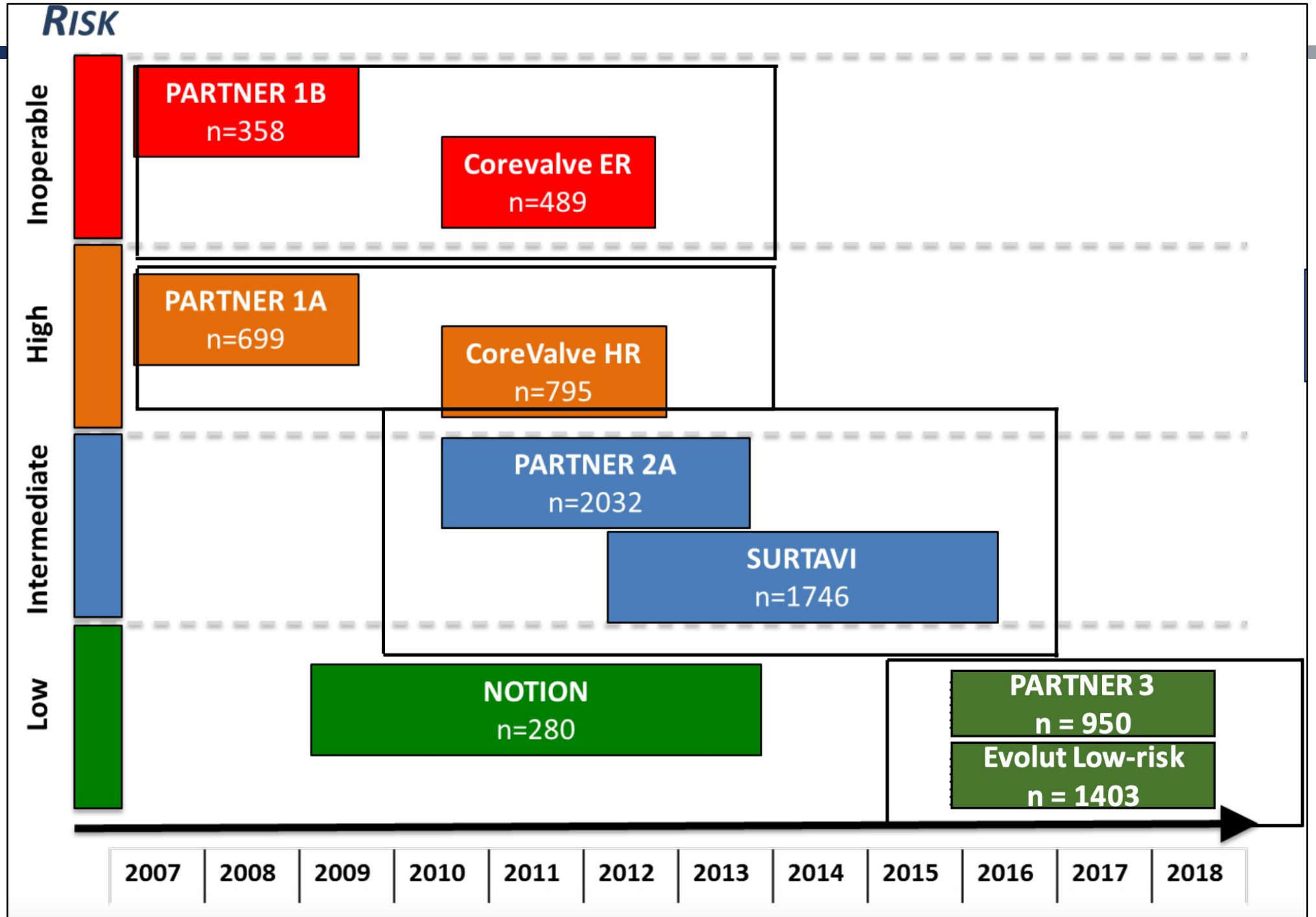
TAVI V „NOVÝCH“ INDIKACÍCH

MARTIN MATES
KARDIOLOGICKÁ KLINIKA 1. LF UK A NEMOCNICE NA HOMOLCE

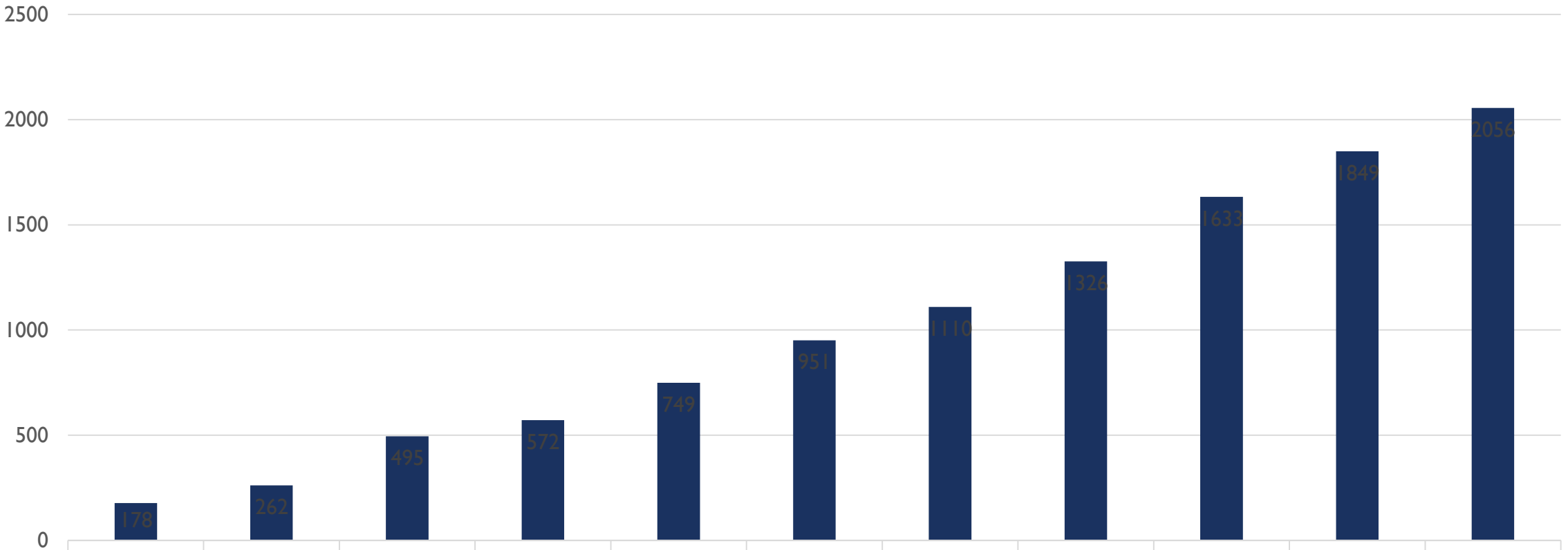
Asymptomatická aortální stenóza

Středně těžká aortální stenóza a dysfunkce LK

TAVI u žen


RISK
Inoperable
High
Intermediate
Low
PARTNER 1B
n=358
Corevalve ER
n=489
PARTNER 1A
n=699
CoreValve HR
n=795
PARTNER 2A
n=2032
SURTAVI
n=1746
NOTION
n=280
PARTNER 3
n = 950
Evolut Low-risk
n = 1403
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018

POČTY TAVI V ČESKÉ REPUBLICE



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
n	178	262	495	572	749	951	1110	1326	1633	1849	2056

ASYMPTOMATICKÁ AORTÁLNÍ STENÓZA

1. Falešně asymptomatická
2. **Skutečně asymptomatická**
3. Nelze určit

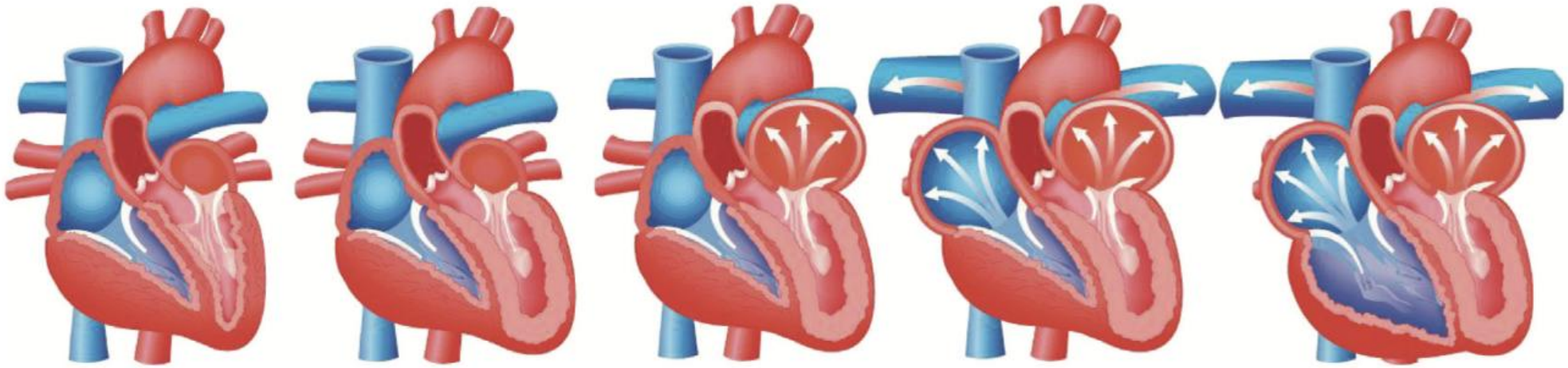
Roční mortalita 1-2%

GUIDELINES

DYSFUNKCE LEVÉ KOMORY ABNORMÁLNÍ ZÁTĚŽOVÝ TEST KRITICKÁ STENÓZA

B) Asymptomatická aortální stenóza		
Intervence je doporučena u asymptomatických pacientů s těžkou aortální stenózou a systolickou dysfunkcí levé komory (EF LK < 50 %), pokud dysfunkce není způsobena jinou příčinou.	I	B
Intervence je doporučena u asymptomatických pacientů s těžkou aortální stenózou s prokazatelnými symptomy při zátěžovém testu.	I	C
Intervence by měla být zvážena u asymptomatických pacientů s těžkou aortální stenózou a systolickou dysfunkcí levé komory (EF LK < 55 %), pokud dysfunkce není způsobena jinou příčinou.	IIa	B
Intervence by měla být zvážena u pacientů s těžkou aortální stenózou a trvalým snížením krevního tlaku o > 20 mm Hg během zátěžového testu.	IIa	C
Intervence by měla být zvážena u asymptomatických pacientů s těžkou aortální stenózou s EF LK > 55 % a normálním zátěžovým testem, pokud je procedurální riziko nízké a je přítomen alespoň jeden z následujících parametrů: • těsná aortální stenóza (střední gradient ≥ 60 mm Hg a nebo V_{max} > 5 m/s) • těžké kalcifikace aortální chlopně (ideálně stanovené CT) a zvyšování V_{max} ≥ 0,3 m/s/rok • významně zvýšený BNP (> trojnásobné zvýšení oproti normální hodnotě pro daný věk a pohlaví) potvrzené opakovaným měřením, bez jiné vysvětlující příčiny	IIa	B

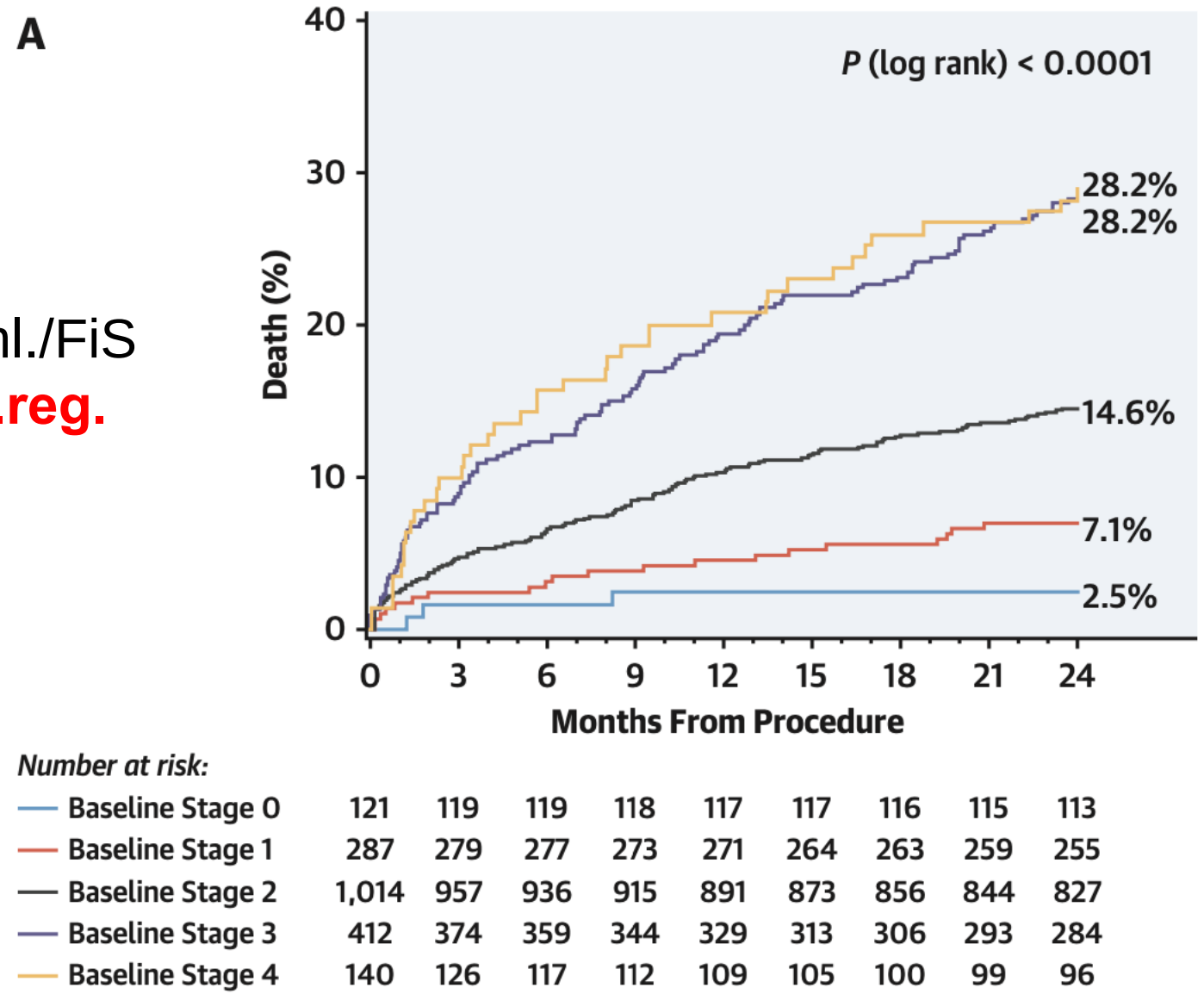
FIGURE 1 Aortic Stenosis Staging Classification Based on Extent of Cardiac Damage



