



VFN PRAHA

# **Beyond one size fits all in MSP and cardiogenic shock**

**Karlovy Vary 2024**

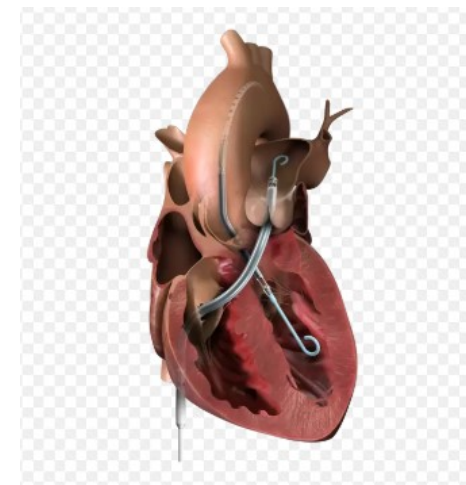
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# Klíčové RCTs u kardiogenního šoku na MSP

- ECMO CS = **rutinní** časná implantace ECMO u selektované populace CS versus časně konzervativní péče s možností pozdější implantace ECMO
- ECLS-SHOCK = **rutinní** časná ECMO u AMICS versus konzervativní péče umožňující použití jiné MSP
- DANGER SHOCK = **rutinní** časná Impella u STEMI-CS versus konzervativní péče umožňující použití jiné MSP

**„one-size-fits-all approach“**





# Často kladená otázka

**Měli bychom opustit použití VA ECMO u KŠ a začít více používat Impellu CP ?**



# Hlavní limitace ECLS shock

## ECLS-SHOCK (n=417) Limitations

### 1. CS definition.

2. Predominance (**78%**) of patients with about **misdiagnosis** of shock and the death which could not be influenced

3. Use of MCS in standard arm - **28%** interventions (12.5% crossover rate - Impella devices).

4. Involvement of a large number of only 4.7 patients per center/year).

5. Short median duration of ECMO therapy (**2.7 days**).

& Belohlavek, J. (2024). Current Opinion in Critical Care, 10-1097.

- Systolic blood pressure <90 mmHg >30 min or catecholamines required to maintain pressure >90 mmHg during systole
- Signs of impaired organ perfusion with at least **one** of the following criteria
  - (1) Altered mental status
  - (2) Cold, clammy skin and extremities
  - (3) Oliguria with urine output <30 ml/h
- Arterial lactate >3 mmol/l

Amato, M., Piccini, P., Piccini, P., Piccini, P., Piccini, P., Piccini, P., et al. American Heart Journal, 2024.



# Hlavní limitace ECLS shock

## ECLS-SHOCK (n=417) Limitace

1. CS definition.

2. Predominance (**78%**) of patients with **misdiagnosis** of shock leading to death which could not be influenced by ECLS.

3. Use of MCS in standard arm of the trial (12.5% crossover to Impella devices).

4. Involvement of a large number of centers (44) and with low recruitment rate (average of only 4.7 patients per center/year).

5. Short median duration of ECMO therapy (2.7 days).

Rob, D., & Belohlavek, J. (2024). Current Opinion in Critical Care, 10-1097.

Rob, D., et al. (2022). Resuscitation, 175, 133-141.

