Sympózium Edwards Lifesciences Czech Republic s.r.o…ve spolupráci s ČAIK

Současné a budoucí trendy v léčbě srdečních chlopní

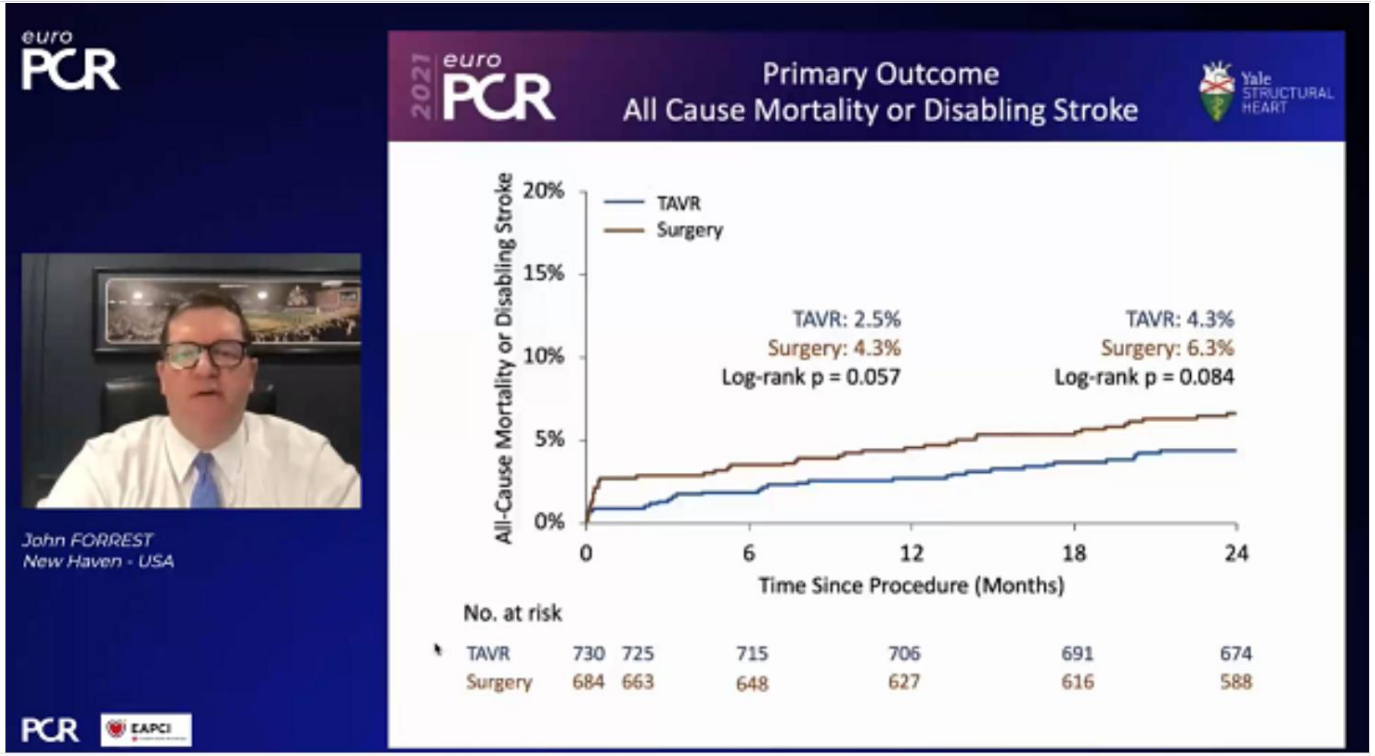
TAVI v roce 2024

Petr Kala

Interní kardiologická klinika FN Brno a LF MU

6.5.2024

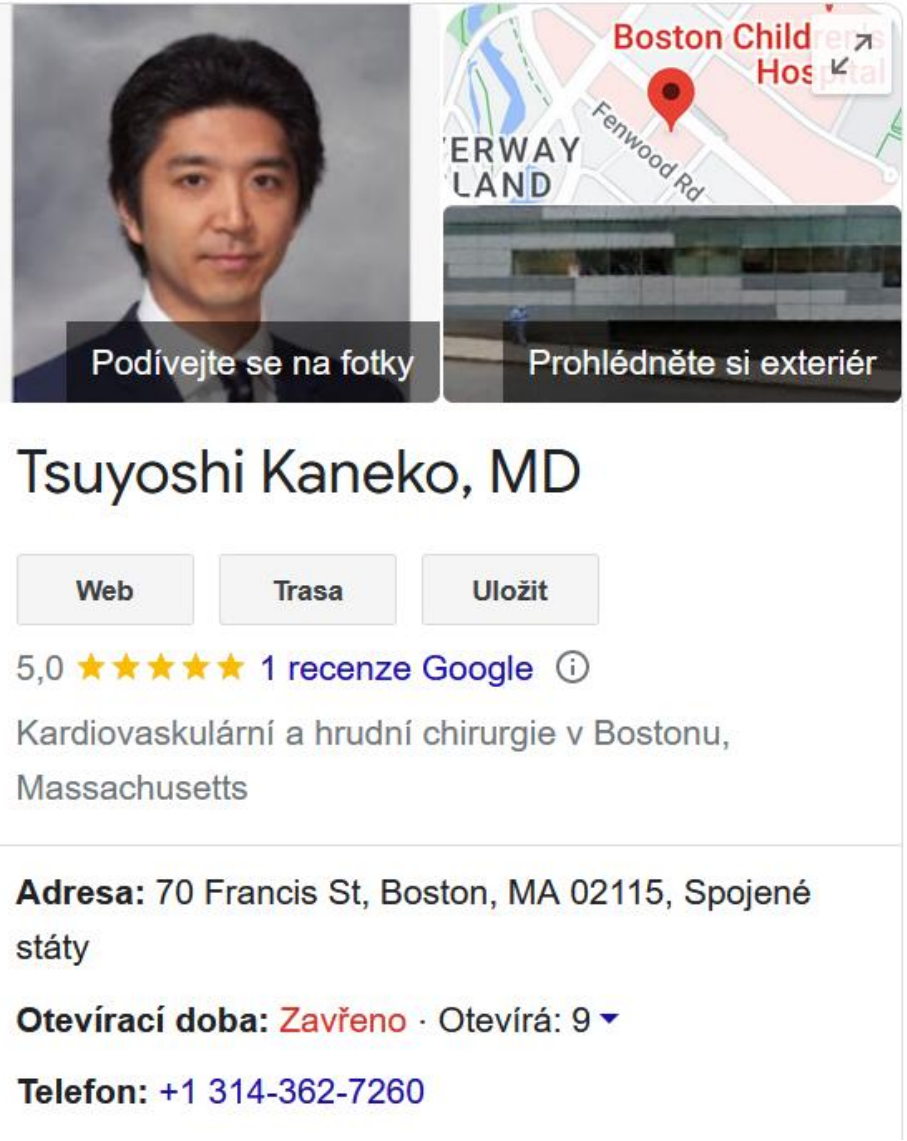
EVOLUT low-risk – 2 leté sledování



- Lehký **PVL** po implantaci byl 26.6% po TAVI a 2.6% po **SAVR** ($P < 0.001$).
- **PPM -** Patient-prosthesis mismatch **TAVI** lehký-střední 10% vs 24% po SAVR ($P < 0.001$).
- *Pozn. Pacienti s bikuspidní chlopní nebo anatomií nevhodnou k TAVI byli vyloučeni.* [1]

Kontroverze studií TAVI vs SAVR?

- TCTMD news … the treatment protocols for SAV
  flexibility when it came to adjunctive procedures.
  operating room, we were allowed to treat it becau
  said T. Kaneko. “Surgeons are always told you sh
  you’re in the operating room. There’s not going t

