„Top news“ intervenční kardiologie

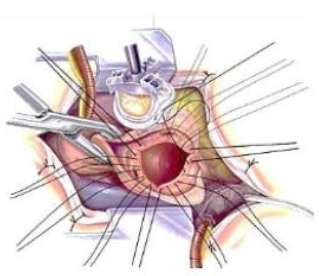
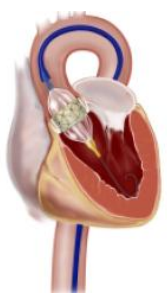
chlopenní vady
ICHS
kardiogenní šok

Michael Želízko

IK+E M

TAVI vs SAVR: „low-risk“ indikace

NOTION trial – 10 let follow-up


NOTION trial *(Nordic Aortic Valve Intervention Trial)* follow-up 10 let

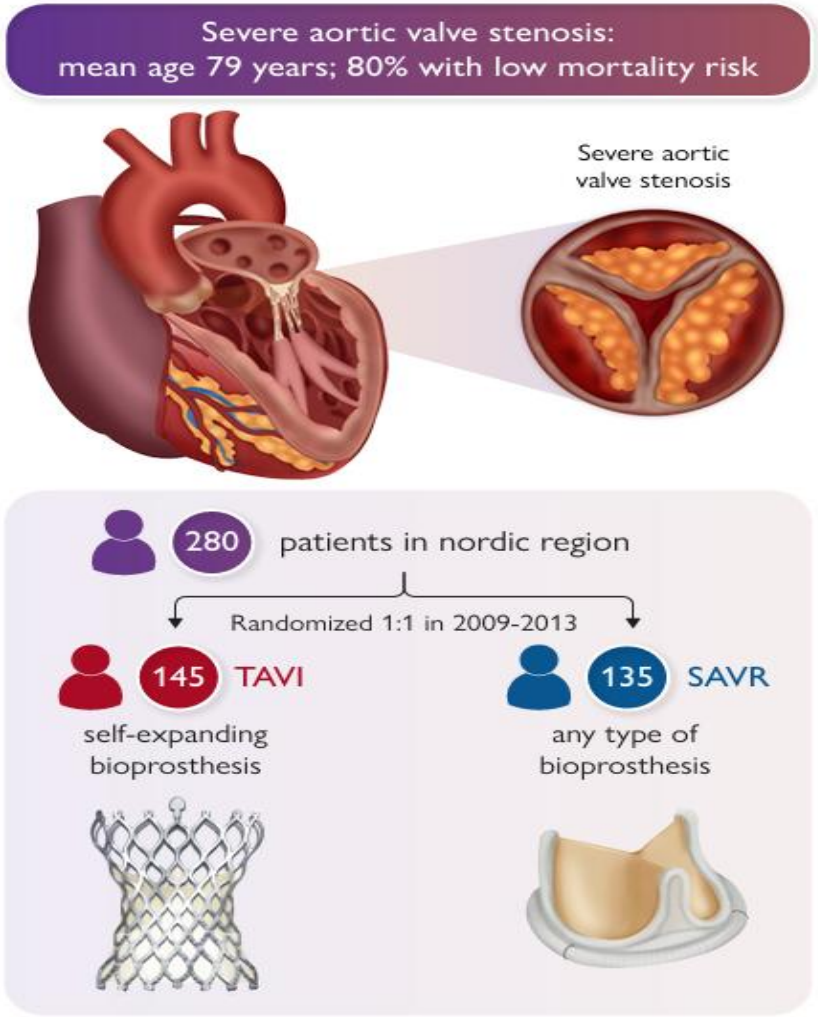
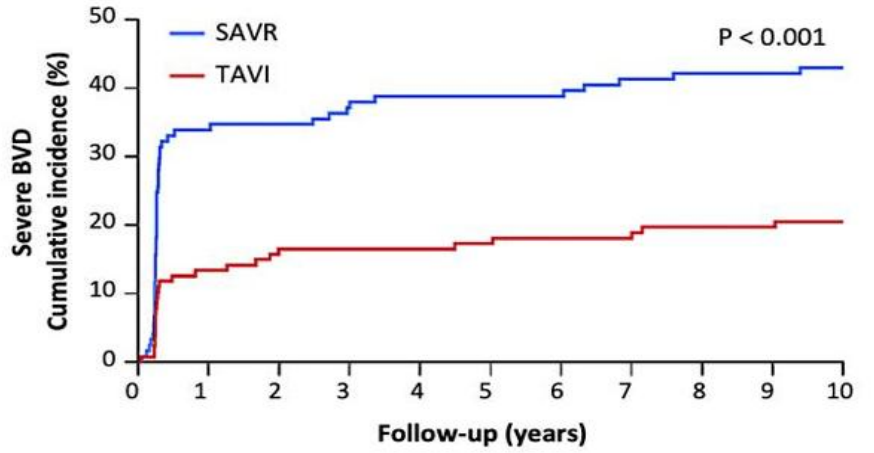


Table 1 Adverse outcomes

	TAVI ($n = 145$)	SAVR ($n = 135$)	*P*-value
All-cause mortality	62.7	64.0	.8
Cardiovascular death	49.5	51.2	.7
Stroke[a]	9.7	16.4	.1
Stroke with sequelae	6.9	10.4	.3
Transient ischaemic attack	9.7	6.7	.3
Myocardial Infarction	11.0	8.2	.4
New-onset atrial fibrillation	52.0	74.1	<.01
New permanent pacemaker	44.7	14.0	<.01

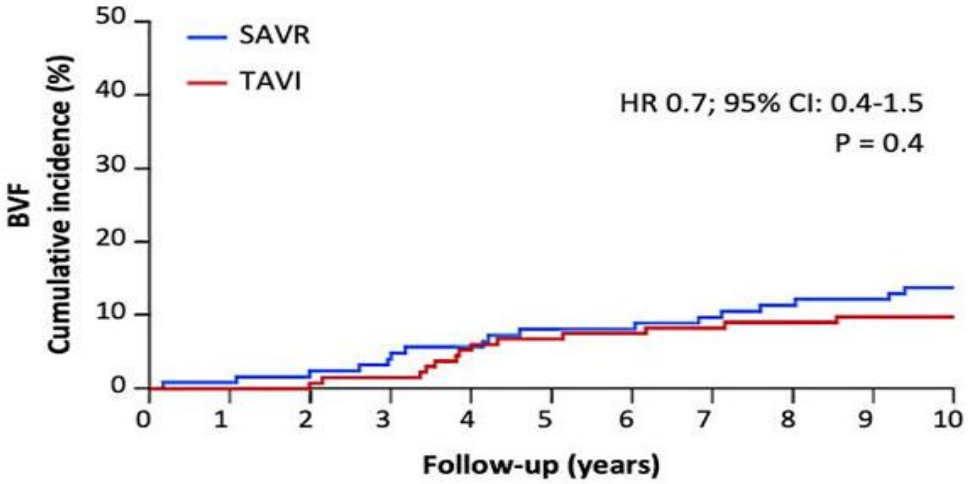
Dysfunkce (BVD) a selhání (BVF) bioprotézy



Patients at risk

TAVI	127	108	102	95	91	79	69	62	53	46	40
SAVR	121	80	79	74	68	65	58	50	42	37	33

	TAVI	SAVR	p value
Severe BVD	**20.5%**	**43.0%**	**<0.001**
Severe SVD	1.5%	10.0%	0.004
Severe non-SVD	12.6%	31.9%	<0.001
Severe paravalvular leak	2.6%	0	0.08
Severe patient-prosthesis mismatch	10.2%	31.9%	<0.001
Clinical valve thrombosis	0	0	-
Endocarditis	7.2%	7.4%	0.95



Patients at risk

TAVI	134	132	128	118	109	96	82	73	63	54	47
SAVR	124	123	120	111	102	93	81	72	60	52	44

	TAVI	SAVR	p value
BVF	**9.7%**	**13.8%**	**0.3**
Valve-related death	5.0%	3.7%	0.6
Severe SVD	1.5%	10.0%	0.004
Aortic valve re-intervention	4.3%	2.2%	0.3

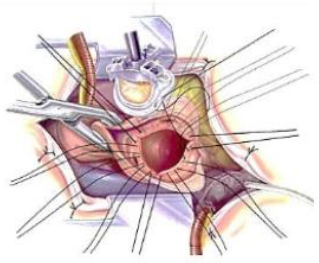
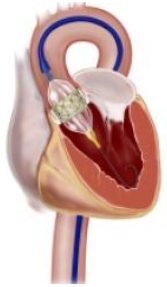
NOTION Trial - závěry

- **Žádný rozdíl mezi TAVI a SAVR po 10 letech v mortalitě, CMP či IM**
- Více implantací PM ve skupině TAVI (45% vs 14%)
  - bez vlivu na mortalitu
- Vyšší výskyt fibrilace síní ve skupině SAVR (74% vs 52%)
  - bez vlivu na výskyt CMP
- Stejný klinický efekt TAVI vs SAVR (NYHA I-II po 10 letech 84% vs 81%)
- Větší EOA, nižší AVG, … více PVL (2,6%) ve skupině TAVI
- Méně častá strukturální dysfunkce či selhání chlopně ve skupině TAVI vs SAVR
  - 9,7% vs 13,8% TAVI vs SAVR
- Vysoký výskyt PPM ve skupině SAVR (32%)
- Překvapivě vysoký počet endokarditid v obou skupinách (7,4%)

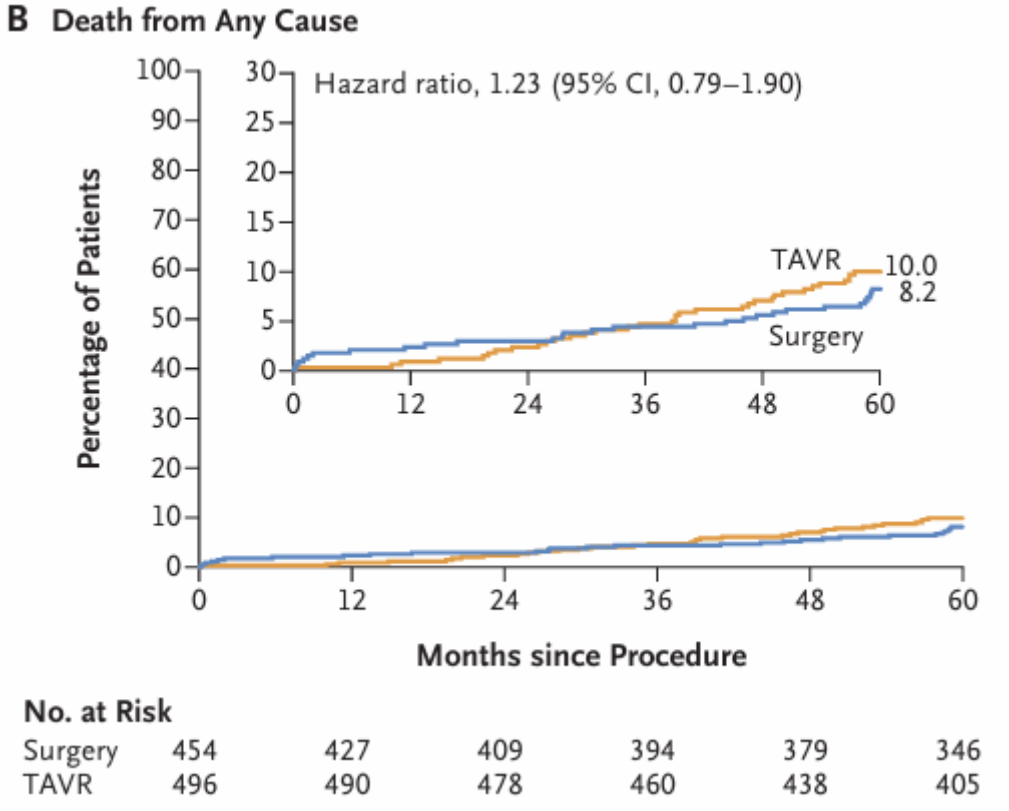
European Heart Journal (2024) 00, 1–9
https://doi.org/10.1093/eurheartj/ehae043

