TAVI u pacientů s nízkým rizikem - komentář -

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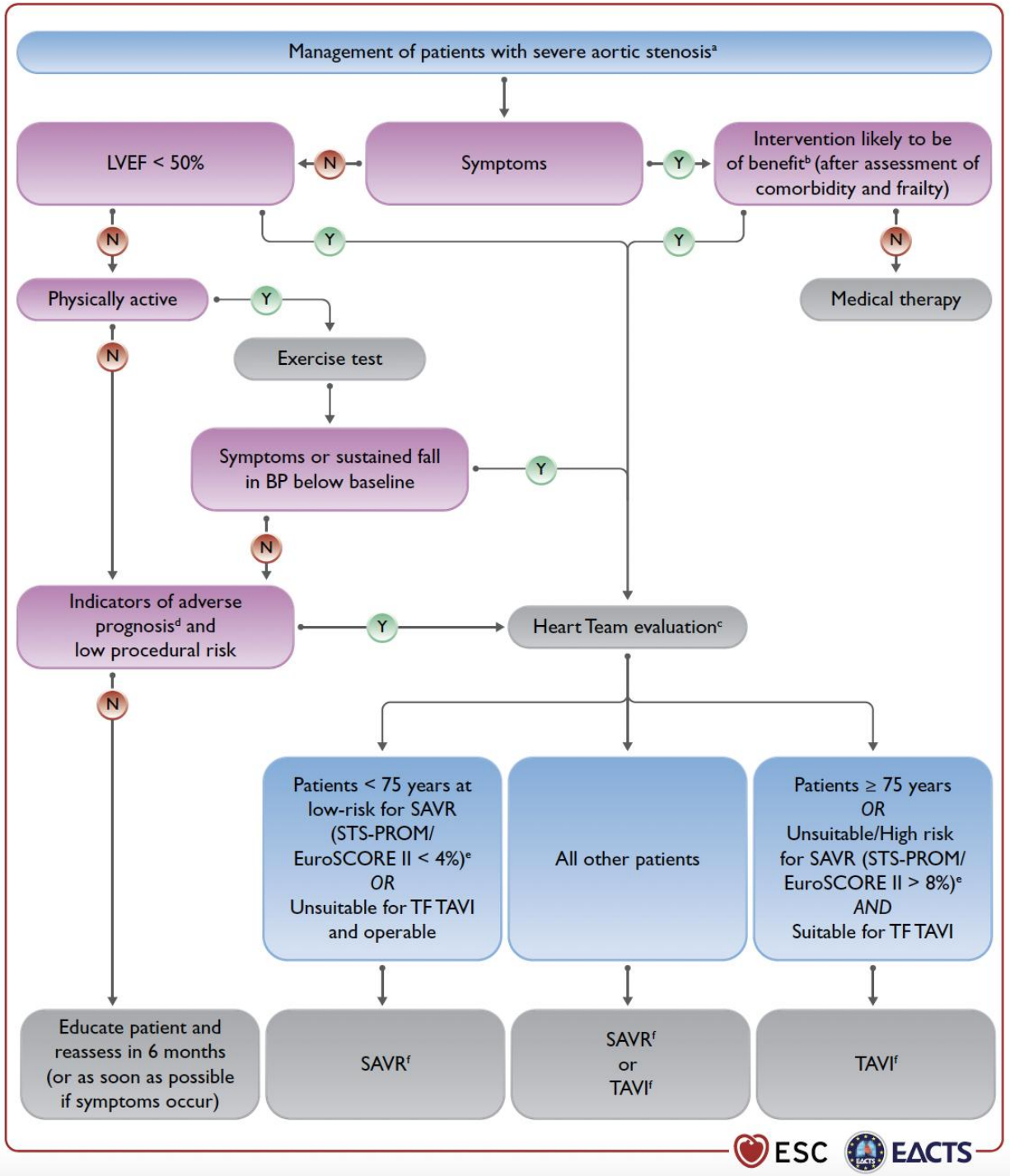
ESC
European Society of Cardiology

European Heart Journal (2021) **00**, 1–72
doi:10.1093/eurheartj/ehab395

ESC/EACTS GUIDELINES

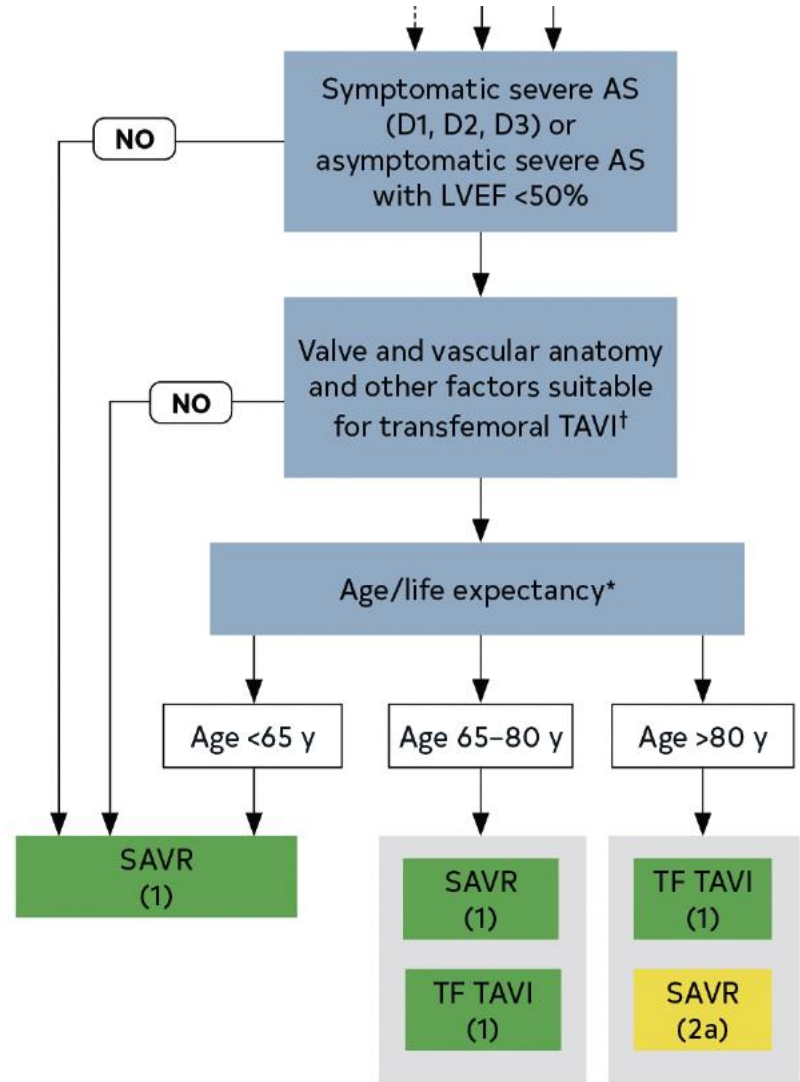
2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)