Stages/Criteria	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
	No Cardiac Damage	LV Damage	LA or Mitral Damage	Pulmonary Vasculature or Tricuspid Damage	RV Damage
Echocardiogram		Increased LV Mass Index >115 g/m^2 (Male) >95 g/m^2 (Female)	Indexed LA Volume >35 mL/m^2	Systolic Pulmonary Hypertension >60 mm Hg	Moderate-Severe Right Ventricular Dysfunction
		E/e' >14	Moderate-Severe Mitral Regurgitation	Moderate-Severe Tricuspid Regurgitation	
		LV Ejection Fraction <50%	Atrial Fibrillation		

J Am Coll Cardiol 2022;80:783–800

1. Bez poškození srdce
2. Poškození levé komory
3. Poškození levé síně/mitr.chl./FiS
4. **Plicní hypertenze/trikusp.reg.**
5. **Dysfunkce pravé komory**



J Am Coll Cardiol 2022;80:783–800

Baseline Stage of Cardiac Damage (N = 1,974)

Stage 0 (6.1%)

Stage 1 (14.5%)

Stage 2 (51.4%)

Stage 3 (20.9%)

Stage 4 (7.1%)

Aortic Valve Replacement

1-Year Post-AVR Change in Stage of Cardiac Damage

Improvement 15.6%

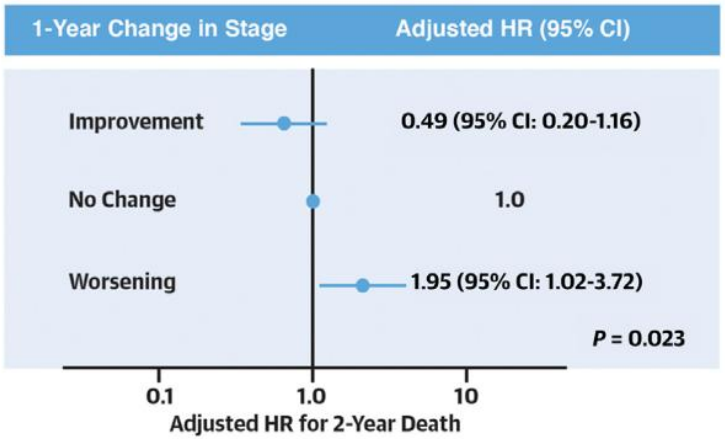
No Change 57.9%

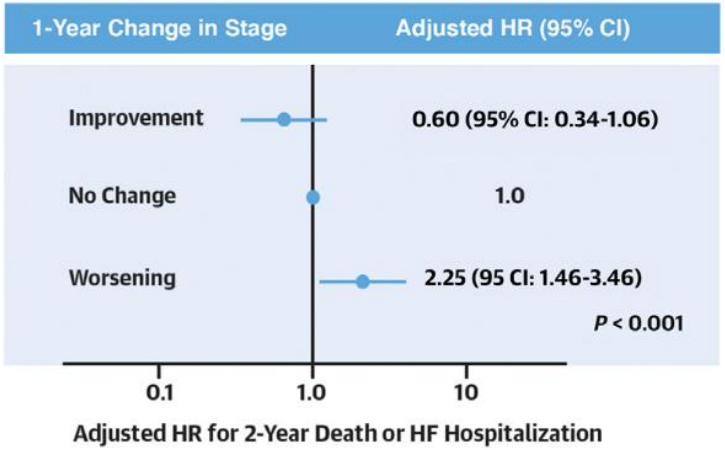
Worsening 26.5%

Predictor of 1-Year Worsening in Cardiac Damage

- Hypertension: OR: 1.73; 95% CI: 1.01-2.96; *P* = 0.044
- Surgical AVR: OR: 2.04; 95% CI: 1.52-2.74; *P* < 0.0001

Impact of 1-Year Change in Stage of Cardiac Damage on 2-Year Clinical Outcomes





Généreux P, et al. J Am Coll Cardiol. 2022;80(8):783-800.

AVATAR studie

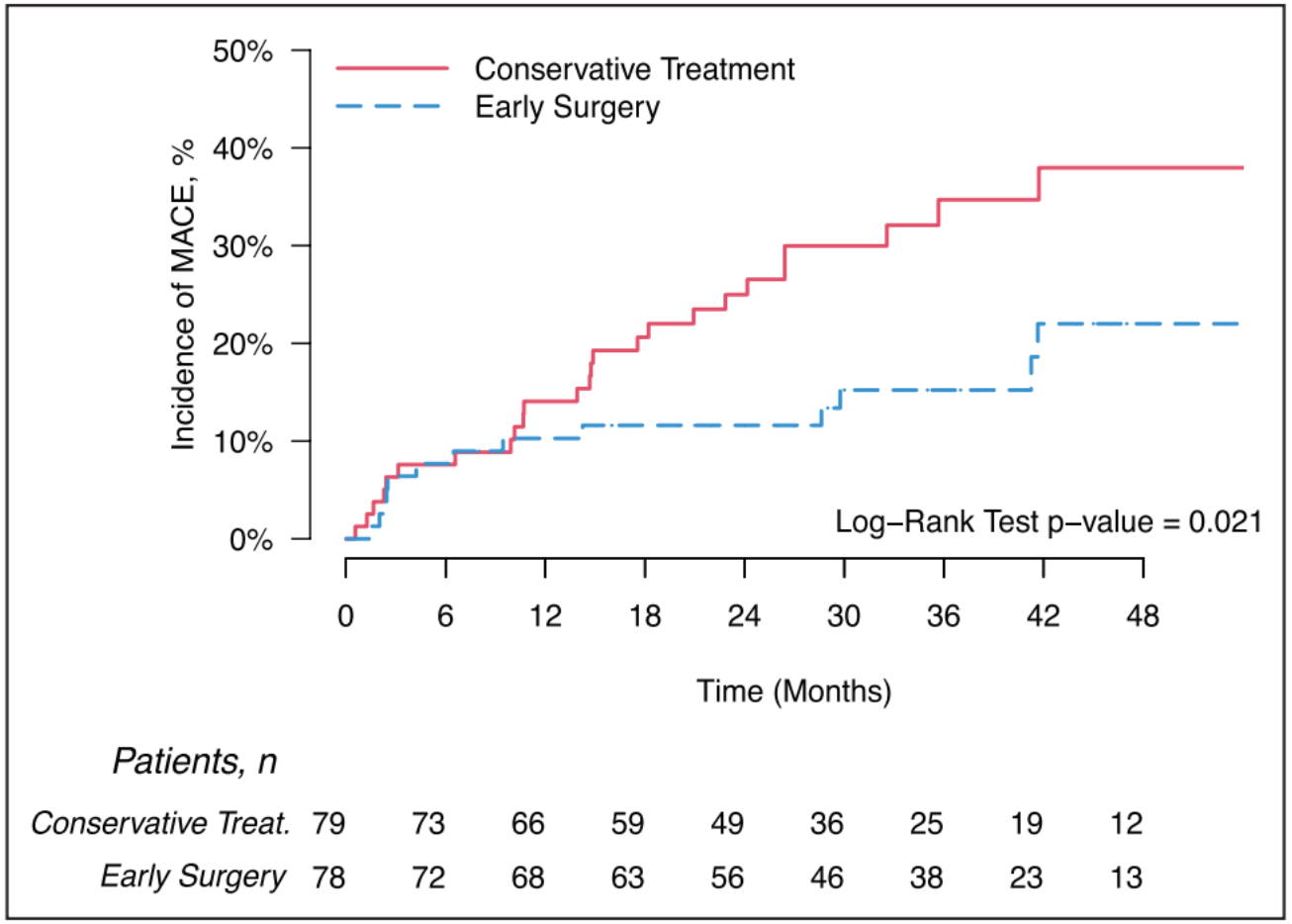
Kardiochirurgie vs. Konzervativní

Circulation

ORIGINAL RESEARCH ARTICLE

Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis: The AVATAR Trial

Marko Banovic, MD, PhD; Svetozar Putnik, MD, PhD; Martin Penicka, MD, PhD; Gheorghe Doros, PhD; Marek A. Deja, MD, PhD; Radka Kockova, MD, PhD; Martin Kotrc, MD; Sigita Glaveckaite, MD, PhD; Hrvoje Gasparovic, MD, PhD; Nikola Pavlovic, MD, PhD; Lazar Velicki, MD, PhD; Stefano Salizzoni, MD, PhD; Wojtek Wojakowski, MD, PhD; Guy Van Camp, MD, PhD; Serge D. Nikolic, PhD; Bernard Iung, MD; Jozef Bartunek, MD, PhD; on behalf of the AVATAR Trial Investigators*



EARLY TAVI studie

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

P. Généreux, A. Schwartz, J.B. Oldemeyer, P. Pibarot, D.J. Cohen, P. Blanke, B.R. Lindman, V. Babaliaros, W.F. Fearon, D.V. Daniels, A.K. Chhatriwalla, C. Kavinsky, H. Gada, P. Shah, M. Szerlip, T. Dahle, K. Goel, W. O'Neill, T. Sheth, C.J. Davidson, R.R. Makkar, H. Prince, Y. Zhao, R.T. Hahn, J. Leipsic, B. Redfors, S.J. Pocock, M. Mack, and M.B. Leon, for the EARLY TAVR Trial Investigators*

This article was published on October 28, 2024, at NEJM.org.
DOI: 10.1056/NEJMoa2405880

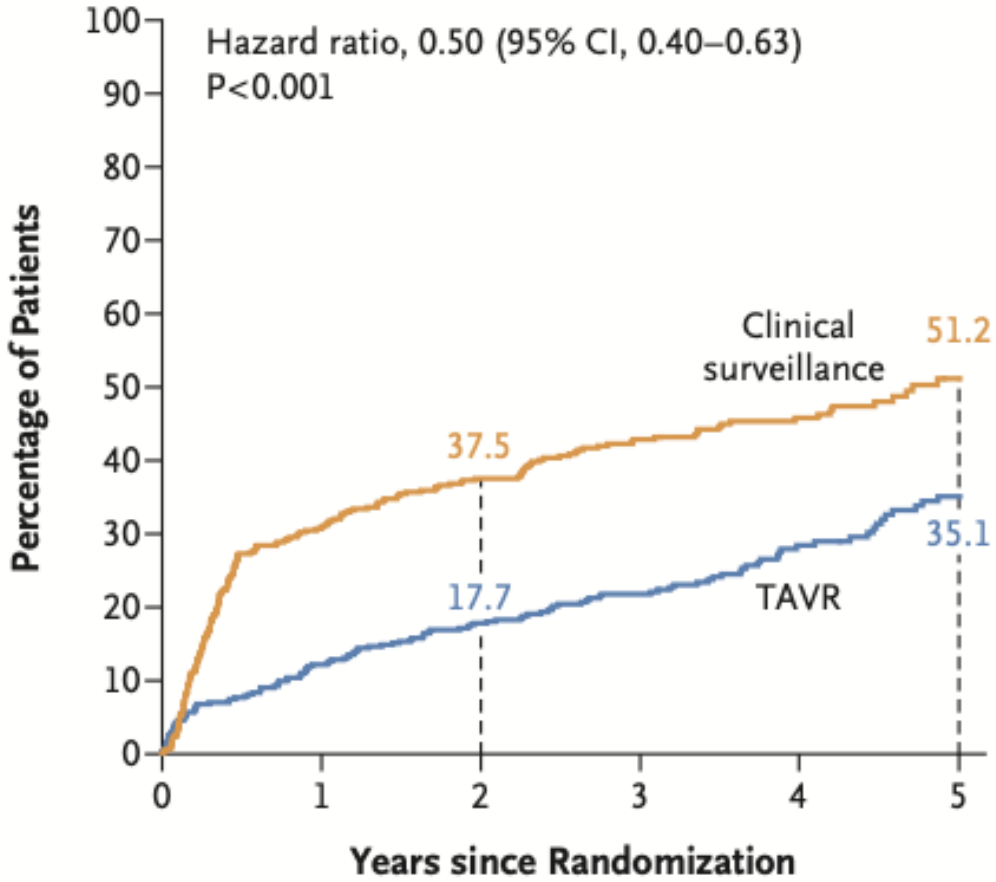
901 pacientů, průměrný věk 76 let
1:1 randomizace TAVI (Sapien) vs. Konzerv.
Medián sledování 3,8 roku

