

TAVI vs. chirurgická náhrada aortální chlopně.

Jak se správně rozhodnout?

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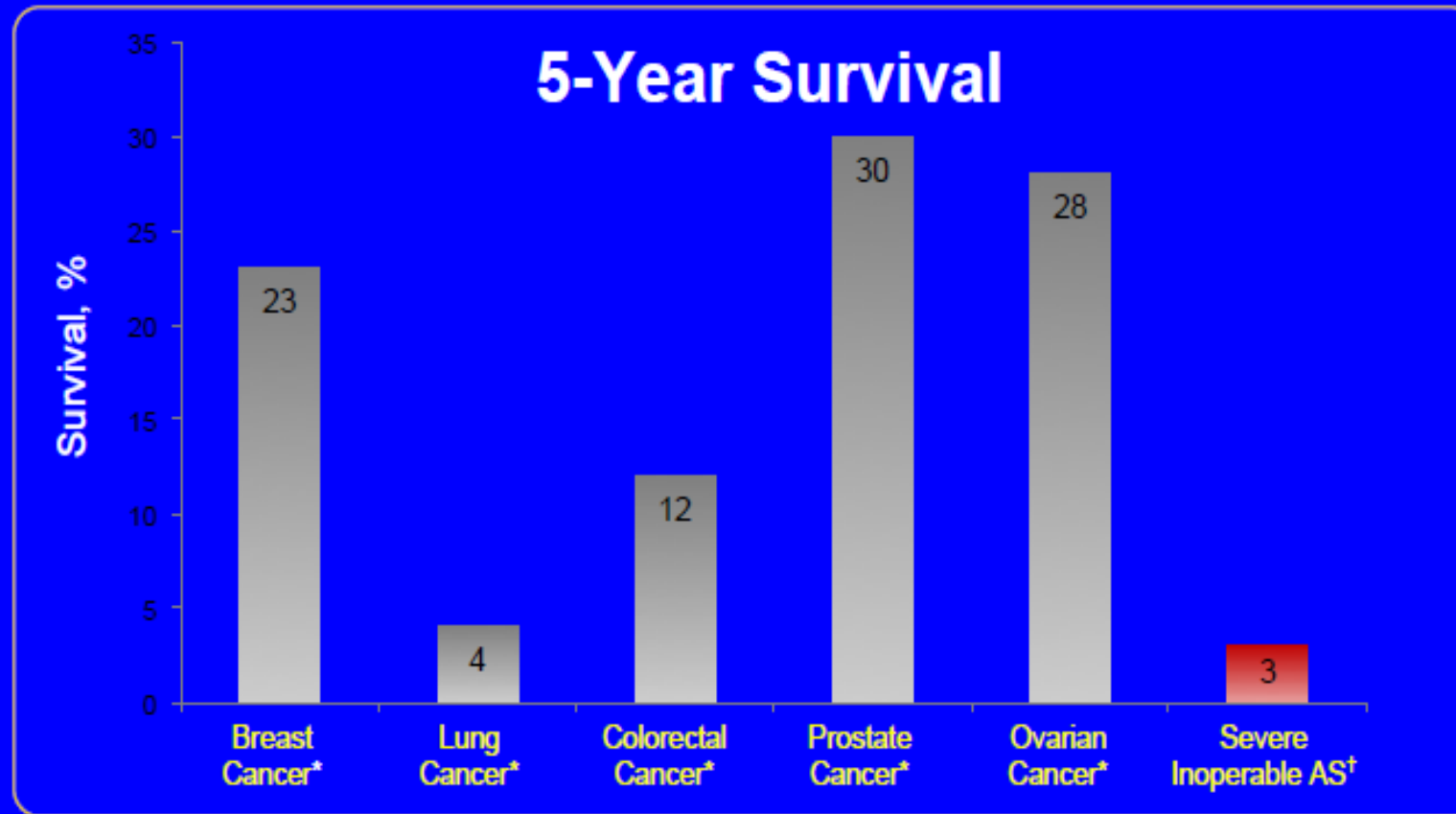
Kvantifikace Ao stenózy:

Stupeň AoS	1. lehká	2. střední	3. těžká
AVAI (cm ² /m ²)	> 0,8	0,6*–0,8	< 0,6
AVA (cm ²)	> 1,5	1,5–1	< 0,75–1
PG mean (mm Hg)	< 25	25–40	> 40
„Peak-to-peak“ gr. (mm Hg)	< 30	30–60	> 60
PGmax (mm Hg)	< 36	36–64	> 64
Vmax (m/s)	< 3	3–4	> 4
poměr Vmax Ao/LVOT			> 4

Rychlá progrese vady do symptomatického stadia:

- významné kalcifikace v chlopni, rizikové ff. AS
- významná HLK, dysfunkce LK
- vysoká průtoková rychlost na Ao ústí – 5-5,5 m/s
- vysoká hladina natriuretických peptidů
- vzestup středního gr. při zátěži > 20 mmHg

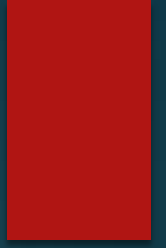
Mortality With Standard Therapy Is Worse Than With Certain Metastatic Cancers



*National Institutes of Health. National Cancer Institute. Surveillance Epidemiology and End Results. Cancer Stat Fact Sheets. <http://seer.cancer.gov/statfacts/>. Accessed November 16, 2010.

† Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuzcu.

Chirurgie



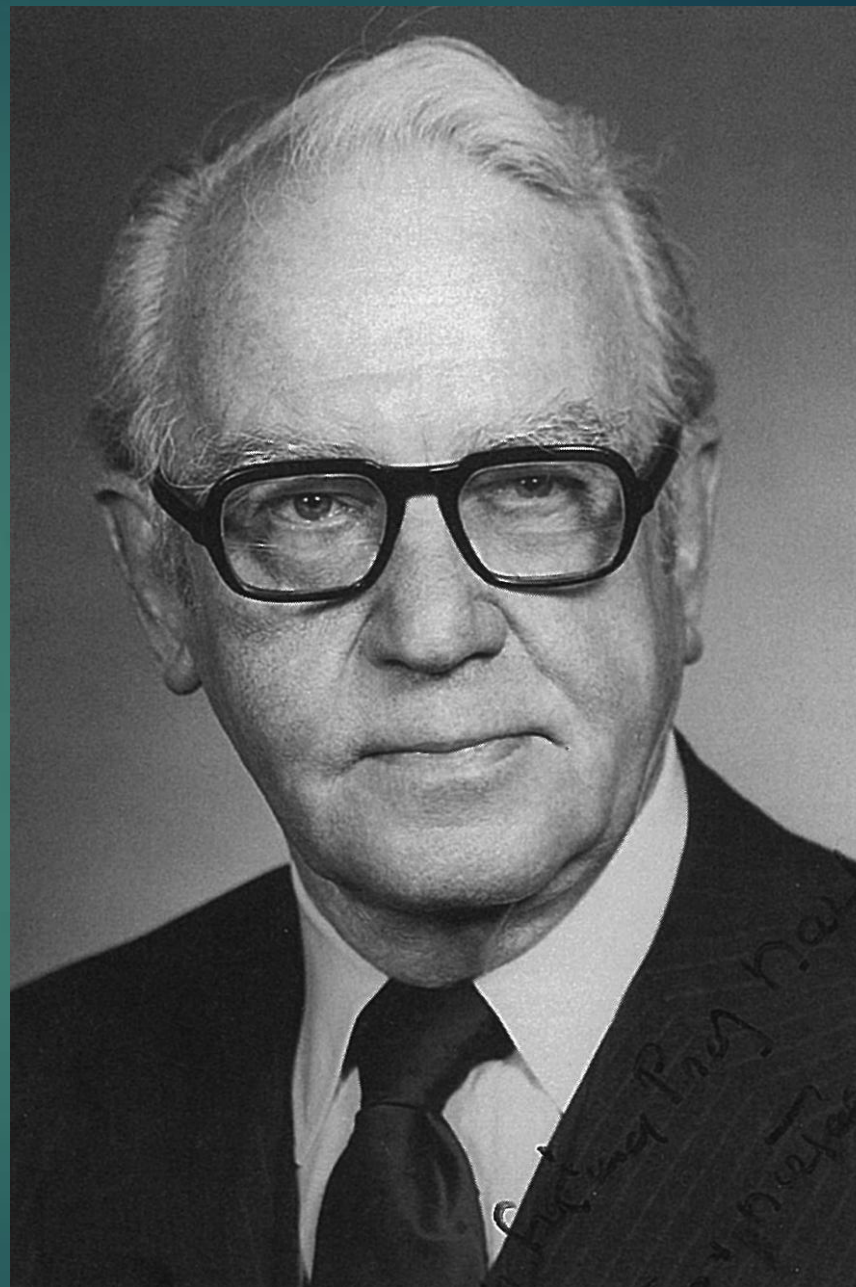
AVR (mech. chlopní)