ACC/AHA CLINICAL PRACTICE GUIDELINE

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease



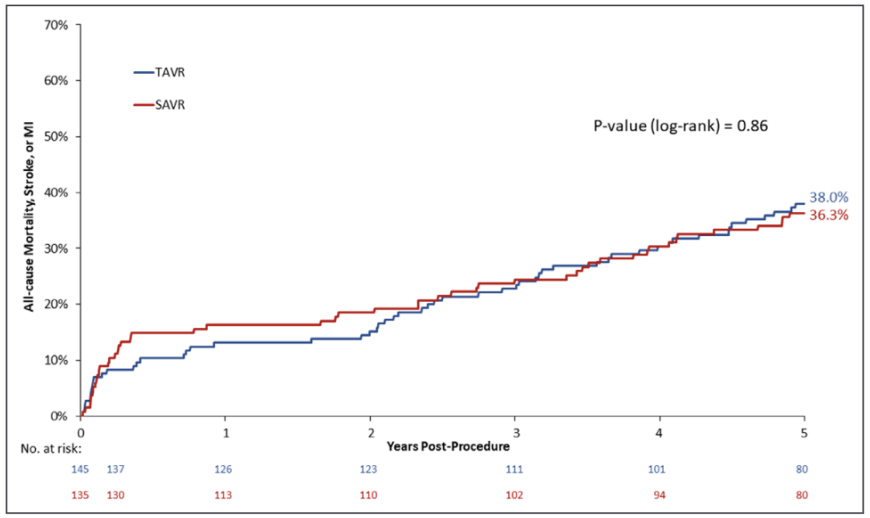
Circulation

ORIGINAL RESEARCH ARTICLE

Five-Year Clinical and Echocardiographic Outcomes From the NOTION Randomized Clinical Trial in Patients at Lower Surgical Risk

Editorial, see p 2724

Hans Gustav Hørsted Thyregod, MD, PHD

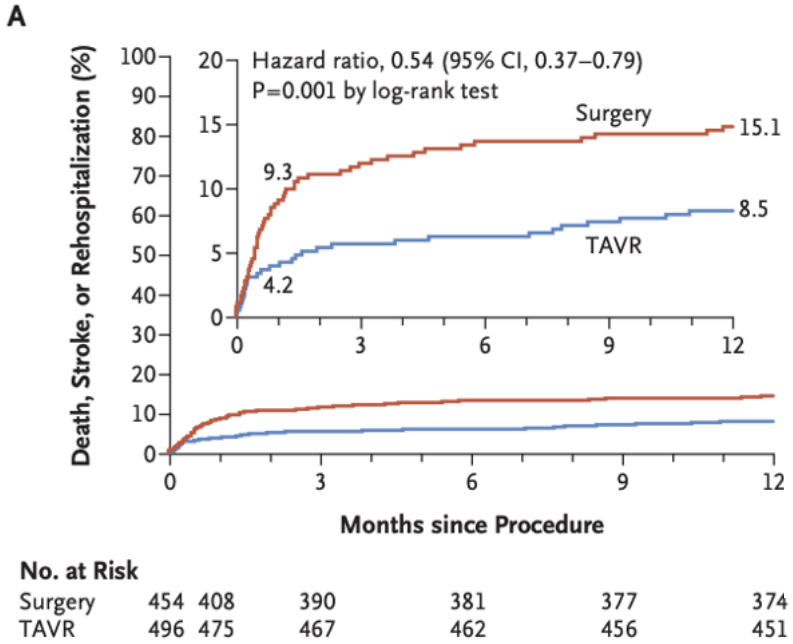


PARTNER 3

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 MAY 2, 2019 VOL. 380 NO. 18

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen,



Evolut Low Risk

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 79, NO. 9, 2022
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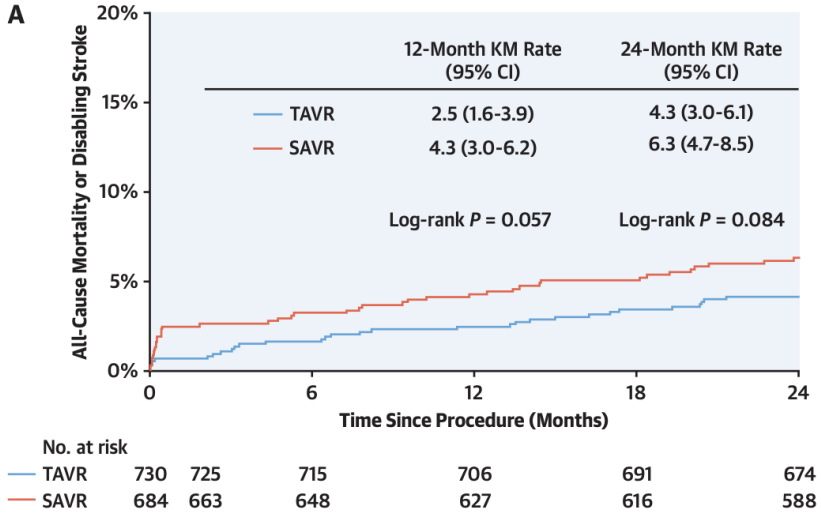
2-Year Outcomes After Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients

John K. Forrest, MD,[a,b] G. Michael Deeb, MD,[c,d] Steven J. Yakubov, MD,[e] Joshua D. Rovin, MD,[f]