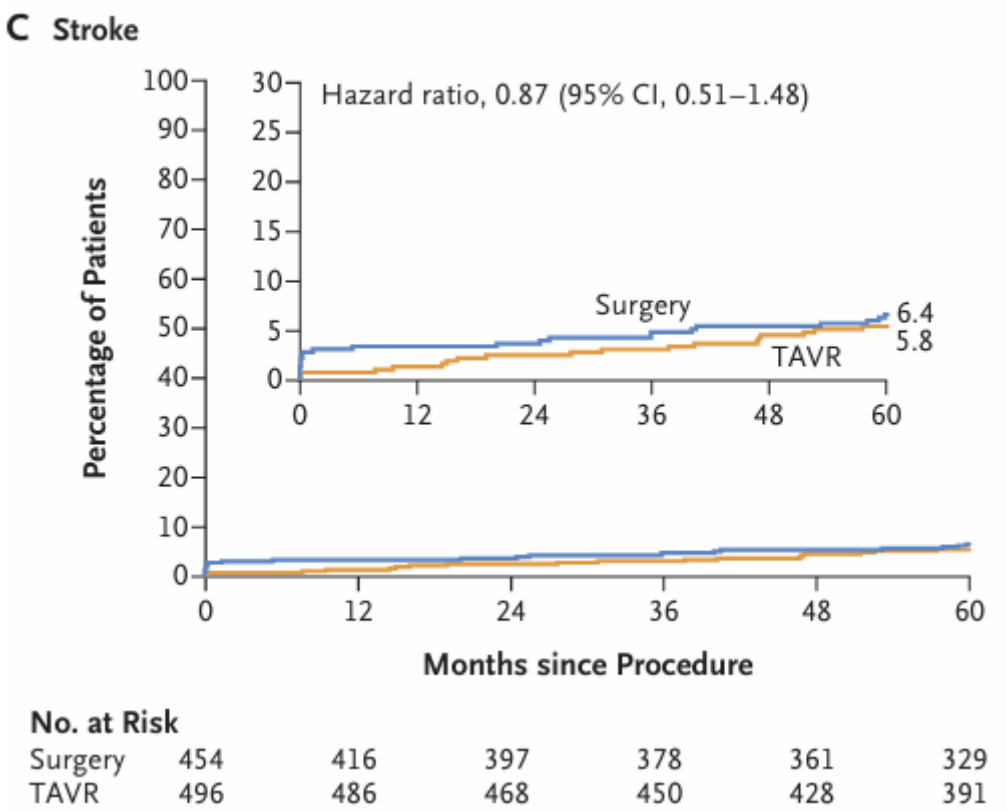
TAVI vs SAVR: „low-risk“ indikace

PARTNER 3 trial – 5 let follow-up

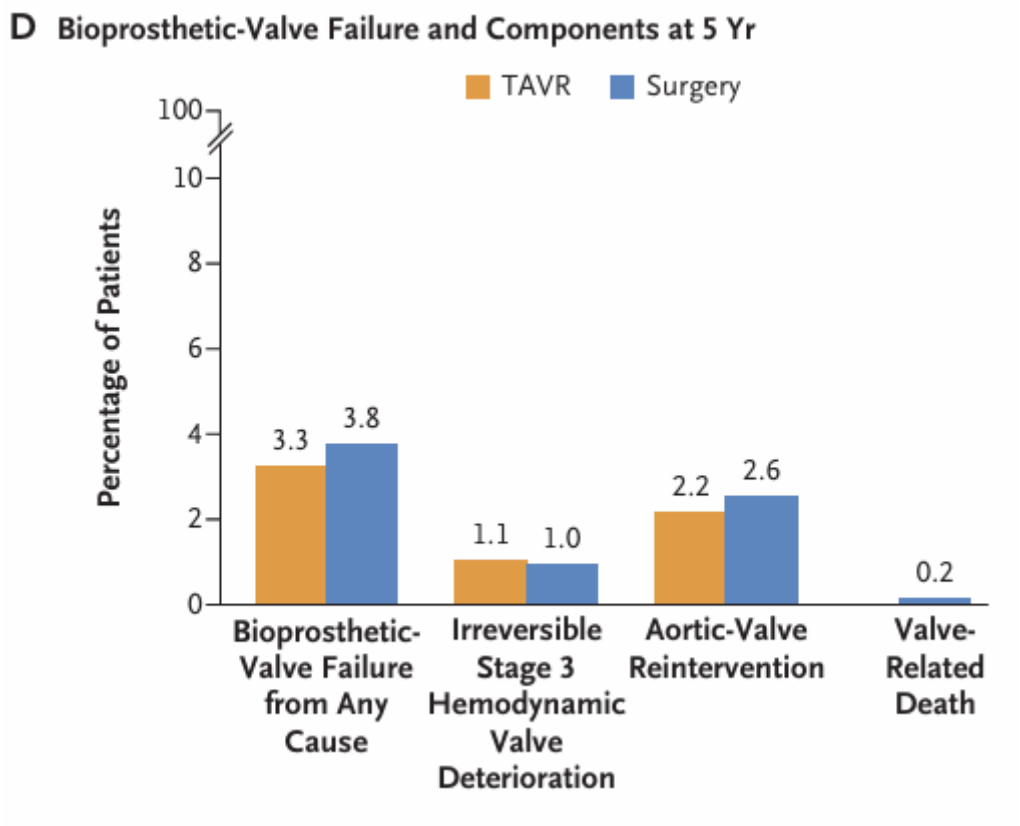



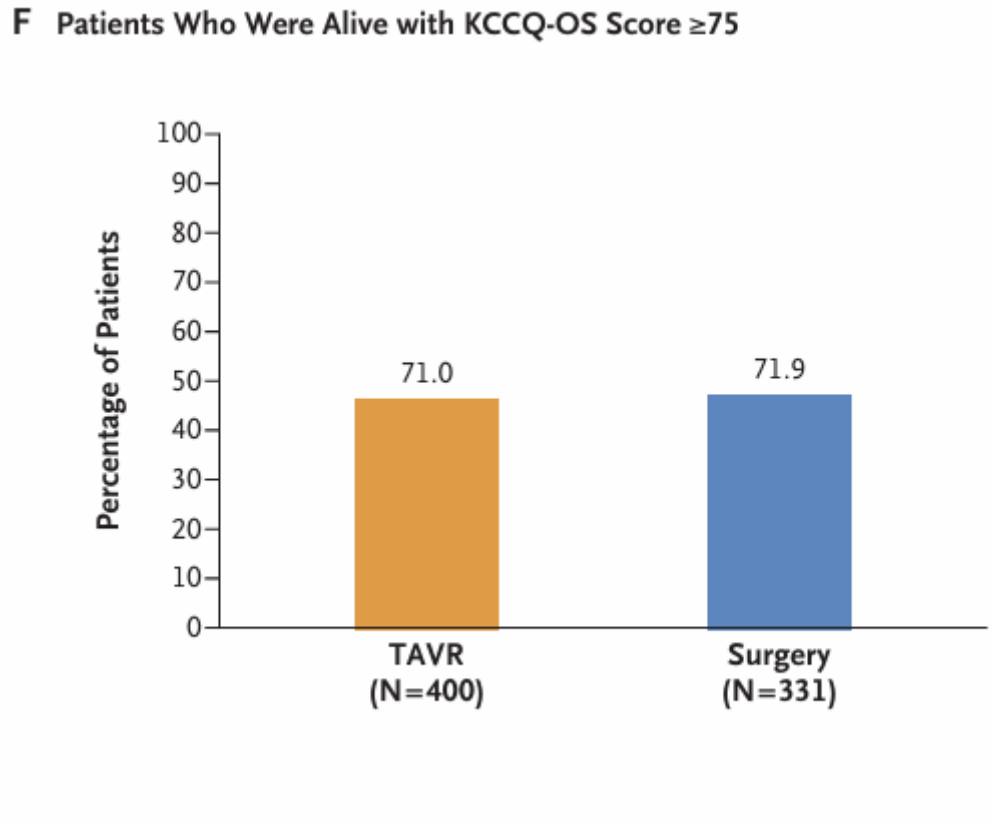

PARTNER 3 trial – 5 leté sledování





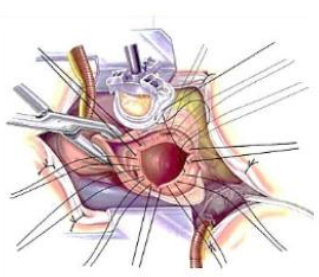
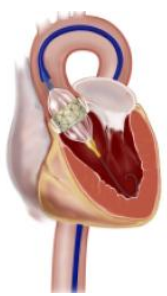
PARTNER 3 trial – 5 leté sledování