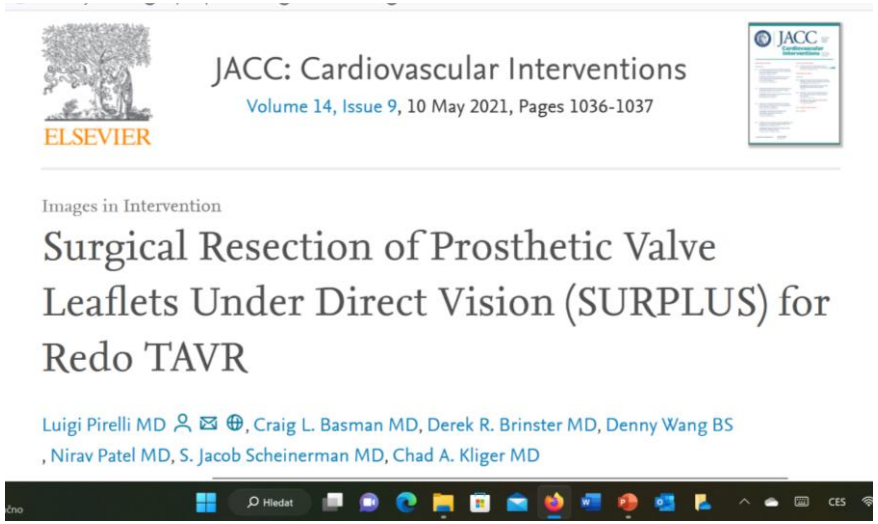


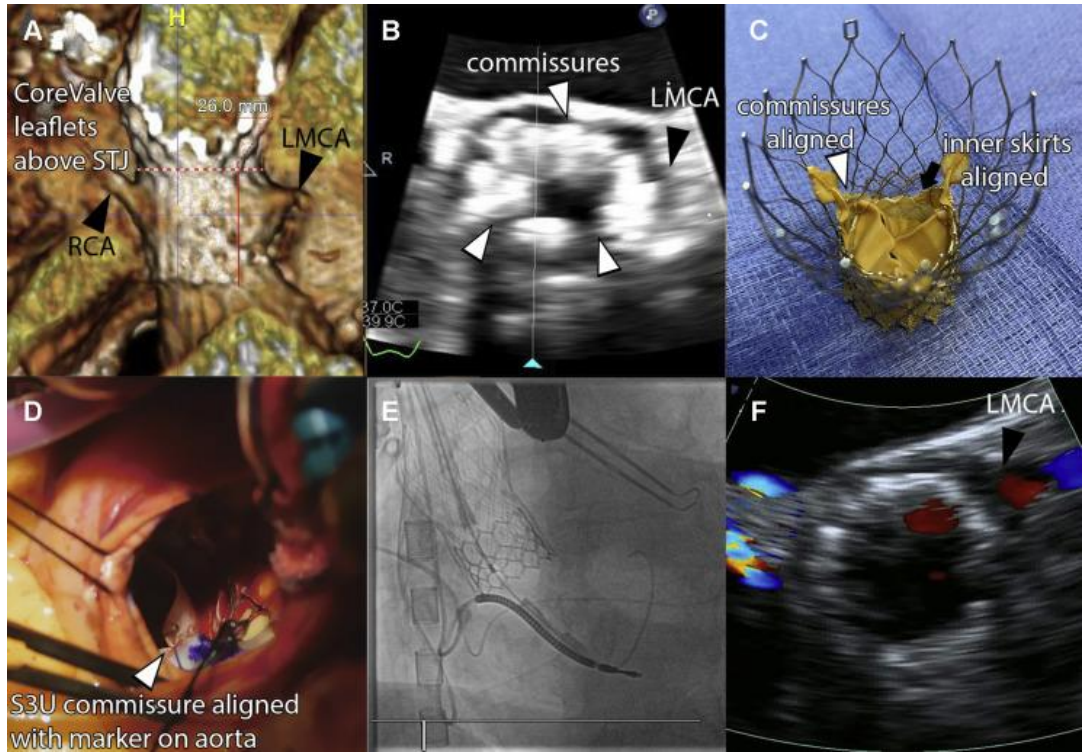
- U pacientů s nízkým rizikem je SAVR vs TAVI spojena s vyšším rizikem úmrtí a úmrtí/CMP krátce po operaci a rozdíl je eliminován v delším sledování.

•Lower-risk (patients with low and low/intermediate risk): PARTNER 3, Evolut Low-Risk, NOTION, and UK TAVI

- **Častěji po (první) SAVR**
  - Nově FISI
  - Velké krvácení
  - AKI
- **Častěji po (první) TAVI**
  - Nově PM
  - Cévní komplikace
  - PVL

Low risk většinou = nižší věk..a dlouhý život před sebou..s velkou pravděpodobností více procedur..
SAVR/SAVR/SAVR? SAVR/TAVI? TAVI/SAVR? Atd..





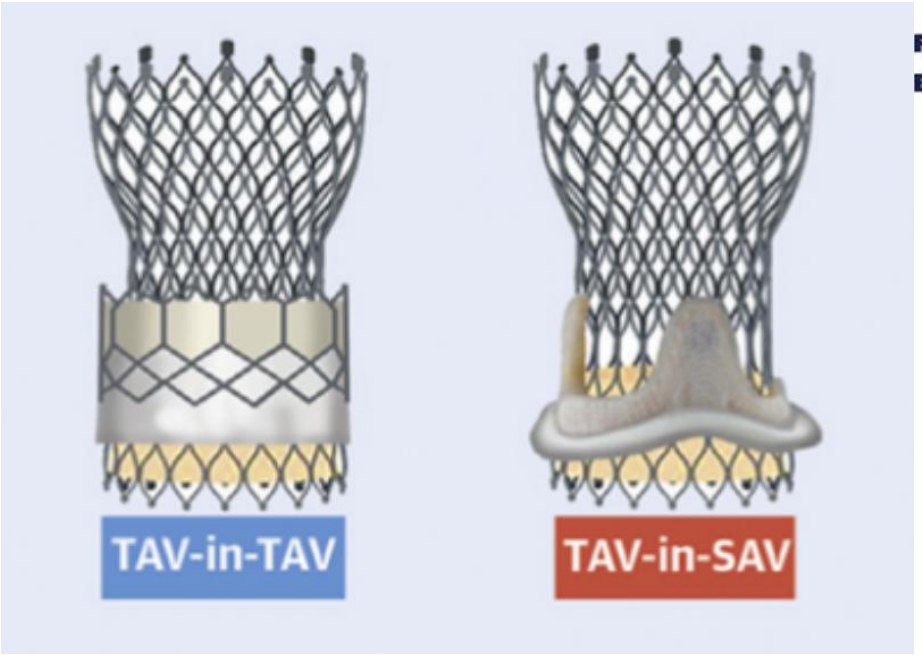
MUNT MED

NEWS • Daily News

TAVR Yields Similar Success in Failed TAVR or Surgical Valves

But as the patient population shifts younger, strategies for "lifetime management" will be required, experts say.