Celková mortalita

NOTION

Table. Clinical Outcomes at 5 Years for TAVR and SAVR Patients

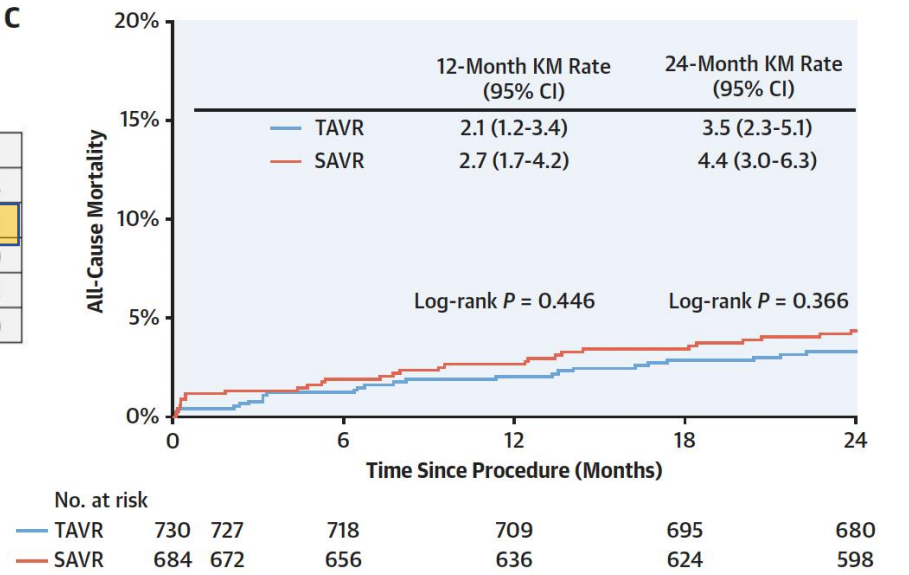
Outcome (%)	TAVR (n=145)	SAVR (n=135)	*P* Value
All-cause mortality, stroke, or MI*	55 (38.0)	49 (36.3)	0.86
All-cause mortality*	40 (27.6)	39 (28.9)	0.75
Cardiovascular mortality	30 (20.8)	31 (23.0)	0.62
Stroke	13 (9.0)	10 (7.4)	0.65
TIA	9 (6.2)	5 (3.7)	0.33
MI	11 (7.7)	10 (7.4)	0.96
Atrial fibrillation	34 (23.4)	82 (60.8)	<0.0001
Pacemaker†	58 (41.7)	10 (7.8)	<0.0001
Aortic valve reintervention	3 (2.1)	1 (0.7)	0.35
Valve endocarditis‡	9 (6.2)	6 (4.4)	0.51

PARTNER 3

2-Year Outcomes

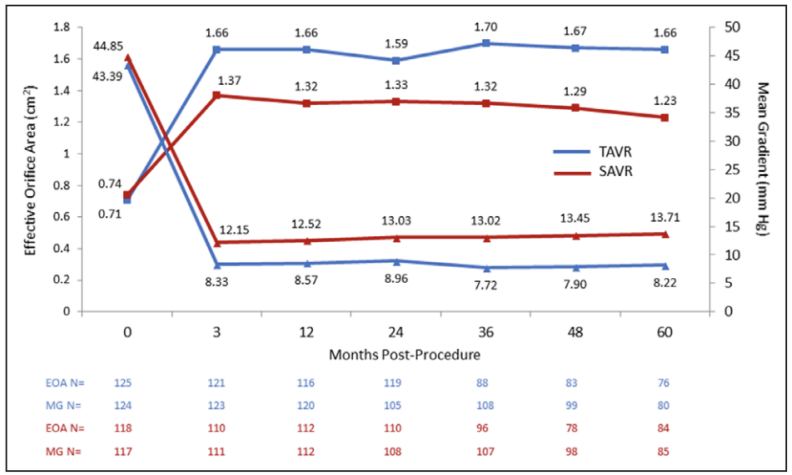
	Surgery	TAVR	HR	95% CI
Primary Endpoint	17.4%	11.5%	0.63	0.45-0.88
Death	3.2%	2.4%	0.75	0.35-1.63
Stroke	3.6%	2.4%	0.66	0.31-1.40
Death or Disabling Stroke	3.8%	3.0%	0.77	0.39-1.55
Rehospitalization	12.5%	8.5%	0.67	0.45-1.00

