

Němec P.

# Centrum pro mechanickou náhradu oběhu má být v každém PCI centru - proti



Centrum  
kardiovaskulární  
a transplantační  
chirurgie



**Proč ?**

- Zvládnutí KŠ u pacientů s IM
- Bezpečné provedení rizikové PCI

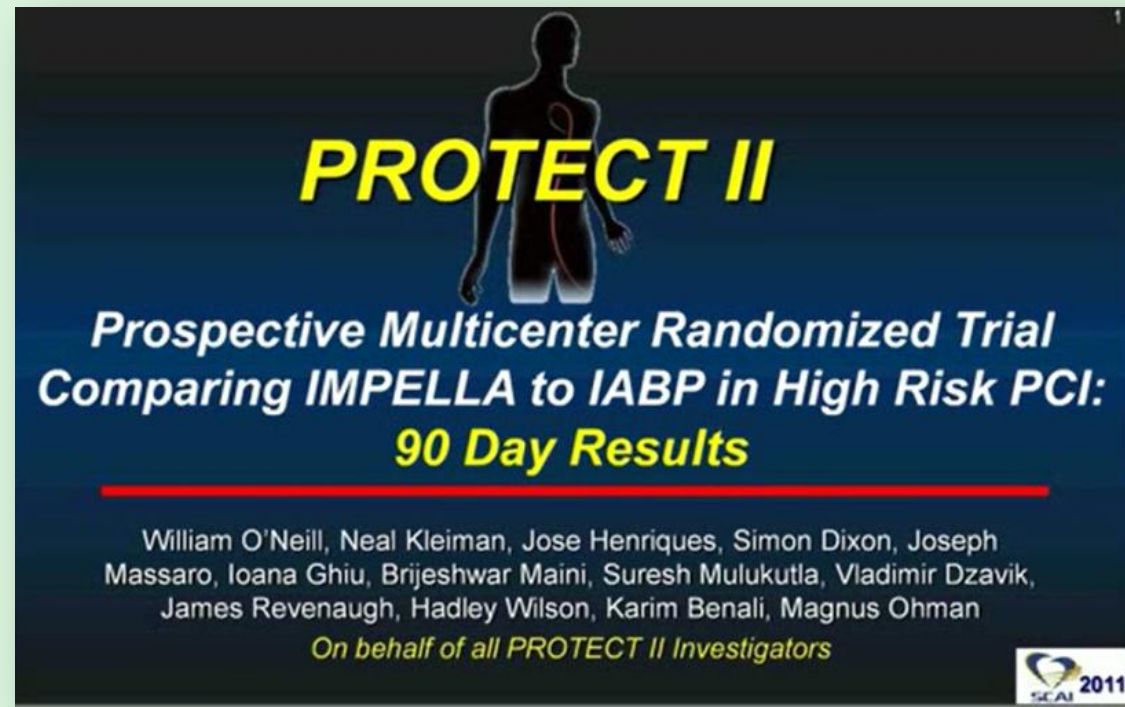
# Současné možnosti podpory oběhu

	Farmakologická	IABK	Tandem-heart	Impella	ECLS/ECMO	LVAD
Výhody						
Průtok (L/min)	< 0,5	0,5	3-5	2,5-5	4-6	4-8
Koronární perf	↑	↑↑	↑↑	↑↑	↑↑	↑↑
LVEDP	↑	↓	↓↓	↓↓	↑↑↑↑	↓↓↓↓
Limitace						
Arytmie	*	-	-	-	-	-
CMP	-	**	*	*	**	***
Ischemie DK	NA	*	**	*	***	NA
Krvácení	NA	**	***	*/**	****	****
Cena	**	***	****	*****	*****	*****

**Impella,  
Tandem-heart**

- Je tento typ podpory účinnější než IABK?

# PROTECT II




**PROTECT II**

*Prospective Multicenter Randomized Trial  
Comparing IMPELLA to IABP in High Risk PCI:  
90 Day Results*

---

William O'Neill, Neal Kleiman, Jose Henriques, Simon Dixon, Joseph Massaro, Ioana Ghiu, Brijeshwar Maini, Suresh Mulukutla, Vladimir Dzavik, James Revenaugh, Hadley Wilson, Karim Benali, Magnus Ohman

*On behalf of all PROTECT II Investigators*

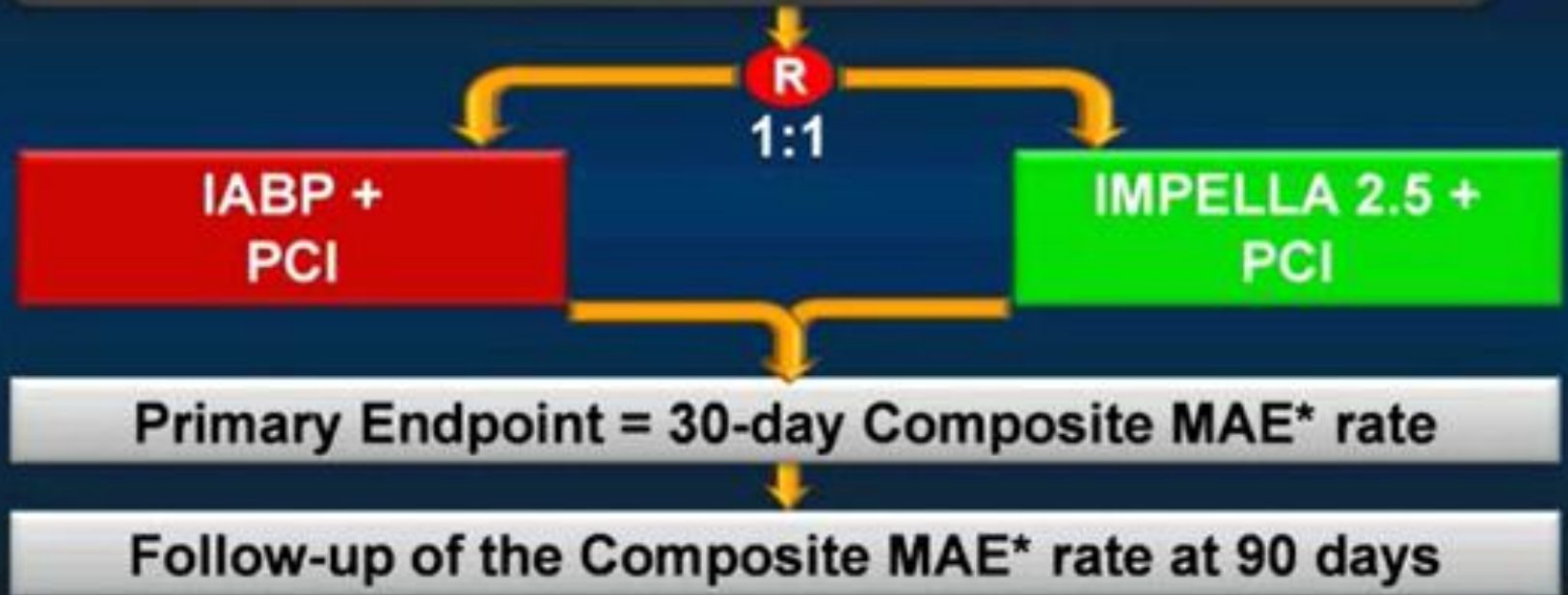


- První prospektivní randomizovaná studie se svolením FDA
- Pacienti vyžadující hemodynamickou podporu během rizikové PCI
- Srovnání IABK a Impella 2,5

# PROTECT II

## PROTECT II Trial Design

Patients Requiring Prophylactic Hemodynamic Support  
During Non-Emergent High Risk PCI on  
Unprotected LM/Last Patent Conduit and LVEF $\leq$ 35% OR  
3 Vessel Disease and LVEF $\leq$ 30%



\*Major Adverse Events (MAE) :

Death, Stroke/TIA, MI (>3xULN CK-MB or Troponin) , Repeat Revasc, Cardiac or Vascular Operation of Vasc. Operation for limb ischemia, Acute Renal Dysfunction, Increase in Aortic insufficiency, Severe Hypotension, CPR/VT, Anglo Failure