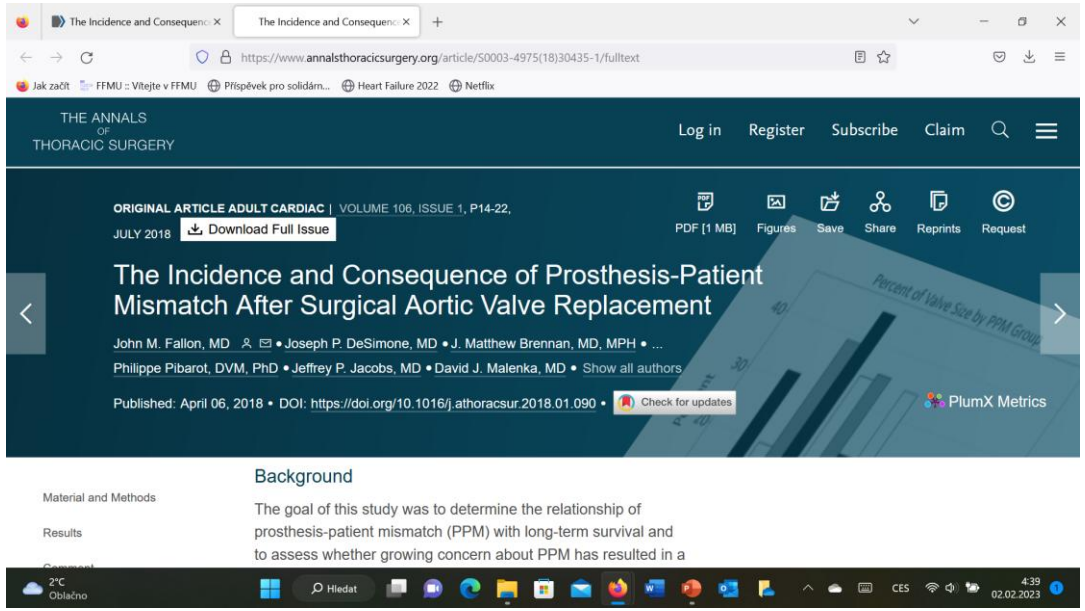
by Caitlin E. Cox | JANUARY 07, 2021

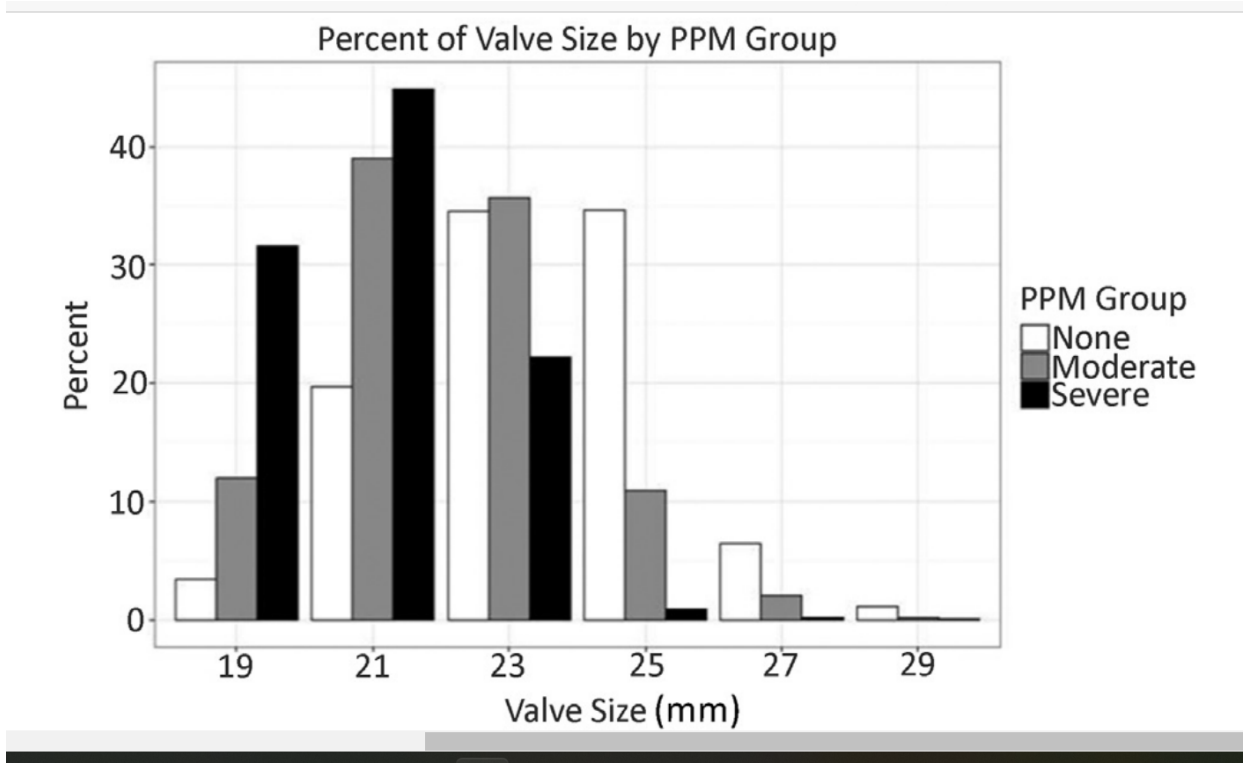


FAKULTNÍ NEMOCNICE BRNO

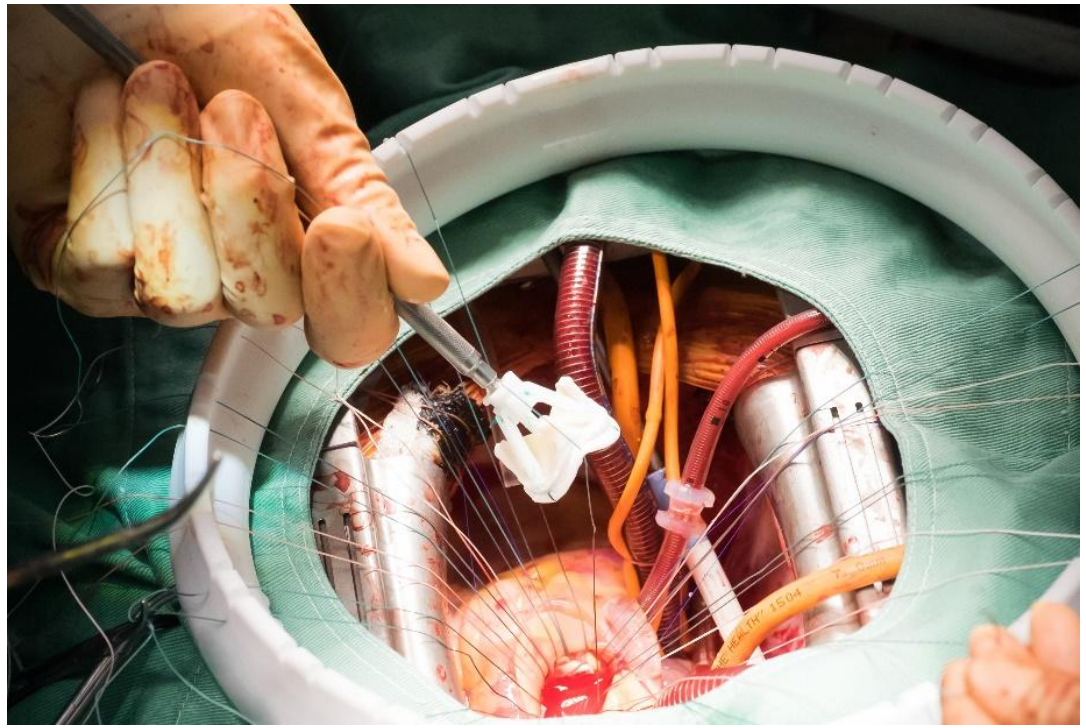
	TAV-in-TAV (N = 165)	TAV-in-SAV (N = 165)	*P* Value
Procedural Success	72.7%	62.4%	0.045
Procedural Safety	70.3%	72.1%	0.715
Mean Aortic Valve Area, cm^2	1.55	1.37	0.040
Mean Residual Gradient, mm Hg	12.6	14.9	0.011
New Pacemaker	10.9%	7.8%	0.251
≥ Moderate Residual AR at 30 Days	8.4%	4.8%	0.463
Mild AR			
30 Days	36.1%	17.2%	0.003
1 Year	36.2%	12.1%	0.001
Mortality			
30 Days	3.0%	4.4%	0.570
1 Year	11.9%	10.2%	0.633

PPM – patient-prosthesis mismatch





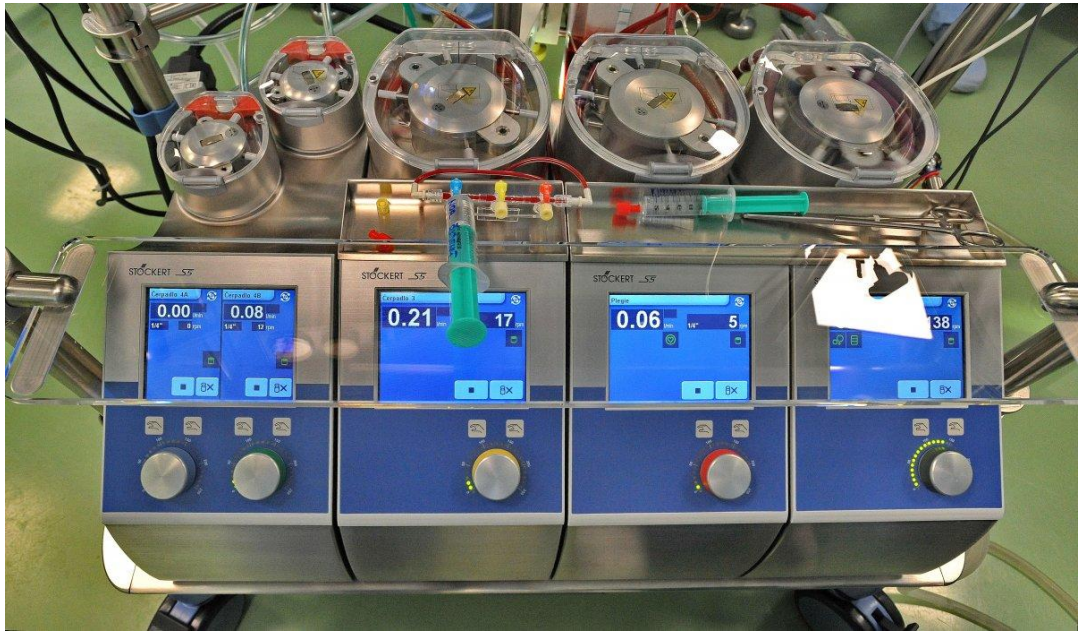
PPM – patient-prosthesis mismatch



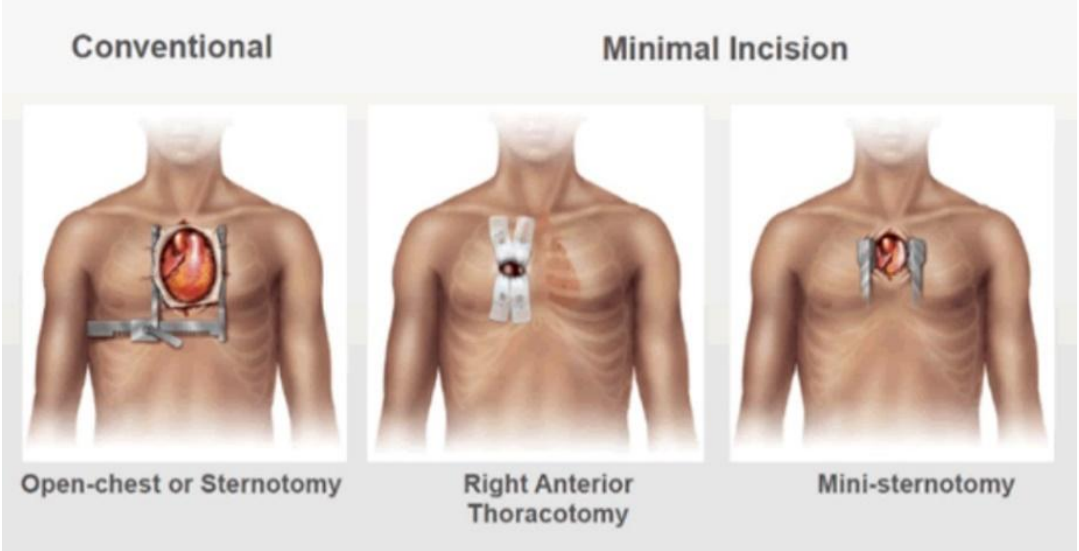
- Žádný: > 0.85 cm2/m2 (35%)
- Střední: ≤ 0.85 to ≥ 0.65 cm2/m2 (54%)
- Těžký: < 0.65 cm2/m2 (11%)

  - Četnost PPM byla spojena s velikostí anulu pouze u **SAVR** - 39.0% u velkých anulů, 53.2% u středních, 66.7% u malých.
  - **TAVR** bylo spojeno s nižším výskytem PPM než u SAVR – u pacientů s malým/středním anulem 30.0% resp. 22.4% bez PPM a bez rozdílu u velkých anulů.

Co mě také zajímá a z čeho bych měl obavy?



https://www.cktch.cz/usek-mimotelniho-obehu/d1009



https://www.cardiothoracic-surgeon.co.uk/treatments/keyhole-aortic-valve-surgery/

Psychický stav po KCH operaci (nejen otázka MO)

Heart & Lung
Volume 47, Issue 4, July–August 2018, Pages 408-417

Delirium after cardiac surgery. Incidence, phenotypes, predisposing and precipitating risk factors, and effects

Gianfranco Sanson RN, PhD [a], Yuliya Khlopenyuk RN, BSN [a], Sara Milocco RN [b], Massimiliano Sartori RN, BSN [a], Lorella Dreas MD [b], Adam Fabiani RN, BSN, MSN [b]

Show more

- Delirium / neúplně vyjádřené delirium - incidence 30.7% resp. 31.2% v kolísavé intenzitě v průběhu několika dnů, prodlužuje hospitalizaci.
- Nezávislé prediktory: FISI, benzodiazepiny/opiody, zhoršení sluchu, MO, střední TK.

Nejen psychický stav po operaci ale hraje roli …možnosti zlepšení?

Review > Anaesthesiologie. 2022 Sep;71(9):663-673. doi: 10.1007/s00101-022-01190-z.
Epub 2022 Aug 20.

[Enhanced recovery after surgery (ERAS®) in cardiac anesthesia]

[Article in German]
J C Kubitz [1], A-M Schubert [2], L Schulte-Uentrop [2]