Evolut Low Risk

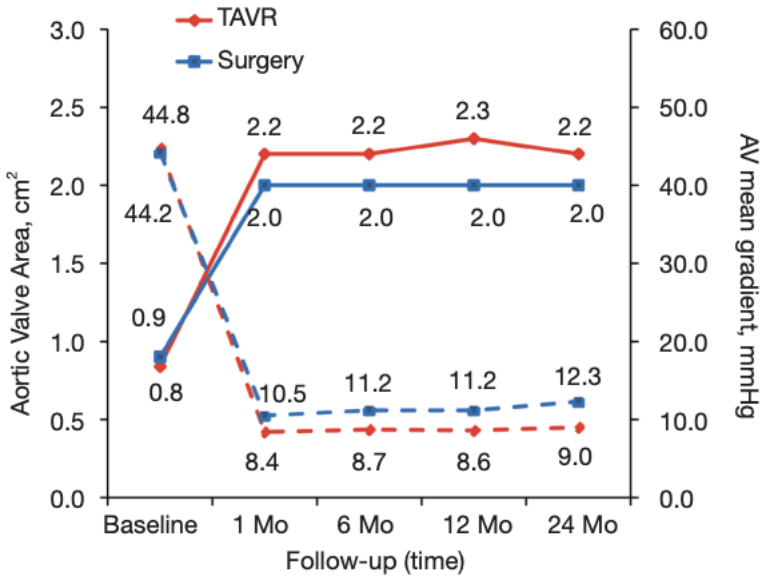


Plochy aortálního ústí a střední gradient na chlopni

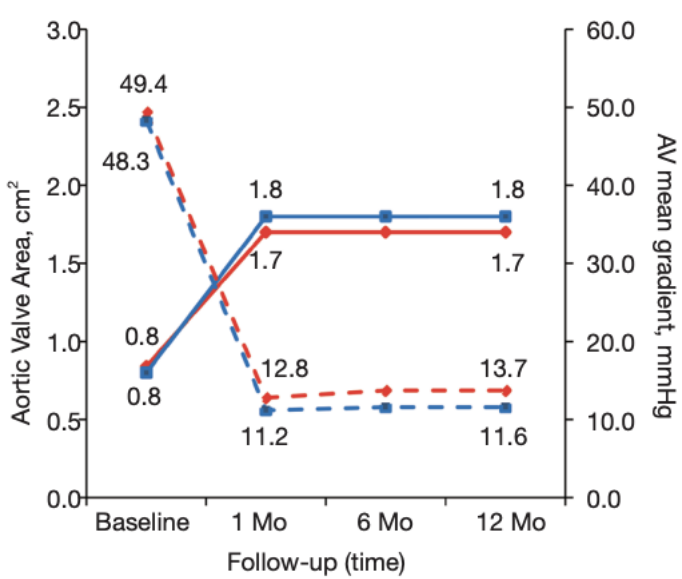
NOTION trial



Evolut low risk trial



PARTNER 3 trial



Braghiroli J. Cardiovasc. Diag and Ther. 2020;10:59-71

Velikost TAVI a chirurgických chlopní

Partner 3:
- 20 mm … 2.2%
- 23 mm … 29.2%
- 26 mm … 47.6%
- 29 mm … 21%

20 – 23 mm: 31.4%

Evolut low risk
- 23 mm … 1.2%
- 26 mm … 19.6%
- 29 mm … 42.7%
- 34 mm … 32.9%

23 mm: 1.2%

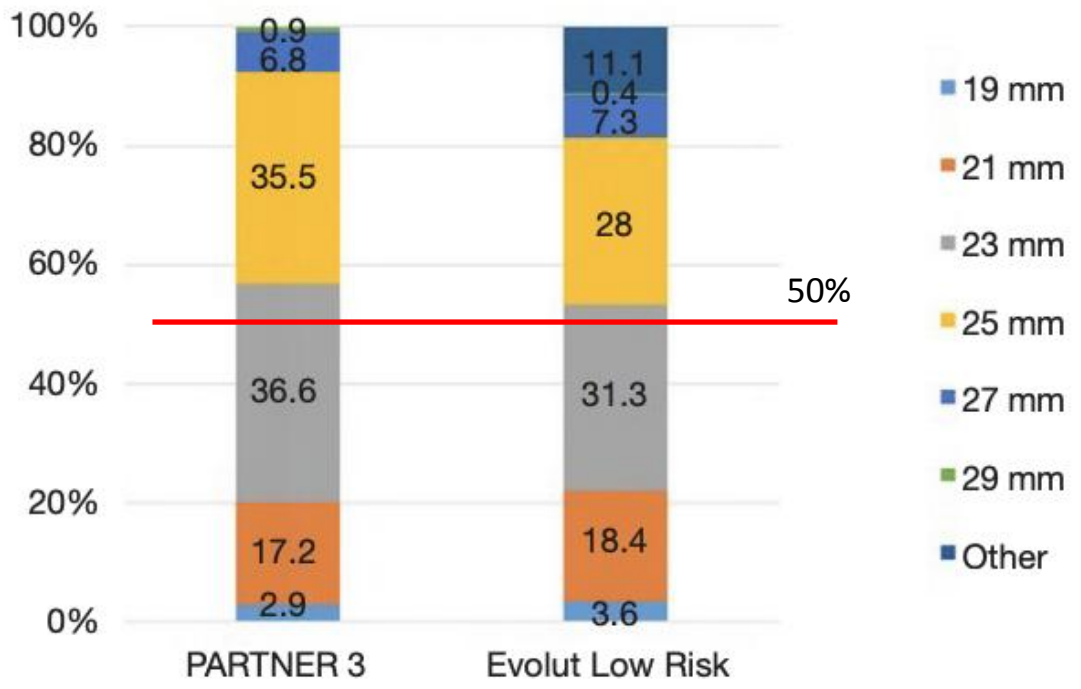


Figure 3 Surgical valve sizes.

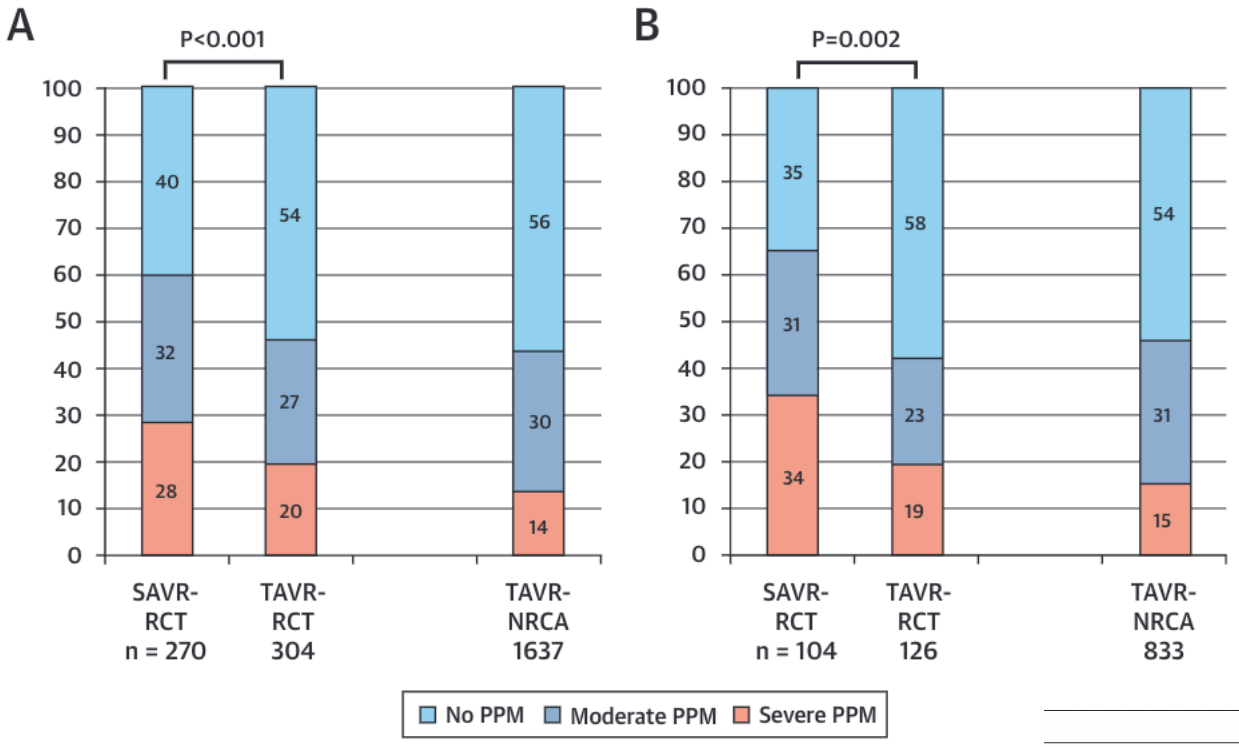
Braghiroli J. Cardiovasc. Diag and Ther. 2020;10:59-71