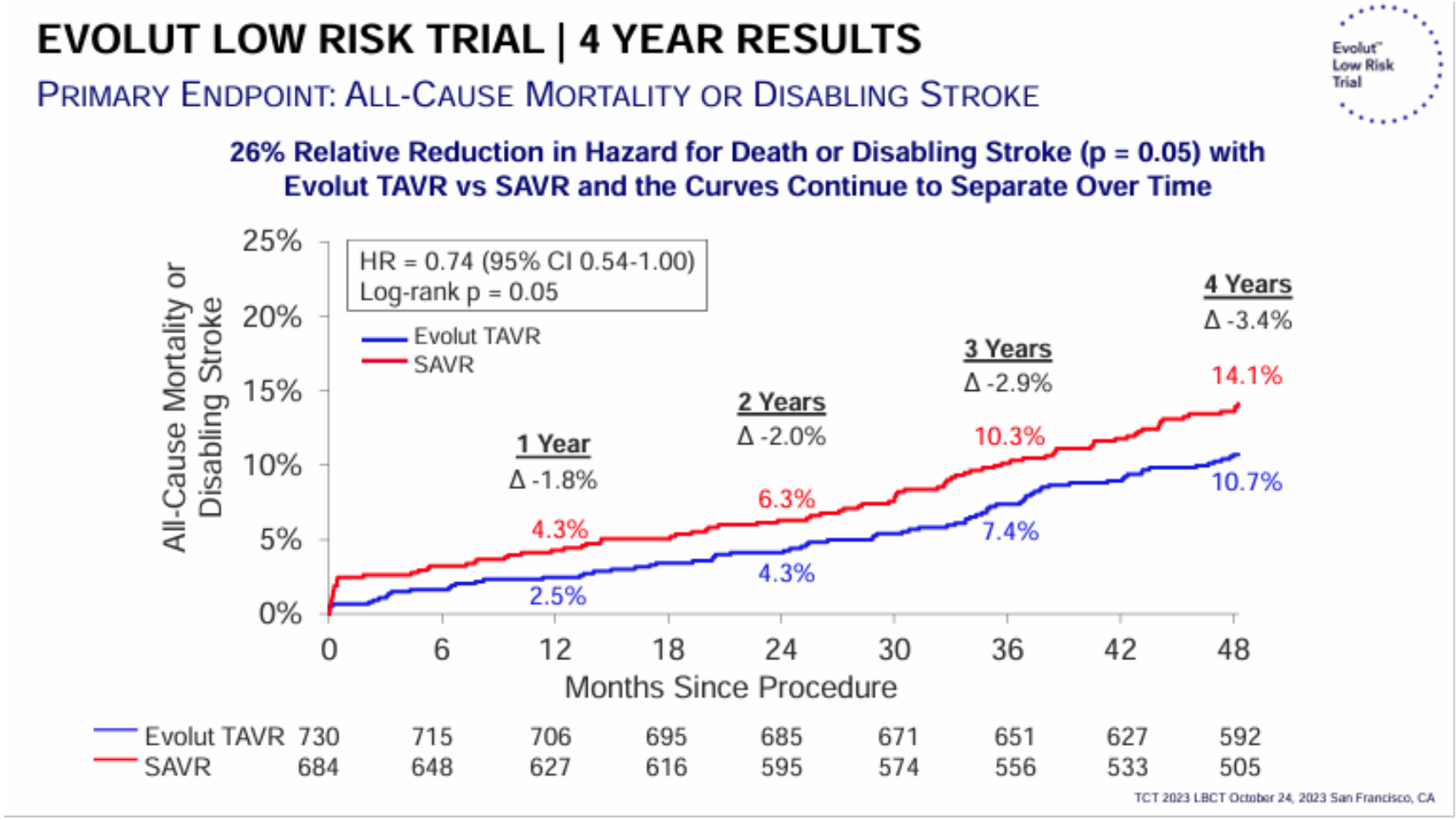


TAVI vs SAVR: „low-risk“ indikace

EVOLUT low risk trial – 4 roky follow-up


Evolut low risk trial - 4 roky follow up



Evolut low risk trial - 4 roky follow up

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

SECONDARY ENDPOINTS AT 4 YEARS

Evolut™ Low Risk Trial

Secondary Endpoint	Evolut TAVR	SAVR	P Value
All-cause mortality, %	9.0 (64)	12.1 (76)	0.07
Cardiovascular mortality, %	5.3 (37)	7.3 (46)	0.12
Disabling stroke, %	2.9 (20)	3.8 (24)	0.32
AV hospitalization[a], %	10.3 (71)	12.1 (75)	0.27
All-cause mortality, disabling stroke, or AV rehospitalization	18.0 (128)	22.4 (144)	0.04
Myocardial infarction, %	4.8 (33)	2.6 (17)	0.06
Permanent pacemaker implant[b], %	24.6 (171)	9.9 (62)	<0.001
Permanent pacemaker implant[c], %	23.8 (171)	9.7 (63)	<0.001
Atrial fibrillation, %	14.0 (100)	40.8 (276)	<0.001
Reintervention, %	1.3 (9)	1.7 (10)	0.63

Data are reported as Kaplan-Meier estimate % (n) and compared by log-rank p value. [a]Hospitalization due to signs and symptoms of aortic valve disease, including symptoms of heart failure. [b]Patients with pacemaker or ICD at baseline are not included. [c]Patients with pacemaker or ICD at baseline are included.

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

BIOPROSTHETIC VALVE PERFORMANCE AT 4 YEARS

Evolut™ Low Risk Trial

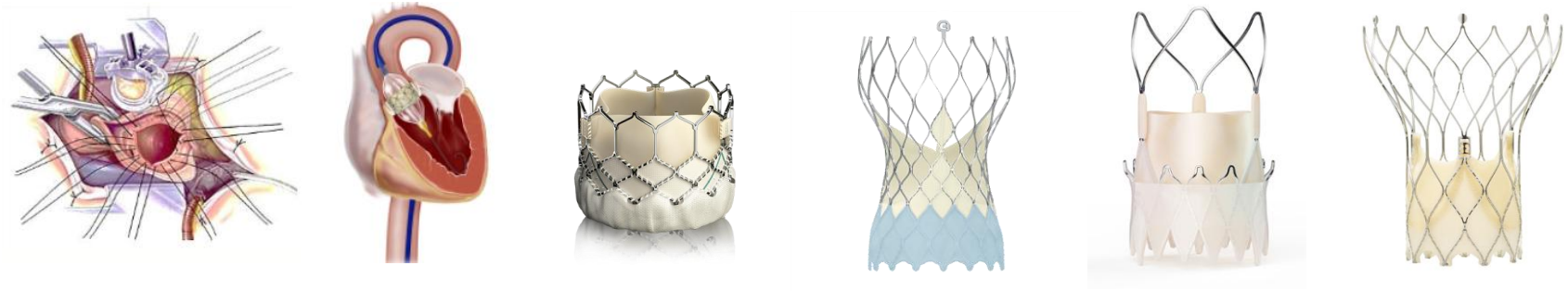
Significantly Less Mean Gradient ≥ 20 mmHg and Severe PPM With Evolut vs Surgery

Parameter	Evolut TAVR	SAVR	P Value
Mean gradient ≥ 20 mm Hg[a]	**4.0 (20/497)**	**8.9 (39/438)**	**0.002**
Severe PVR[a], %	0.0 (0/496)	0.0 (0/426)	N/A
Severe PPM (VARC-3)[a], %	**1.1 (7/611)**	**3.5 (19/549)**	**0.008**
Valve endocarditis[b], %	0.9 (6)	2.2 (13)	0.06
Clinical or subclinical valve thrombosis[b], %	0.7 (5)	0.6 (4)	0.84
Clinical thrombosis, %	0.3 (2)	0.2 (1)	0.61
Subclinical thrombosis, %	0.4 (3)	0.5 (3)	0.91

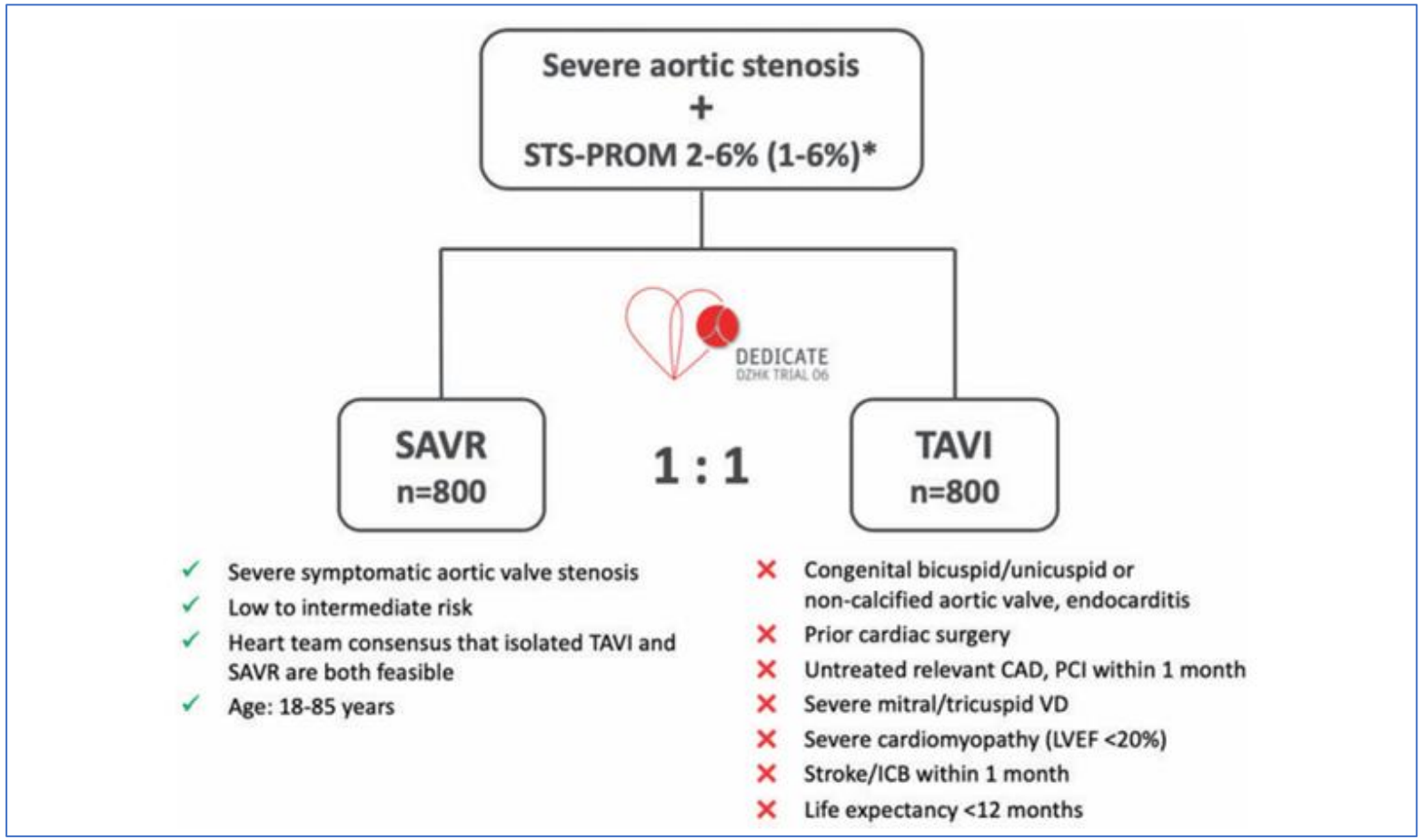
[a]Non-cumulative data based on the 4-year (MG, PVR) or 30-day (PPM) echo, reported as proportion % (n), and compared by chi-square test. [b]Cumulative rates reported as Kaplan-Meier estimates % (n) and compared by log-rank test.
MG = mean gradient; PPM = patient-prosthesis mismatch; PVR = paravalvular regurgitation