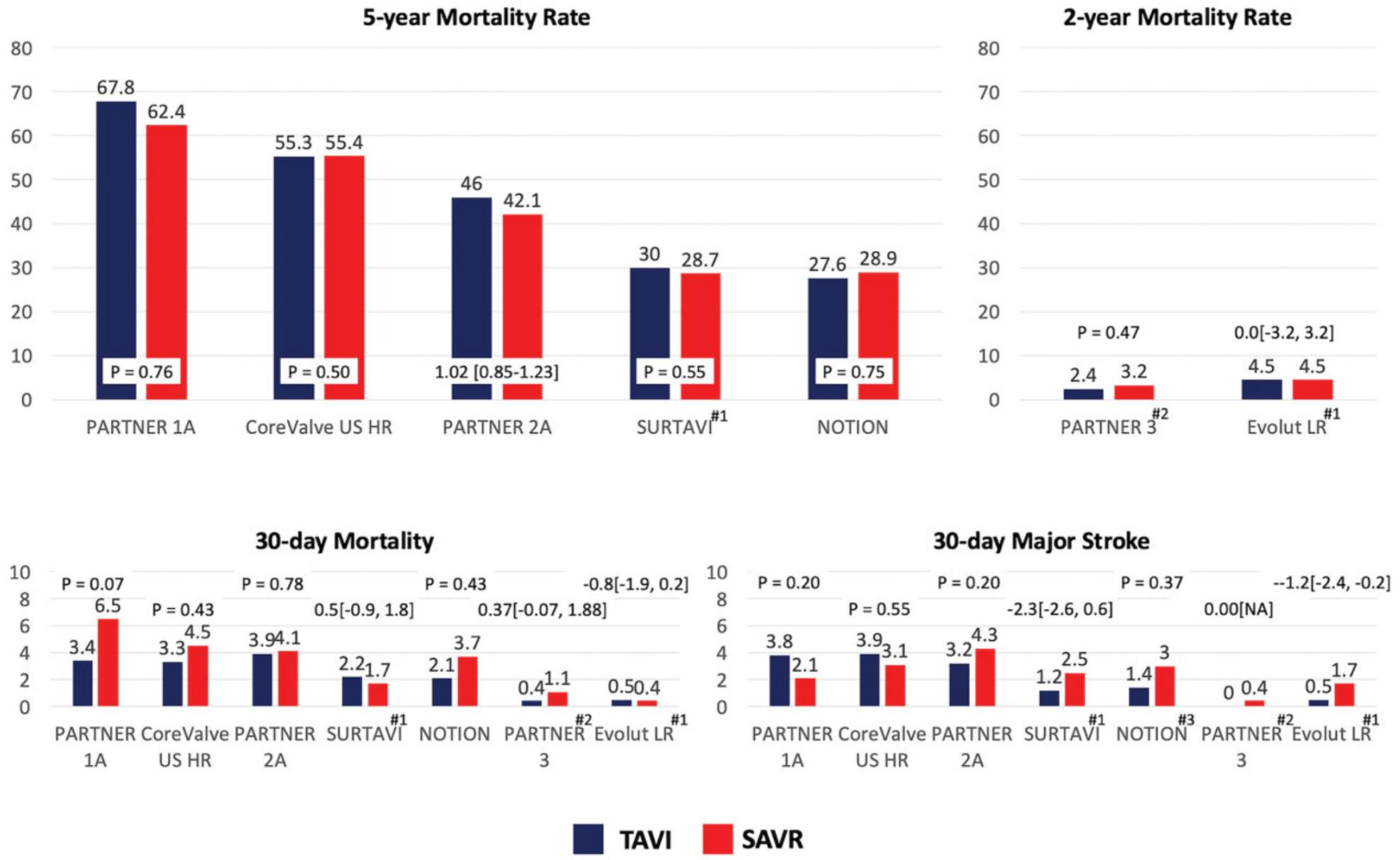
Affiliations + expand

PMID: 35987897 DOI: 10.1007/s00101-022-01190-z

Abstract in English, German

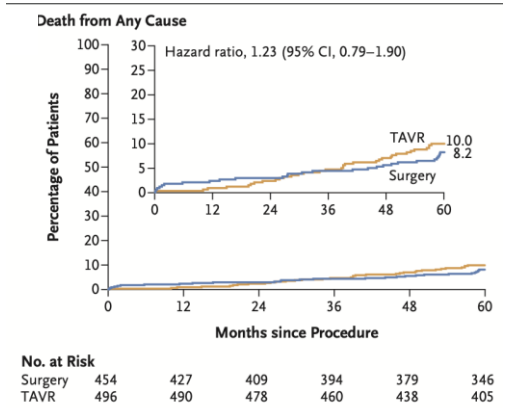
Enhanced Recovery After Cardiac Surgery (ERACS) is a multidisciplinary and multiprofessional treatment approach in cardiac surgery. Recently, a transfer and adaptation of enhanced recovery after surgery (ERAS) protocols from other disciplines, such as colorectal surgery, to cardiac surgery has been performed in different settings. First, prehabilitation programs have been established and investigated to improve patients' physical, psychological and nutritional status including treatment of preoperative anemia. Second, intraoperative therapeutic steps are described, such as infection reduction bundles, rigid sternal closure and guidance of perioperative anesthesia. For this, the use of short-acting agents, goal-directed fluid management and multimodal anesthesia are among the

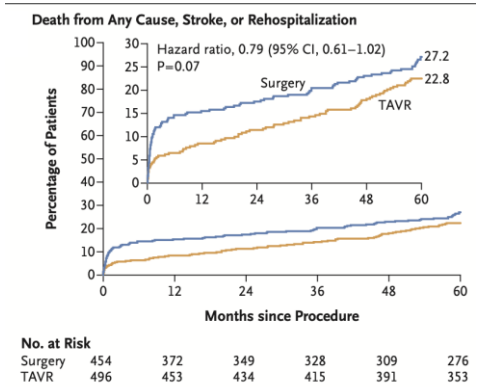
TAVI vs. SAVR RCTs

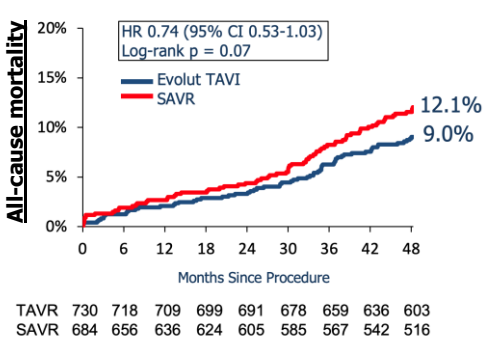


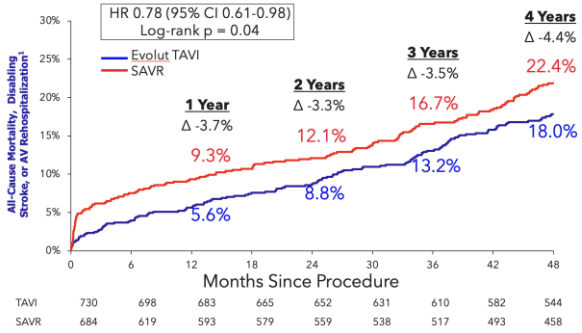
Windecker et al. EHJ 2022;43:2729-50air

Low-Risk RCT
Klinické sledování 4 – 5 let





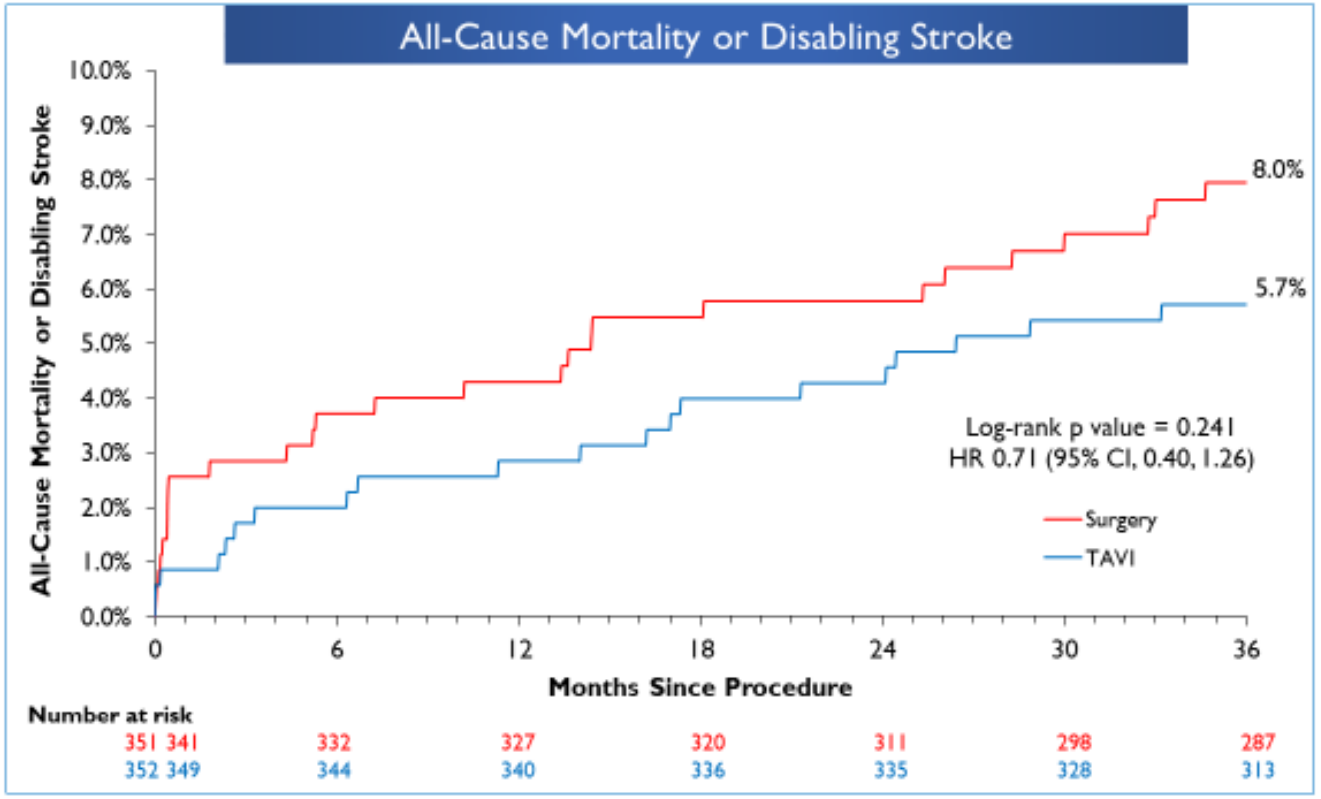




M Mack et al. NEJM 2023; M Reardon @ TCT 2023

TAVI vs. SAVR < 75 let

TAVI vs Surgery in Evolut Low Risk Patients Aged < 75 Years - 3-Year Outcomes **Prům. věk 69 let, STS ≈ 2%**



All-cause mortality and disabling stroke was compared in the TAVI and surgery groups through 3 years.