Střední gradient 47 mmHg, AVA 0,9±0,2
Nízké riziko (STS 1,6)
Asymptomatický statut →
- Negativní treadmill test (90%) nebo klinické hodnocení

NT-proBNP 275 pg/ml

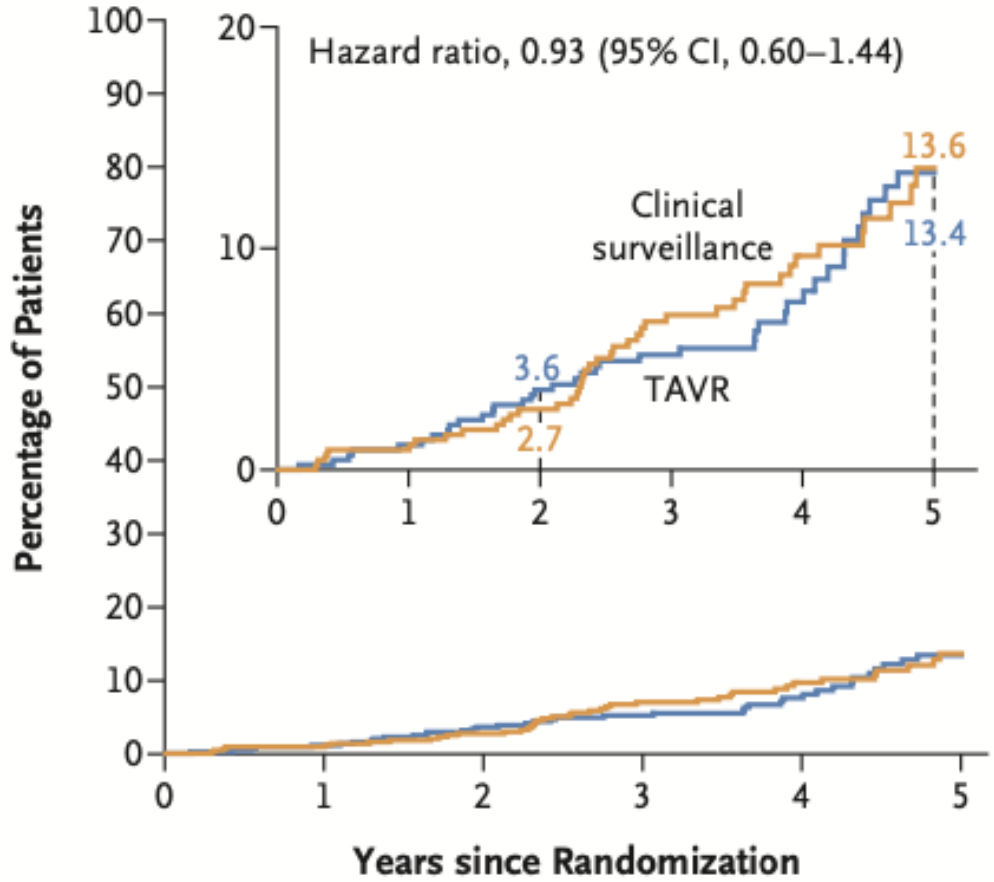
Exclusion: EFLK < 50%, STS>10

A **Death, Stroke, or Unplanned Hospitalization for Cardiovascular Causes (%)**



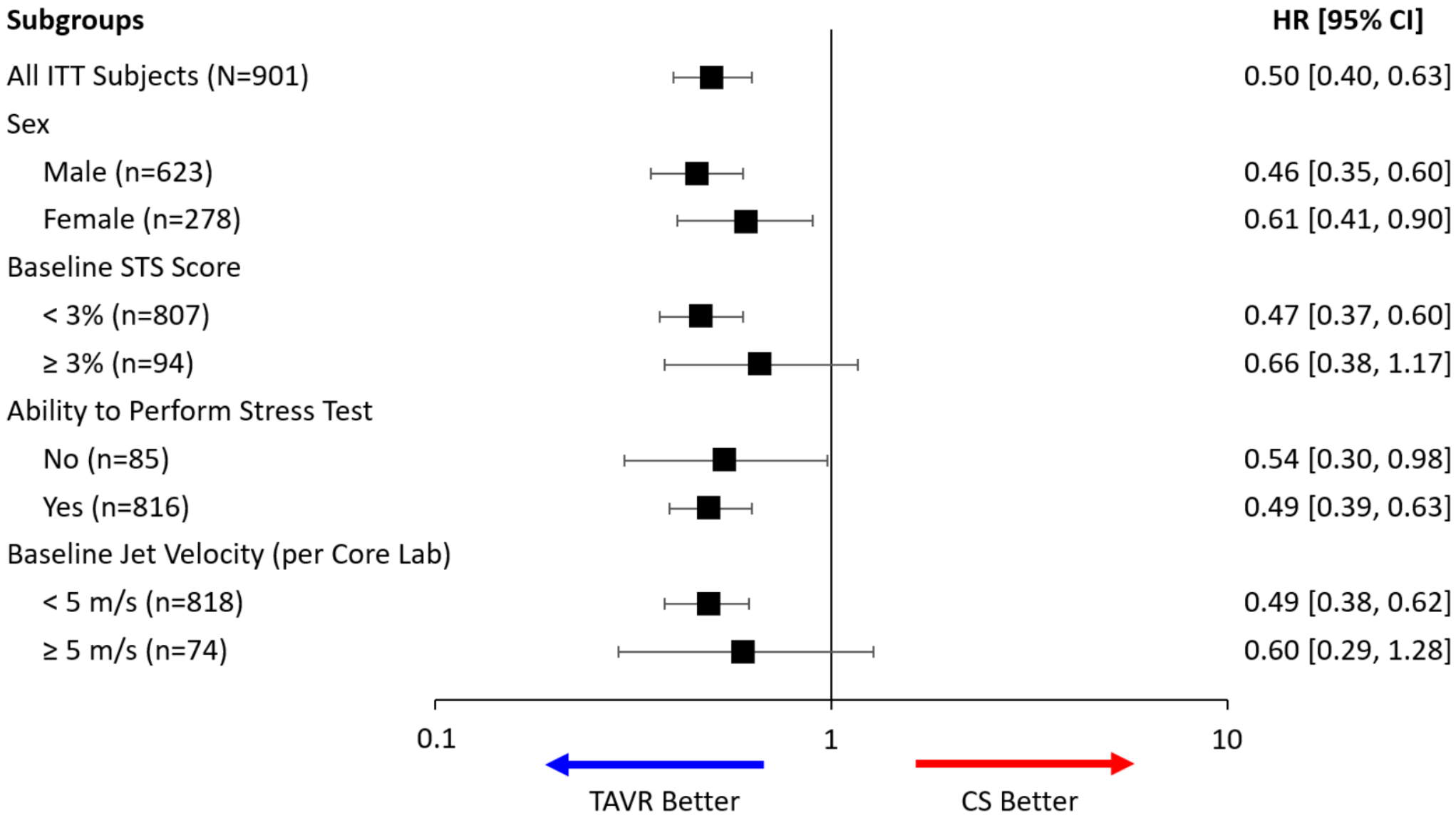
No. at Risk						
TAVR	455	390	363	285	142	103
Clinical surveillance	446	305	266	187	117	46

B **Death from Any Cause**

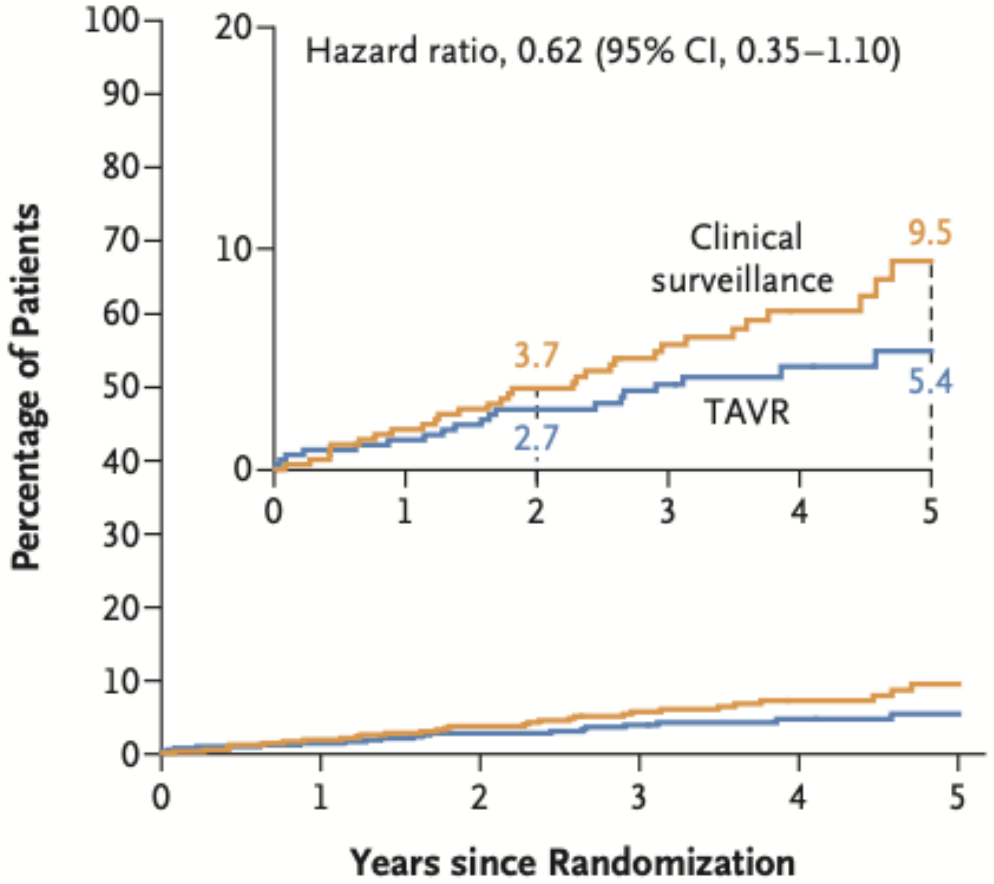


No. at Risk						
TAVR	455	439	425	346	187	136
Clinical surveillance	446	436	418	310	199	95