Dwight Emary Harken
(1910 – 1993)

Boston, 10. 3. 1960



Harkenova kuličková chlopeň



Xenografty Alain Frederic Carpentier (*1933)

1965 – AVR stentovaným xenograftem

1967 – MVR stentovaným xenograftem

1968 – glutaraldehyd k fixaci a sterilizacaci xenograftů



Náhrady srdečních chlopní

Mechanické srdeční chlopně:

- kuličkové, diskové, dvoulisté

Biologické srdeční chlopně:

Bioprotézy:

- stentované bioprotézy
- stentless bioprotézy
- sutureless bioprotézy
- transkatetrální bioprotézy

Homografty (alografty)

Autografty (pulmonální – Ross, perikard – Ozaki)

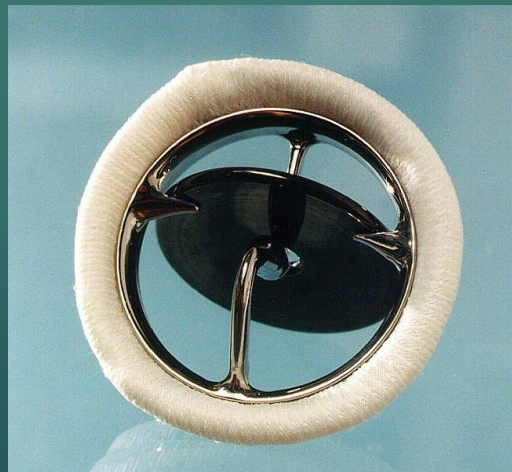


Björk-Shiley



St Jude Medical

Medtronic-Hall

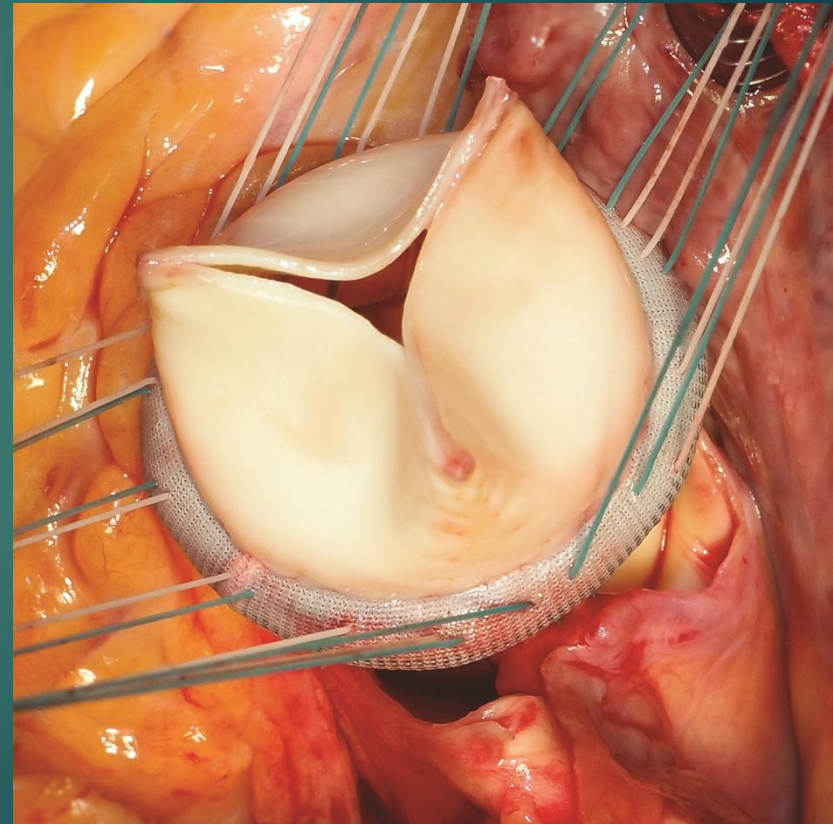


Perikardiální bioprotézy

Sorin – Pericarbon, Soprano
(1985)