## Charakteristika

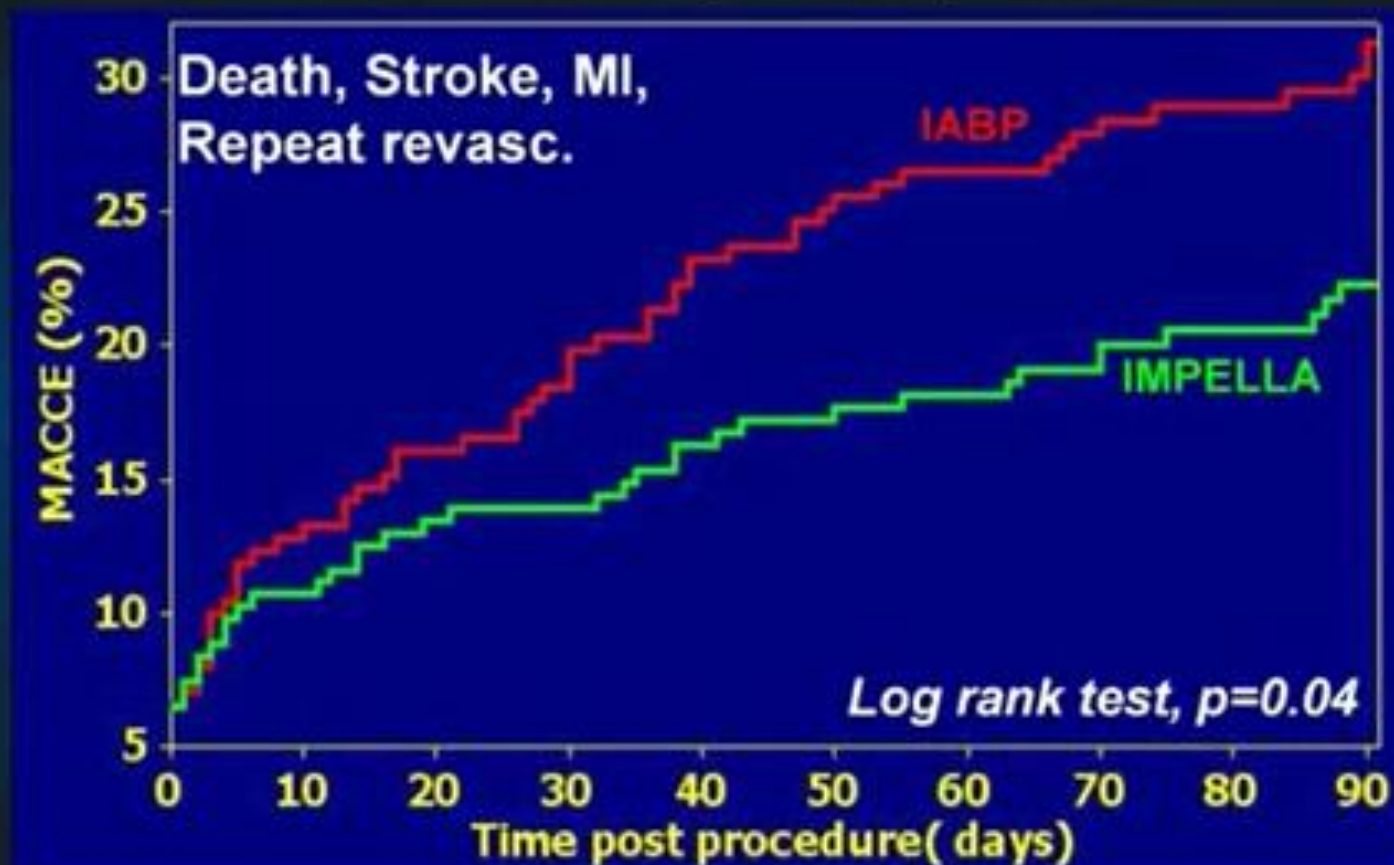
	IABK (223)	Impella (224)	p
IIb/IIIa inhibitory	26,1	13,5	0,001
SVG nebo RA	17,5	25,4	0,41
Doba podpory (h)	8,2	1,9	0,001
Na podpoře po výkonu (%)	37,7	5,7	0,001

# Výsledky



## PROTECT II MACCE\*\*

Per Protocol Population, N=426



using  $\times 8$ ULN threshold for biomarkers or Q-wave for Peri-procedural MI (Stone et al Circulation 2001;104:642-647) and  $2 \times$ ULN threshold for biomarkers for Spontaneous MI (Universal MI definition)



# Výsledky

- Použití Impelly je bezpečné
- Vyšší hemodynamická účinnost
- Klinický profit
- Nižší MACCE

# Impella CP

## Journal of the American College of Cardiology

October 2016>

DOI: 10.1016/j.jacc.2016.10.022

Just Accepted



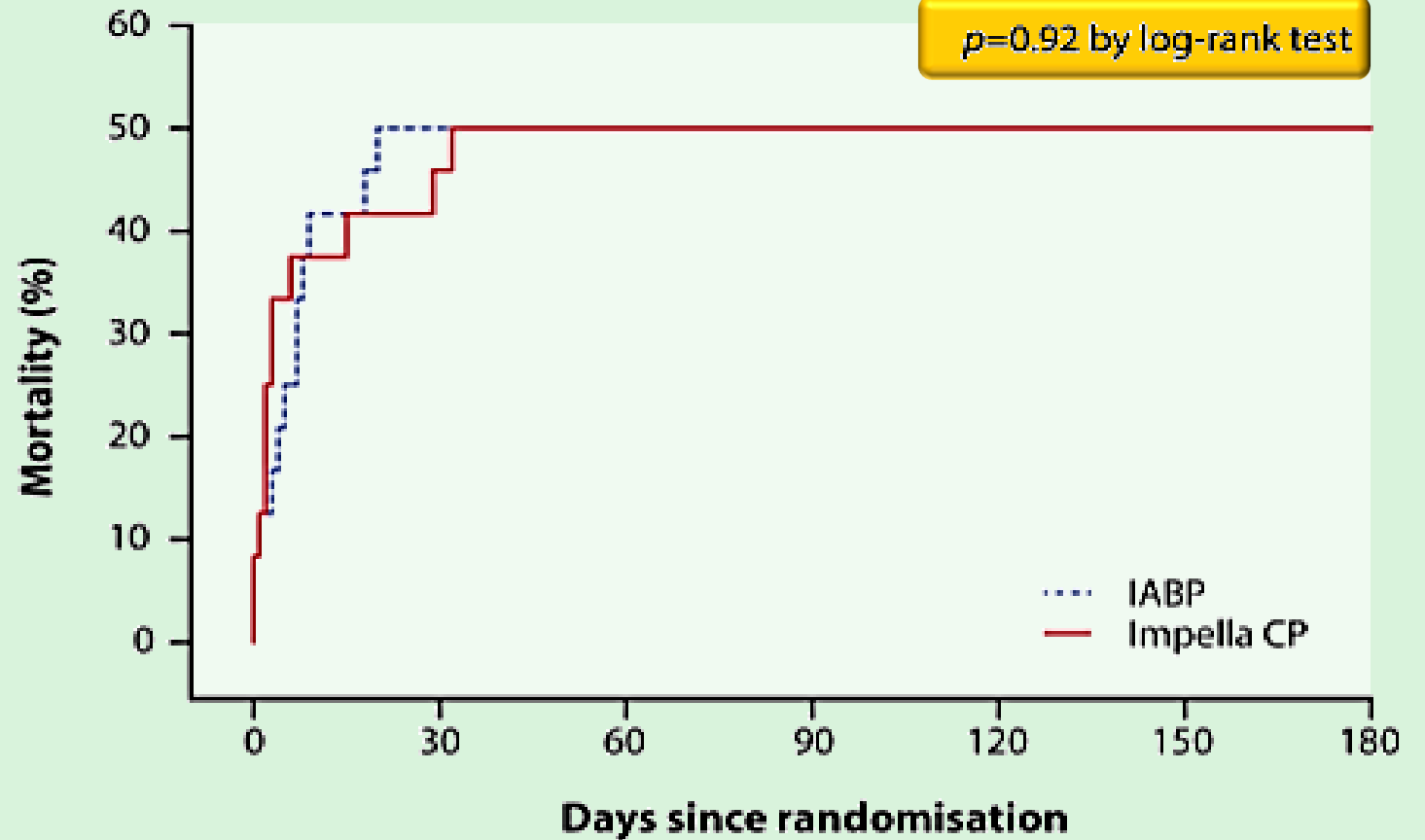
### Impella CP Versus Intra-Aortic Balloon Pump in Acute Myocardial Infarction Complicated by Cardiogenic Shock: The IMPRESS trial