TAVI = transcatheter aortic valve implantation

TAVI vs Surgery:

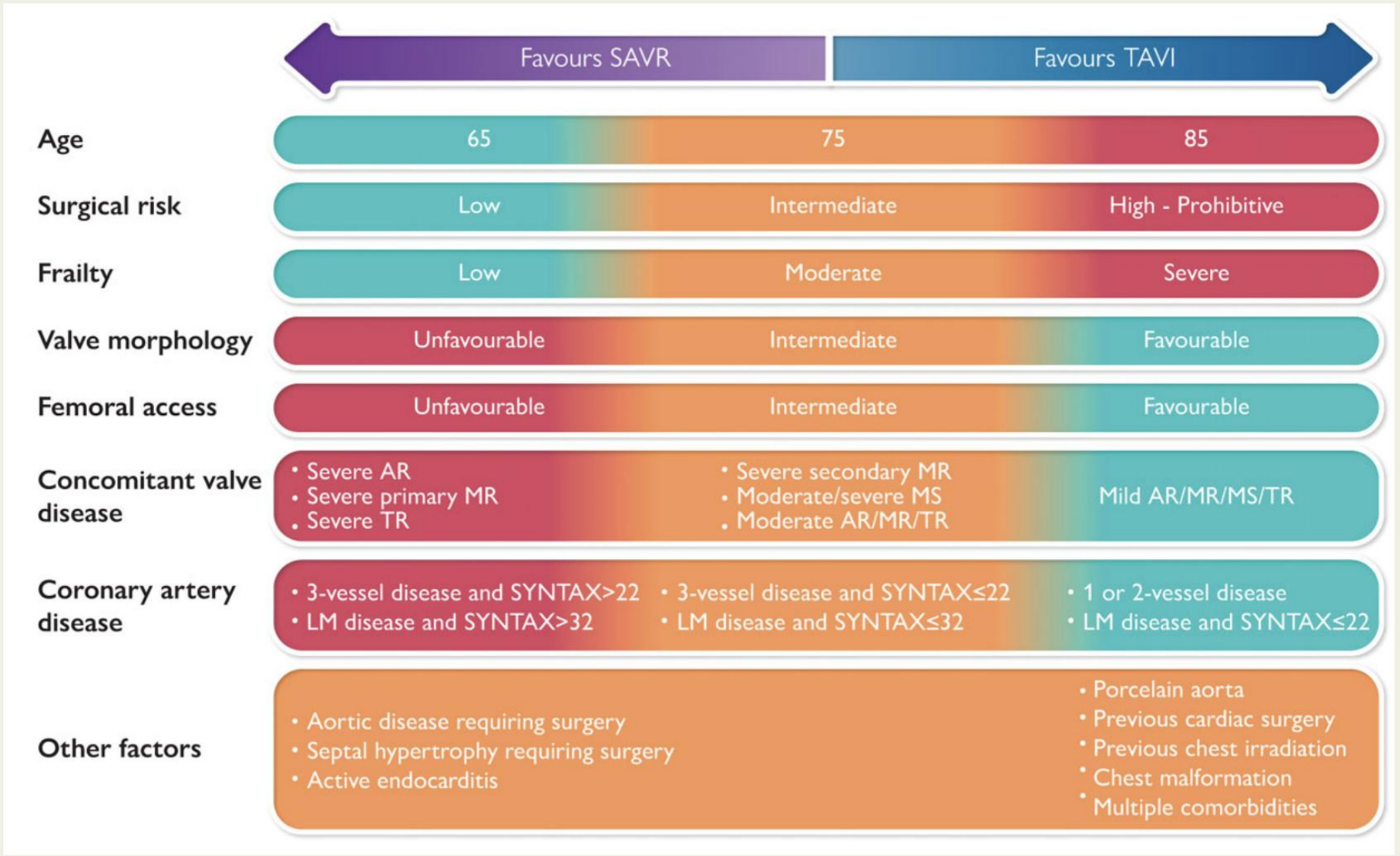
Similar rates of all-cause mortality or disabling stroke

TAVI:

- Significantly better haemodynamic valve performance
  - Mean Aortic Gradient: 9.7 vs 12.9 mm Hg, $P < 0.001$
  - Effective Orifice Area: 2.2 vs 1.9 cm^2, $P < 0.001$
- Earlier improvement in patient quality of life
  - KCCQ Overall Summary Score: 88.9 at 1-month post-procedure
- Lower disabling stroke rate 0.6% vs 2.9%, P = 0.019
- Lower atrial fibrillation rate 13.3% vs 36.4%, P < 0.001

T. Modine, D. Tchetche, NM Van Mieghem et al. In press

Hledání optimální léčby pro konkrétního pacienta

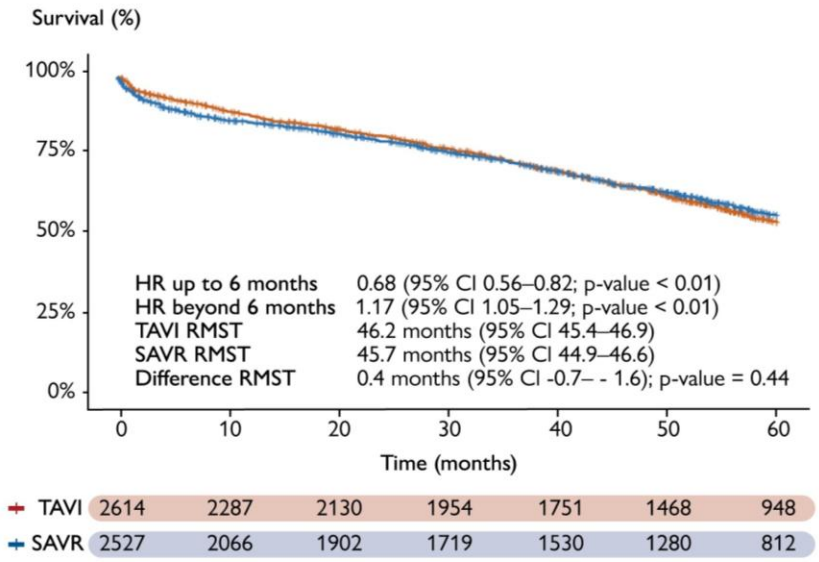


European Heart Journal (2022) **43**, 2729–2750

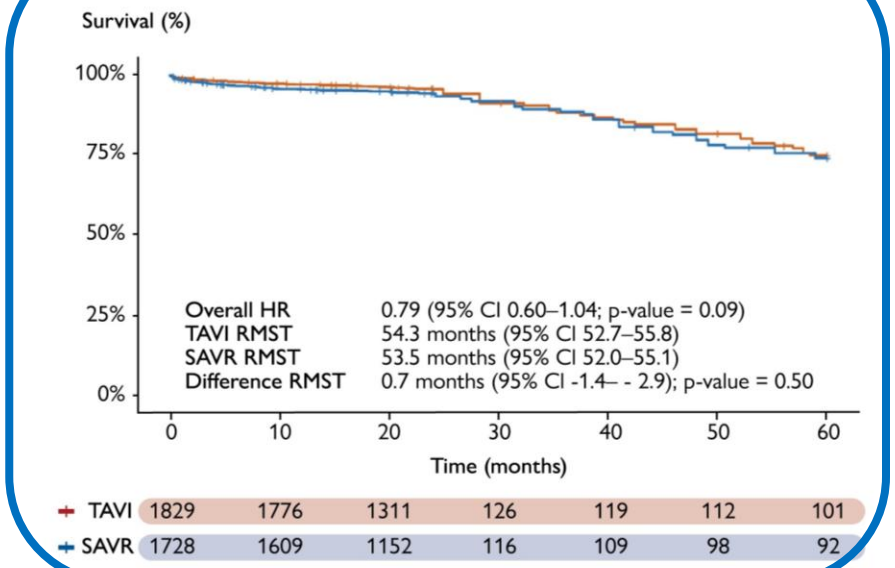
Endpoint	Point estimate [95% CI]	I^2	P
Early outcomes in lower-risk trials			
All-cause death	0.67 [0.47, 0.96]	0	0.031
Death or disabling stroke	0.68 [0.50, 0.92]	0	0.014
Stroke	0.91 [0.46, 1.80]	66.7	0.788
Late outcomes in lower-risk trials			
All-cause death	0.90 [0.69, 1.17]	0	0.432
Death or disabling stroke	0.85 [0.63, 1.15]	24.4	0.286
Stroke	0.93 [0.66, 1.31]	0	0.688
Early outcomes in higher-risk trials			
All-cause death	0.93 [0.81, 1.08]	0	0.345
Death or disabling stroke	0.90 [0.79, 1.02]	0	0.108
Stroke	0.93 [0.68, 1.27]	52.1	0.641
Later outcomes in higher-risk trials			
All-cause death	1.04 [0.96, 1.13]	0	0.339
Death or disabling stroke	1.04 [0.96, 1.13]	0	0.360
Stroke	0.94 [0.75, 1.18]	43.3	0.588

Favours TAVI Favours SAVR

All-cause mortality in higher risk trials



All-cause mortality in lower risk trials



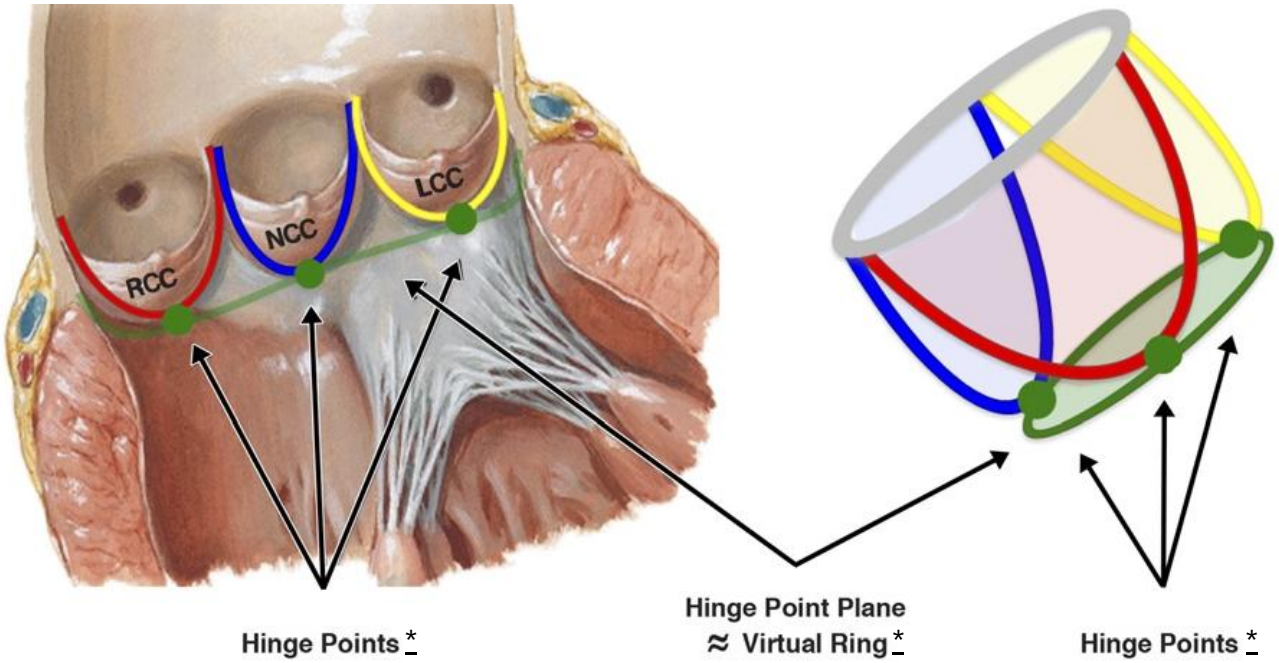
TAVI vs SAVR u pacientů s nízkým rizikem

- **Výhody SAVR (oproti TAVI/TAVR)**
  - Nižší výskyt PVL, cévních komplikací.
  - Nižší nutnost implantace PM proti samo-expandibilní chlopni.
- **Limitace SAVR (oproti TAVI/TAVR)**
  - Nutnost mimotělního oběhu a CA s poměrně časnou psychickou deteriorací.
  - Velká operace s delší hospitalizací, vyšším rizikem krvácení, FISI, AKI a vyšší krátkodobou mortalitou, otázka estetická i funkční.
  - Pacienti (většinou) preferují TAVI, která je v USA spojena s nižší cenou po 2 letech.
  - Osobní přání – SAVR pouze s chlopněmi umožňujícími re-do proceduru (SAVR/TAVI)

Sizing chlopně

3D zhodnocení z CT!