PPM: patient-prosthesis-mismatch

PARTNER Cohort A

všichni pacienti

pacienti s annulem < 20 mm



PPM: AVAi < 0.85 cm2/m2

těžký PPM: AVAi < 0.65 cm2/m2

Pibarot P. JACC 2014;64:1323-34

PARTNER 3

	Baseline		30 Days		
	TAVR (N=495)	Surgery (N=453)	TAVR (N=495)	Surgery (N=453)	Treatment Effect [95% CI]
Patient-Prosthesis Mismatch*†					
Moderate	N/A	N/A	29.8% (140/470)	23.3% (92/395)	6.5% [0.6%, 12.4%]
Severe	N/A	N/A	4.3% (20/470)	6.3% (25/395)	-2.1% [-5.1%, 0.9%]

Evolut Low Risk

	30 Days			1 Year			2 Year		
	TAVR	Surgery	95% BCI for difference	TAVR	Surgery	95% BCI for difference	TAVR	Surgery	95% BCI for difference
Patient-prosthesis mismatch	N = 609	N=541		N = 341	N = 293		N = 59	N = 53	
None – no. (%)	542 (89.0)	433 (80.0)		318 (93.3)	223 (76.1)		56 (94.9)	45 (84.9)	
Moderate – no. (%)	60 (9.9)	84 (15.5)		17 (5.0)	46 (15.7)		1 (1.7)	7 (13.2)	
Severe – no. (%)	7 (1.1)	24 (4.4)		6 (1.8)	24 (8.2)		2 (3.4)	1 (1.9)	

Nutnost implantace trvalého kardiostimulátoru TAVI vs. SAVR

Partner 3:

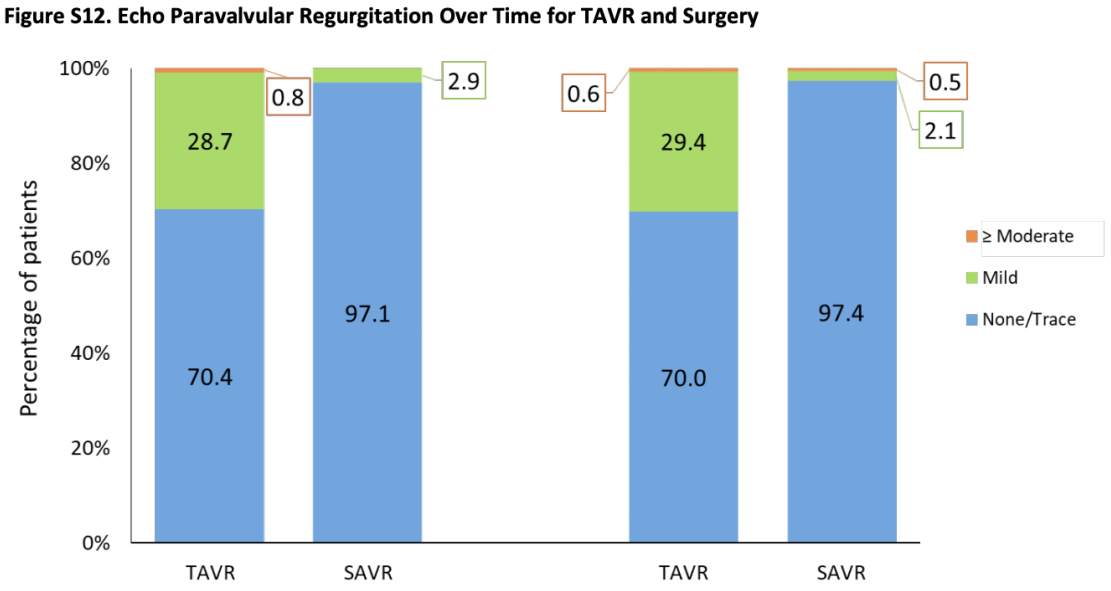
- 30 dnů: 6.5% vs. 4.0%,
- 12 měsíců: 7.3% vs. 8%

Evolut low risk

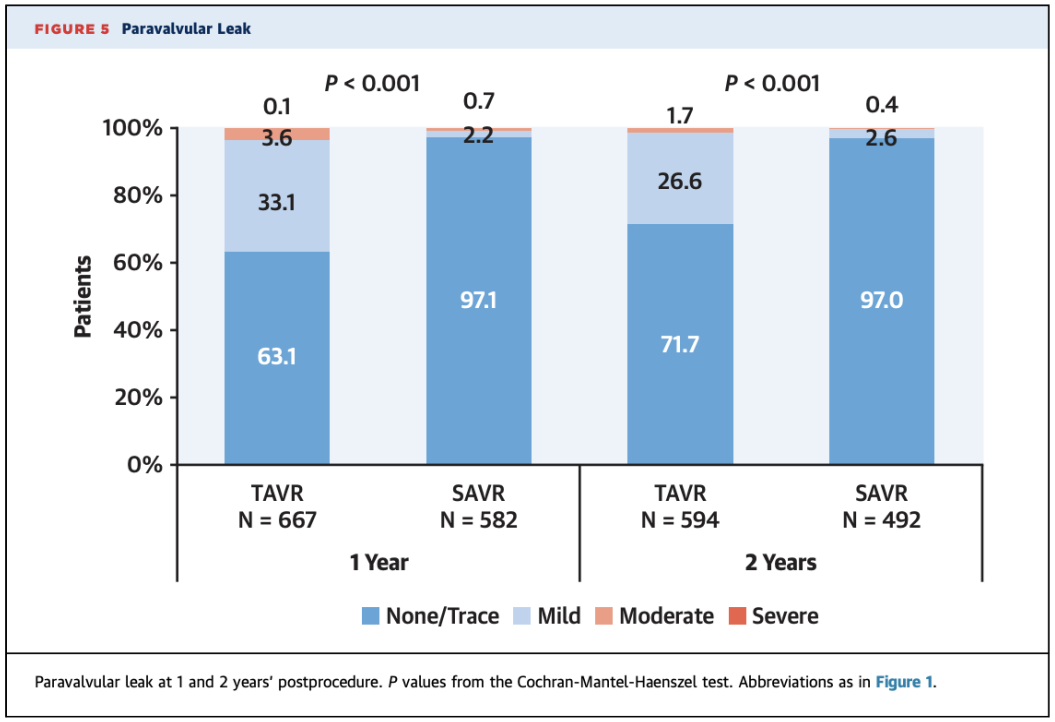
- 30 dnů: 17.4% vs. 6.1%
- 12 měsíců: 19.4% vs. 6.7%