Dagmar M. Ouweneel, Erlend Eriksen, Krischan D. Sjauw, Ivo M. van Dongen, Alexander Hirsch, Erik J.S. Packer, M. Marije Vis, Joanna J. Wykrzykowska, Karel T. Koch, Jan Baan, Robbert J. de Winter, Jan J. Piek, Wim K. Lagrand, Bas A.J.M. de Mol, Jan G.P. Tijssen, José P.S. Henriques

- Multicentrická, prospektivní, randomizovaná studie
- AIM komplikovaný KŠ, všichni na ÚPV
- Porovnání mortality při použití IABK nebo Impella CP
- Trvání podpory IABK 48h, Impella 49h



# Výsledky



Number at risk

IABP	24	12	11	11	11	11	11
Impella CP	24	13	12	12	12	12	12

- **Není rozdíl ve výsledcích**

# Impella

- Použití
  - Riziková PCI
  - Akutní srdeční selhání, KŠ

- Výsledky jsou závislé na:  
správná indikace, včasné nasazení

# ECMO

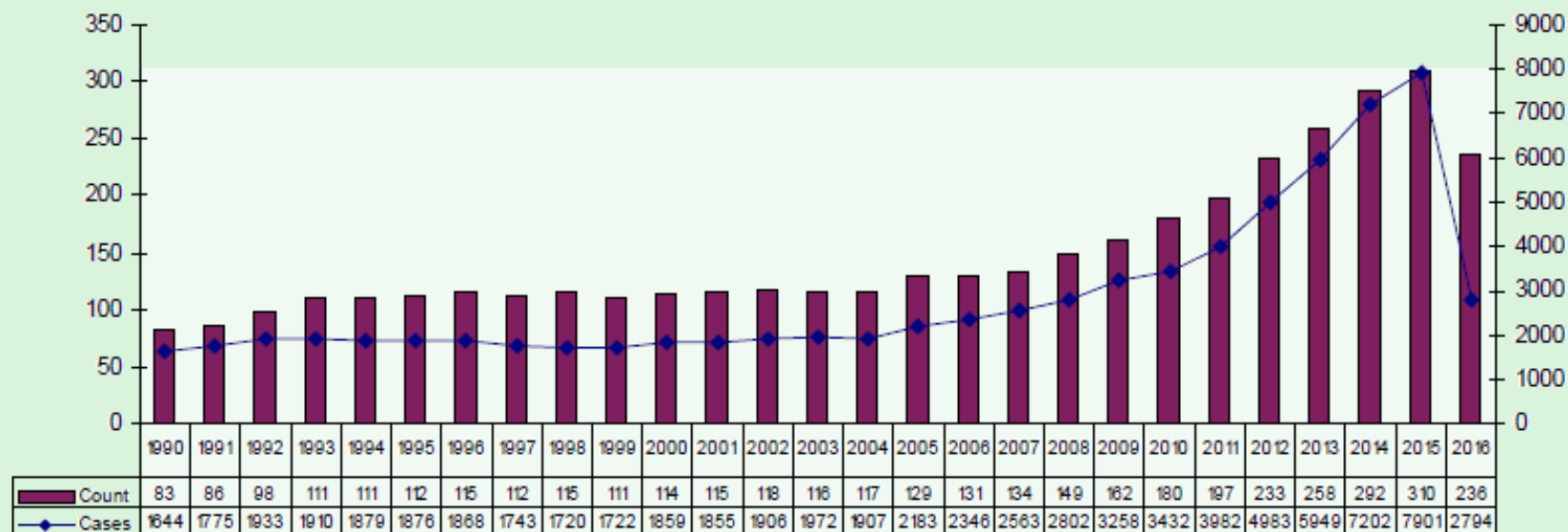
- Složitější technologie
- Oxygenace
- Multioborový tým
- Komplikace

# Výsledky

- registr ELSO

(dospělí)

Selhání	n	Odpojení	Propuštění
Kardiální	9025	56%	41%
Respirační	10601	66%	58%
Po KPR	2885	39%	29%



# Výsledky v-a ECMO

Table. Summary of Recent Studies With Survival to Discharge Results After VA ECMO

Study	Indication	Study Period	Number of Patients	Survival to Discharge (%)	30-day Survival
Bakhtiary et al <sup>30</sup>	Cardiogenic shock	2003-06	45	28.9	47%
Belle et al <sup>31</sup>	Cardiogenic shock; Cardiac arrest	2006-10	51	27.4	NA
Chamogeorgakis et al <sup>32</sup>	Cardiogenic shock	2006-11	61	14.8	36.1%
Formica et al <sup>33</sup>	Cardiogenic shock	2002-09	42	38.1	52.4%
Kim et al <sup>34</sup>	Cardiogenic shock	2006-10	27	59.3	63%
Lamarche et al <sup>35</sup>	Cardiogenic shock	2000-08	32	44	43.8%
Lin et al <sup>36</sup>	Cardiac arrest	2004-06	55	29.1	34.5%
Liu et al <sup>37</sup>	Cardiac arrest	2007-10	10	40	40%
Smedira et al <sup>38</sup>	Cardiogenic shock	1992-99	202	38	24%
Doll et al <sup>39</sup>	Cardiogenic shock	1997-2002	219	24	24%
Beurtheret et al <sup>40</sup>	Cardiogenic shock; Cardiac arrest	2005-09	87	36.8	NA



## American Journal of Respiratory and Critical Care Medicine

### Position Paper for the Organization of Extracorporeal Membrane Oxygenation Programs for Acute Respiratory Failure in Adult Patients

Alain Combes<sup>1</sup>, Daniel Brodie<sup>2</sup>, Robert Bartlett<sup>3</sup>, Laurent Brochard<sup>4</sup>, Roy Brower<sup>5</sup>, Steve Conrad<sup>6</sup>, Daniel De Backer<sup>7</sup>, Eddy Fan<sup>8</sup>, Niall Ferguson<sup>8</sup>, James Fortenberry<sup>9</sup>, John Fraser<sup>10</sup>, Luciano Gattinoni<sup>11</sup>, William Lynch<sup>3</sup>, Graeme MacLaren<sup>12</sup>, Alain Mercat<sup>13</sup>, Thomas Mueller<sup>14</sup>, Mark Ogino<sup>15</sup>, Giles Peek<sup>16</sup>, Vince Pellegrino<sup>17</sup>, Antonio Pesenti<sup>18</sup>, Marco Ranieri<sup>19</sup>, Arthur Slutsky<sup>4</sup>, and Alain Vuylsteke<sup>20</sup>; The International ECMO Network (ECMONet)

+ Author Affiliations





# ECMO centra

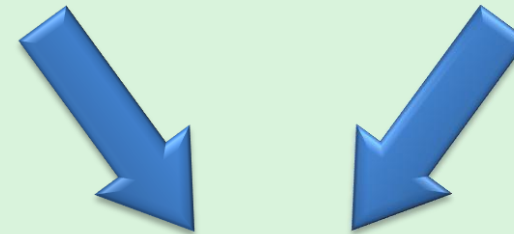
- Lokalizace – nemocnice terciálního typu
- Dostatečná oblast – 6 pts/centrum/rok
- Multidisciplinární ECMO tým (6 členů... specialista na ECMO 24h denně,...)
- Nelékařský personál (JIP, koordinátor,)
- Existence protokolu (indikace, KI, systém péče, údržba přístrojů, ukončení léčby,...)
- Vzdělávací kurz (min. 64h)