TAVI vs SAVR: „low-risk“ indikace

DEDICATE low risk trial – 1 rok

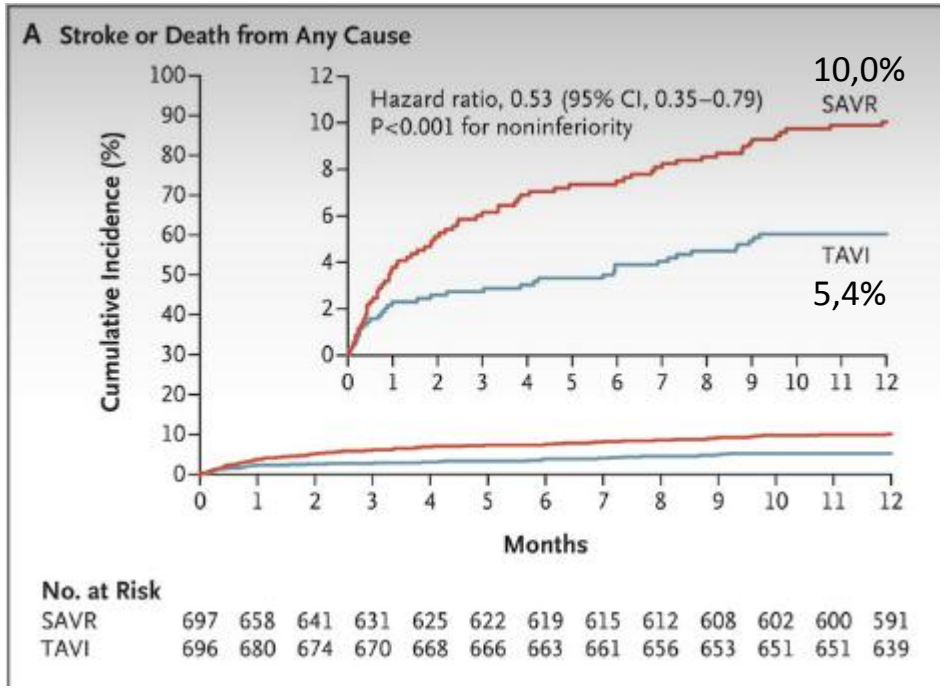


DEDICATE trial: TAVI vs SAVR in low risk pts.



Jakýkoliv typ TAVI či SAVR protézy („real life“)

DEDICATE trial:



N= 701 TAVI x 713 SAVR pts.
Age average 74,3y
Male 57%
Prim. endpoint – ITT at 1 year:
Death: SAVR 6,2% vs TAVI 2,6%
Stroke: SAVR 4,7% vs TAVI 2,9%

Crossover to TAVI 10%

- Vascular access complications, 0.7% for SAVR vs. 7.9% for TAVI, a more than 10-fold difference.
- Bleeding, 17.2% and 4.3%, respectively, a 76% lower risk with TAVI.
- New-onset left bundle branch block, 17.5% and 32%, a twice greater risk for TAVI.
- New-onset atrial fibrillation, 30.8% and 12.4%, a 64% lower risk with TAVI.
- New permanent pacemaker implantation, 6.7% and 11.8%, which is almost twice the risk with TAVI.

TAVI – dnešní indikace

Jasná indikace k TAVI

- Významná a symptomatická AS
- CT jako klíčové vyšetření
- Rozhodnutí heart-teamu
- Vysoké, střední i nízké riziko
- Věk nad 70 let

- Výběr typu chlopně dle anatomie a rizika PM/PVL/AF/koronární tepny
- Doživotní strategie léčby AS (SAVR – TAVI, TAVI – TAVI)

Individuální indikace

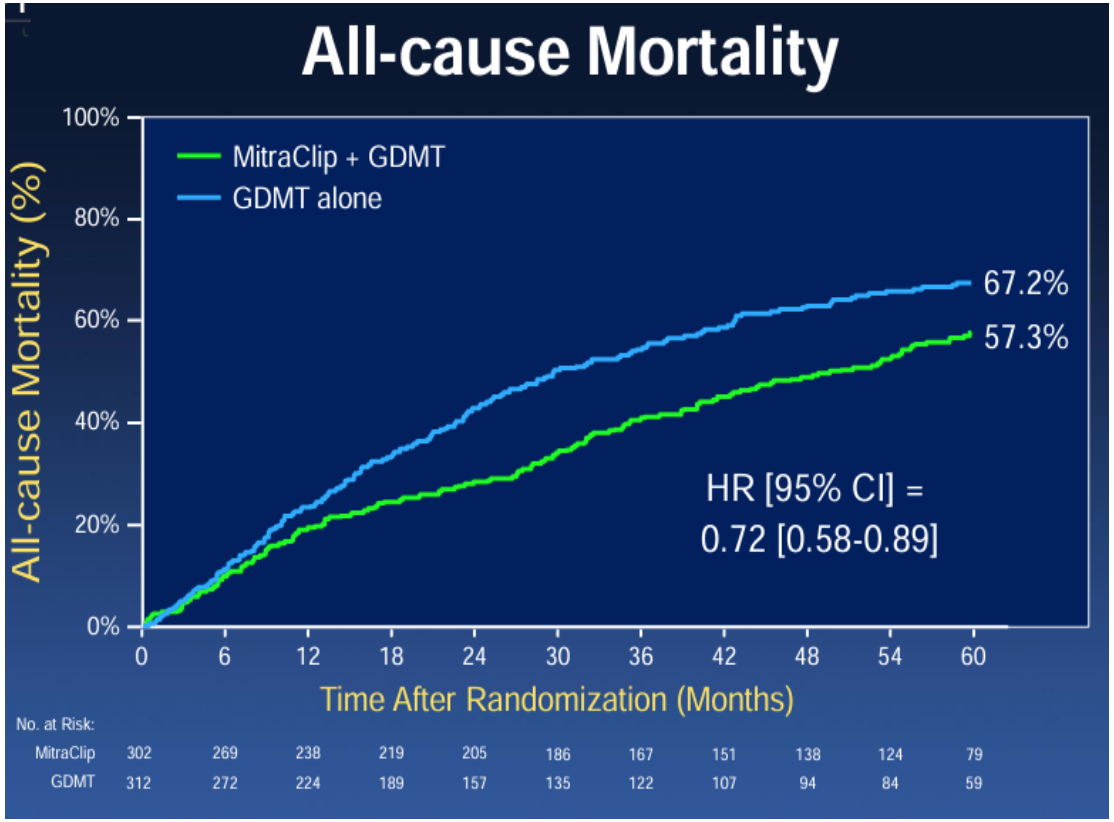
- Bikuspidní aortální chlopeň
- Nevhodná anatomie kořene aorty
- Nemožnost transfemorálního přístupu
- Low-flow, low-gradient AS

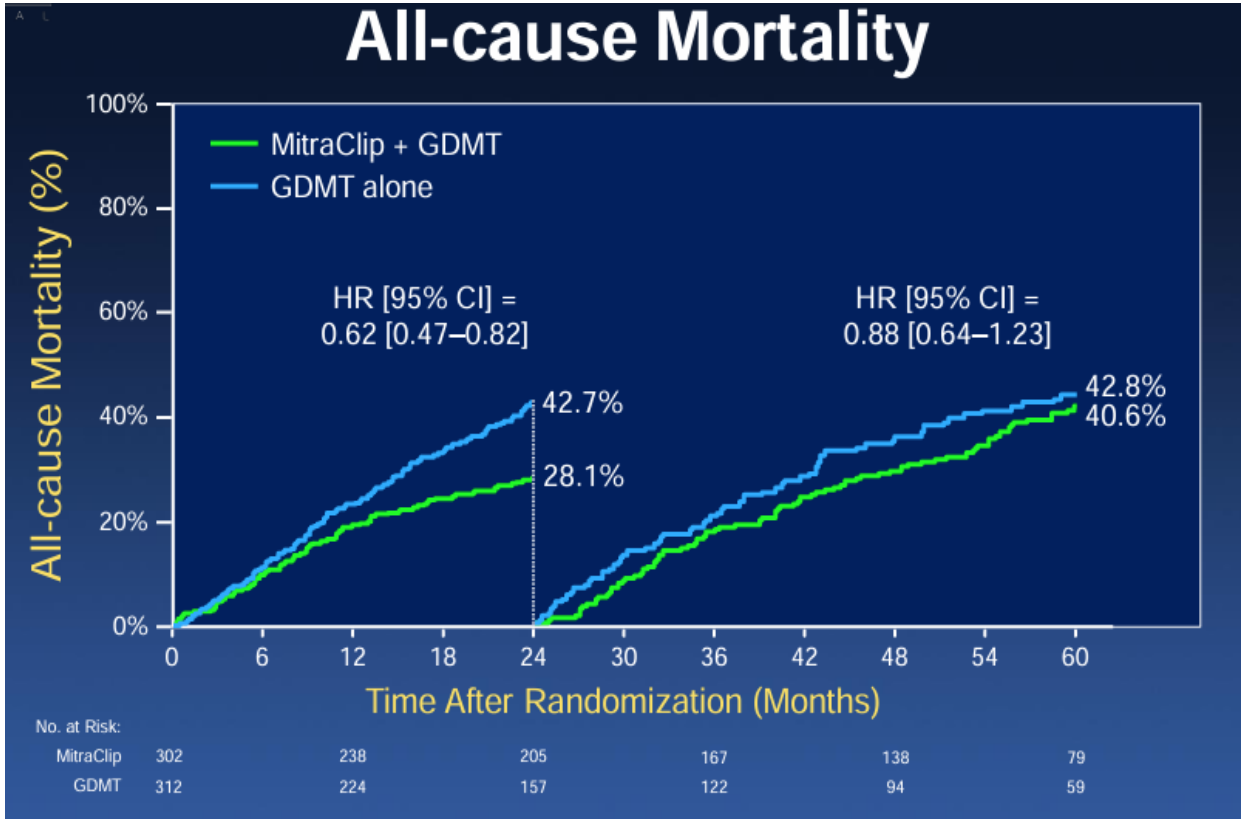
- Oligosymptomatická AS
- Časná indikace u středně významné AS (EARLY-TAVI)

Mitrální regurgitace:
transkatether edge-to-edge repair (TEER)