Paravalvulární regurgitace

PARTNER 3



Evolut Low Risk



PARTNER 3 – komplikace

	30 Days			1 Year		
	TAVR (N = 496)	**Surgery (N = 454)**	**Treatment Effect [95% CI]**	**TAVR (N = 496)**	**Surgery (N = 454)**	**Treatment Effect [95% CI]**
Death, Stroke, or Rehospitalization†	4.2% (21)	9.3% (42)	0.45 [0.27, 0.76]	8.5% (42)	15.1% (68)	0.54 [0.37, 0.79]
Death						
From any cause	0.4% (2)	1.1% (5)	0.37 [0.07, 1.88]	1.0% (5)	2.5% (11)	0.41 [0.14, 1.17]
Cardiac death	0.4% (2)	0.9% (4)	0.46 [0.08, 2.49]	0.8% (4)	2.0% (9)	0.40 [0.12, 1.30]
Non-cardiac death	0.0% (0)	0.2% (1)	0.00 [NA]	0.2% (1)	0.5% (2)	0.44 [0.04, 4.88]
Stroke						
Any stroke	0.6% (3)	2.4% (11)	0.25 [0.07, 0.88]	1.2% (6)	3.1% (14)	0.38 [0.15, 1.00]
Disabling stroke	0.0% (0)	0.4% (2)	0.00 [NA]	0.2% (1)	0.9% (4)	0.22 [0.03, 2.00]
Non-disabling stroke	0.6% (3)	2.0% (9)	0.30 [0.08, 1.12]	1.0% (5)	2.2% (10)	0.45 [0.15, 1.32]
TIA	0.0% (0)	0.7% (3)	0.00 [NA]	1.0% (5)	1.1% (5)	0.89 [0.26, 3.06]
Death or stroke	1.0% (5)	3.3% (15)	0.30 [0.11, 0.83]	1.8% (9)	4.9% (22)	0.36 [0.17, 0.79]
Death or disabling stroke	0.4% (2)	1.3% (6)	0.30 [0.06, 1.51]	1.0% (5)	2.9% (13)	0.34 [0.12, 0.97]
Rehospitalization†	3.4% (17)	6.5% (29)	0.53 [0.29, 0.97]	7.3% (36)	11.0% (49)	0.65 [0.42, 1.00]
Major vascular complications	2.2% (11)	1.5% (7)	1.44 [0.56, 3.73]	2.8% (14)	1.5% (7)	1.83 [0.74, 4.55]
Life-threatening / disabling, or major bleeding	3.6% (18)	24.5% (111)	0.12 [0.07, 0.21]	7.7% (38)	25.9% (117)	0.25 [0.17, 0.37]
Life-threatening / disabling bleeding	1.2% (6)	11.9% (54)	0.09 [0.04, 0.22]	2.8% (14)	12.8% (58)	0.20 [0.11, 0.36]
Myocardial infarction	1.0% (5)	1.3% (6)	0.76 [0.23, 2.50]	1.2% (6)	2.2% (10)	0.54 [0.20, 1.49]

	3 Days	
	TAVR	**Surgery**
Patients requiring transfusion (≥ 1 unit)	10/496 (2.0%)	121/454 (26.7%)
Patients requiring ≥4 units	4/496 (0.8%)	33/454 (7.3%)

S11. Acute Kidney Injury

Endpoint	TAVR n/N (%)	Surgery n/N (%)	Difference [95% CI]*
Acute kidney injury stages†	7/496 (1.4)	39/454 (8.6)	-7.2 [-9.96, -4.40]
Stage I	5/496 (1.0)	31/454 (6.8)	-5.8 [-8.30, -3.34]
Stage II	0 /496(0.0)	5/454 (1.1)	-1.1 [N/A]
Stage III	2/496 (0.4)	3/454 (0.7)	-0.3 [-1.19, 0.67]

S18. Asymptomatic Valve Thrombosis TAVR 1.0% vs. SAVR 0.2% / rok, 2.6% vs. 0.7% /2 roky, p=0.02

Event Onset (Days post-procedure)	Treatment Arm	Gradient Change	Abnormal Echo or CT findings	Duration of Anticoagulant therapy
29	TAVR	8 mmHg (14.5 -> 22.8)	Echo	Ongoing
35	TAVR	11 mmHg (15 -> 26.5)	CT	Ongoing
40	TAVR	10 mmHg (22.3 -> 32)	Echo	Ongoing
107	TAVR	4 mmHg (18.4 -> 22.3)	CT	Ongoing
189	TAVR	18 mmHg (15 -> 33)	Echo	Ongoing
197	Surgery	6 mmHg (17 -> 23)	CT	Ongoing

CT denotes computed tomography; TTE, transthoracic echocardiography

Table S4. Procedural Complications

Complication	TAVR n/N (%)	Surgery n/N (%)
Procedural deaths (during index hospitalization)	2/496 (0.4)	4/454 (0.9)
≥2 Transcatheter valves implanted*	1/496 (0.2)	NA
Valve embolization	0 /496(0.0)	NA
Annulus rupture	1/496 (0.2)	NA
Aortic dissection	0/496 (0.0)	0/454 (0.0)
Coronary obstruction	1/496 (0.2)	2/454 (0.4)
Ventricular perforation	1/496 (0.2)	2/454 (0.4)
Access site infections	2/496 (0.4)	6/454 (1.3)