- Strategie výkonu
- Komlexní posouzení anulu a umístění kalcia (LVOT, supra-anulárně, cípky…)
- Výběr správné velikosti TAVI bioprotézy



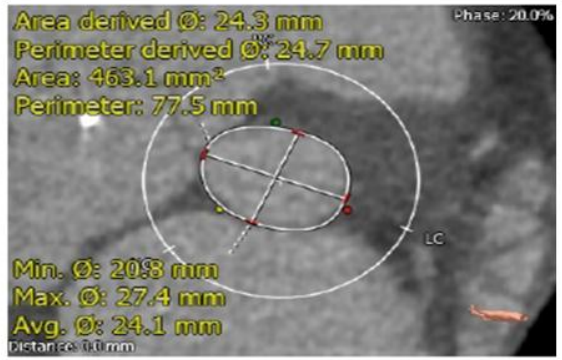
Kasel, A.M. et al; Standardized Imaging for Aortic Annular Sizing

Co nás zajímá při CTA v protokolu TAVI!

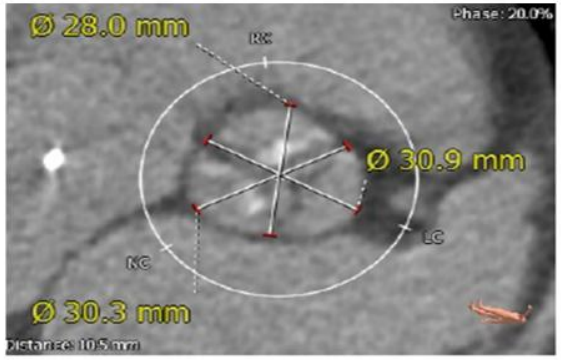
Typical CT measurements

Cedars Sinai
Smidt Heart Institute

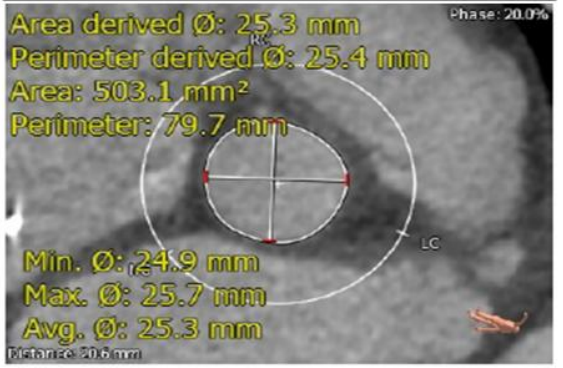
Annulus



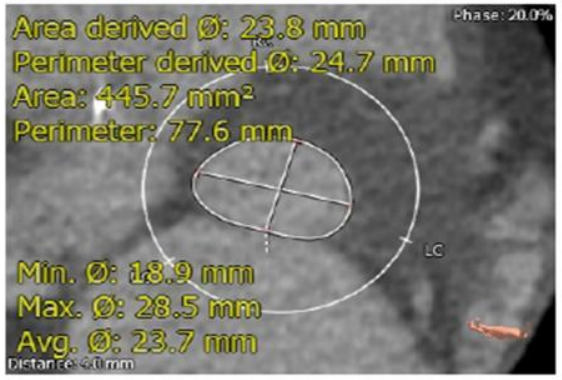
Sinus of Valsalva



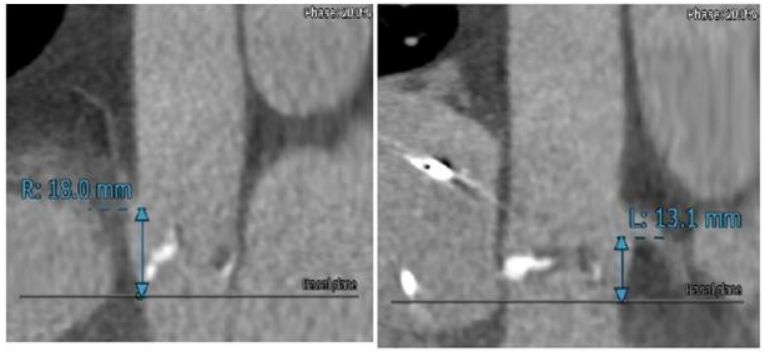
Sinotubular Junction



LVOT

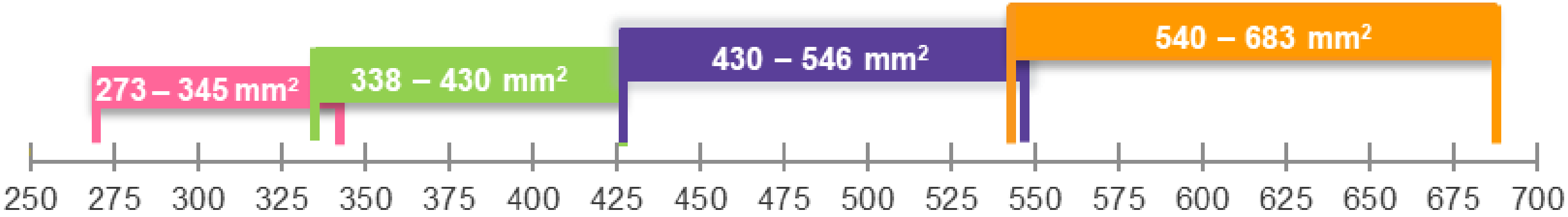


Coronary Artery Height



Sizing chlopně: Sapien

CT planimetrie! Flexibilita u hraničních rozměrů



15.5 mm

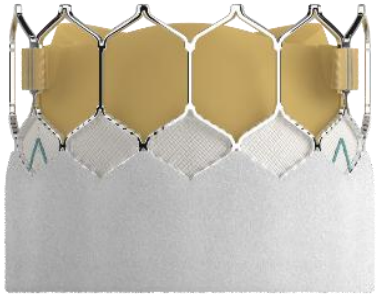
20 mm

18 mm

23 mm

20 mm

26 mm

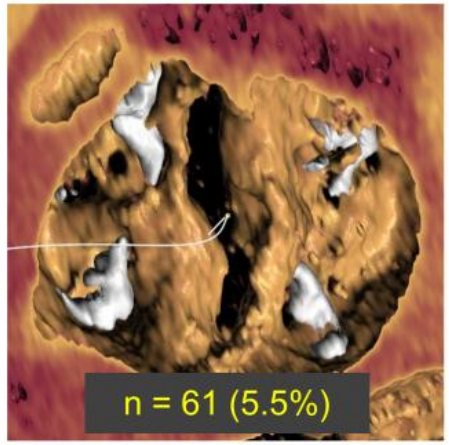


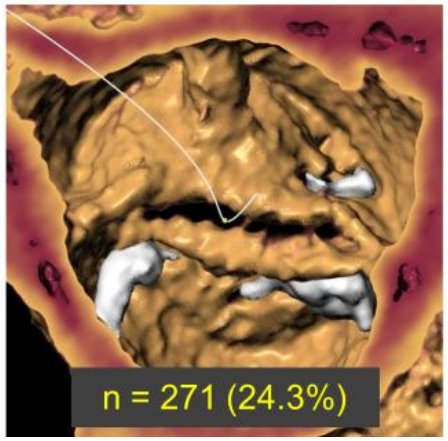
22.5 mm

29 mm

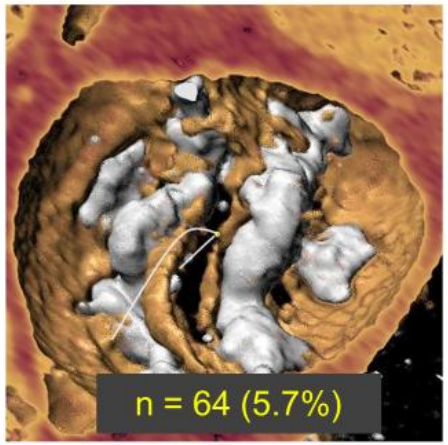
TAVI u bikuspidní chlopně?

