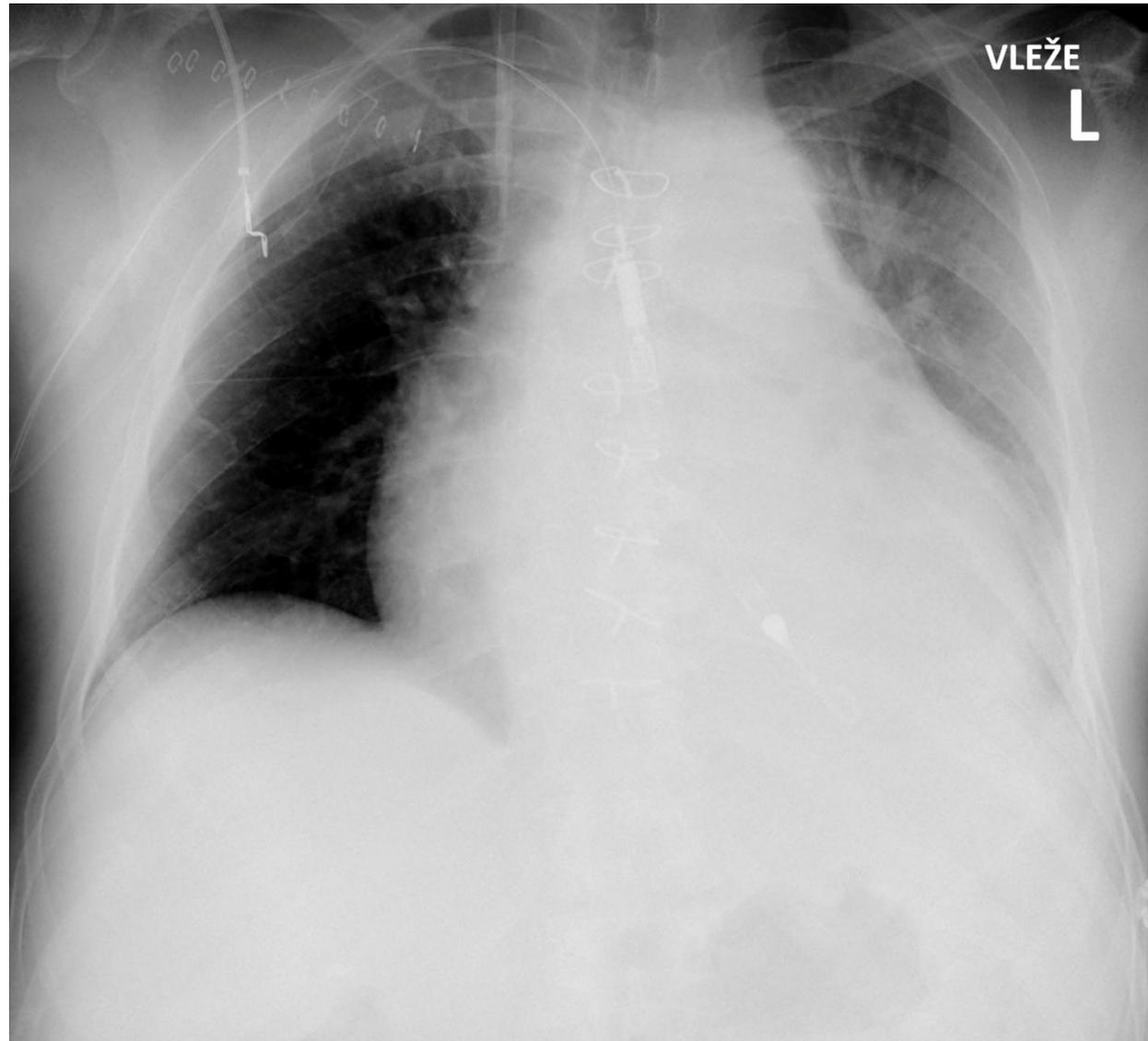
Shrnutí

- Technologie umožňující bezpečnou prodlouženou oběhovou podporu
- Možnost pre-emptivního odlehčení srdce s těžkou dysfunkcí pro bezpečnější kompletní kardiochirurgické intervence
- U vysoce rizikových podskupin pacientů
- U pacientů doposud již za hranicí akceptabilní indikace
- Potenciál změny paradigmatu současných algoritmů
- Prospektivní multicentrické studie nezbytné pro validaci strategie

Kazuistika IKEM – Vysoce rizikový výkon + Impella 5.0/5.5

- Muž – 61 let
- Těžká aortální insuficience 4/4
- LVEDD 81 mm; LVESS 70 mm, EF LK 25%
- Anomální spojka ACS – plicnice
- AVR bio + ligatura spojky ACS – plicnice + Impella 5.5
- 8. POD explantace Impella 5.5

Kazuistika – Vysoce rizikový výkon + Impella 5.0/5.5



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- 8. POD explantace Impella 5.5
- **Follow-up 6 měsíců: NYHA II., EF 40-45%, LVEDD 68 mm**
- **Follow-up 6 měsíců: NYHA II., EF 40-45%, LVEDD 65 mm**