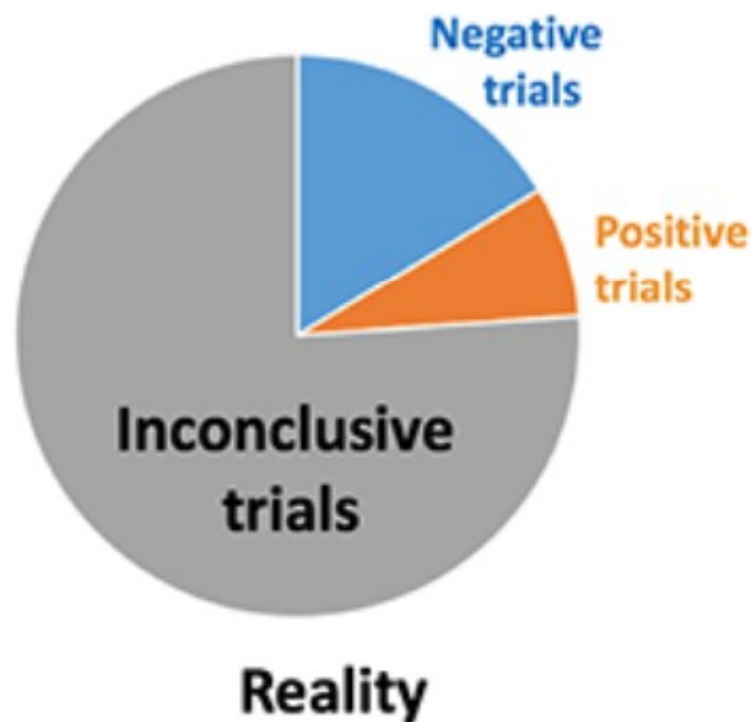
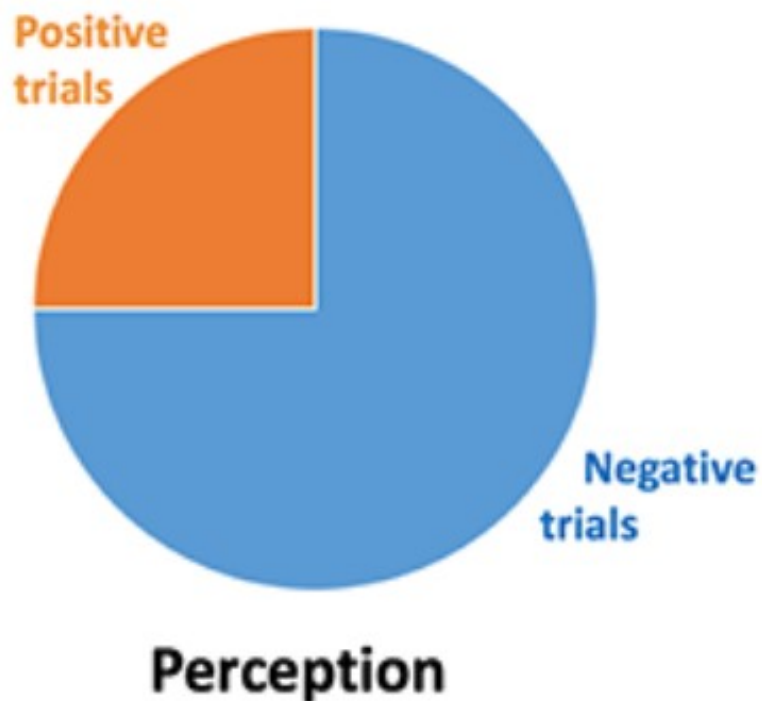
	Overall (n=697)	No prehospital ROSC (n=163)	Prehospital ROSC (n=534)	P value
<b>Hospitalization treatment</b>				
<b>ECLS</b>	119/697 (17%)	112/163 (69%)	<b>7/534 (1%)</b>	<b>&lt;0.001</b>



# Hlavní limitace ECLS shock

## ECLS-SHOCK (n=417) Limitations

1. CS definition
2. Predominant concerns about mortality (average cause of death was primarily ECMO-related)
3. Use of interventions (primarily Impella catheters)
4. Involvement of patients (average only 4.7 patients per center/year)
5. Short median duration of ECMO therapy (2.7 days).





# Hlavní limitace ECLS shock

## ECLS-SHOCK (n=417) Limitations

. CS definition.

. Predominance (**78%**) of patients with cardiac arrest and stable ROSC raising concerns about misdiagnosis of shock and the neurological impairment as the leading cause of

patients receiving ECMO at hospitals with more than 30 adult annual ECMO cases had significantly lower rates of mortality (adjusted odds ratio, 0.61; 95% confidence interval, 0.46–0.80) compared with adults receiving ECMO at hospitals with less than six annual cases.

dependent devices).

. Involvement of a large number of centers (44) and with low recruitment rate (average only 4.7 patients per center/year).

. Short median duration of ECMO therapy (2.7 days).

, D., & Belohlavek, J. (2024). Current Opinion in Critical Care, 10-1097.

Barbaro, Ryan P., et al. *American journal of respiratory and critical care medicine* 191.8 (2015): 894-901.