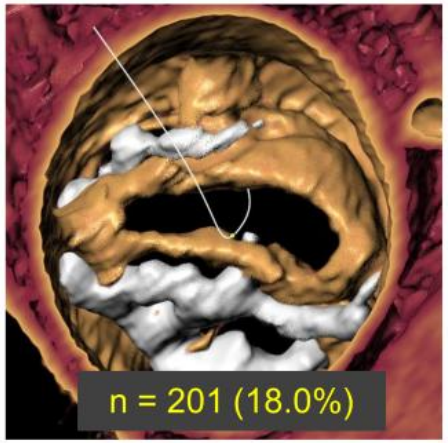
Low TAVR risk
Mild leaflet calcium
No raphe/raphe non-calcified

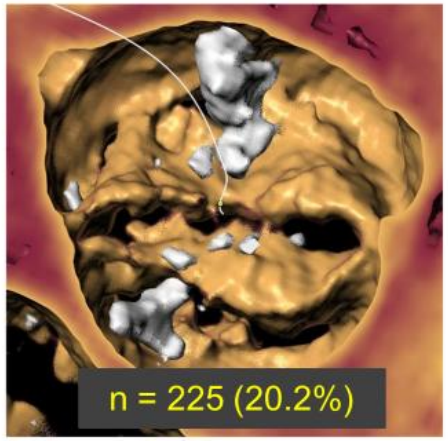




Intermediate TAVR risk
Excess leaflet calcium OR
Severely calcified raphe

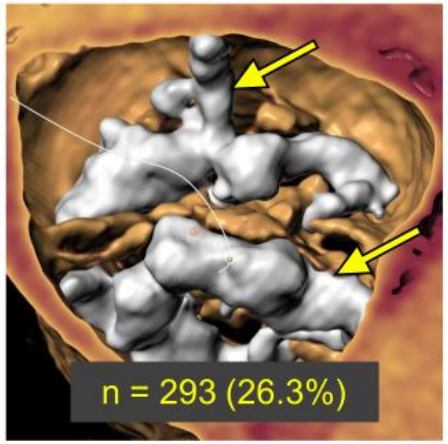




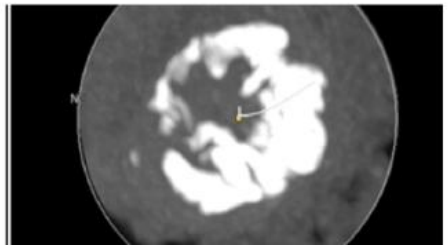


Modified from Yoon and Makkar, JACC 2020; n>1000

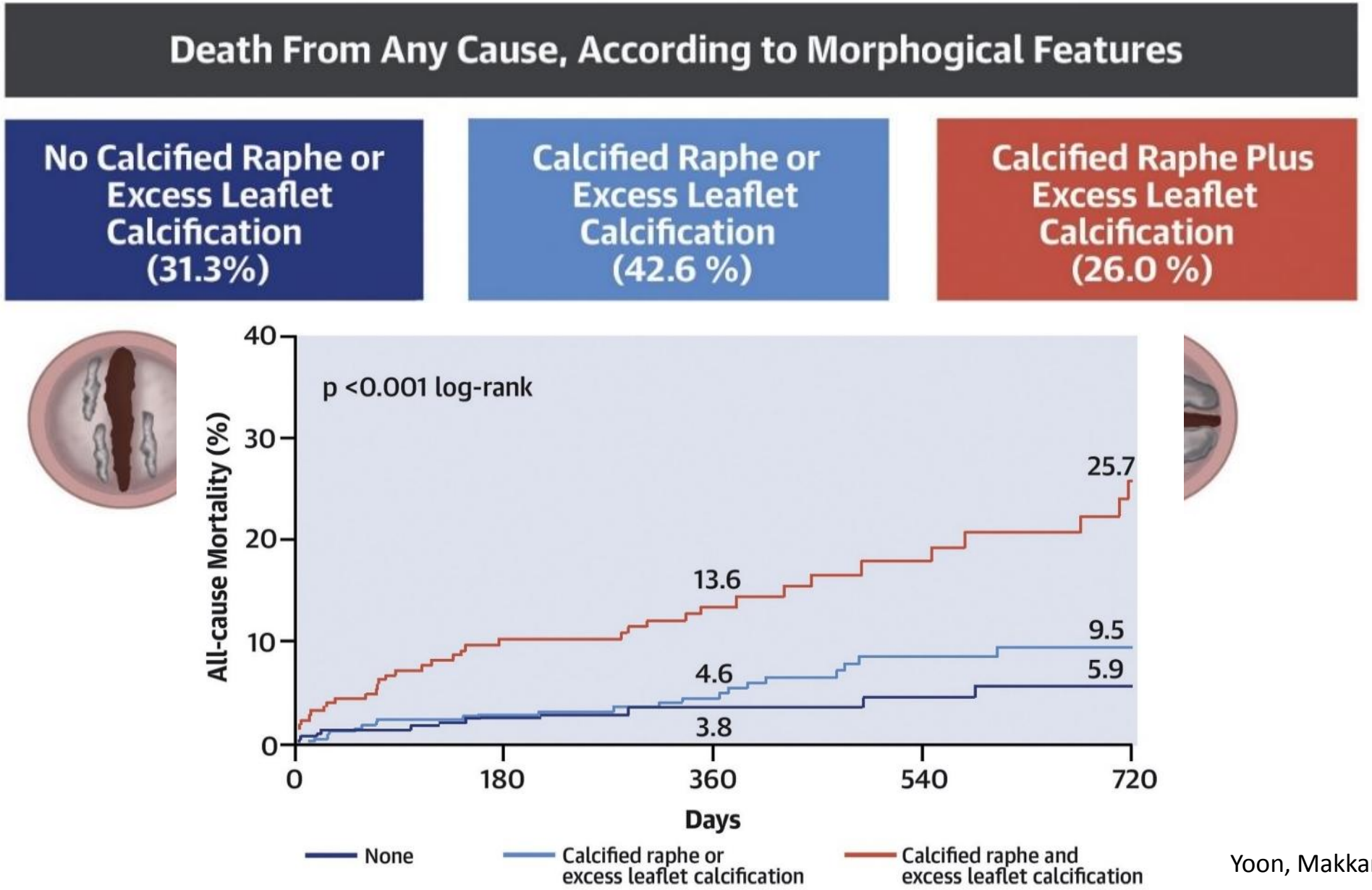
High TAVR risk
Excess leaflet calcium
AND
Severely calcified raphe



ALSO
CIRCUMFERENTIAL/ ANNULAR
CALCIUM



TAVI u low-risk bikuspidní chlopně



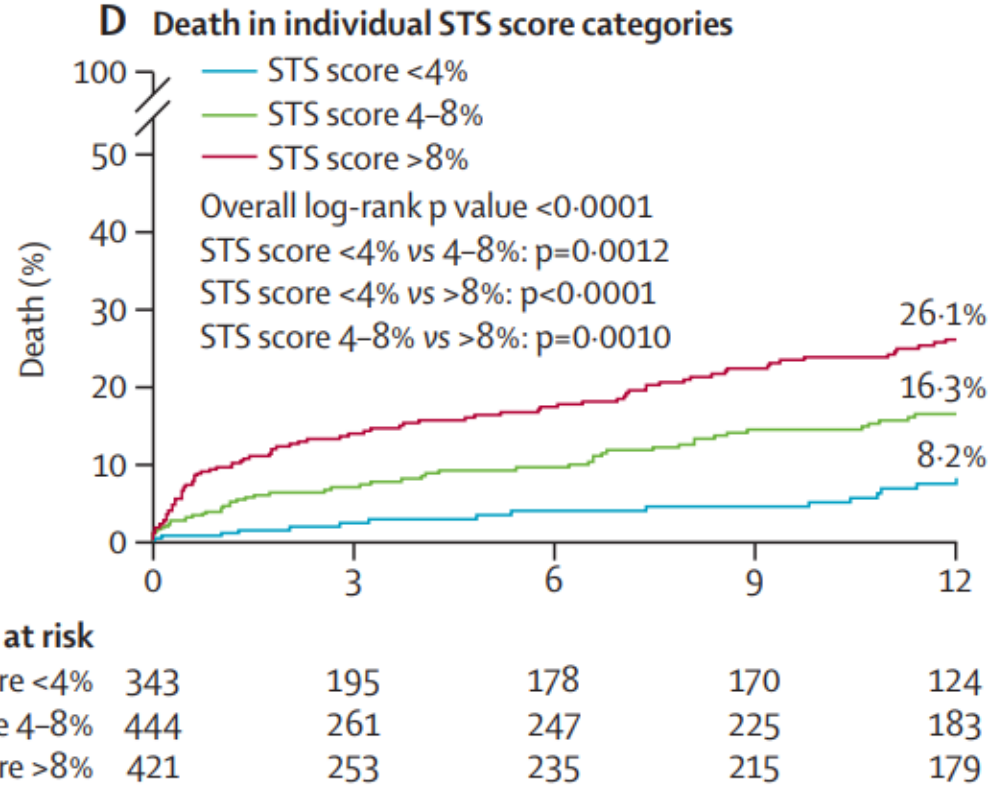
Yoon, Makkar et al. JACC 2020

Outcomes of repeat transcatheter aortic valve replacement with balloon-expandable valves: a registry study

Raj R Makkar, Samir Kapadia, Tarun Chakravarty, Robert J Cubeddu, Tsuyoshi Kaneko, Paul Mahoney, Dhairya Patel, Aakriti Gupta, Wen Cheng, Susheel Kodali, Deepak L Bhatt, Michael J Mack, Martin B Leon, Vinod H Thourani