Data are patient counts (%). *Valve in valve or valve with embolization

Evolut Low Risk - komplikace

TABLE 2 Outcomes at 2 Years

	Interim Bayesian Rates (95% BCI)			Kaplan-Meier Estimates (95% CI) at 2 Years		
	TAVR (n = 725)	SAVR (n = 678)	Delta (95% BCI)	TAVR (n = 730)	SAVR (n = 684)	Delta (95% CI)
All-cause mortality or disabling stroke	5.3	6.7	−1.4 (−4.9 to 2.1)	4.3 (3.0 to 6.1)	6.3 (4.7 to 8.5)	−2.0 (−4.5 to 0.4)
All-cause mortality	4.5	4.5	0.0 (−3.2 to 3.2)	3.5 (2.3 to 5.1)	4.4 (3.0 to 6.3)	−0.9 (−3.0 to 1.2)
Cardiovascular	2.8	3.5	−0.7 (−3.3 to 1.9)	2.2 (1.4 to 3.6)	3.3 (2.2 to 5.1)	−1.1 (−2.9 to 0.7)
Aortic valve reintervention	0.7	1.2	−0.5 (−2.2 to 0.6)	0.8 (0.4 to 1.9)	0.8 (0.3 to 1.9)	0.1 (−0.9 to 1.0)
Valve thrombosis	0.6	0.5	0.1 (−1.2 to 1.3)	0.3 (0.1 to 1.2)	0.2 (0.0 to 1.2)	0.1 (−0.4 to 0.6)
Valve thrombosis (subclinical)	0.4	0.6	−0.2 (−1.6 to 1.0)	0.6 (0.2 to 1.5)	0.5 (0.1 to 1.5)	0.1 (−0.7 to 0.9)
Valve endocarditis	0.2	1.6	−1.3 (−3.3 to −0.2)	0.4 (0.1 to 1.3)	0.9 (0.4 to 2.1)	−0.5 (−1.4 to 0.4)
All stroke	4.9	5.3	−0.3 (−3.2 to 2.4)	5.8 (4.3 to 7.9)	5.6 (4.0 to 7.7)	0.2 (−2.3 to 2.8)
Disabling	1.1	3.5	−2.3 (−4.8 to -0.4)	1.5 (0.8 to 2.8)	2.7 (1.7 to 4.4)	−1.2 (−2.8 to 0.4)
Nondisabling	3.9	2.2	1.6 (−0.3 to 3.7)	4.3 (3.0 to 6.1)	3.0 (1.9 to 4.8)	1.3 (−0.8 to 3.3)
Permanent pacemaker implantation[a]	23.8	7.0	16.7 (12.7 to 21.1)	21.8 (18.9 to 25.2)	8.2 (6.2 to 10.8)	13.6 (9.7 to 17.5)
Permanent pacemaker implantation[b]	23.0	6.7	16.3 (12.3 to 20.4)	21.1 (18.2 to 24.4)	7.9 (6.0 to 10.4)	13.2 (9.4 to 17.0)
Life-threatening or disabling bleeding	4.5	9.8	−5.3 (−8.7 to −2.1)	4.3 (3.0 to 6.1)	9.3 (7.3 to 12.0)	−5.1 (−7.8 to −2.3)
Major vascular complication	3.8	3.6	0.2 (−2.0 to 2.2)	3.8 (2.6 to 5.6)	3.5 (2.3 to 5.4)	0.3 (−1.8 to 2.4)
Myocardial infarction	2.2	1.6	0.6 (−1.0 to 2.4)	2.2 (1.3 to 3.6)	1.6 (0.9 to 3.0)	0.6 (−0.9 to 2.1)
Aortic valve hospitalization	5.4	7.9	−2.5 (−6.1 to 1.0)	5.3 (3.9 to 7.3)	7.1 (5.3 to 9.5)	−1.8 (−4.5 to 0.9)

Dlouhodobá prognóza po TAVI (FU 5-10 let)

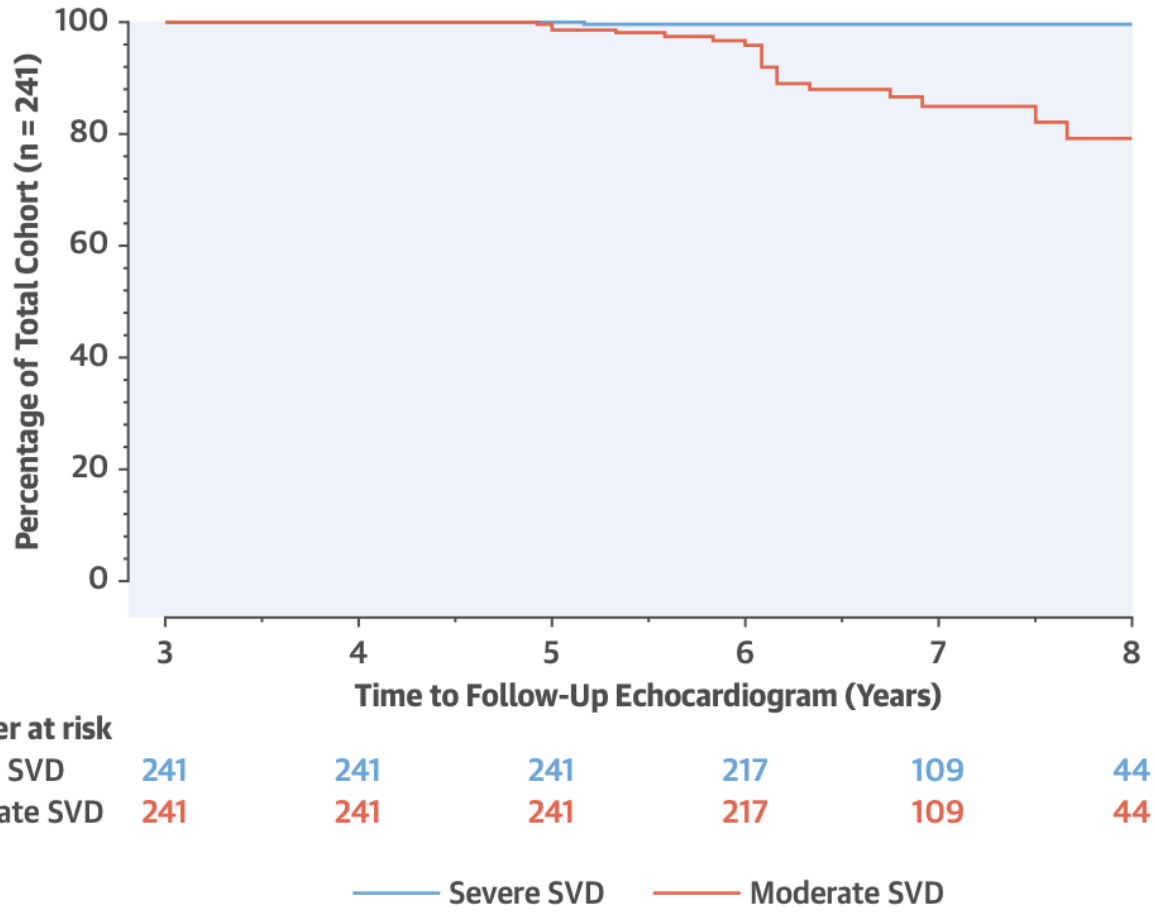
TABLE 1 Baseline Characteristics of the Study Population