# Hlavní limitace DanGer shock

## DANGER-shock (n=355)

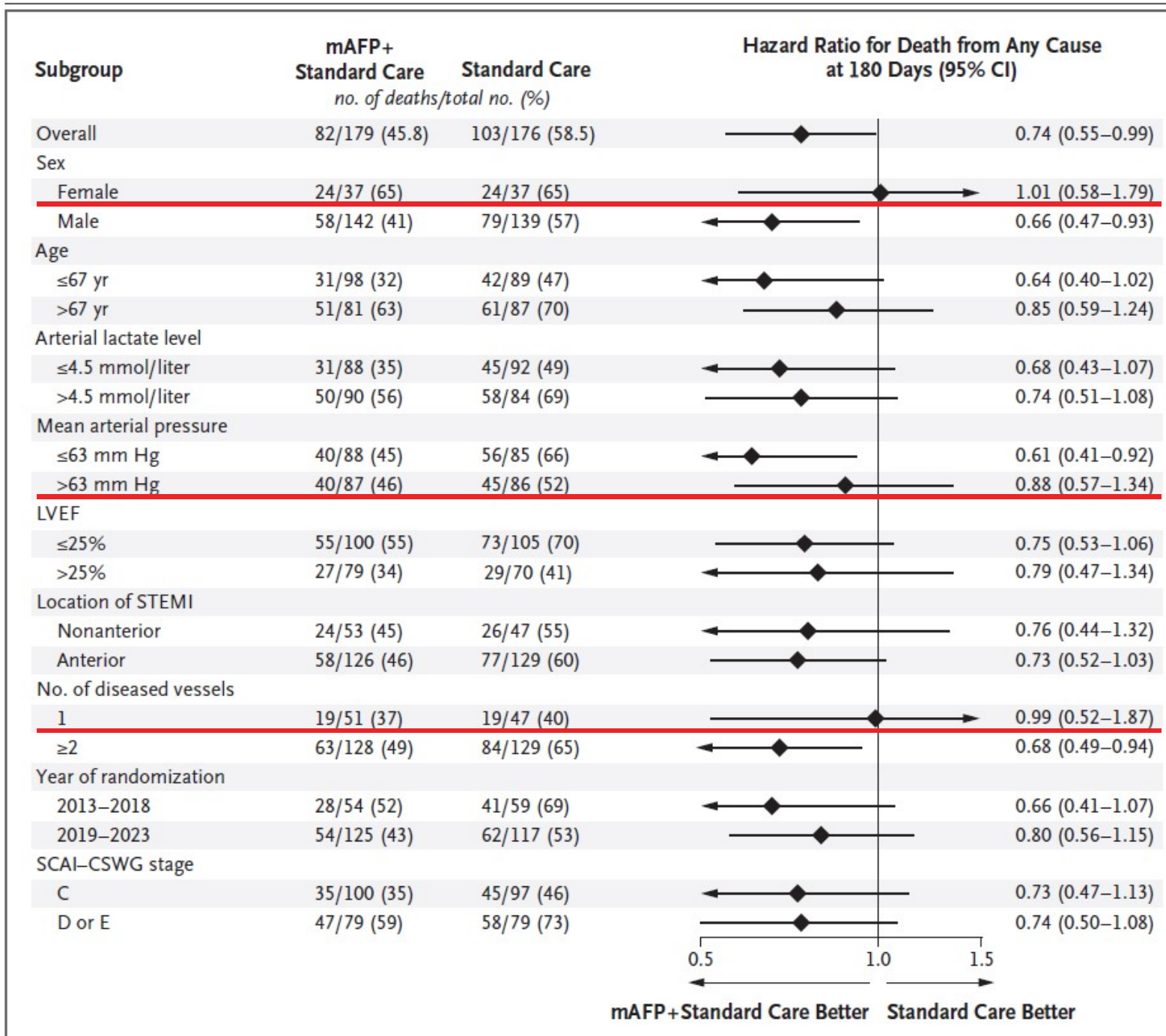
Fragile study results, low **fragility index of 4**, **non-significant 180-day mortality results for the as-treated population**, **no signs of benefit in several predefined subgroups.**

Significant unexplained variability in mortality was observed between centers in Denmark and Germany.

Randomization process spanned over **10 years** and slow recruitment, potentially introducing temporal variations in clinical practices.

The use of MCS (including VA ECMO, Impella CP and Impella 5.5 **>20%** patients), in the control arm may have confounded results.





**Figure 2.** Subgroup Analysis of the Primary End Point.

# Proč jsou studie u šoku tak obtížné?



- Kardiogenní šok je **heterogenní** a **dynamický** syndrom, a proto potřebuje vysoce **individualizovanou** léčbu !
- **Žádná RCT** nedokáže tento fakt postihnout.
- Rutinní použití jakékoli intervence u KŠ nedává smysl.



# Často kladená otázka

**Měli bychom opustit použití VA ECMO u KŠ a začít více používat Impellu CP ?**



# Ne a proč ?

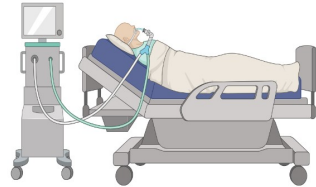
- 1) RCT mají celou řadu důležitých limitací + aplikovatelnost výsledků do klinické praxe je omezená
- 2) Každá MSP má svoje výhody i nevýhody, různé kombinace, eskalace a de-eskalace
- 3) MSP v některých situacích slouží jako záchranná léčba „last treatment option“ a nemají tak náhradu (použití i v kontrolní větvi)

Správná otázka není ANO/NE, ale  
KOMU, KDY, a JAKOU PODPORU ?