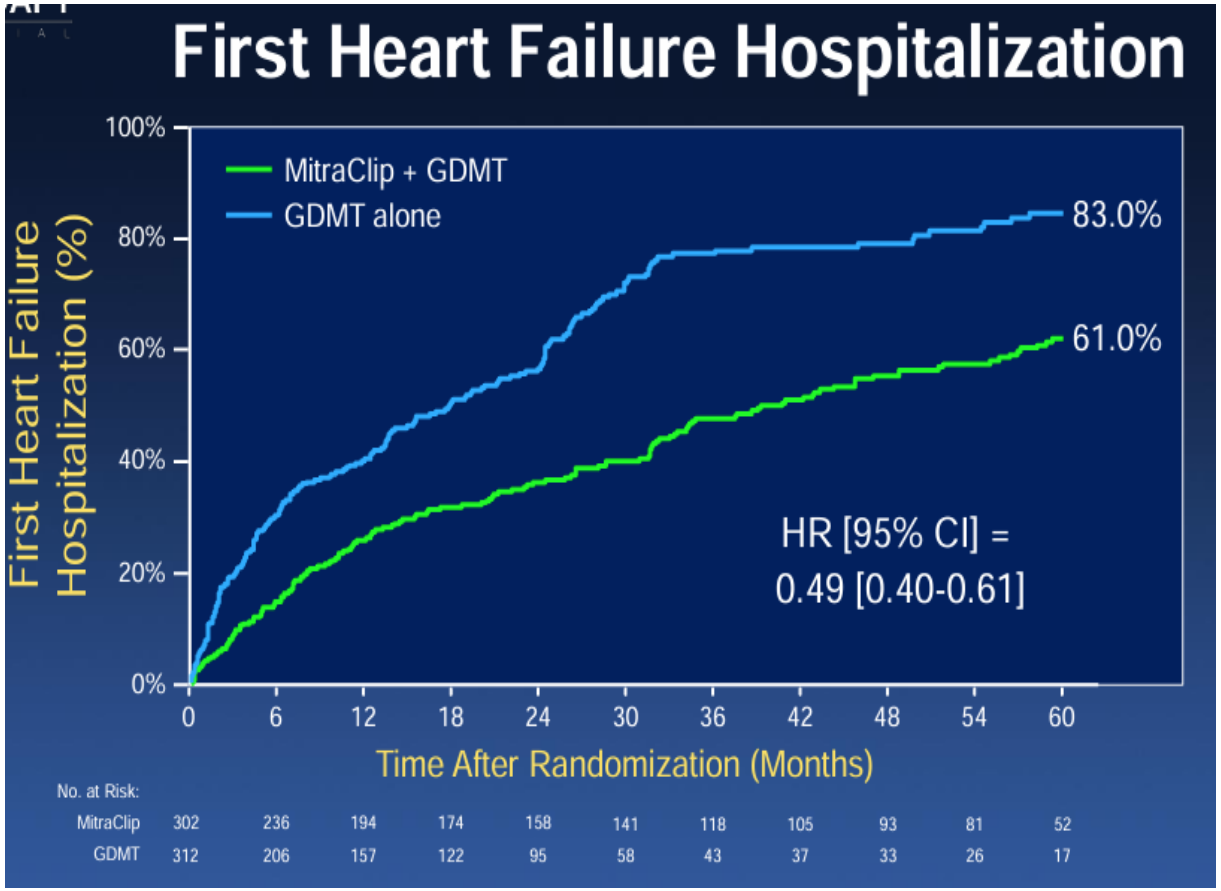
COAPT 5 let follow-up

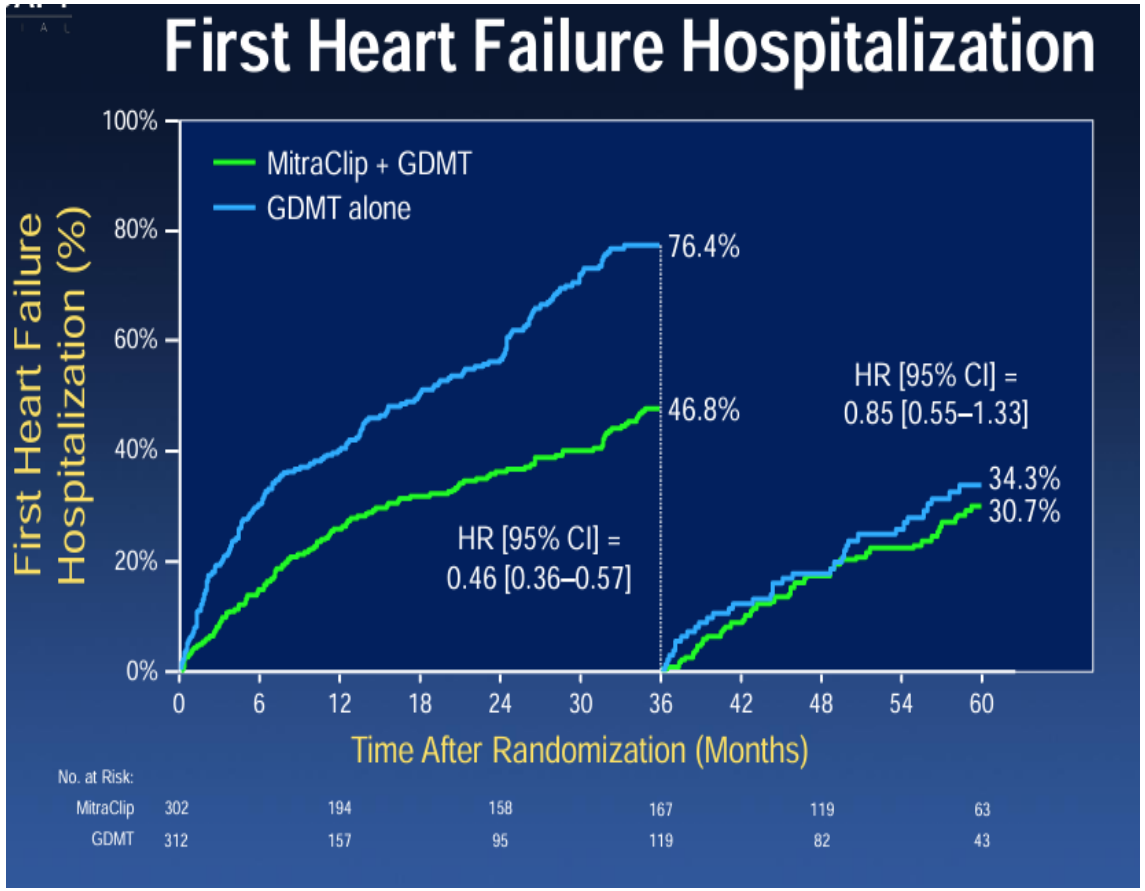
COAPT 5 let follow-up





COAPT 5 let follow-up





COAPT – závěry a doporučení

- TEER /MitraClip/ v léčbě mitrální regurgitace je bezpečná metoda, snižuje riziko úmrtí a potřebu hospitalizací pro srdeční selhání
- Efekt je konzistetntní napříč podskupinami (věk, pohlaví, závažnost MR, EF LK, etiologie, chirurgické riziko)
- Mortalita konzervativně léčených nemocných je vysoká v prvních 2 letech (43% vs 28 %)
- Efekt výkonu se snižuje po 2-3 letech
- **Nemocní se srdečním selháním vhodní pro TEER mají být identifikováni a léčeni pomocí TEER co nejdříve**

Trikuspidální regurgitace

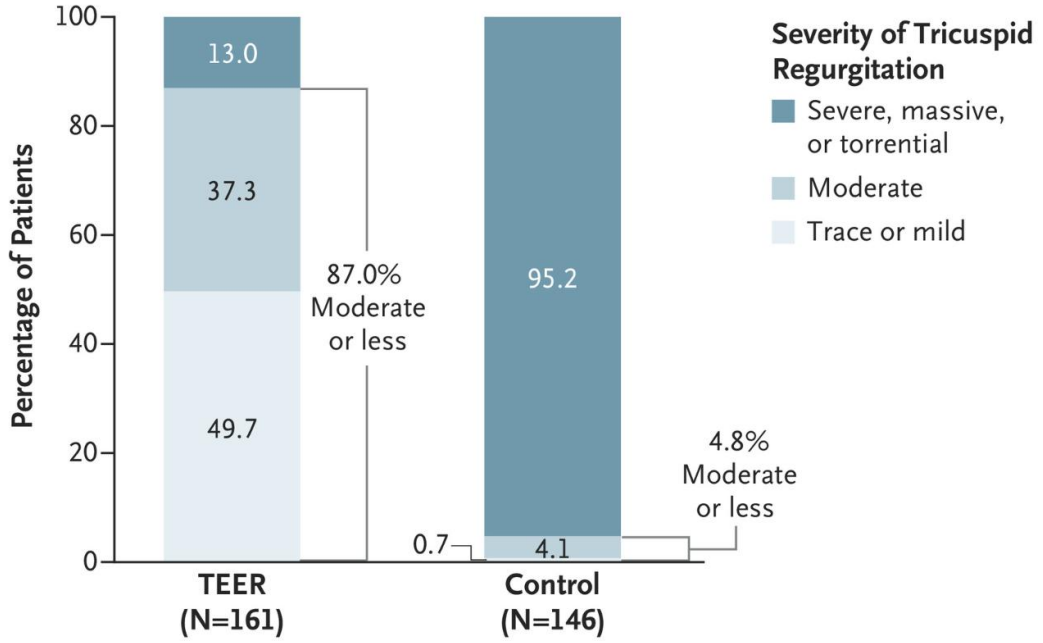
TRILUMINATE trial

Závažnost trikuspidální regurgitace ve 30. dni

Design studie

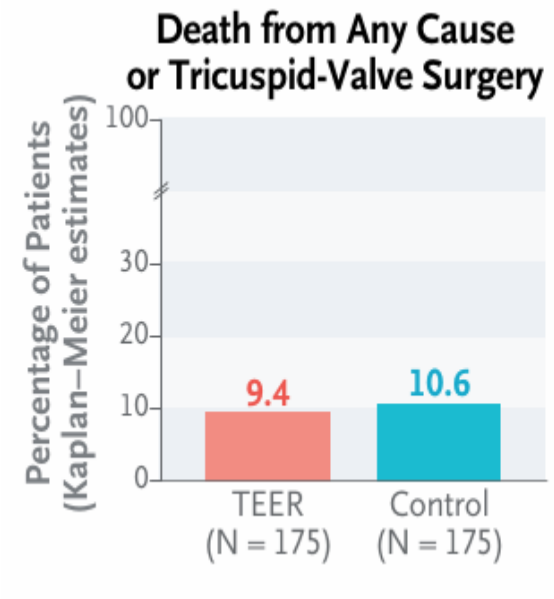
- Významná symptomatická trikuspidální regurgitace
- N=350, 1:1 TEER vs OMT
- Průměrný věk 78 let
- Prim. Endpoint: úmrtí, operace TR chlopně, hospitalizace pro srdeční selhání, kvalita života (KCCQ) v 1. roce