Figure S3. Forest Plot of Pre-specified Subgroup Analyses



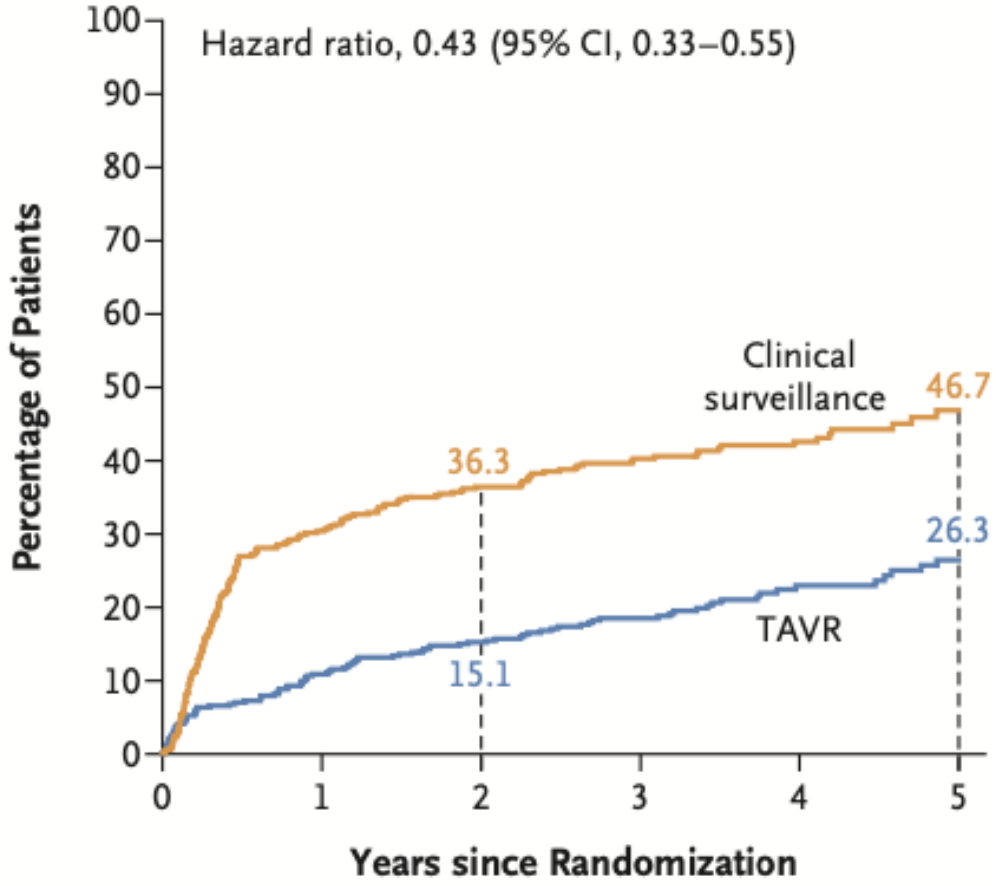
C Stroke



No. at Risk

TAVR	455	433	415	335	180	130
Clinical surveillance	446	429	406	295	185	87

D Unplanned Hospitalization for Cardiovascular Causes



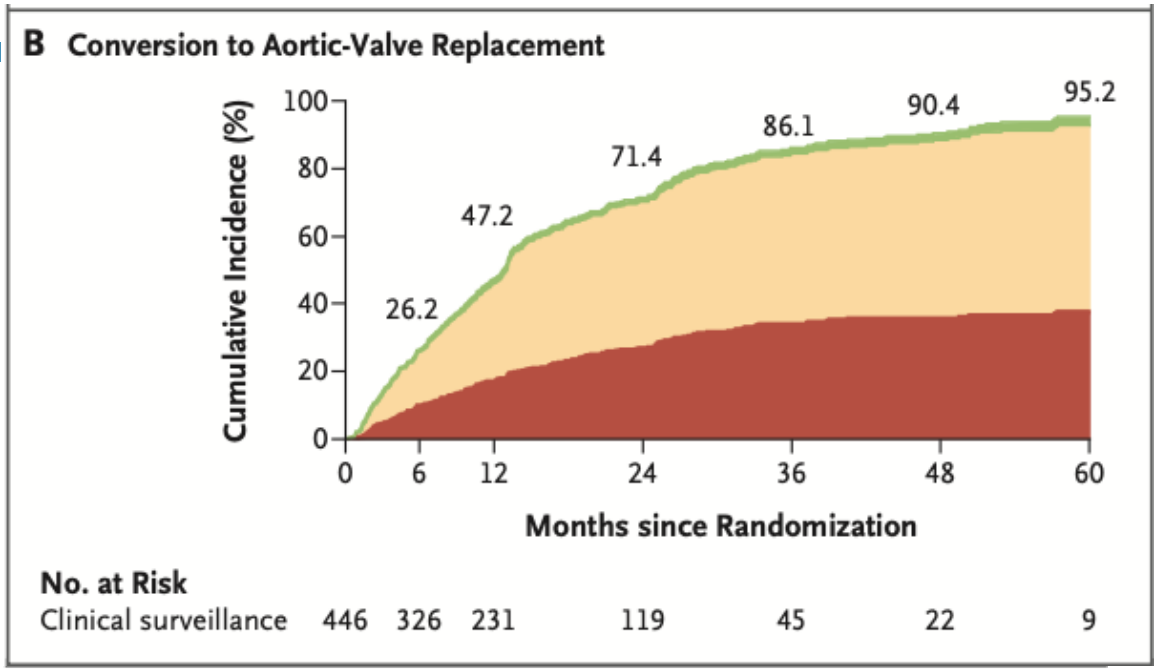
No. at Risk

TAVR	455	392	365	287	142	103
Clinical surveillance	446	306	267	189	118	46

Konverze na TAVI u 388 pacientů (87%) během sledování median 3,8 roku

47% během prvních 12 měsíců
95% během 60 měsíců

11 pacientů v konzervativní větvi zemřelo před konverzí do TAVI



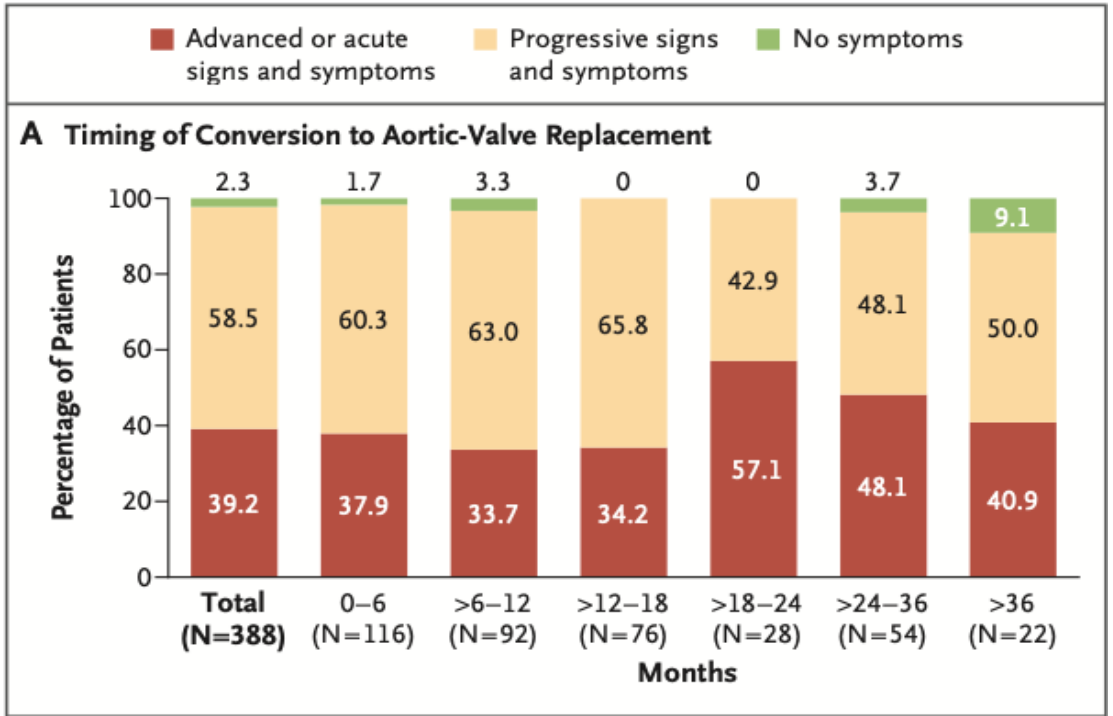
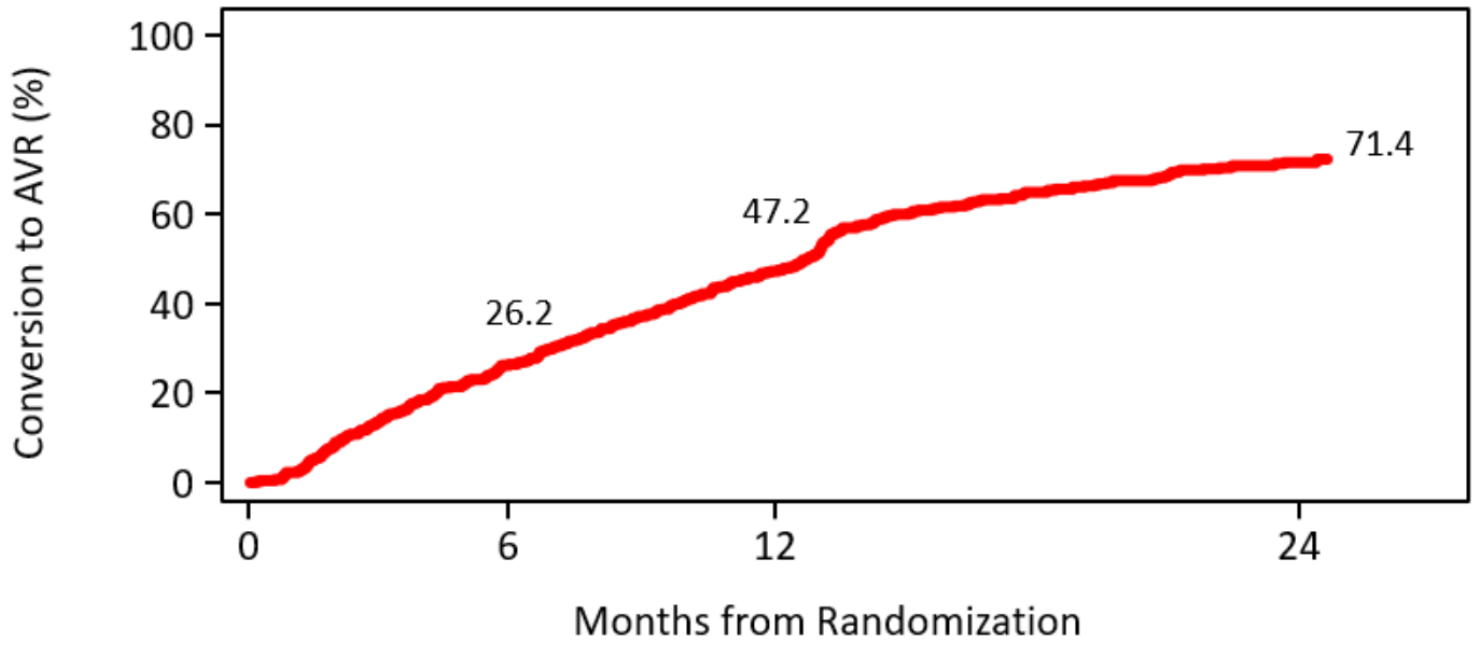


Figure S5. Conversion to AVR in the Clinical Surveillance Arm Through 2 Years



Konverze na TAVI

Screening → Před výkonem

Progrese významnosti AS
Pokles EFLK
Vzestup NT-proBNP
Více FiS
6 minutový walk test

STŘEDNĚ TĚŽKÁ AORTÁLNÍ STENÓZA

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER
VOL. ■, NO. ■, 2024

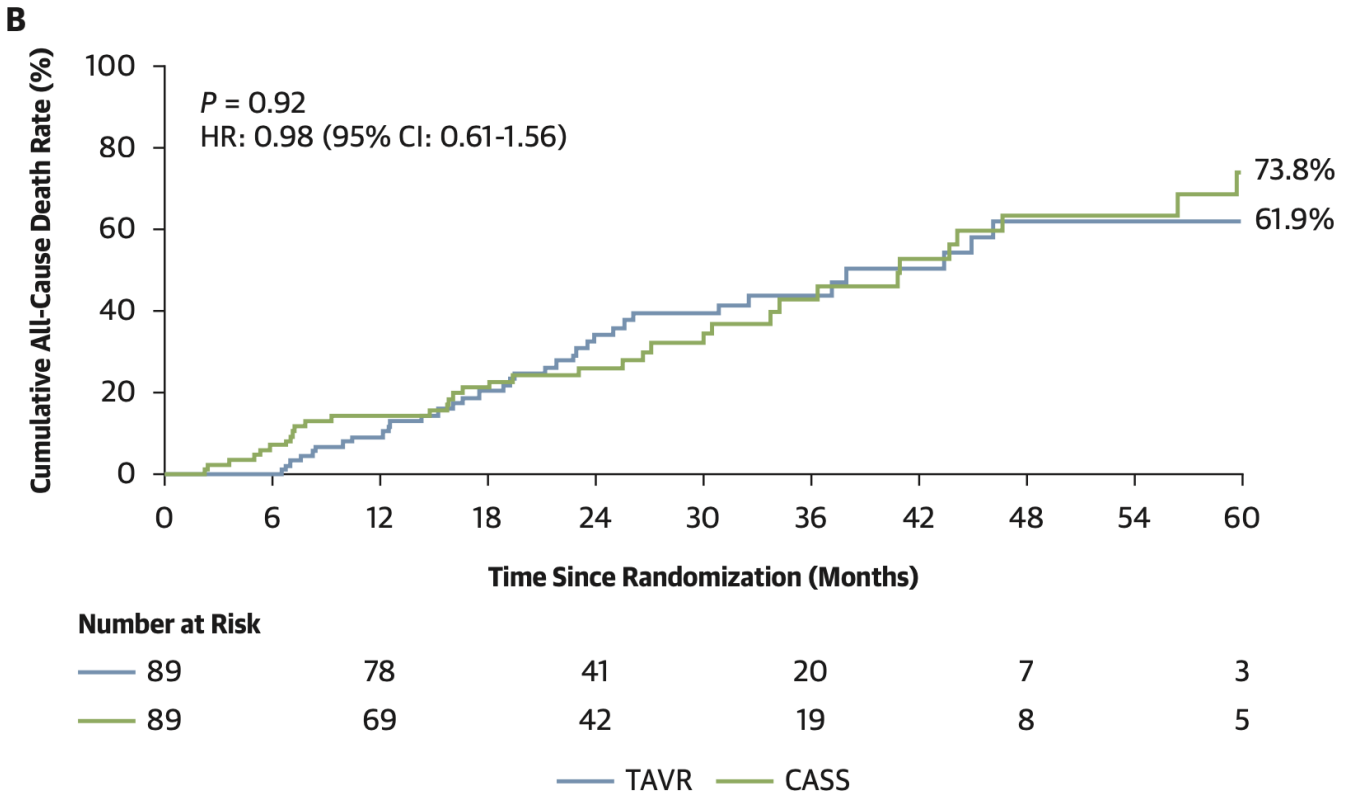
TAVR UNLOAD

77 let, STS 4,4 + 3,4
56% NYHA 3/4
ICHS 76%
EFLK 39%
AVA 1,2 cm2, střední gradient 18,8 mmHg

Medián sledování 23 měsíců
Konverze na TAVI u 43% během 12 M
Bezpečnost a klinická efektivita 12 M

Transcatheter Aortic Valve Replacement in Patients With Systolic Heart Failure and Moderate Aortic Stenosis

TAVR UNLOAD



Recruiting

Evolut™ EXPAND TAVR II Pivotal Trial

ClinicalTrials.gov ID NCT05149755

Sponsor Medtronic Cardiovascular

Information provided by Medtronic Cardiovascular (Responsible Party)

Last Update Posted 2025-02-13

Počet pacientů: 2250
Začátek 2021 Primární data 2029 Kompletní ukončení 2037

Recruiting

PROGRESS: Management of Moderate Aortic Stenosis by Clinical Surveillance or TAVR (PROGRESS)

ClinicalTrials.gov ID NCT04889872

Sponsor Edwards Lifesciences

Information provided by Edwards Lifesciences (Responsible Party)

Last Update Posted 2025-02-20

Počet pacientů: 650
Začátek 2022 Primární ukončení 2026 Kompletní ukončení 2034

AORTÁLNÍ STENÓZA U ŽEN

Smaller aortic root/annuli, smaller LVOT
Smaller AVA, lower SV, lower AV gradient