# The patient-tailored management of MCS use in CS

1.

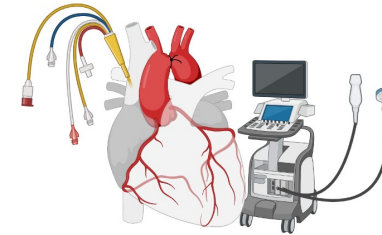


**Patient characteristics**

Age, comorbidities, performance status



LV, RV, valves function  
CO, coronary arteries



Clinical trajectory, recovery chances

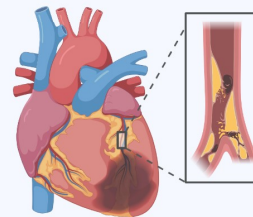


2.

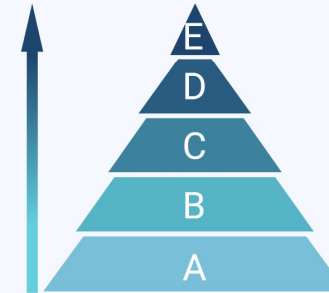


**Cardiogenic shock characteristics**

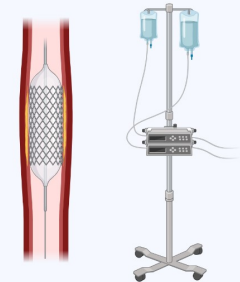
Etiology



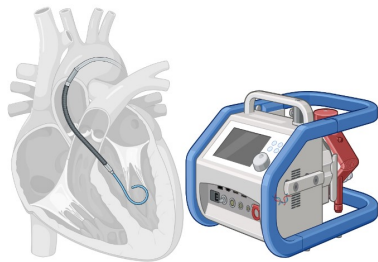
Shock severity, CO, CI



Response to therapies

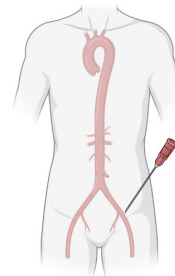


3.