# Guidelines



EUROPEAN  
SOCIETY OF  
CARDIOLOGY®

- For ECMO centres
- For training and continuing education of specialists



ČESKÁ  
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SPOLEČNOST





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European Journal of Cardio-thoracic Surgery 40 (2011) 676–681

EUROPEAN JOURNAL OF  
CARDIO-THORACIC  
SURGERY

[www.elsevier.com/locate/ejcts](http://www.elsevier.com/locate/ejcts)

## Guideline

# Position article for the use of extracorporeal life support in adult patients

Andreas Beckmann<sup>a</sup>, Christoph Benk<sup>b</sup>, Friedhelm Beyersdorf<sup>b,\*</sup>, Gerd Haimerl<sup>c</sup>,  
Frank Merkle<sup>d</sup>, Carlos Mestres<sup>e</sup>, John Pepper<sup>f</sup>, Alexander Wahba<sup>g</sup> and  
on behalf of the ECLS Working Group<sup>1</sup>

<sup>a</sup> German Society for Thoracic and Cardiovascular Surgery, Berlin, Germany

<sup>b</sup> Department of Cardiovascular Surgery, University Hospital Freiburg, Hugstetter Str. 55, 79106 Freiburg, Germany

<sup>c</sup> Centre for Applied Simulation, University of Applied Sciences Furtwangen, Villingen-Schwenningen, Germany

<sup>d</sup> German Heart Center Berlin, Berlin, Germany

<sup>e</sup> Department of Cardiovascular Surgery, Hospital Clinico, University of Barcelona, Barcelona, Spain

<sup>f</sup> Royal Brompton Hospital, Department of Surgery, London, UK

<sup>g</sup> St. Elisabeth Department of Cardiac-thoracic Surgery, Trondheim, Norway

Received 24 January 2011; accepted 2 May 2011; Available online 17 June 2011



- Týmová spolupráce
- Lékař má prokázat zkušenost
  - Indikace, KI
  - Kanylace tepen i žil včetně kanylací pro omezení periferní ischemie
  - Řešení cévních komplikací
  - Možnosti dekomprese LK
  - Znalost monitorace parametrů k zabránění ischemie CNS, myokardu ..
- Perfuzionista
  - 100 MTO a/nebo 2 roky praxe



# ECMO centrum - UK, Itálie, Rakousko

- ECMO centrum má být v nemocnici III. typu (populace 2-3 milióny)
- Doporučený objem 20-25 pacientů ročně, ne méně než 10, learning curve 20 pacientů
- Týmová spolupráce – 24h denně
- Standardizované protokoly - lepší výsledky
- Přístrojové vybavení

# Přítomnost specialisty

## Cardiac Intensivists Improve Clinical Outcomes for Patients with Cardiogenic Shock

Association Between Presence of a Cardiac Intensivist and Mortality in an Adult Cardiac Care Unit

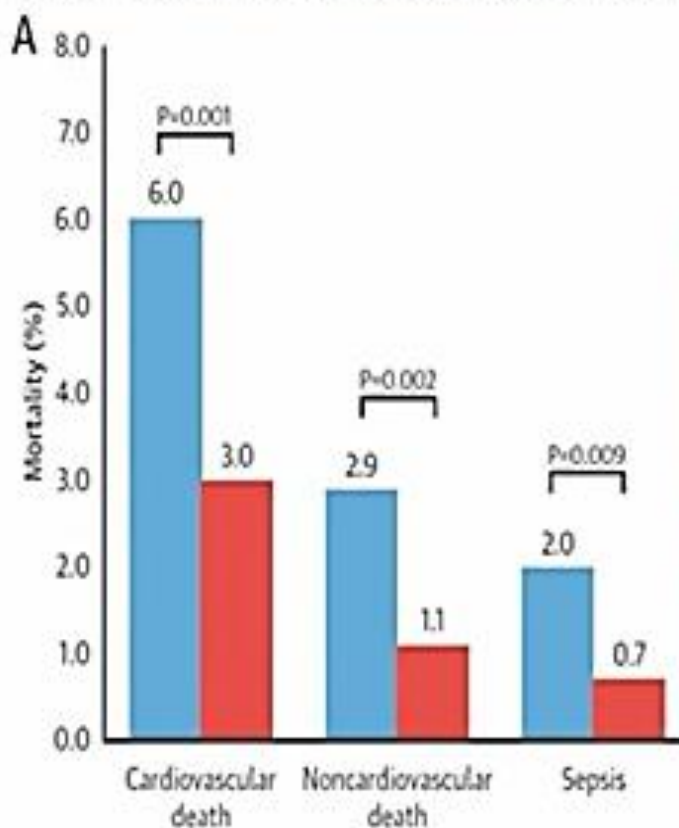


TABLE 2 Treatment Characteristics

	Total Patients			Standardized Difference (%)
	Low-Intensity (n = 616)	High-Intensity (n = 1,815)	p Value	
Inotropes or vasopressors	203 (33.0)	506 (27.9)	0.02	-9.5
Dopamine	117 (19.0)	170 (9.3)	<0.001	-21.5
Nonepinephrine	125 (20.3)	321 (17.7)	0.15	-5.7
Dobutamine	99 (16.1)	248 (13.7)	0.14	-2.2
Vasopressin	25 (4.1)	51 (2.8)	0.12	-3.3
Epinephrine	12 (2.0)	104 (5.7)	<0.001	8.2
Milrinone	4 (0.7)	29 (1.6)	0.08	2.4
Intra-aortic balloon pump	52 (8.4)	53 (2.9)	<0.001	-21.6
Extracorporeal membrane oxygenation	33 (5.4)	102 (5.6)	0.81	0.6
Mechanical ventilation	115 (18.7)	289 (15.9)	0.11	-5.3
Continuous renal replacement therapy	69 (11.2)	116 (7.5)	0.004	-9.5

# Komplikace

- Kanylace
  - Malpozice kanyl (zejména venózní)
  - Disekce tepny
  - Končetinová ischemie (12,5% to 22,6%), compartment sy nebo fasciotomie 10,3%
- Porucha koagulace
  - Krvácení 26,8% to 56,6%, DIC 5%
  - Hemolýza 18%
  - Stáza krve v LK, aortě – tromby
  - Trombóza systému 10%
- Neurologické komplikace (8-50%)

# Komplikace

- Selhání levého srdce, plicní edém
- Renální selhání (35,5% to 74,0%), nutnost RRT (36,7% to 55,5%)
- Infekce 19,5% to 44,0% (25% sepse, 36% pneumonie)
- SIRS (systémová zánětlivá odpověď) – reakce na ne-endotelizovaný cizí povrch systému (vasodilatace, poruchy koagulace, trombocytopenie)



# Další osud pacienta

- Úspěšné odpojení
- Řešení komplikací
- Přejít na jiný typ podpory

# Další osud pacienta

- Úspěšné odpojení
- Řešení komplikací
- Přejít na jiný typ podpory

**Je to v silách každého PCI centra ?**

**Ne**

# Transport

- Transport je rizikový

514 transportů, u 31,4% komplikace (65% patientských – ztráta objemu, 15% personálních – nedostatečná kontrola vybavení, 13% se vztahovalo k vozidlu – energie, místo)  
nikdo neumřel