Mitroflow, Mitroflow PRT
(1982) (2011)



TAVI



TAVI

transfemorálně antegrádně (2002)

Alain Cribier, Rouen



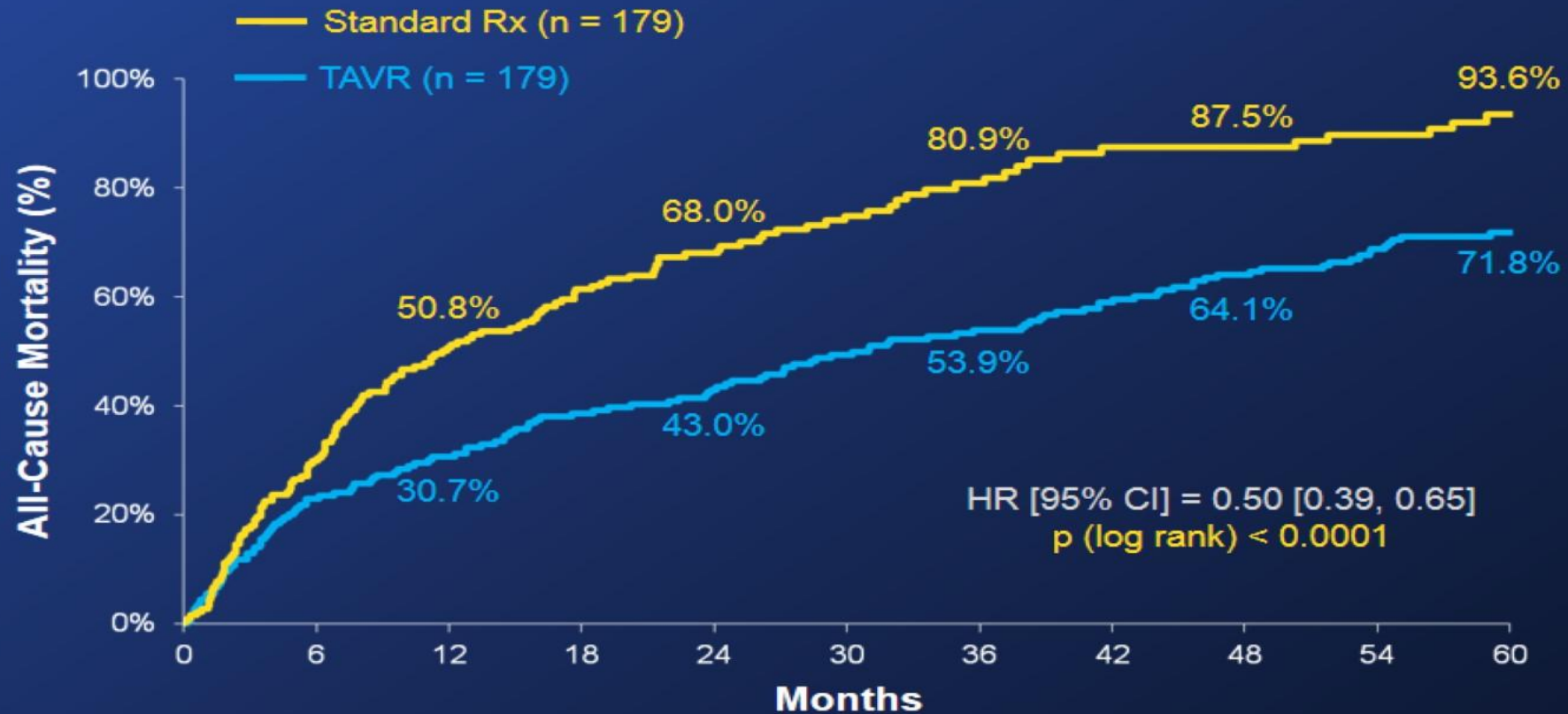
transfemorálně retrográdně (2005)
transapikálně (2006)