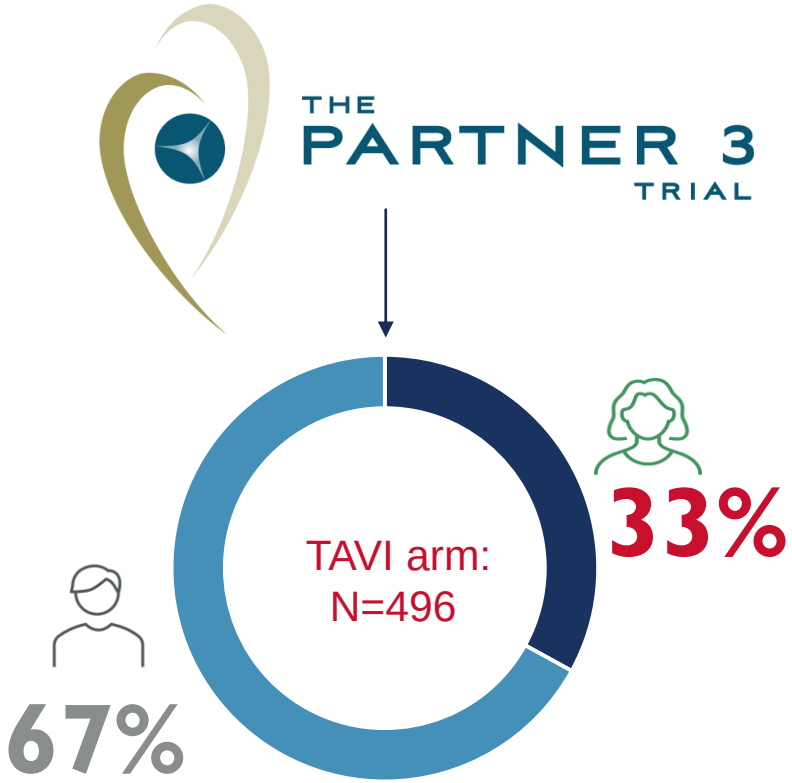
Less aortic valve calcification load and fibrotic prominence

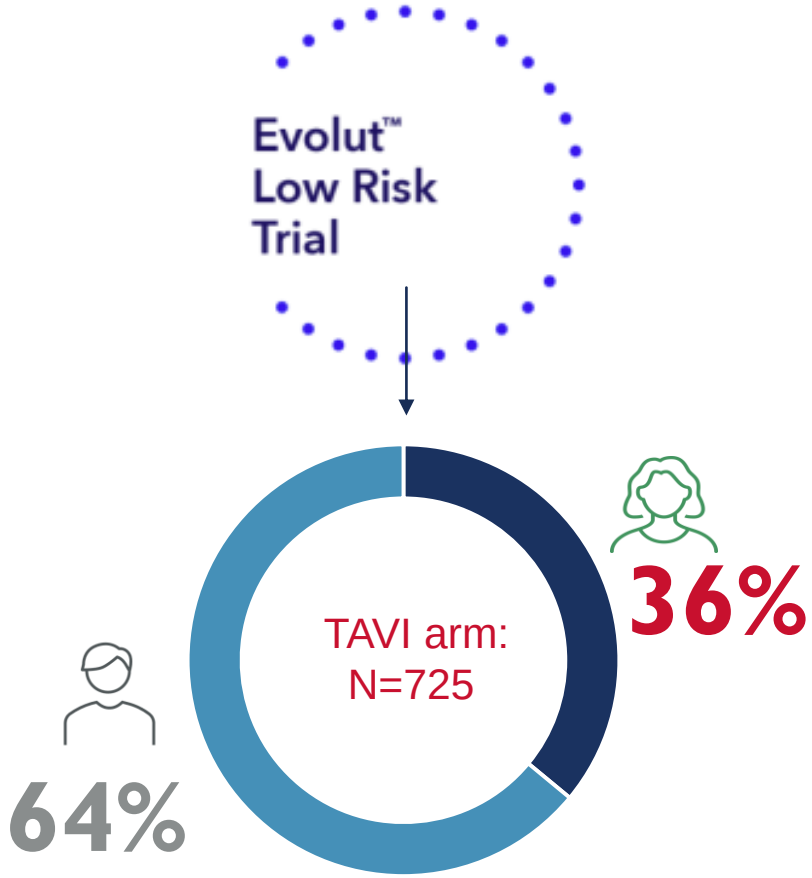
Aortic stenosis in women

High prevalence of paradoxical Low-flow, low-gradient AS (i.e. with preserved LVEF)

Concentric LVH, smaller LV cavity, higher filling pressure, higher relative wall thickness, lower LV mass index

J Thorac Dis 2024;16(9):6308-6319





Studie TAVI vs. SAVR u pacientů s nízkým rizikem – zastoupení žen

1. Mack MJ, Leon MB, Thourani VH *et al*. Transcatheter aortic valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019; **380**: 1695–705.
2. Popma JJ, Deeb GM, Yakubov SJ *et al.* Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019; **380:** 1706–715.

Studie **RHEIA -** TAVI vs. SAVR u žen

Key Inclusion and Exclusion Criteria

RHEIA

Inclusion:

Women with severe symptomatic AS meeting the following criteria:

- High gradient severe AS

  or

- Low gradient severe AS

per ESC guidelines

Exclusion:

- Bicuspid aortic valve
- Unicuspid aortic valve
- Non-calcified aortic valve
- Complex coronary artery disease
- Other anatomical features increasing the risk of complications with TAVI or surgery

Procedural Findings

TAVI

	%
Valve type:	
SAPIEN 3 / SAPIEN 3 ULTRA	43% / 57%

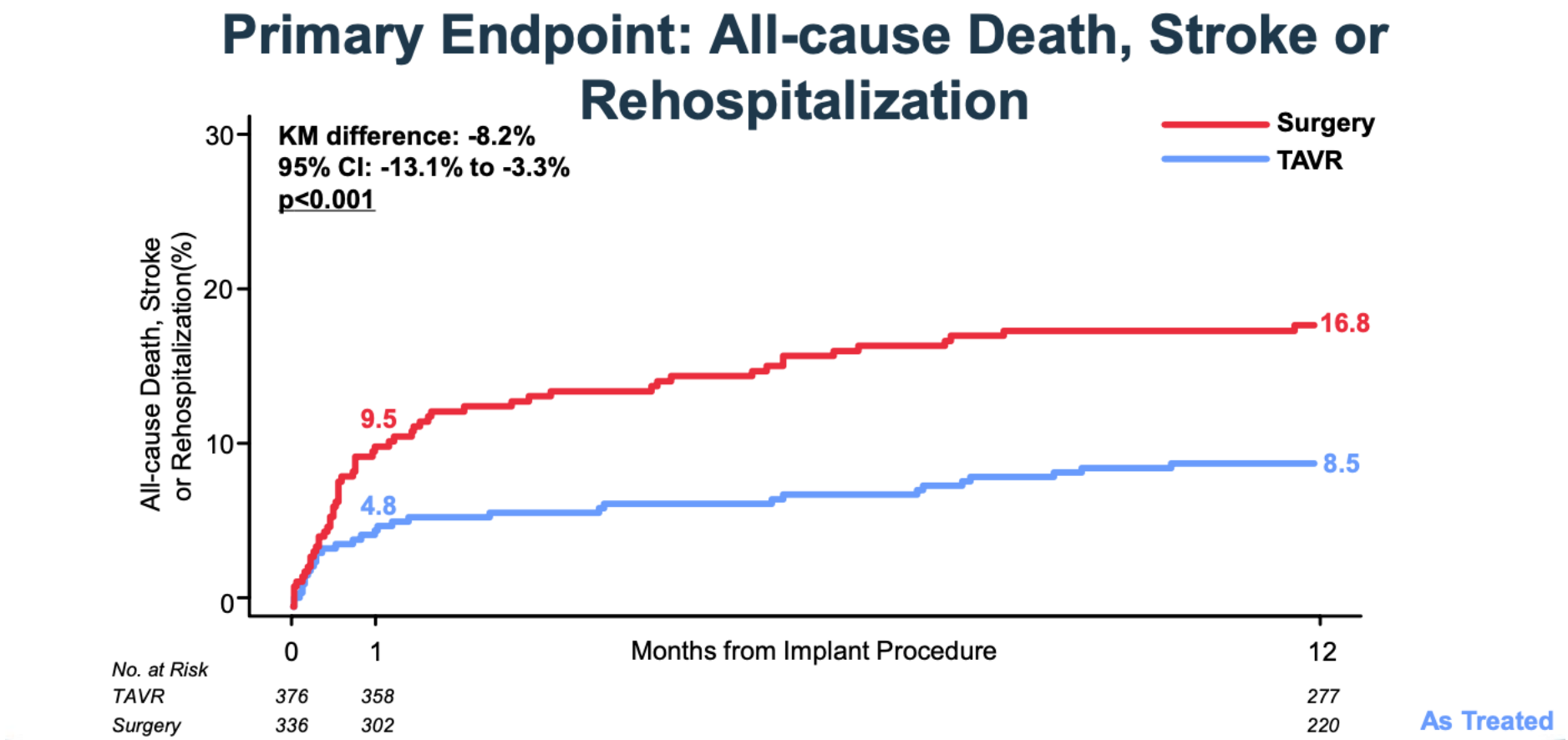
Concomitant procedures	%
Percutaneous Coronary Intervention	0%
Pacemaker implantation	0.5%
Other	0%

Surgery

	%
Valve type:	
Edwards Magna Ease / Intuity	59.7% / 12.2%
Livanova Perceval	15.5%
Surgery approach:	
Full / Mini sternotomy	66.3% / 27.3%

Concomitant procedures	%
CABG	6.8%
Aortic annulus enlargement	0%
Surgery for AF	2.9%
Ascending Aorta replacement	1.5%
Mitral valve intervention	0.5%
Tricuspid valve intervention	1.0%
Other	0.5%

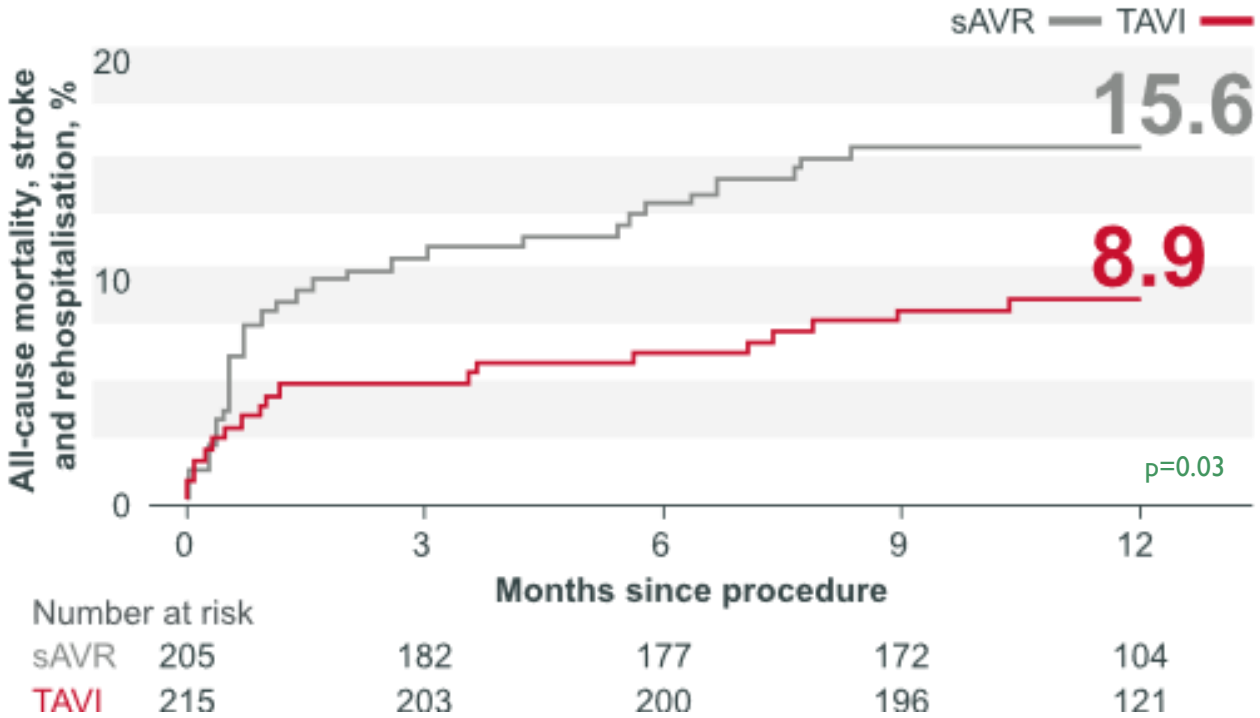
Studie **RHEIA -** TAVI vs. SAVR u žen



Studie **RHEIA -** TAVI vs. SAVR u žen

RHEIA

Primary outcome



Key secondary outcomes

Permanent pacemaker implantation
TAVI: 8.8%
sAVR: 2.9%
Difference (95% CI): **+5.9% (1.5, 10.4)**
p=0.01

New onset atrial fibrillation
TAVI: 3.3%
sAVR: 28.8%
Difference (95% CI): **−25.5% (−32.2, −18.9)**
p<0.001