- Transport je bezpečný

review 1481 pacientů, přežití 68%, 2 úmrtí během transportu



**Důvody  
omezit  
počty  
pracovišť**

≠ Snížit dostupnost a kvalitu péče

= Zabezpečit kvalitní péči, omezit riziko komplikací

# Jak zlepšit kvalitu

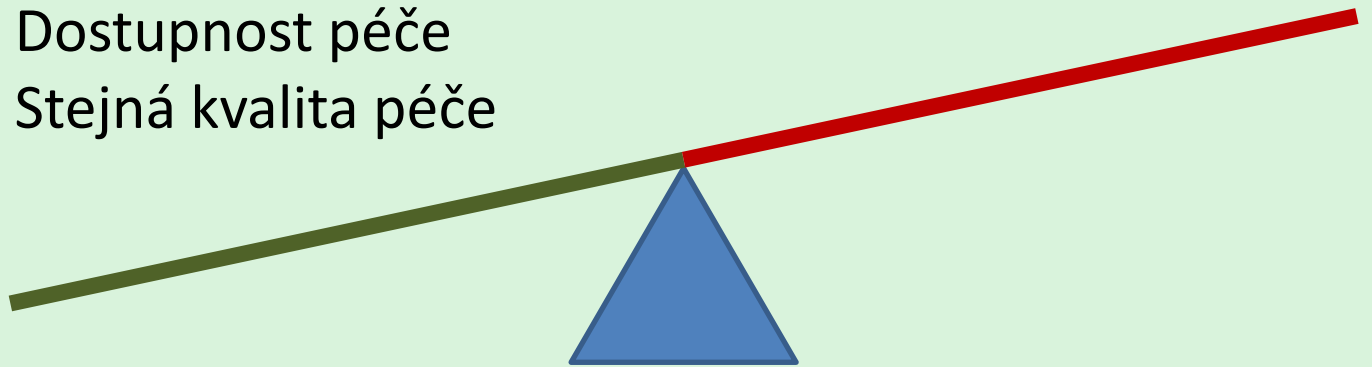
- Zkušenost
  - Týmový přístup
  - Časnější intervence
  - Jasná indikační kritéria
  - Selektce pacientů
- Lepší technologie
  - Biokompatibilita
  - Dekomprese LK
- Perioperační péče
  - Protokol
  - Menší kanyly
  - Kanylace třísel ?
  - Současná IABK

# Důvody

Pro

Proti

Dostupnost péče  
Stejná kvalita péče



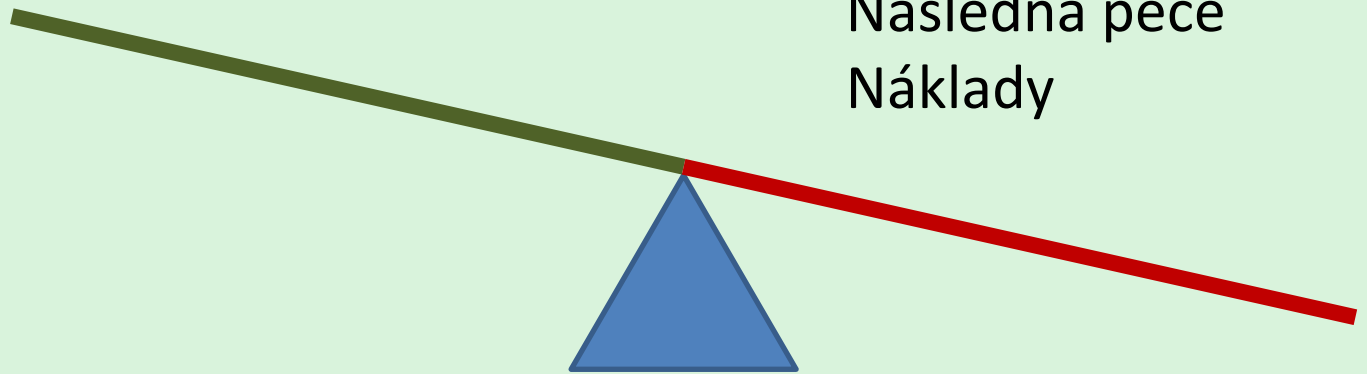
# Důvody

Pro

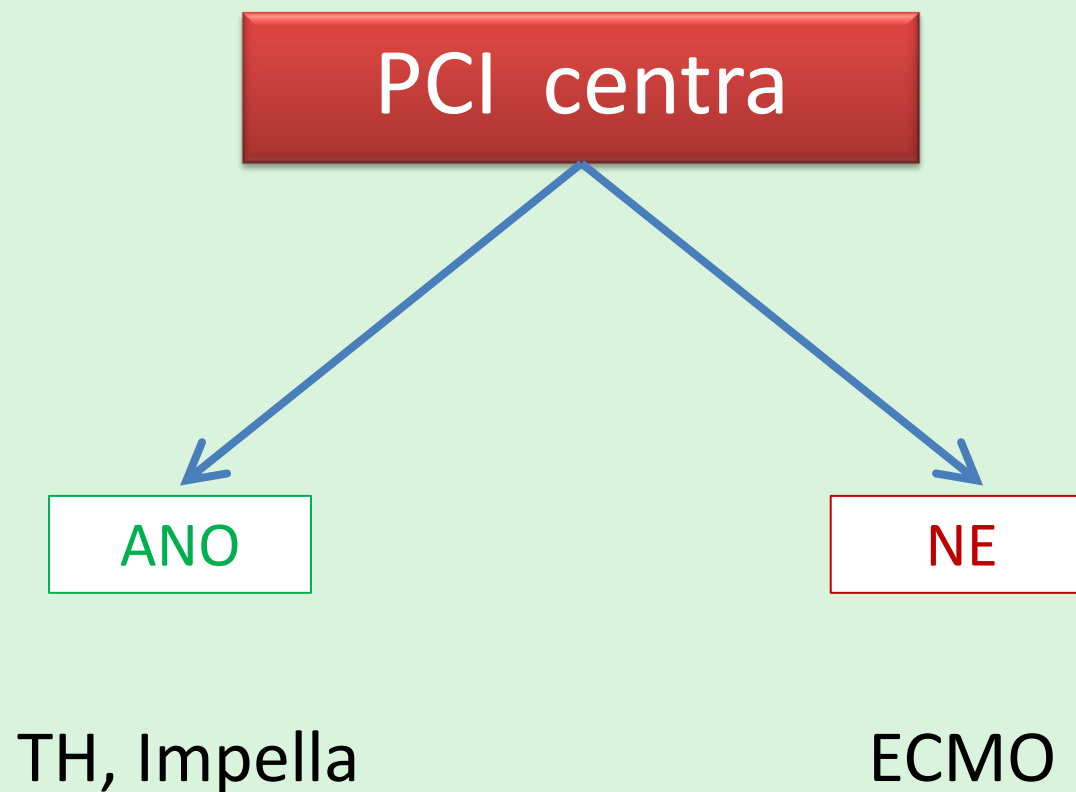
Dostupnost péče  
Stejná kvalita péče

Proti

Multidisciplinární přístup  
Řešení komplikací  
Následná péče  
Náklady



# Závěr





# ECMO - NE

- Multidisciplinární přístup – faktory patient-related, logistické a institucionální (personál, technologie)
- Finančně náročná metoda  
– zdroje je třeba spotřebovat efektivně
- Komplikace – časté a obtížně řešitelné