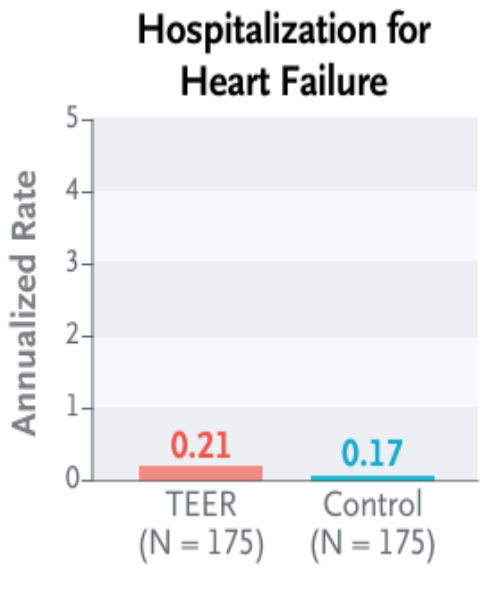
Technická úspěšnost výkonu (30.den)

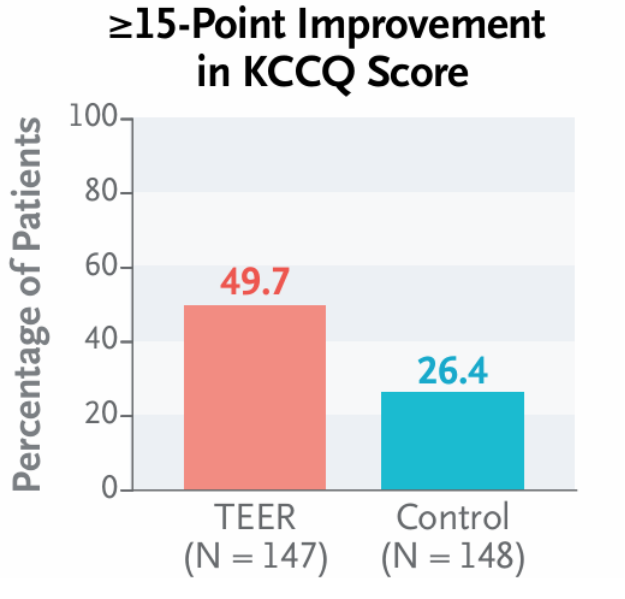


Kvalita života po TEER (1. rok)

hodnoceno Kansas City Cardiomyopathy Questionnaire (KCCQ)







CONCLUSIONS

In patients with symptomatic, severe tricuspid regurgitation, TEER was safe and was associated with a greater improvement in quality of life than medical therapy alone.

ICHS – role PCI u stabilní AP

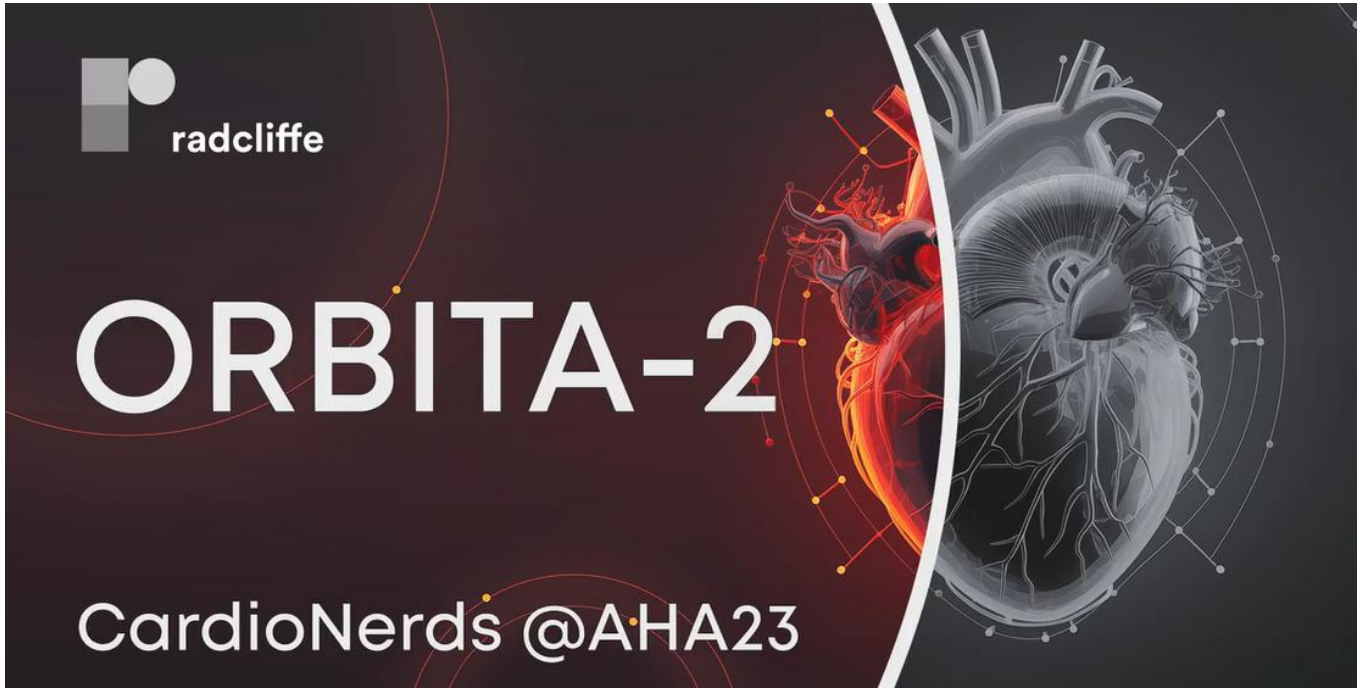
~~COURAGE~~
~~FAME-2~~
~~ORBITA~~

ORBITA-2

A Placebo-Controlled Trial of Percutaneous Coronary Intervention for Stable Angina

Authors: Christopher A. Rajkumar, M.B., B.S., Michael J. Foley, M.B., B.S., Fiyyaz Ahmed-Jushuf, M.B., B.S., Alexandra N. Nowbar, Ph.D., Florentina A. Simader, M.D., John R. Davies, Ph.D., Peter D. O'Kane, M.D., +28, for the ORBITA-2 Investigators* Author Info & Affiliations

Published November 11, 2023 | N Engl J Med 2023;389:2319-2330 | DOI: 10.1056/NEJMoa2310610
VOL. 389 NO. 25