Male	126/235 (54.0)
Age, yrs	79.3 ± 7.47
Logistic EuroSCORE	19.7 ± 12.3
Prior cardiac surgery	92/223 (41.3)
Pulmonary disease	60/223 (26.9)
Previous stroke/TIA	43/223 (19.3)
Peripheral vascular disease	60/234 (26.0)
Creatinine >200 μmol/l	10/223 (4.5)
Atrial fibrillation	54/219 (25.0)
Previous MI	60/234 (25.6)
Diabetes mellitus	52/223 (23.3)
Peak gradient	80.6 ± 26.2
Aortic valve area	0.67 ± 0.3
Left ventricular function	
Normal, LVEF ≥50%	163/235 (69.7)
Moderately impaired, 30%–49%	51/235 (22.8)
Severely impaired, <30%	20/235 (8.5)
PA pressure >60 mm Hg	39/227 (17.2)
Annulus diameter, mm	22.7 ± 2.3

TABLE 2 Procedural Data

General anesthesia	172/234 (73.5)
Access	
Transfemoral	179/223 (80.3)
Transapical	31/223 (13.9)
Subclavian	8/223 (3.6)
Transaortic	5/223 (2.2)
Valve type	
Sapien	45/233 (19.3)
Sapien XT	35/233 (15.0)
CoreValve	149/233 (64.0)
Portico	4/233 (1.7)
Pre-dilatation (BAV)	214/234 (91.5)

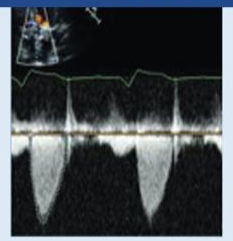
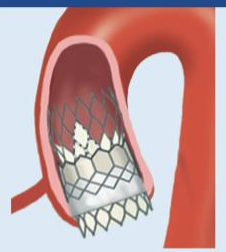
CENTRAL ILLUSTRATION Freedom From Structural Valve Deterioration Over Time: Kaplan-Meier Curve



Blackman, D.J. et al. J Am Coll Cardiol. 2019;73(5):537–45.

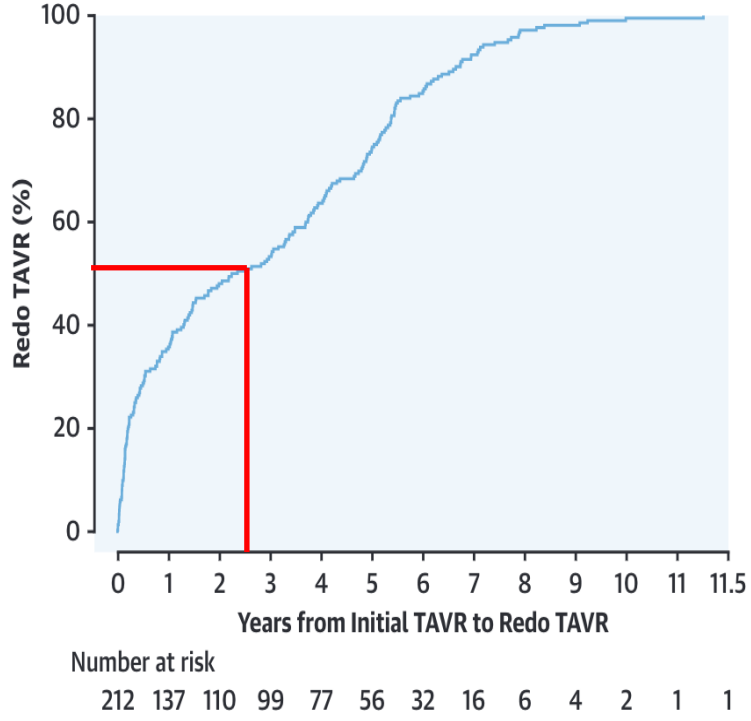
Re TAVI v případě , že tato byla potřeba

CENTRAL ILLUSTRATION Repeated Transcatheter Aortic Valve Replacement for Transcatheter Heart Valve Dysfunction

	Incidence	Residual Gradient	Coronary Flow Obstruction	Mortality at 30 days
Redo-TAVR For:				
Failed TAVR Valve	0.22%	13 mm Hg	0.7%	1.4%
Failed TAVR Procedure	0.11%	11.5 mm Hg	1.3%	5.4%

Landes, U. et al. J Am Coll Cardiol. 2020;75(16):1882-93.

FIGURE 2 First TAVR to Redo-TAVR Time Interval Distribution



SVD (structural valve deterioration) u chirurgických chlopní

- Průměrně 1% / 5 let, 10-30% / 10 let , 20-50% / 15 let
  - Mitroflow (Sorin) 3.8 let
  - Trifecta (SJM) 6 let
  - Hancock II (Medtronic) 10 let
  - Carpentier-Edwards Perimount (Edwards Lifescience) 19 let

Blackman D. JACC 2019;73:537-45,
Pibarot P. Circulation 2009;119;

Závěry

Výsledky studií NOTION, PARTNER 3, Evolut Low Risk svědčí pro non-inferiorní postavení TAVI ve srovnání s chirurgickou implantací aortální bioprotézy u pacientů s nízkým rizikem, kteří mají trikuspidální aortální chlopeň bez masivních kalcifikací, bez nízkého odstupu koronárních tepen, významných jiných valvulopatií a s nekomplikovaným femorálním přístupem

TAVI je ve srovnání se SAVR spojena s vyšším efektivním ústím aortální chlopně, nižšími transvalvulárními gradienty. Dále má nižší výskyt CMP, fibrilace síní, závažných krvácivých komplikací a akutního renálního poškození

TAVI ve srovnání se SAVR vede k častější implantaci trvalého kardiostimulátoru, četnějšímu výskytu paravalvulární aortální regurgitace a zřejmě i subklinické trombóze chlopně

V současné době není dostatek dlouhodobých dat pro TAVI (zejména pro moderní chlopně), ale z limitovaných dat nevyplývá vyšší riziko selhání chlopně než u chlopní chirurgických a je dokumentován nižší výskyt patient-prothesis mismatch. Otázkou zůstává dlouhodbý dopad subklinické trombózy chlopně a přístup do koronárních tepen zejména po re-TAVI