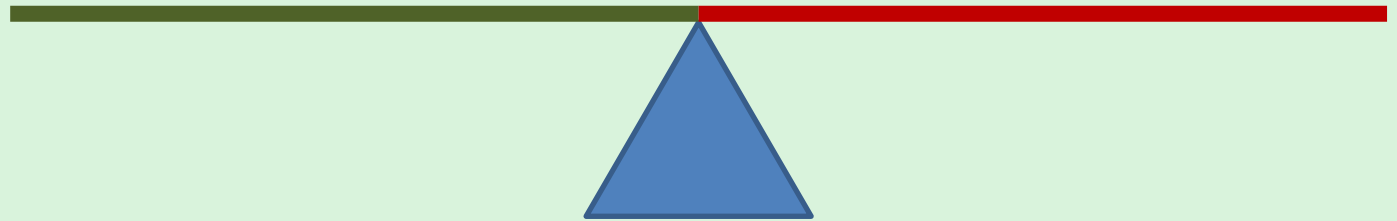
Děkuji za pozornost

# Důvody

Pro

Proti

Dostupnost péče  
Stejná kvalita péče



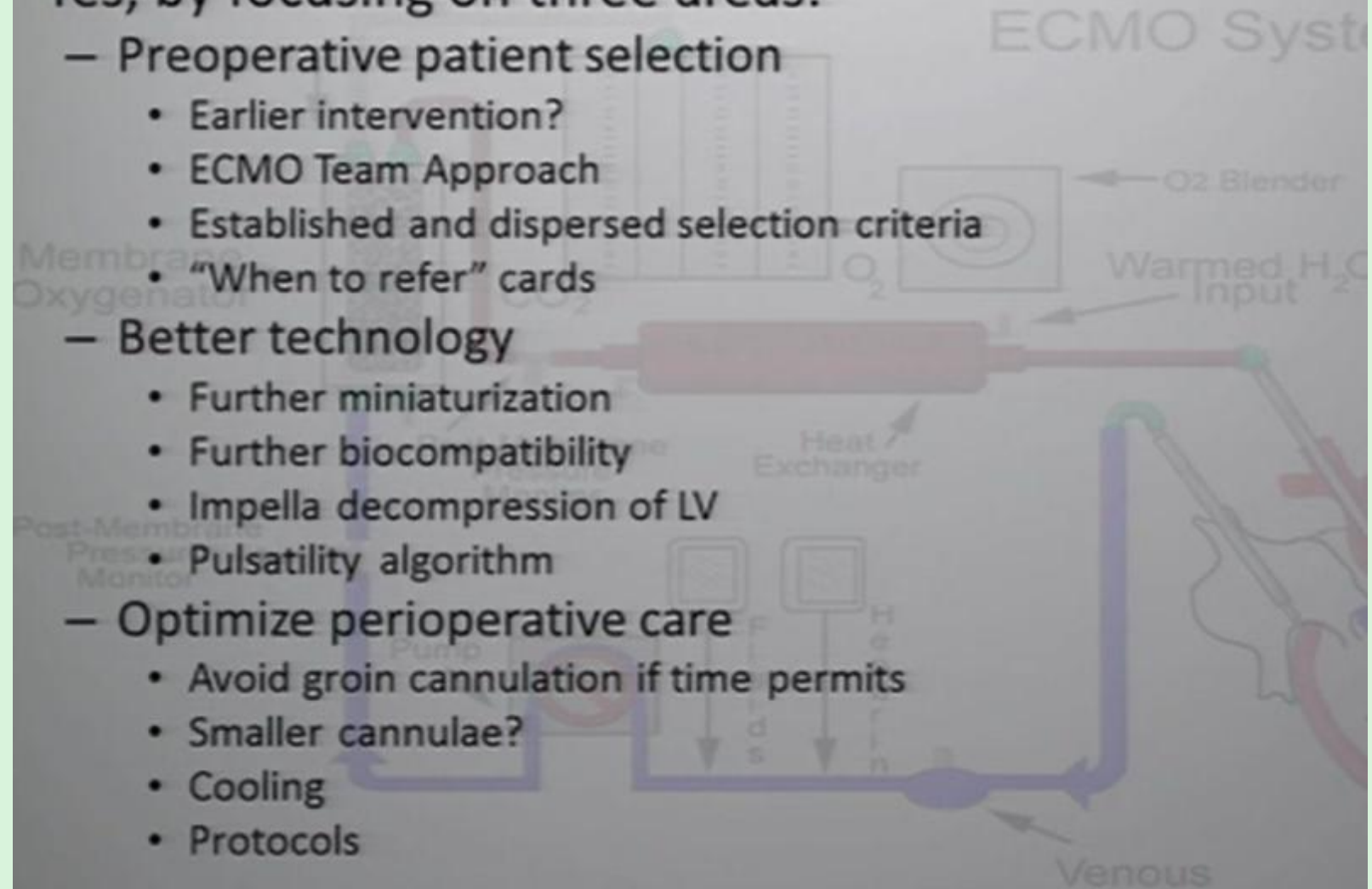
ecmo



# Can We Do Better?

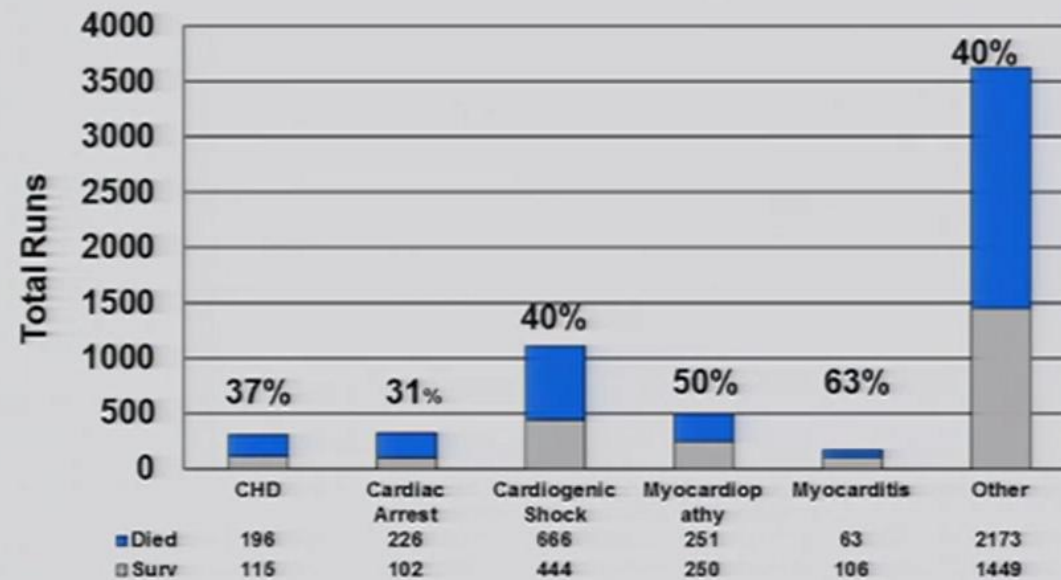
Yes, by focusing on three areas:

- Preoperative patient selection
  - Earlier intervention?
  - ECMO Team Approach
  - Established and dispersed selection criteria
  - “When to refer” cards
- Better technology
  - Further miniaturization
  - Further biocompatibility
  - Impella decompression of LV
  - Pulsatility algorithm
- Optimize perioperative care
  - Avoid groin cannulation if time permits
  - Smaller cannulae?
  - Cooling
  - Protocols



# Registr ELSO

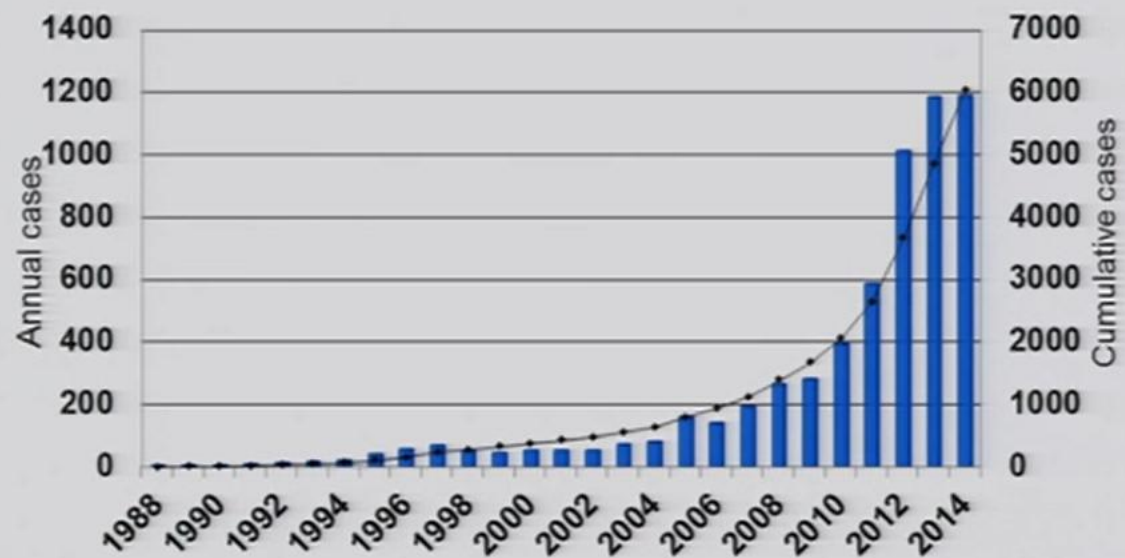
Adult Cardiac Diagnoses and Survival



ELSO Registry January 2015



### Cardiac Cases By Year 16 years old and over



ELSO Registry January 2015



# Rizikové faktory pro ECMO

- Věk

– nad 70 let – přežití 30,5% x 43,1% (pod 70 let)