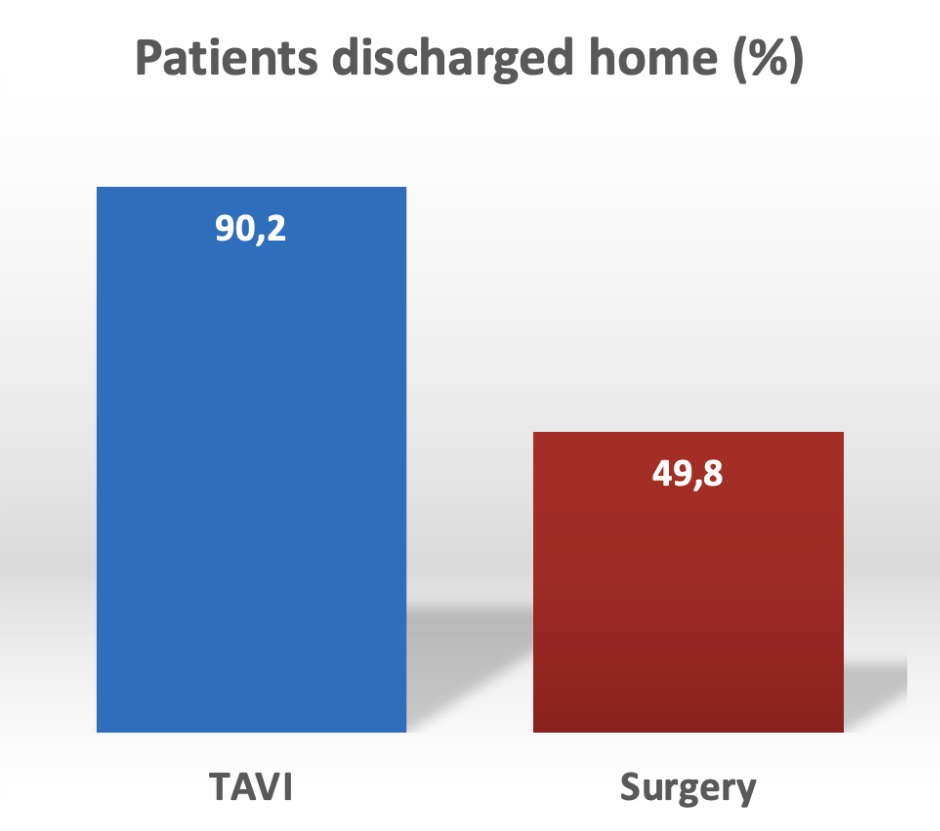
Primary Endpoint Components at 1 year

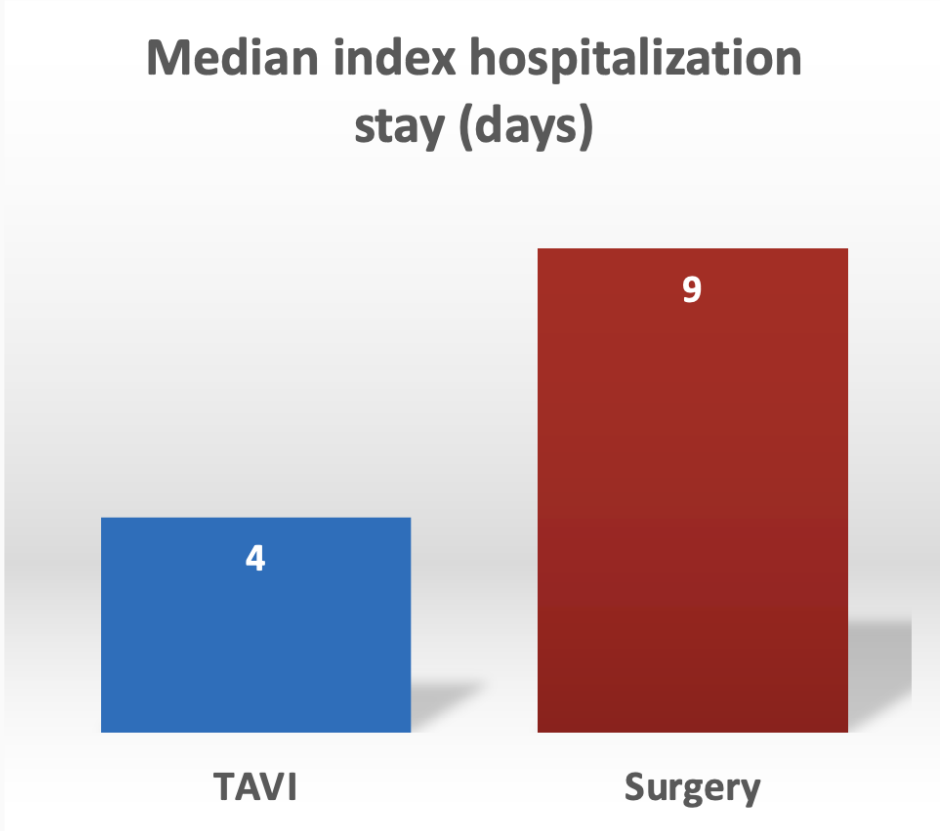
RHEIA

	TAVI (N=215)	Surgery (N=205)	TAVI- Surgery	P-Value
Death	**2 (0.9%)**	**4 (2.0%)**	**-1.0% [-3.3%, 1.3%]**	0.44
Cardiac death	1 (0.5%)	1 (0.5%)	0.0% [-1.3%, 1.3%]	1.00
Non-cardiac death	1 (0.5%)	3 (1.5 %)	-1.0% [-2.9%, 0.9%]	0.36
Stroke	**7 (3.3%)**	**6 (3.0%)**	**0.3% [-3.0%, 3.7%]**	1.00
Disabling stroke	2 (0.9%)	3 (1.5%)	-0.6% [-2.7%, 1.6%]	0.68
Non-disabling stroke	5 (2.4%)	3 (1.5%)	0.9% [-1.7%, 3.5%]	0.72
Rehospitalization valve-related or procedure-related or worsening congestive heart failure	**10 (4.8%)**	**23 (11.4%)**	**-6.6% [-11.9%, -1.4%]**	**0.02**

Other Secondary Endpoints

RHEIA





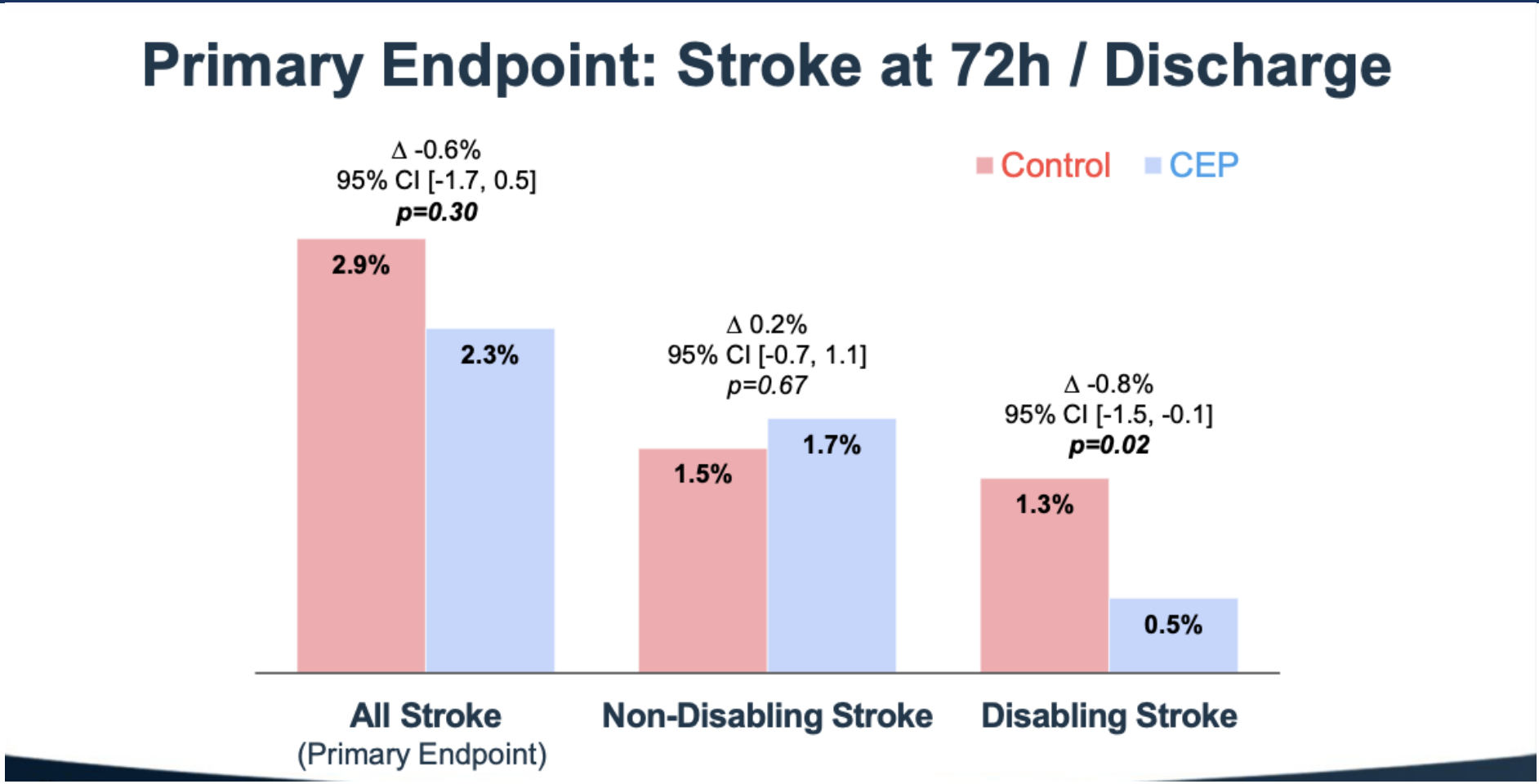
ZÁVĚR

Asymptomatická aortální stenóza

TAVI vs. SAVR u žen

Středně těžká aortální stenóza a dysfunkce levé komory

CÉVNÍ MOZKOVÁ PŘÍHODA – NEUROPROTEKCE BĚHEM VÝKONU

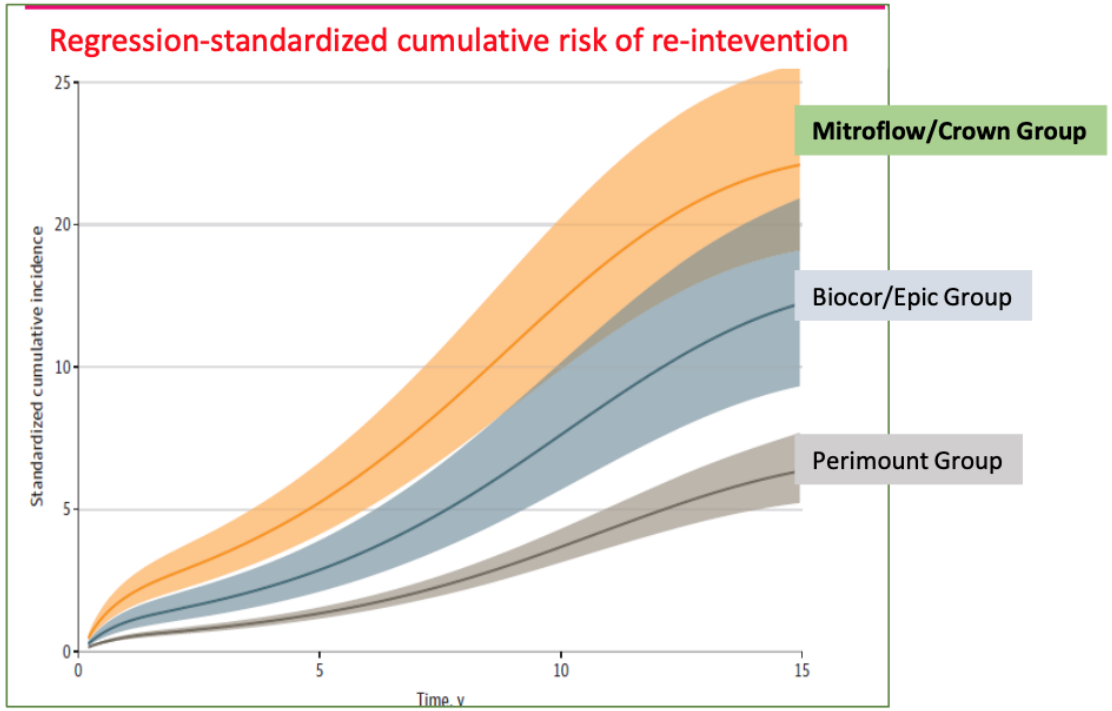


The Protected TAVR study - TCT 2022

What do we know about surgical bioprosthesis?