PCI vs sham PCI

Stop antianginostní terapie

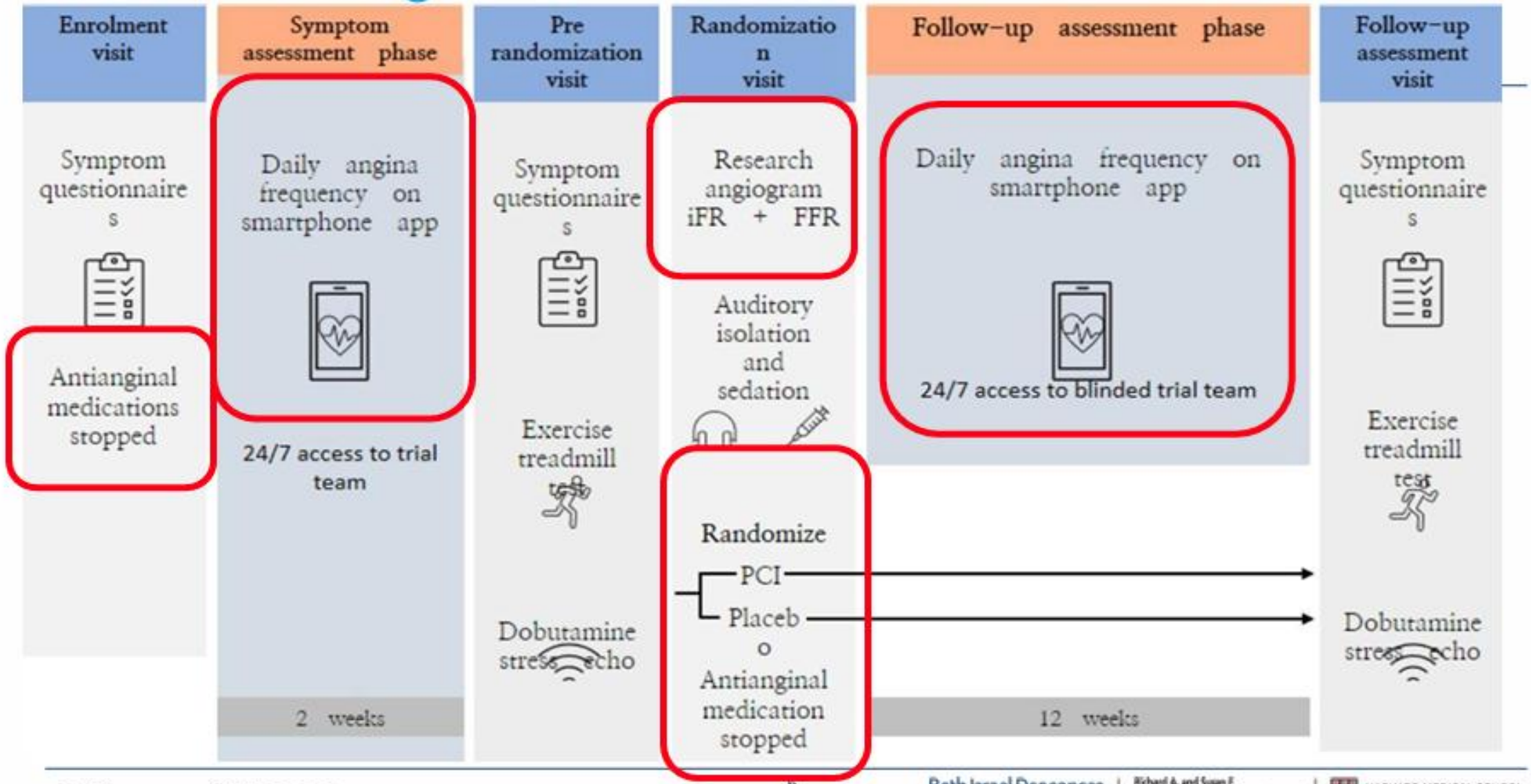
80% SVD

Průkaz ischemie

Randomizace po SKG

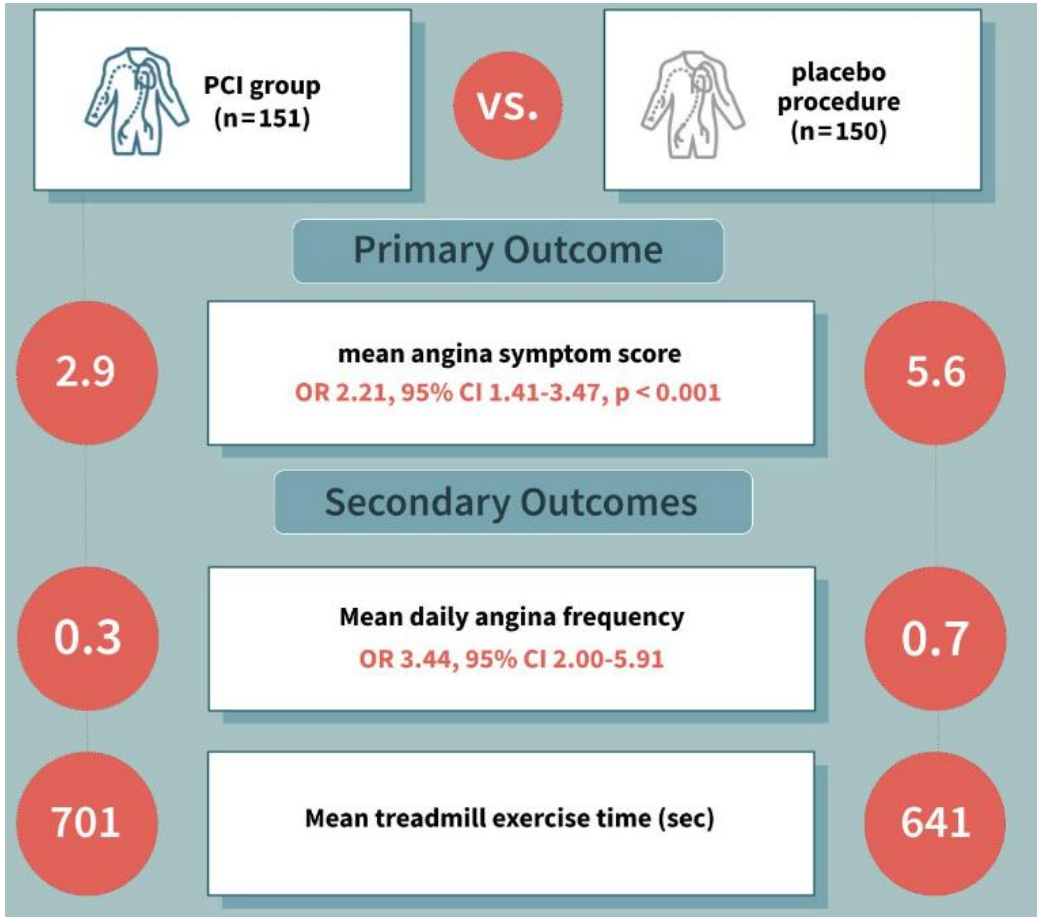
The NEW ENGLAND JOURNAL of MEDICINE

ORBITA II Design



Rajkumar, AHA 2023.

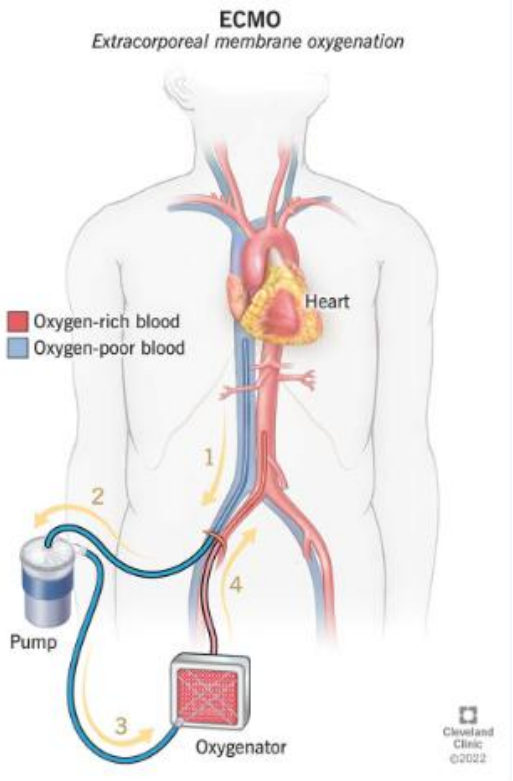
ORBITA-2 prokazuje benefit PCI



Závěry

- PCI zlepšuje symptomy AP (OR 2,21, p< 0,001)
- Benefit PCI je okamžitý
- PCI zlepšuje kvalitu života (SAQ: OR 2,47, p= 0,006)
- PCI zmenšuje rozsah ischemie (stress echo, p<0,0001)
- FFR/iFR dobře predikuje efekt PCI na redukci ischemie (nikoliv na symptomy)

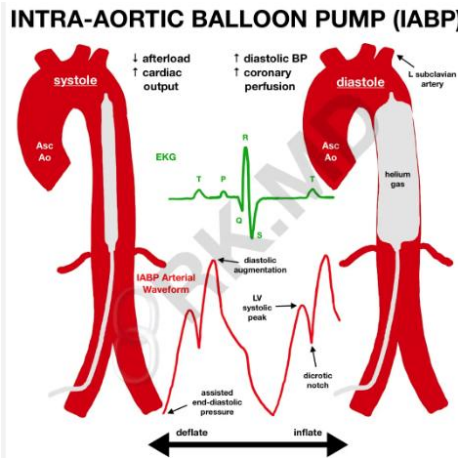
Kardiogenní šok a STEMI

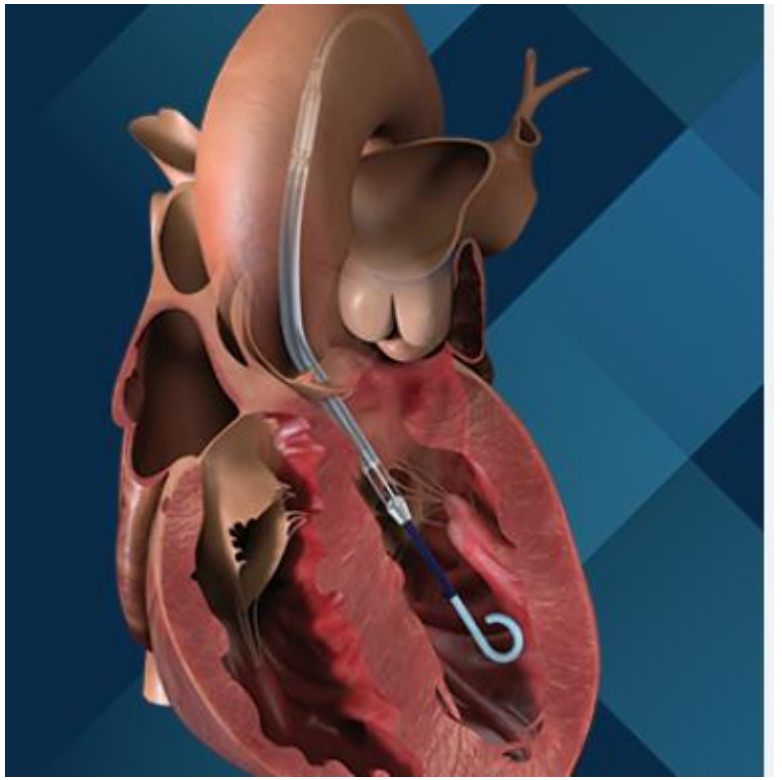


IABP

ECMO

IMPELLA



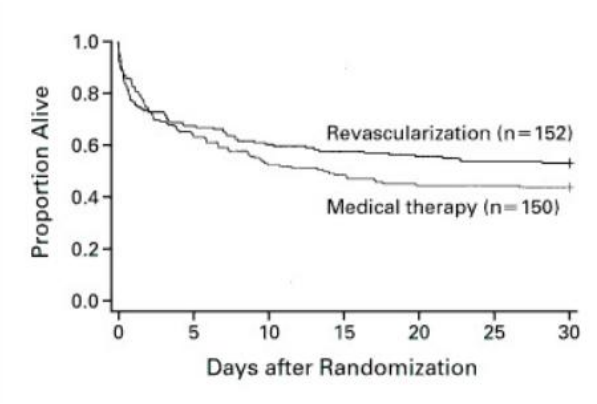


ECMO ↑ afterload

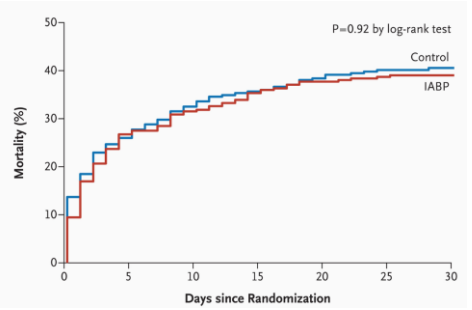
Impella: unloading LV, ↑ koronární perfuze

Kardiogenní šok u AIM

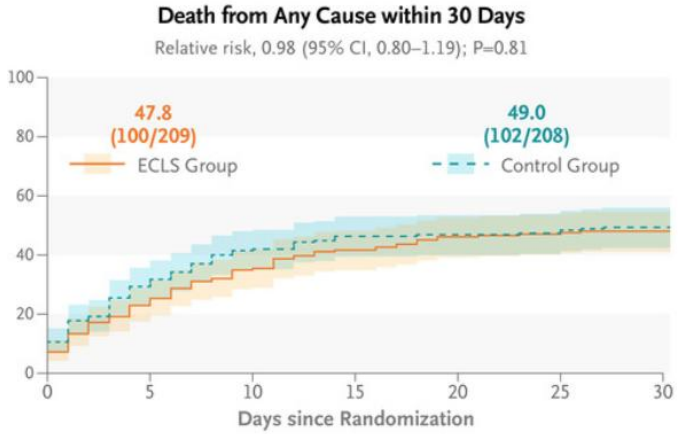
- SHOCK trial (n=302): **revaskularizace** vs iniciální OMT
  - 30-denní přežívání: 53% vs 44%, p=0,109
  - Roční přežívání 47% vs 34%, p= 0,025



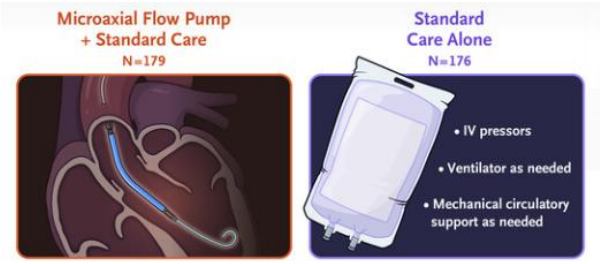
- IABP-SHOCK trial (n=300): IABP + PCI vs NO IABP + PCI
  - 30-denní mortalita 39,7% (IABP) vs 41,3% (NO IABP), p=0,69