## ECLS Wash U/BJH

	2013	2014	2015
N	86	86	106
Male %	63	64	66
Survival %	46.5	43	40
ICU stay (d)	22±29	20±37	20±37
Total Hospital stay(d)	42±56	33±46	30±32
ECMO to LVAD(n)	17	12	14
Transfer on ECMO(n)	4	8	14





## ECLS is a resource-intensive treatment

- Hospital Resources
  - ECMO system (\$\$\$\$\$)
  - Cannulas (\$\$\$)
  - ICU
  - Cath lab, OR
  - Transfusion service
- Human Resources
  - Multidisciplinary decision making call team (Cardiology/Pulmonology/Surgery)
  - Operator and assistants
  - Perfusionists
  - Intensivists
  - Consulting service(Vascular, GI, Neuro, ID, Gen sx etc.)
  - Social/financial services
- Next Steps
  - VAD, HTx, Lung Tx
  - Multidisciplinary LVAD/Htx/Lung Tx team



## Indication ECLS

- **Acute Cardiac Failure**
  - Acute coronary syndrome
  - Myocarditis
  - Acute on chronic CHF
  - Post heart transplant graft failure, rejection
  - Post cardiotomy shock
  - Unknown etiology
- **Respiratory shock**
  - ARDS
  - Acute exacerbation of chronic pulmonary disease
  - Pulmonary emboli
- ? Septic shock
- ? Social indication ? (Young, someone's patient, etc.)

## Indication ECLS: Clinical condition

- Circulatory failure ( $CI < 2.2$ )
- Increasing inotropic/vasopressor support
  - Epi 0.2mcg/kg/min, Norepi 0.2 mcg/kg/min, Vasopressin, Dobutamin 10 mcg/kg/min etc
- Severe acidosis/ elevated lactate)
- Other organ damage(elevated Liver enzymes, creatinine)
- Worsening ventilator setup, prone, bilevel,  $PaO_2/FIO_2$  ratio  $< 100..$
- (Unable to come off CPB)
- Pt is on temporary devices and failing (pVAD, IABP)

## (Relative) Contra-indication ECLS

- Age >80
- Unwitnessed cardiopulmonary arrest, possibly anoxic brain injury
- Chest compressions not initiated within 10 min of arrest
- Asystole
- CPR >60 min
- Hemorrhagic shock
  
- Pre-existing medical conditions:
  - Ischemic/hemorrhagic Stroke
  - COPD severe
  - ESLD
  - ESRD
  - Severe PVD
  - Malignancy with poor prognosis
  - Hypercoagulable state/coagulopathy
  
- Relative C-I (Poor socioeconomic situation)
  - No insurance will leave a huge financial burden to the patient/family and no options of Advanced MCSD
  - MO Medicaid does not support LVAD unless heart transplant eligible
  - No family support



- ***“GO” for ECMO or PVAD (Impella) if your patient condition is***

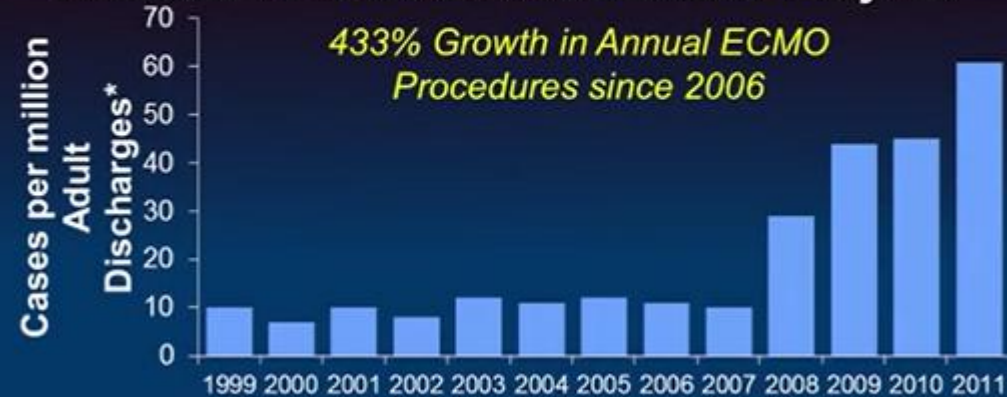
***1) Recoverable***

***or***

***2) Possibly bridged to LVAD/HTx or Lung Tx?***



## Nationwide Inpatient Sample from Healthcare Cost and Utilization Project



Sauer CM, Yuh DD, Bonde P. ASAIO DOI: 10.1097/MAT.0000000000000160  
 \* Data from NIS from HealthCare cost and Utilization Project (HCUP)

## FDA Opinion Similar to Literature

- The literature analysis, the 2 meta-analyses, and this FDA opinion come to similar conclusions

### Summary: ECMO for PCS

- High Mortality
- Consistent results over time (1992-2000 vs. 2005-2010)
  - Successful wean or BTT or transition to VAD
    - + 57% vs. 55%
  - Survival to discharge
    - + 35% vs. 33%
- Survival unaffected by advances/differences in currently available circuit component combinations
- Exponential increase in complications with time
  - Early forced wean or transition to durable VAD

- "Survival unaffected by advances/differences in currently available circuit component combinations."
- "Exponential increase in complications with time; early forced wean or transition to durable VAD."

- Dr. John Laschinger, FDA 515 Panel, 2014





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European Journal of Cardio-thoracic Surgery 40 (2011) 676–681

EUROPEAN JOURNAL OF  
CARDIO-THORACIC  
SURGERY

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## Guideline

# Position article for the use of extracorporeal life support in adult patients

Andreas Beckmann<sup>a</sup>, Christoph Benk<sup>b</sup>, Friedhelm Beyersdorf<sup>b,\*</sup>, Gerd Haimerl<sup>c</sup>,  
Frank Merkle<sup>d</sup>, Carlos Mestres<sup>e</sup>, John Pepper<sup>f</sup>, Alexander Wahba<sup>g</sup> and  
on behalf of the ECLS Working Group<sup>1</sup>

<sup>a</sup> German Society for Thoracic and Cardiovascular Surgery

### 3.1. Indications

ECLS is an advanced medical treatment option that requires medical expertise and puts substantial pressure on hospital resources [5]. The decision to institute ECLS should be based on a team approach where a physician/surgeon with experience in the field of extracorporeal circulatory assistance and a team member.

In the field of ECLS, there should be minimum requirements in education and experience to run an extracorporeal circulation system. The ECLS systems should be applied as teamwork between physicians who have the medical responsibility (including the ability to cannulate the patient, set up all necessary monitoring systems, and the ability to cope with all potential complications immediately) and perfusionists who have the responsibility for the extracorporeal circulation. The use of ECLS systems should be limited to these occupational groups.

ECLS systems need specific medical and technical knowledge in extracorporeal circulation (ECC). There are different previous experiences in 'cardiovascular engineering' for physicians and even for perfusionists. However, it is agreed upon that physicians operating an ECLS system have to have proven experience in (a) indications and contraindications, (b) cannulation of various arterial and venous vessels for immediate start of the ECLS, (c) handling vascular complications secondary to cannulation procedures, (d) techniques avoiding peripheral ischemia after cannulation, (e) various methods to decompress the right and left ventricle, and (f) all monitoring parameters to avoid severe complications such as cerebral hypoxia, myocardial damage, etc.

Perfusionists have to have experience in more than 100 ECC perfusions and more than 2 years of practical experience in perfusion during cardiac surgery procedures.