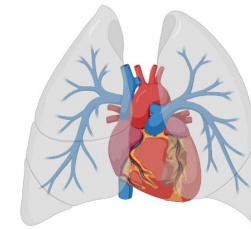


**Device selection and timing**

Vascular access site

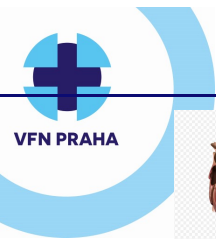


Effect on LV, RV, valves, circulation, lungs

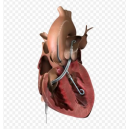


Operator experience, shock teams





# Impella CP



# ECMO

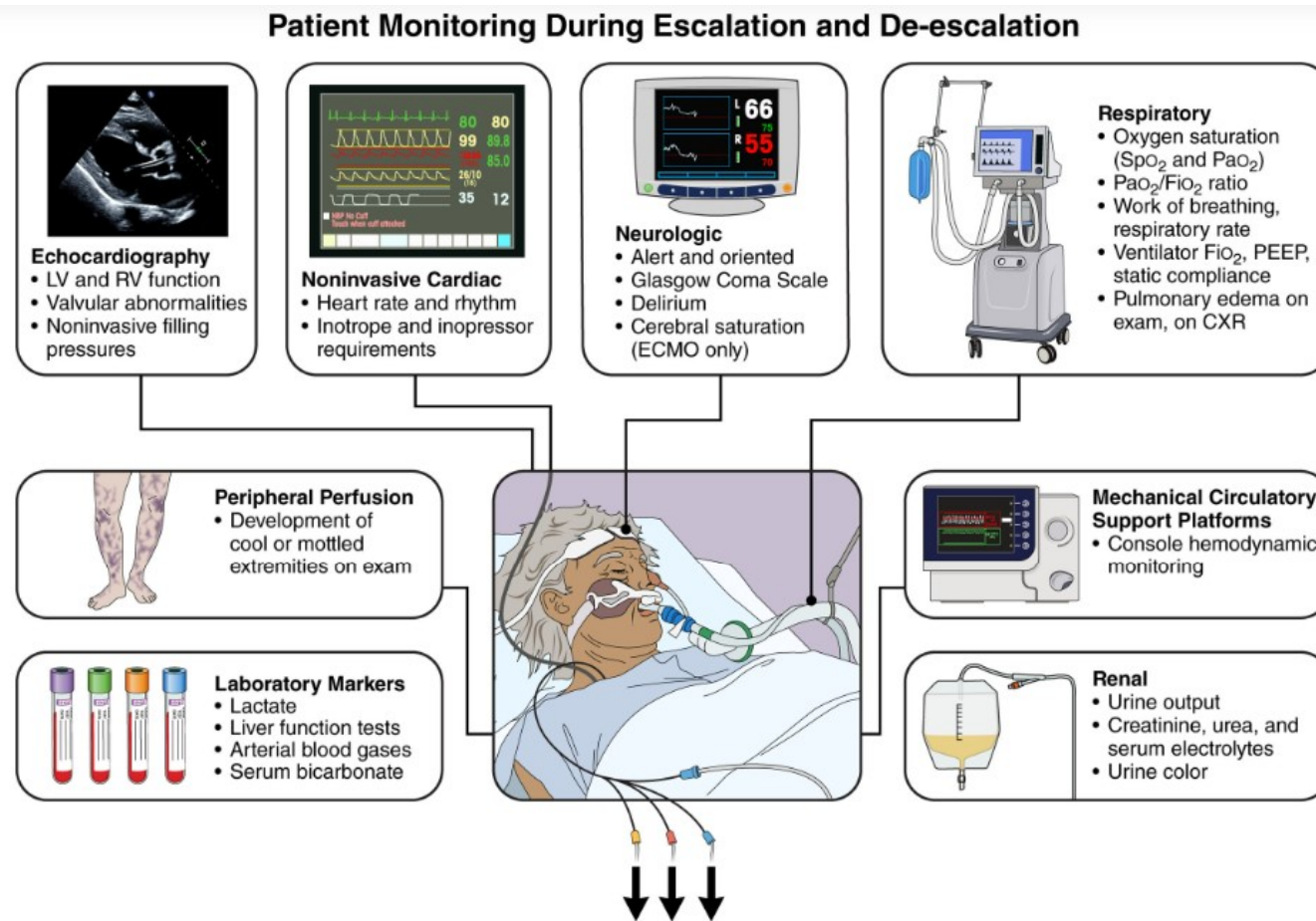


PROS	CONS	PROS	CONS
<b>Active unloading reducing the work</b>	<b>Limited LV support (maximum of 3.8 litres)</b>	<b>Powerful circulatory support (over 5 litres)</b>	<b>Absence of unloading</b>
Small positive RCT in AMICS	<b>Absence of RV support</b>	<b>Right ventricular support</b>	<b>Higher bleeding and vascular risk</b>
Smaller sheath/cannula size	Absence of respiratory support	<b>Respiratory support</b>	Neutral or negative impact
Carbonate infusion for flushing (heparine free)	Absence of distal perfusion cannula	Fast bedside deployment	Larger cannula size
Aortic pressure measurement, CO/CPO (Smart-assist platform)	Risk of hemolysis and kidney injury Fluoroscopy (x-ray) needed for deployment Risk of LV perforation Contraindicated use in mechanical aortic valve and LV thrombus, caution in small ventricles and LVH	Variability of access sites (femoral, jugular for vein, femoral, axillary for arterial)	ECMO associated coagulopathy and thrombocytopenia

# Escalation and deescalation of MCS

Geller, Bram J., et al.

*Circulation* 146.6 (2022): e5



1. Impella CP first → ECMO for circulatory/RV/respiratory support
2. ECMO first → Impella unloading
3. Impella CP/ECMO → Impella 5.5
4. Impella/ECMO/Impella 5.5 → LVAD/Tx program



# Závěr

- **Rutinní použití MSP** u KŠ není správným postupem (absence benefitu u části pacientů, riziko komplikací).
- „STATE OF THE ART“ je u **dobře vybraných** pacientů s dominujícím selháním levé komory **časná** implantace Impella CP a eventuelní eskalace o ECMO u refrakterního šoku v **high-volume** centrech.
- **Potřebujeme nové studie** s jiným designem a velké prospektivní registry, abychom mohli vytvořit léčebné algoritmy jejichž cílem bude „**the right device to the right patient at the right time**“ a **studie zaměřující se na redukci komplikací.**





REVIEW



# Beyond one-size-fits-all in cardiogenic shock: impella, extracorporeal membrane oxygenation or tailored use of mechanical circulatory support?

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*Daniel Rob and Jan Belohlavek*

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**Rob, D., & Belohlavek, J. (2024). Beyond one-size-fits-all in cardiogenic shock: impella, extracorporeal membrane oxygenation or tailored use of mechanical circulatory support?. Current Opinion in Critical Care, 10-1097.**