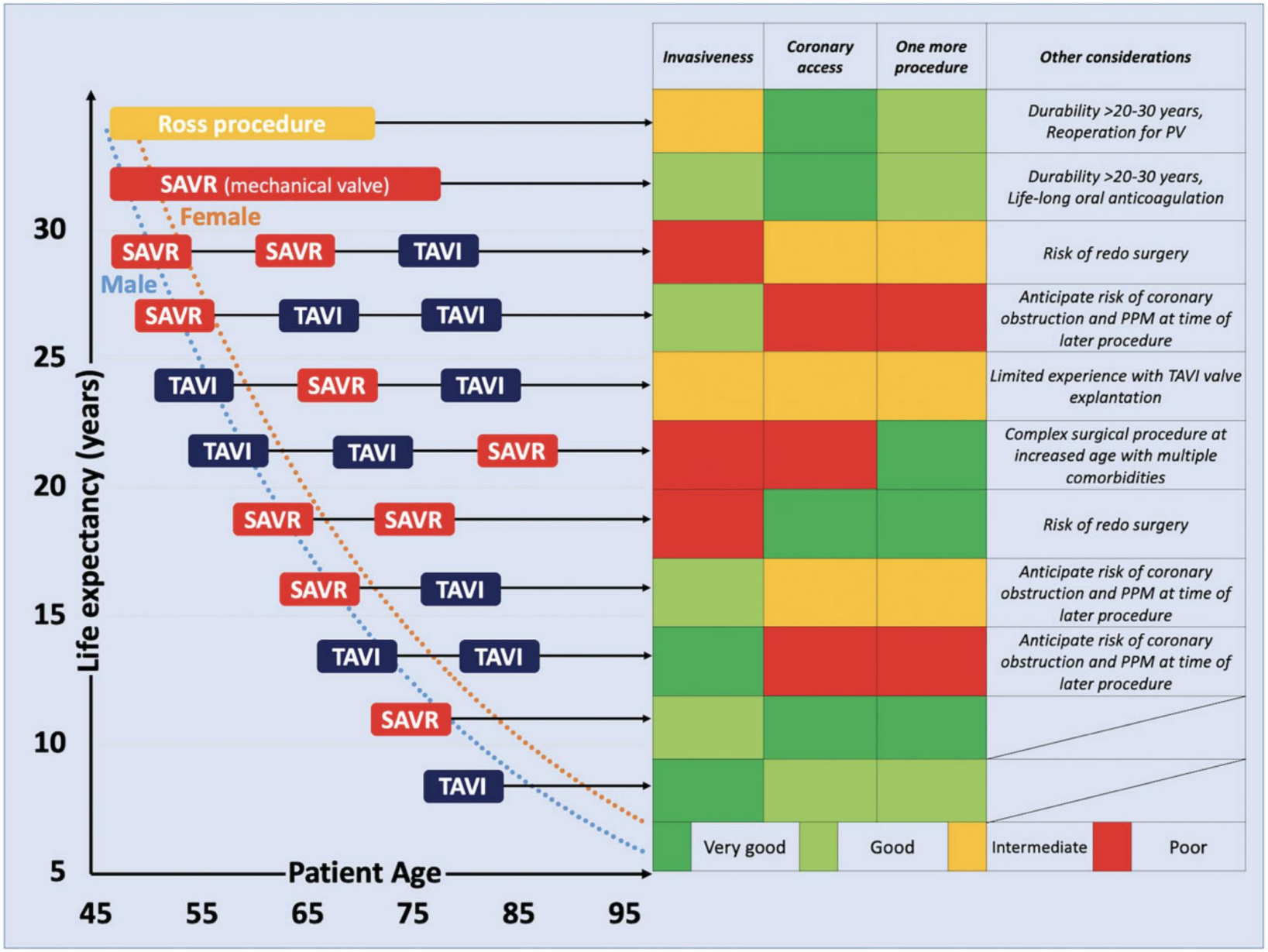
Procedural Complications

	Redo-TAVR *n = 1320*	Native TAVR *n = 1320*	P Value
Conversion to open heart surgery	0.5%	0.2%	0.18
Annulus rupture	0.2%	0.1%	1.00
Need for cardiopulmonary bypass	0.9%	0.6%	0.48
Coronary obstruction or compression	0.3%	0.1%	0.37
Need for a 2nd valve*	0.7%	NA	NA
Aortic dissection	0.2%	0.1%	1.00



Lancet 2023

Kdy TAVI vs SAVR?



Therapy Sequencing

- An important consideration for younger LR patients
- Accounts for age, life expectancy, consequences of therapy choices, and patient preferences
- Shared decision making is embedded in all therapy sequencing discussions!

European Heart Journal (2022) **43**, 2729–2750

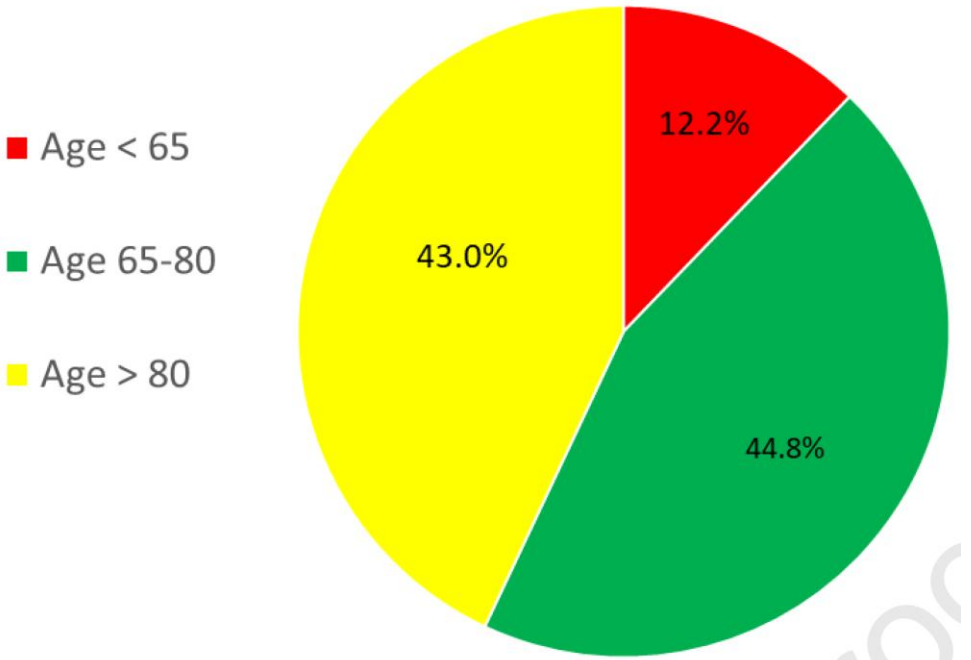
Kam směřujeme?

Mild AS	Moderate AS Symptoms -	Bicuspid	Moderate AS Symptoms +	Severe AS Symptoms -	Severe AS Symptoms +
		NOTION-2	TAVI UNLOAD Progress/Expand	EARLY TAVI EASY AS	PARTNER/EVOLUT
					LOW / INT / HIGH RISK
ACTIVE SURVEILLANCE		Subanalysis TAVR			

2032 ← 2019

Realita v US

Věk < 65: TAVR u 17% vs 48% v letech 2015 vs 2021



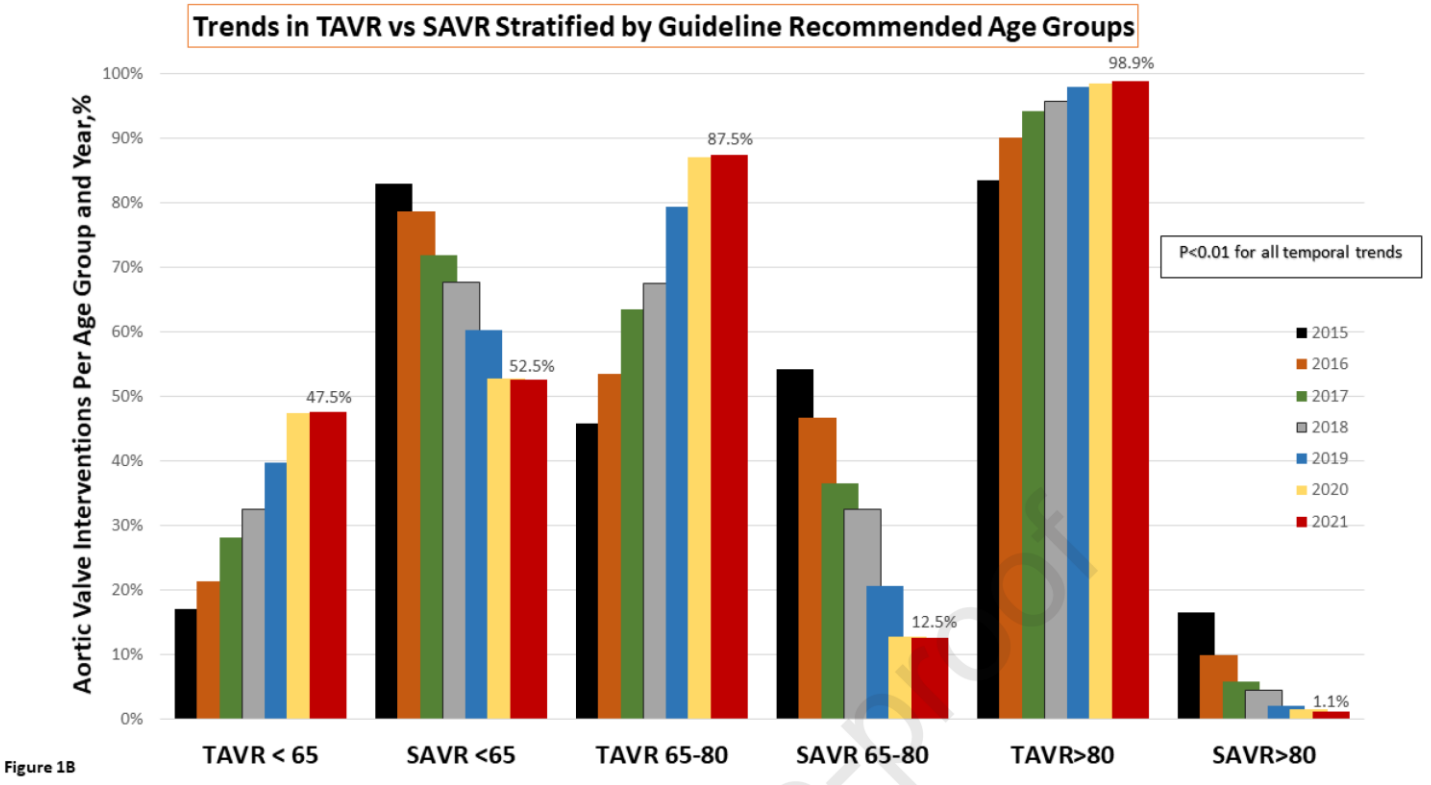


Figure 1B

Age < 65: TAVR rose from 17% to 48%;	***SAVR fell from 83% to 52%.***
Age 65-80: TAVR rose from 46% to 87%;	SAVR fell from 54% to 12%.
Age > 80: TAVR rose from 83% to 99%;	***SAVR fell from 16% to 1%.***

Sharma T, et al. J Am Coll Cardiol. 2022

Shrnutí
TAVI v roce 2024

- **TAVI**
  - je standardem u pacientů s vysokým – středním – nízkým operačním rizikem v mnoha zemích
  - je standardem u pacientů s vysokým event. středním operačním rizikem a ve věku 75 let ve všech zemích
  - v případě první procedury u pacientů mladších a s nízkým rizikem musí být zváženy všechny okolnosti včetně životní prognózy a přání pacienta
  - podmínkou je komplexní naplánování výkonu a minimalizace komplikací (pacienti s bikuspidní chlopní, prevence obstrukce koronárních tepen, cerebrální protekce apod)
  - dá se očekávat posun indikace od pacientů se symptomatickou hemodynamicky významnou Ao stenózou ke středně významné/asymptomatické

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Aortální patologie – máme společný cíl!!!!