## ELSO GUIDELINES FOR TRAINING AND CONTINUING EDUCATION OF ECMO SPECIALISTS

64-140 hodin

Adult					
Respiratory	10,601	6,997	66%	6,121	58%
Cardiac	9,025	5,082	56%	3,721	41%
ECPR	2,885	1,137	39%	848	29%
<b>Total</b>	<b>78,397</b>	<b>54,866</b>	<b>70%</b>	<b>45,345</b>	<b>58%</b>





## Current Pharmacology & Devices

	Inotropic	IABP	Tandem-Heart	pVAD (Impella)	ECLS (C-mag)	LVAD (HM2/HVAD)
<b>Advantages</b>						
Flow (L/min.)	<0.5	0.5	3.5	2.5 - 5.0	4-6	4-8
Coronary Perfusion	↑	↑↑	↑↑	↑↑	↑↑	↑↑
LVEDP	↑	↓	↓↓	↓↓	↑↑↑↑	↓↓↓↓
<b>Limitations</b>						
Arrhythmia	+++	-	-	-	-	-
Stroke	-	++	+	+	++	+++
Limb ischemia	N.A	+	++	+	+++	N.A
Bleeding	N.A	++	+++	+ / ++	++++	++++
Cost	\$\$	\$\$\$	\$\$\$\$	\$\$\$\$\$	\$\$\$\$\$	\$\$\$\$\$

# PROTECT II Study Flow



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Assessed for  
Eligibility  
N=1082

Not Eligible: N=635  
47.8% Met Exclusion criteria  
30% Patient refusal, MD decision  
13% Unknown  
9.2% Referred for CABG

Randomized  
Intent-to-Treat  
N=447

Intent-To-Treat (ITT)  
population  
(N=447)

IABP  
N= 223  
90day F/U, N=220

IMPELLA  
N= 224  
90day F/U, N=222

2 withdrew consent post PCI (alive)  
3 EF >=35%  
3 Not 3VD or ULM  
1 Active MI  
2 Severe PVD or AS  
1 Platelets < 70000

(N=12)

1 withdrew consent post PCI (alive)  
1 EF >=35%  
1 Not 3VD or ULM  
3 Active MI  
1 Severe PVD  
1 Platelets < 70000  
1 Creatinine > 4

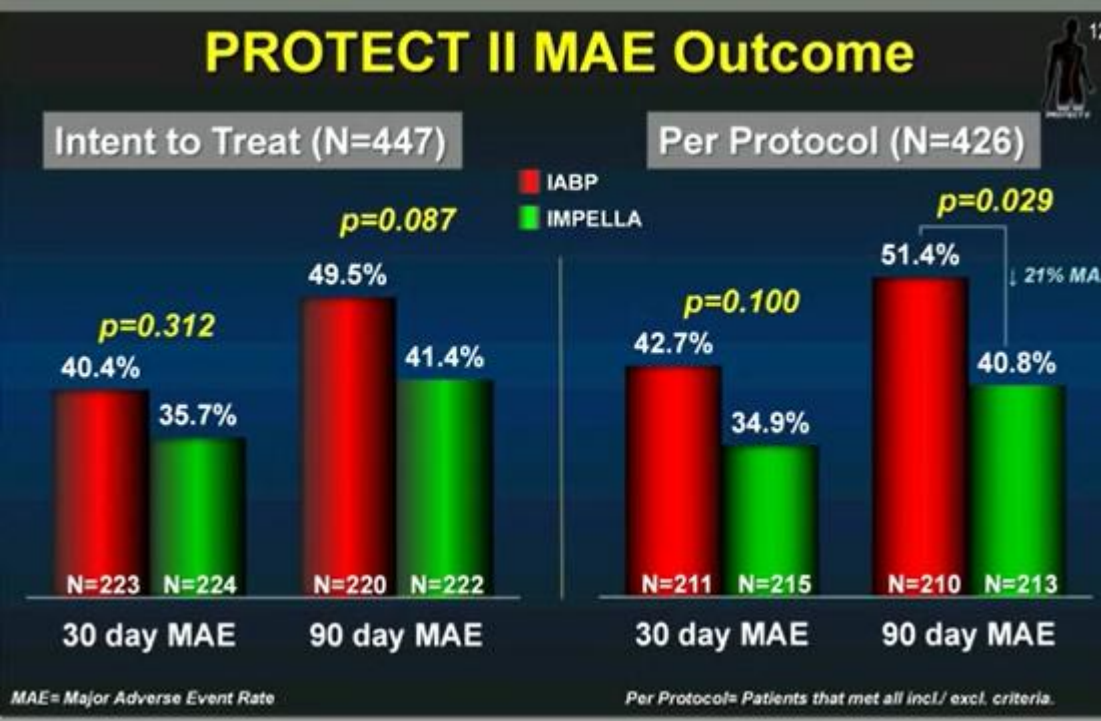
(N=9)

Per Protocol population= Patients that met all inclusion and exclusion criteria.

Per Protocol population was pre-specified and patients were identified prospectively prior to the statistical analysis.



# PROTECT II MAE Outcome



## Conclusion



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- The use of Impella for hemodynamic support during high risk PCI is safe.
- The superior hemodynamic support of Impella appears to have led to significant procedural differences between the two arms.
- Impella arm had strong trends towards superior clinical outcomes for the entire intent-to-treat population with a significant reduction of the MAE rate in the pre-specified per protocol population at 90 day follow-up.
- The clinical benefit was more pronounced for patients undergoing high risk PCI without atherectomy with the Impella support.
- There was a strong trend for lower MACCE rate for the entire intent-to-treat population with a significant reduction of the MACCE rate in the pre-specified per protocol population at 90 day follow-up when a more clinically relevant threshold of CK-MB release for peri-procedural MI\*\* is considered.

\*\*Using x8ULN for biomarkers or Q-wave for Peri-procedural MI (Stone et al Circulation 2001;104:642-647) and 2xULN for Spontaneous MI (Universal MI definition)

**30 day MAE      90 day MAE**

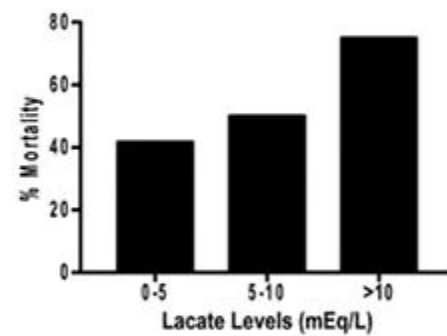
Per Protocol= Patients that met all incl/ excl. criteria.



## Mortality vs Number of Vasopressors/inotropes Pre-Device Implant Among the Total Cohort

— One-way ANOVA  $p=0.02$  —

— One-way ANOVA  $p=0.08$  —



Early and Effective Device Support is Critical for Survival

Esposito and Kapur et al. TCT 2016



# PROTECT II



## Prospective Multicenter Randomized Trial Comparing IMPELLA to IABP in High Risk PCI: 90 Day Results

William O'Neill, Neal Kleiman, Jose Henriques, Simon Dixon, Joseph Massaro, Ioana Ghiu, Brijeshwar Maini, Suresh Mulukutla, Vladimir Dzavik, James Revenaugh, Hadley Wilson, Karim Benali, Magnus Ohman  
On behalf of all PROTECT II Investigators



## Background

- Patients with depressed LV function and complex anatomy have limited treatment options
- Prophylactic IABP in high risk PCI patients associated with increased mortality
- Impella provides superior hemodynamic support
- PROTECT II is the first randomized trial comparing outcomes for patients requiring mechanical support during PCI

## Procedural Differences

Procedural Characteristics	IABP (N=223)	Impella (N=224)	p-value
Use of Heparin	82.4%	93.5%	<0.001
IIb/IIIa Inhibitors	26.1%	13.5%	0.001
Total Contrast Media (cc)	241±114	267±142	0.037
Rotational Atherectomy (RA)	9.5%	14.9%	0.088
Median # of RA Passes/lesion (IQR range)	1 (1-2)	3 (2-5)	0.001
Median # of RA passes/pt (IQR range)	2.0 (2.0-4.0)	5.0 (3.5-8.5)	0.004
Median RA time/lesion (IQR range sec)	40 (20-47)	60 (40-97)	0.005
RA of Left Main Artery	3.1%	8.0%	0.024
% of SVG Treatment or RA use	17.5%	25.4%	0.041
Total Support Time (hour)	8.2±21.1	1.9±2.7	<0.001
Discharge from CathLab on device	37.7%	5.7%	<0.001

<sup>1</sup> Health Research International 2009 report