2. All surgical valves are not equivalent

16 983 Pts
Mean age = 72±5



JAMA Network Open. 2022

Original Investigation | Cardiology

Comparison of Long-term Performance of Bioprosthetic Aortic Valves in Sweden From 2003 to 2018

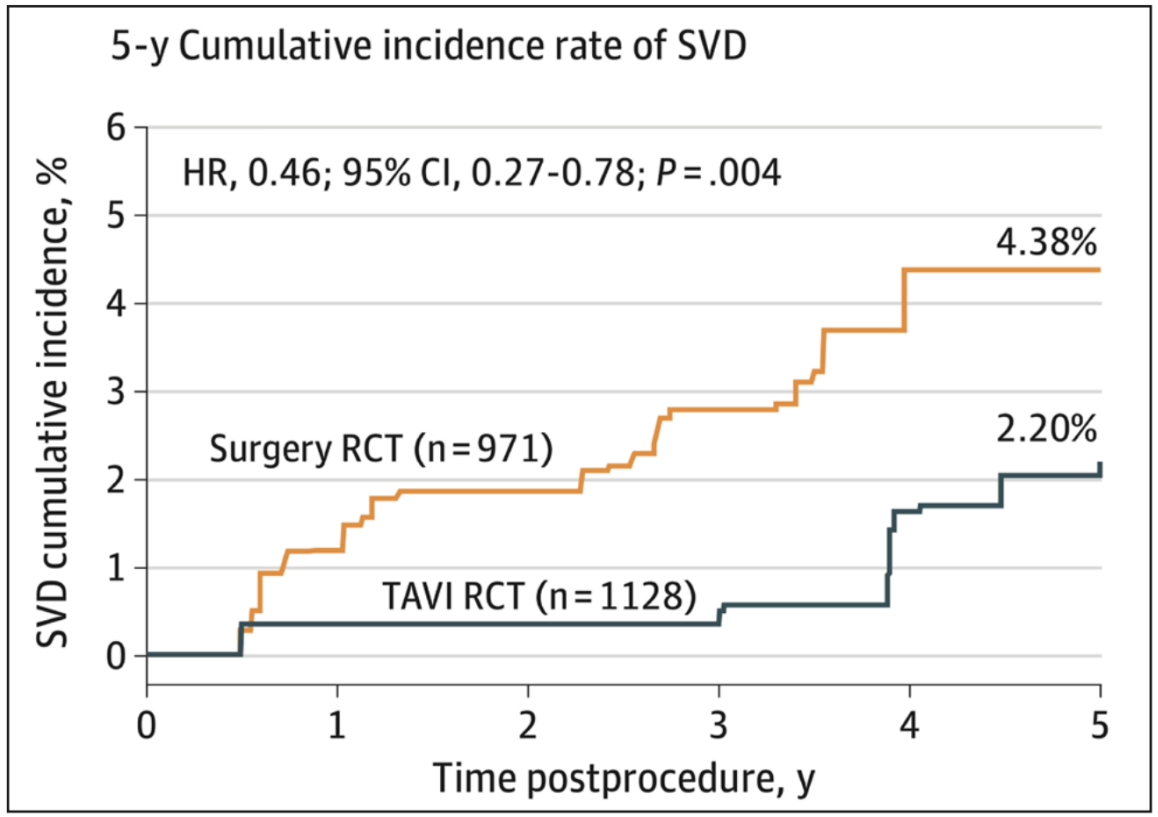
Michael Persson, MD; Natalie Glaser, MD, PhD; Johan Nilsson, MD, PhD; Örjan Friberg, MD, PhD; Anders Franco-Cereceda, MD, PhD; Ulrik Sartipy, MD, PhD

ENGINEERED FOR LONG-TERM DURABILITY

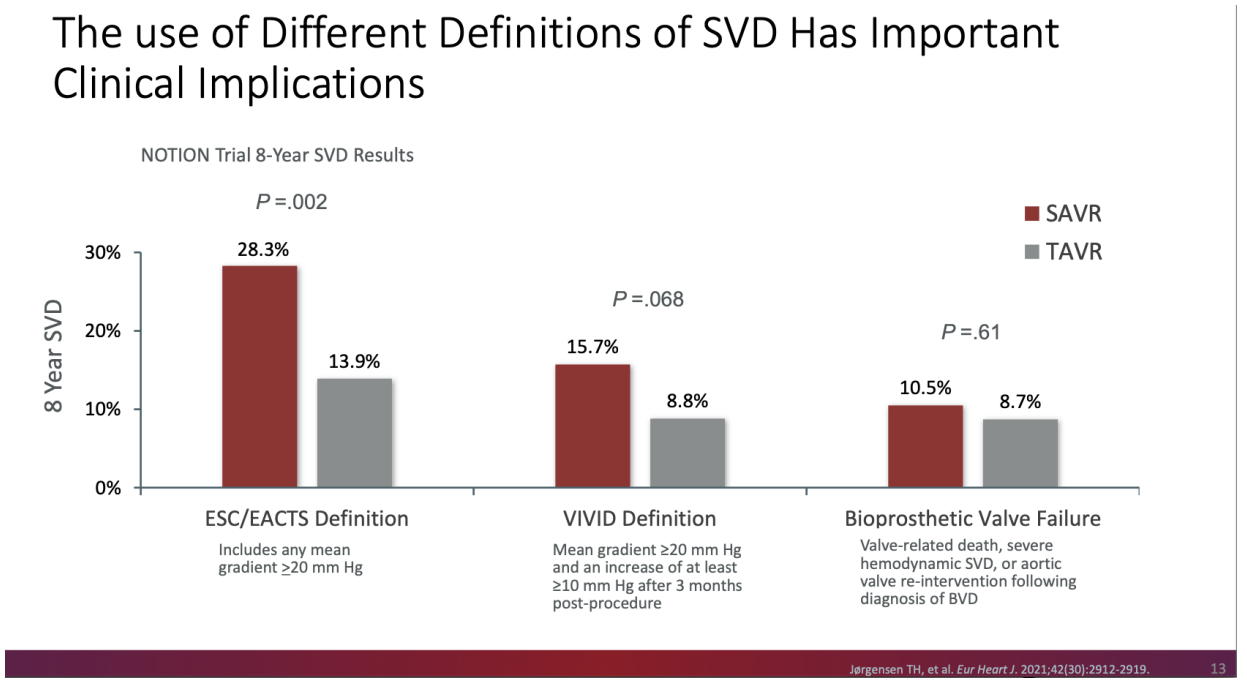
Outstanding published freedom from explant due to structural valve deterioration.[22]

1. A fatigue-resistant, radiopaque, high-strength titanium stent is designed to reduce stress on leaflets during the cardiac cycle and allows for larger EOAs[8,11,23]
2. A pericardial-covered stent to reduce the risk of abrasion and structural valve deterioration[24-26]
3. Computer-controlled tissue thickness and fiber orientation[27]
4. Additional valve protection on an integral valve holder
5. Linx™ Anticalcification (AC) treatment;* a valve treatment that resists calcification four ways[28-34]

TRVANLIVOST CHLOPNÍ



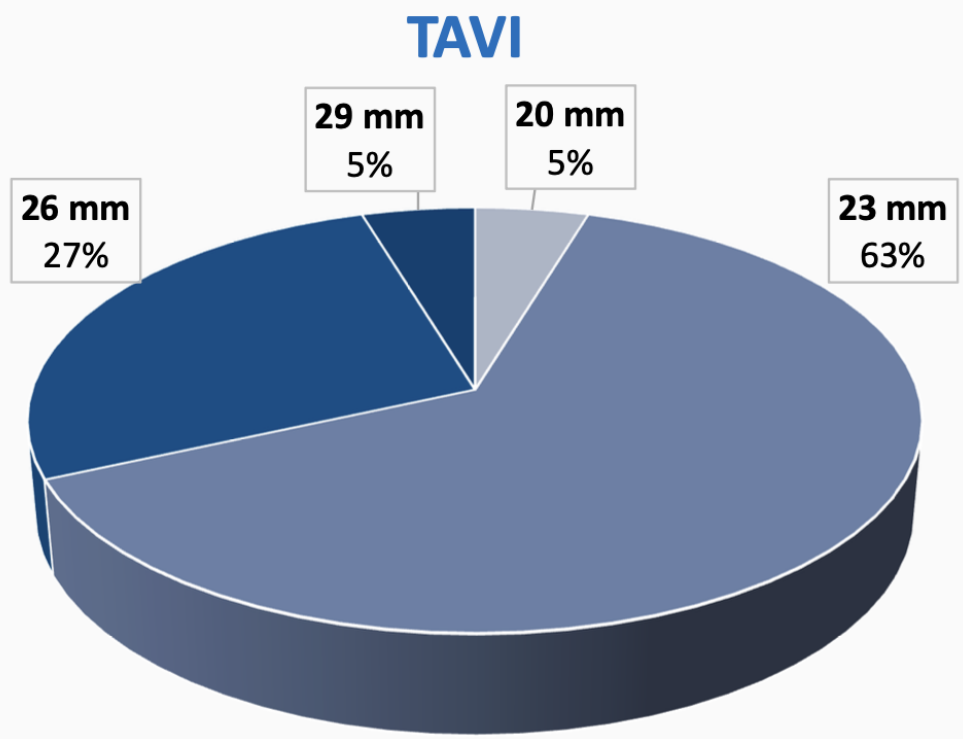
DEFINICE DYSFUNKCE PROTÉZY

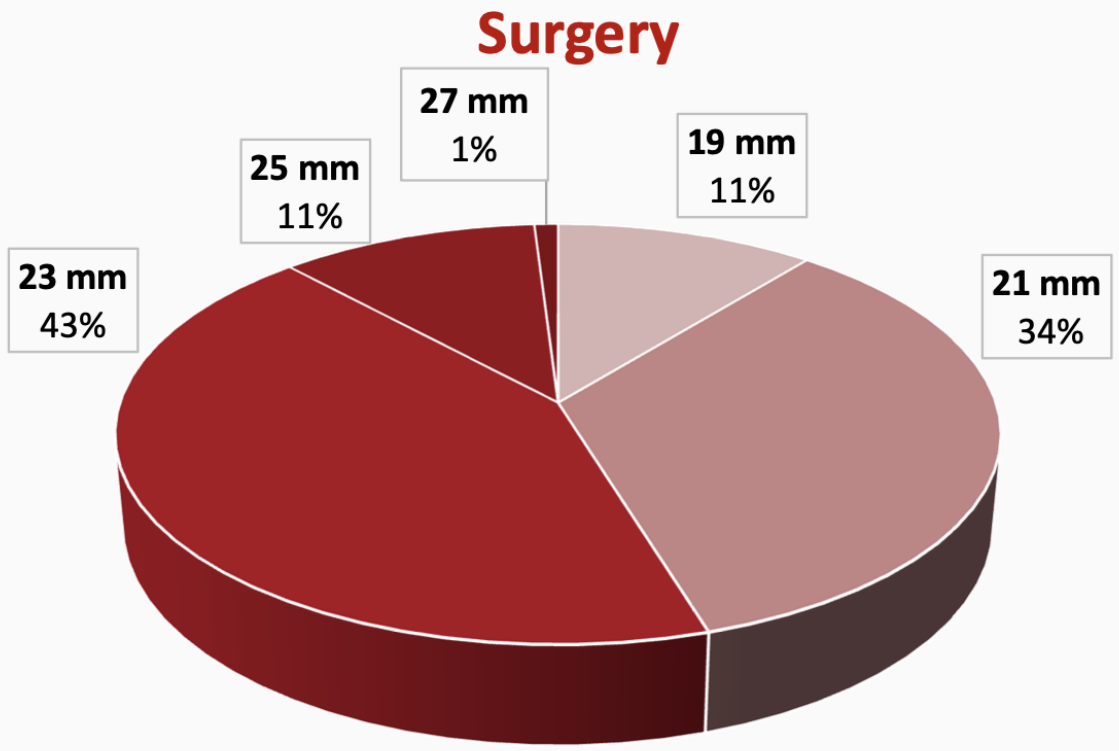


JAMA Cardiol. 2023 Feb 1;8(2):111-119. doi: 10.1001/jamacardio.2022.4627

Valve size distribution

RHEIA

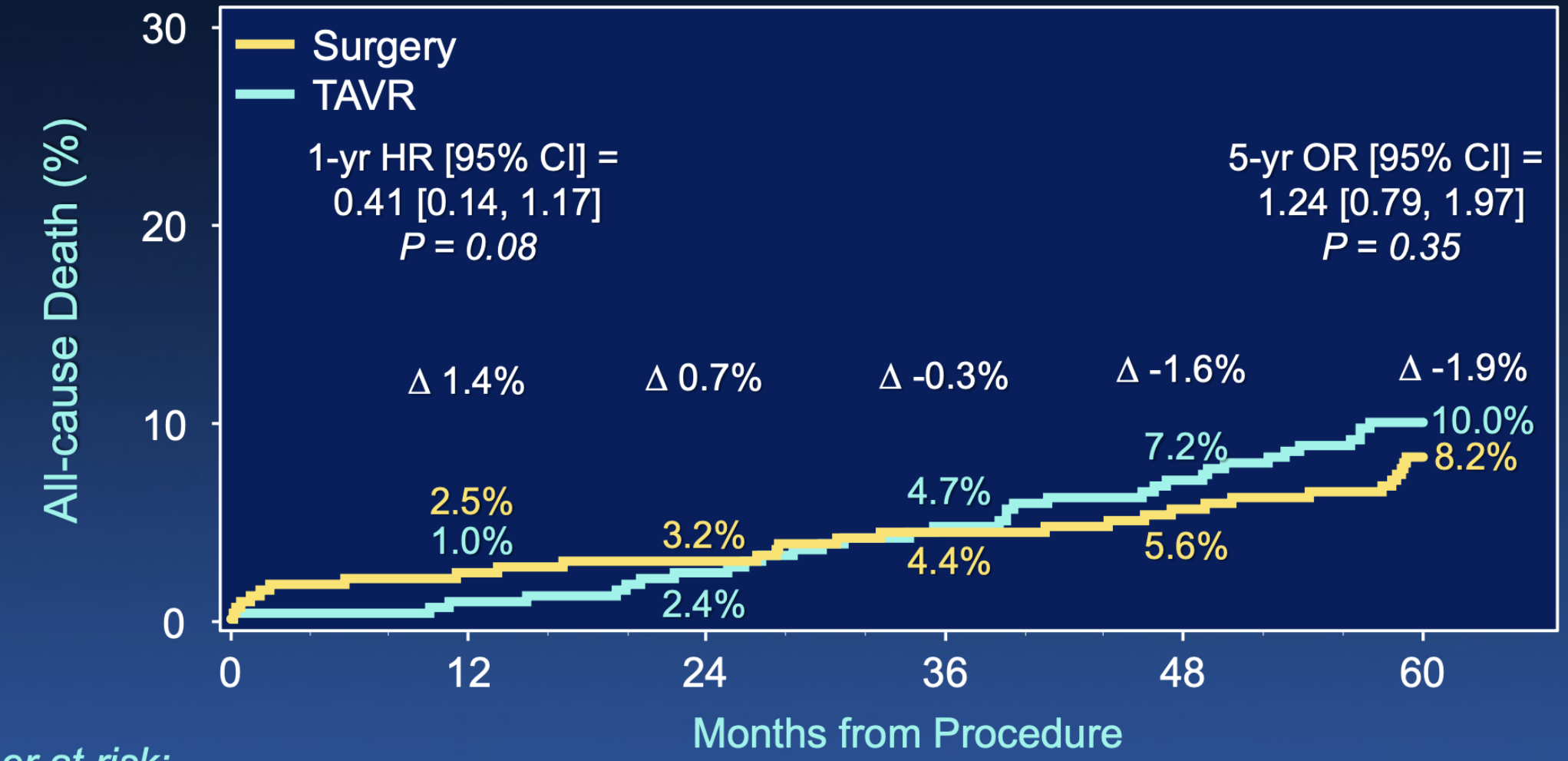




No 29 mm

THE PARTNER 3 TRIAL

All-cause Death



Number at risk:

TAVR	496	490	478	460	438	405
Surgery	454	427	409	394	379	346

THE PARTNER 3 TRIAL

Causes of Death 0-5 Years

CV Causes

Cause, No. of pts	TAVR	Surgery
Cardiac Cause	**8**	**9**
Acute MI	0	2
Cardiac Arrest	2	1
Cardiogenic Shock	0	1
CHF	2	3
Endocarditis	0	1
Sudden Cardiac Death	4	1
Non-coronary Vascular Conditions	**11**	**6**
Procedure-related	2	2
Stroke	3	4
Traumatic Head Injury from Fall	**6**	**0**
Unknown	**7**	**6**
Totals	**26**	**21**

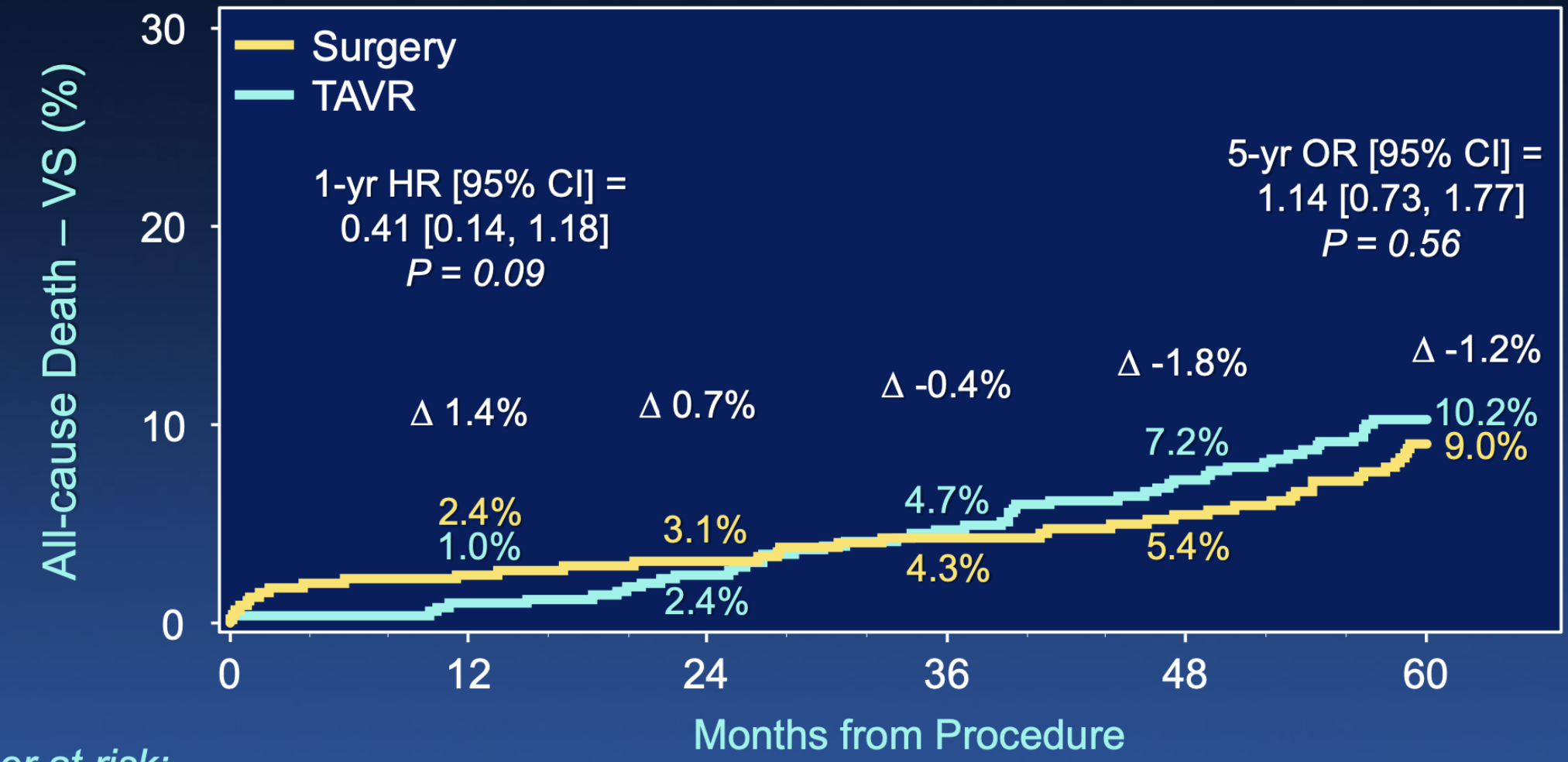
Non-CV Causes

Cause, No. of pts	TAVR	Surgery
Cancer	**9**	**5**
COVID-19	**3**	**1**
Cirrhosis	1	0
MVA	1	1
Parkinson's Disease	0	1
Respiratory Failure*	3	4
Sepsis	**4**	**1**
Suicide	1	0
Totals	**22**	**13**

*Due to chronic respiratory disease or pneumonia

THE PARTNER 3 TRIAL

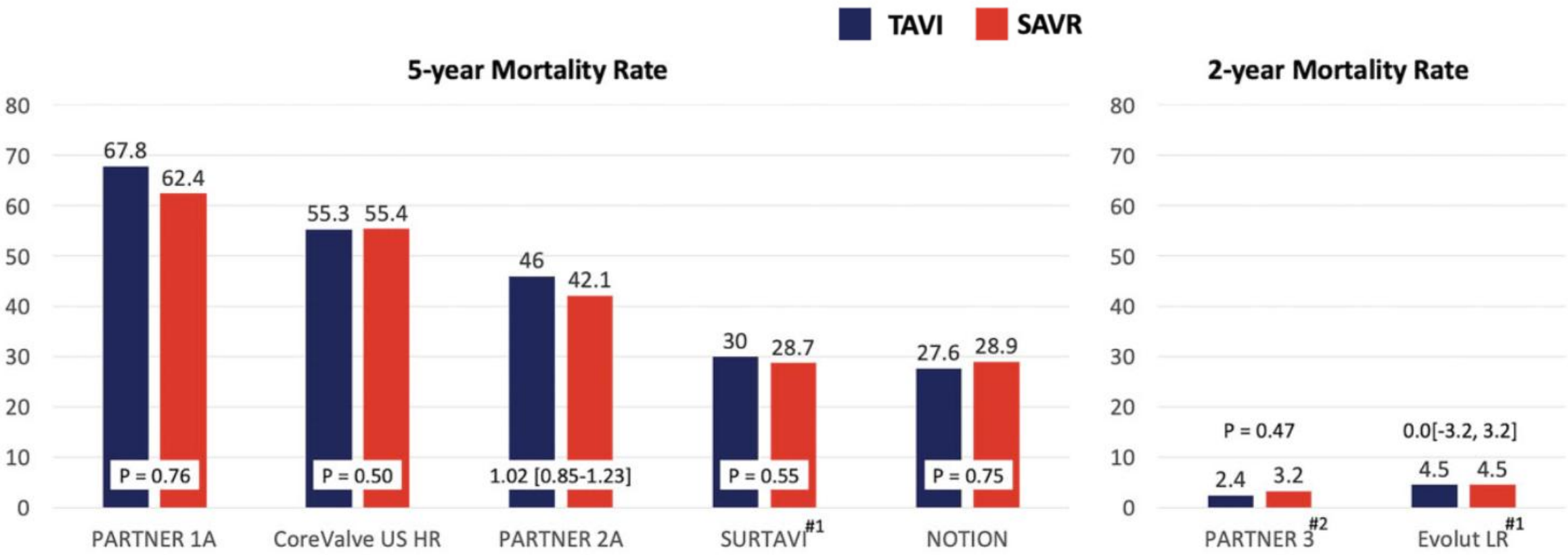
Vital Status Sweep



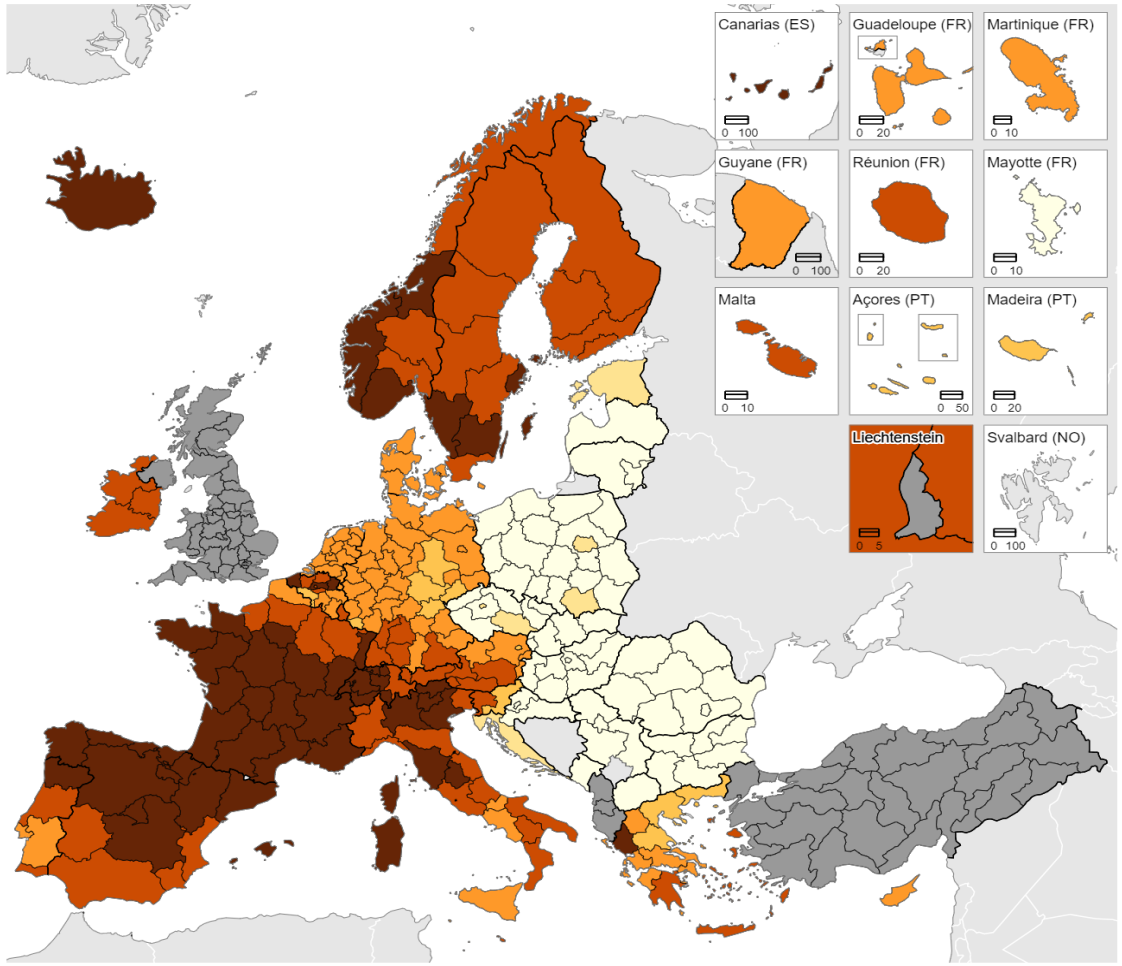
Number at risk:

TAVR	496	490	479	463	445	415
Surgery	454	435	424	413	404	378

MORTALITA – KATETRIZAČNÍ X CHIRURGICKÁ



Life expectancy at 65 years, 2021
(by NUTS 2 region; in years)



Estonia, Cyprus, Latvia, Luxembourg and Malta are single regions at this level of detail. Data not available for Bosnia and Herzegovina, Albania, T iye and Ukraine. Data available for other candidate countries: Montenegro, North Macedonia and Serbia

Očekávaná délka života ve věku 65 let v EU

Průměr 19 let
Rozmezí > 21 let…. <17 let

Průměrná délka života v ČR

Muži 76 let
Ženy 82 let