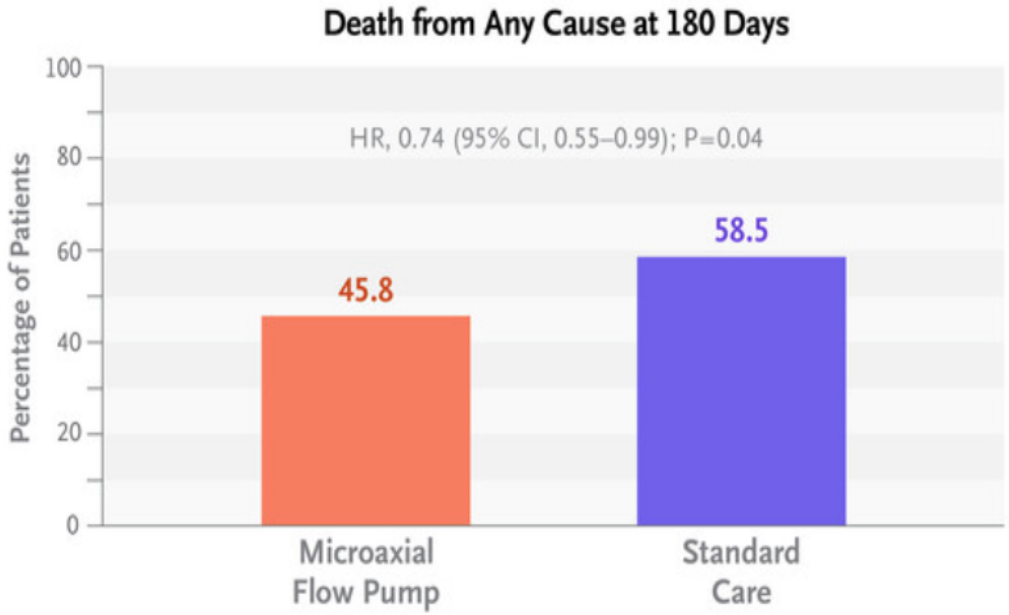


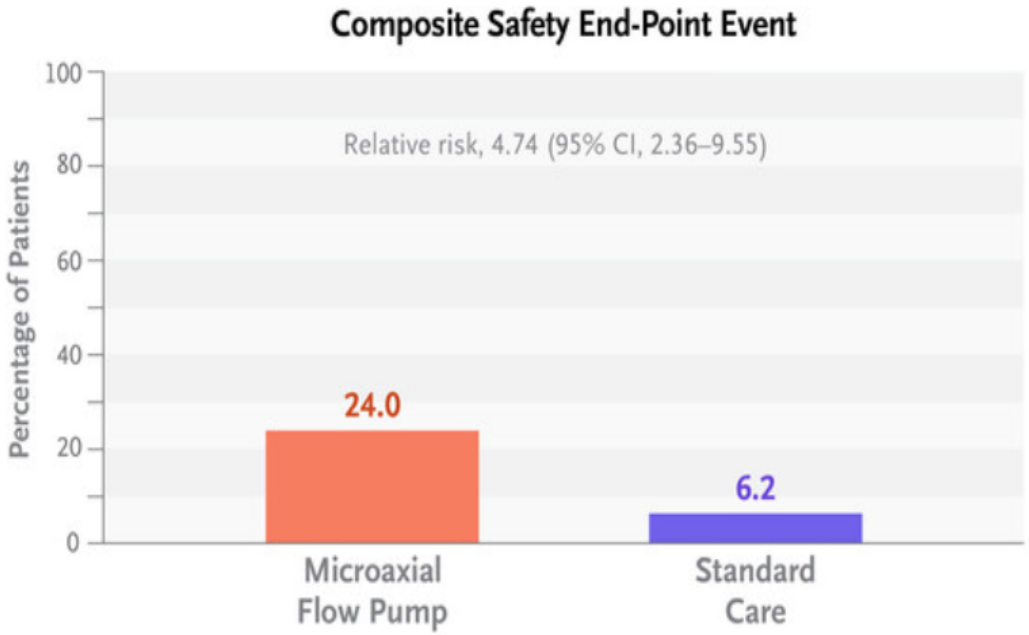
- ECMO a kardiogenní šok:
  - ECLS-SHOCK (n=420): negative
  - ECMO-CS (n=122): negative



Impella u kardiogenního šoku: DanGerShock Trial (n=360)







- **Nemocní s OHCA komatosní a infarkty pravé komory byli vyloučeni**
- 50% non-culprit vessel PCI
- Žádný efekt MSP: ženy, 1VD (analýza podskupin)

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DanGerShock Trial (n=360)

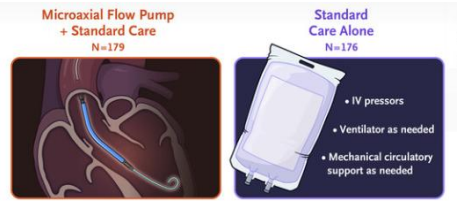
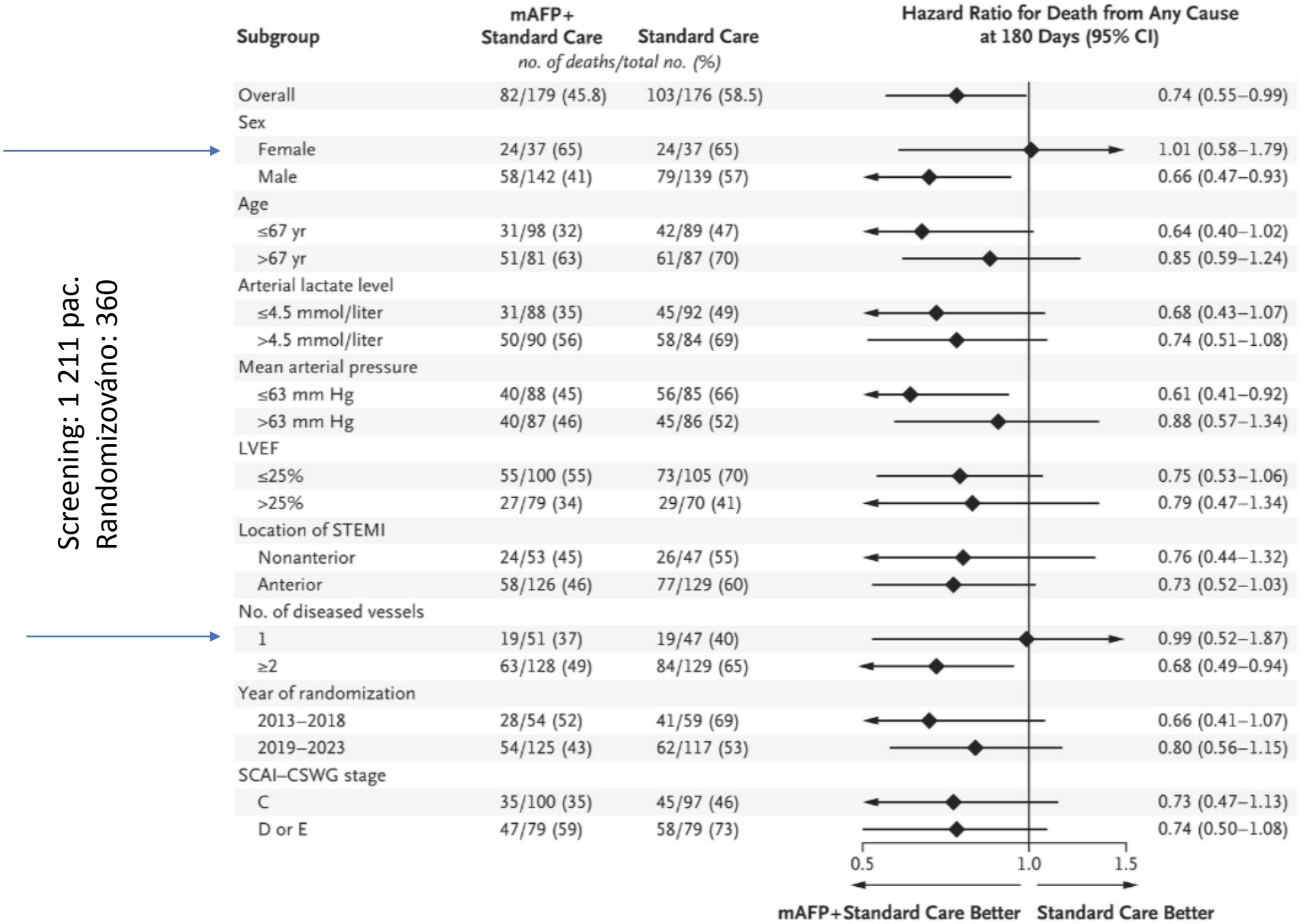


Table 3. End Points and Adverse Events in the Intention-to-Treat Population.*

Event	Microaxial Flow Pump plus Standard Care (N=179)	Standard Care Alone (N=176)	Effect Size (95% CI)†
Primary end point: death from any cause at 180 days — no. (%)	82 (45.8)	103 (58.5)	0.74 (0.55 to 0.99)‡
Secondary end point			
Composite cardiac end point — no. (%)§	94 (52.5)	112 (63.6)	0.72 (0.55 to 0.95)
No. of days alive and out of the hospital (range)¶	82 (0 to 177)	73 (0 to 179)	8 (−8 to 25)
Adverse events			
Composite safety end point — no. (%)‖	43 (24.0)	11 (6.2)	4.74 (2.36 to 9.55)
Moderate or severe bleeding — no. (%)**	39 (21.8)	21 (11.9)	2.06 (1.15 to 3.66)
Limb ischemia — no. (%)	10 (5.6)	2 (1.1)	5.15 (1.11 to 23.84)
Renal-replacement therapy — no. (%)	75 (41.9)	47 (26.7)	1.98 (1.27 to 3.09)
Stroke — no. (%)	7 (3.9)	4 (2.3)	1.75 (0.50 to 6.01)
Cardioversion after ventricular tachycardia or fibrillation — no. (%)	59 (33.0)	52 (29.5)	1.17 (0.75 to 1.83)
Sepsis with positive blood culture†† — no. (%)	21 (11.7)	8 (4.5)	2.79 (1.20 to 6.48)

Screening: 1 211 pac.
Randomizováno: 360



Co může intervenční kardiologie nabídnout Vašim pacientům? … je toho mnohem více

- Invazívní diagnostika
  - Hemodynamická vyšetření, zátěžové testy (PH), EMB
  - Angiografická vyšetření, intrakoronární zobrazení,
  - Funkční hodnocení stenóz FFR/iFR/DPR/angioFR
- Komplexní koronární intervence
  - *PCI u ACS i CCS*, MVD, stenos kmene, CTO …
  - *Mechanické srdeční podpory oběhu* (IABP, ECMO, Impella, Ecpella..)
- Plné spektrum strukturálních intervencí
  - *Chlopenní vady - TAVI*, TMVI, ViV, PTMC,
  - *MitraClip, TriClip*, TENDYNE
  - Katetrizační uzávěry DSS, PFO, LAA, PVL...
  - ASA

IK+E M