John Webb, Vancouver



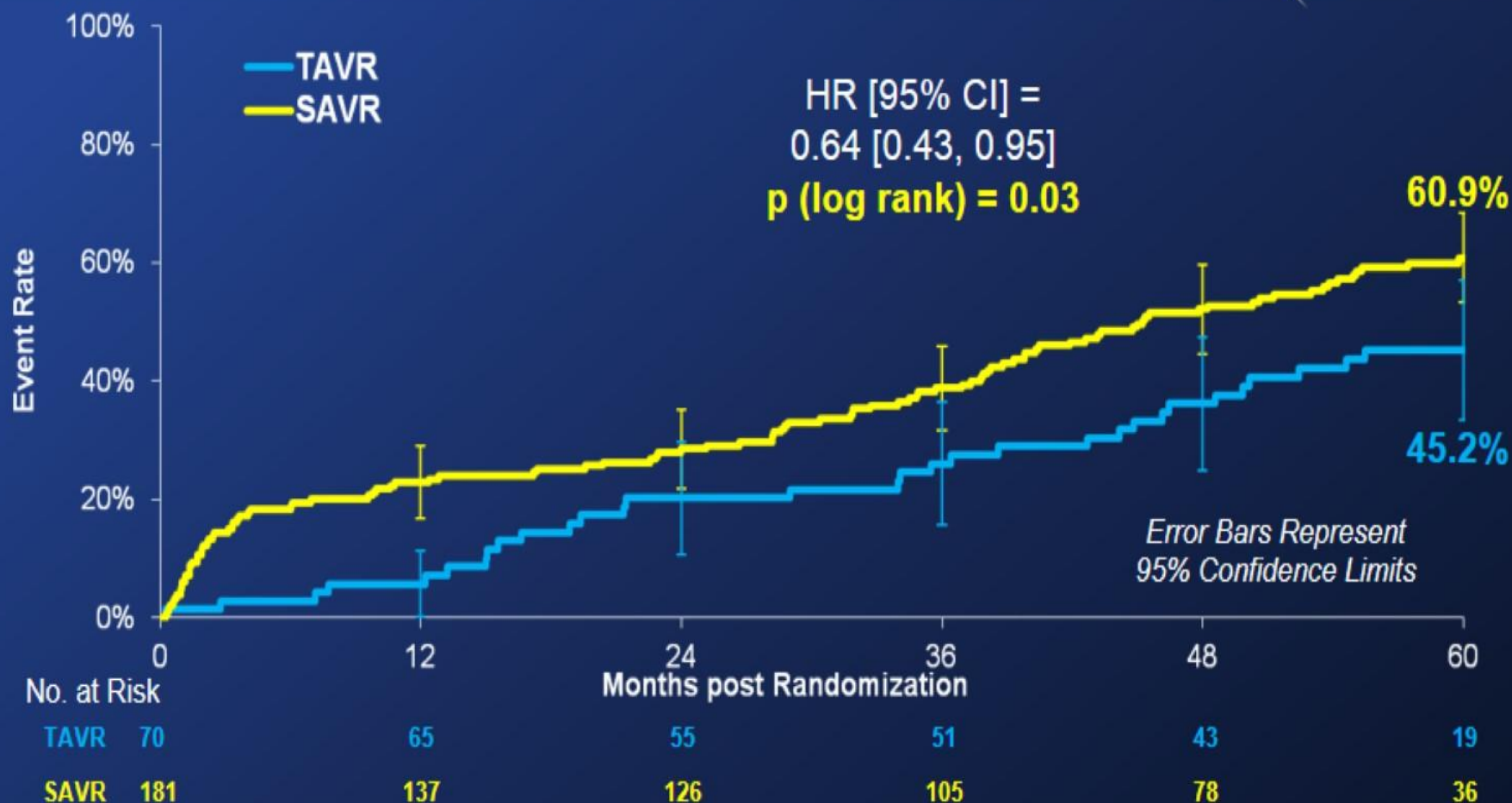
All-Cause Mortality (ITT)

Crossover Patients Censored at Crossover



* In an age and gender matched US population without comorbidities, the mortality at 5 years is 40.5%.

Mortality and None-Trace Total AR Transfemoral Patients



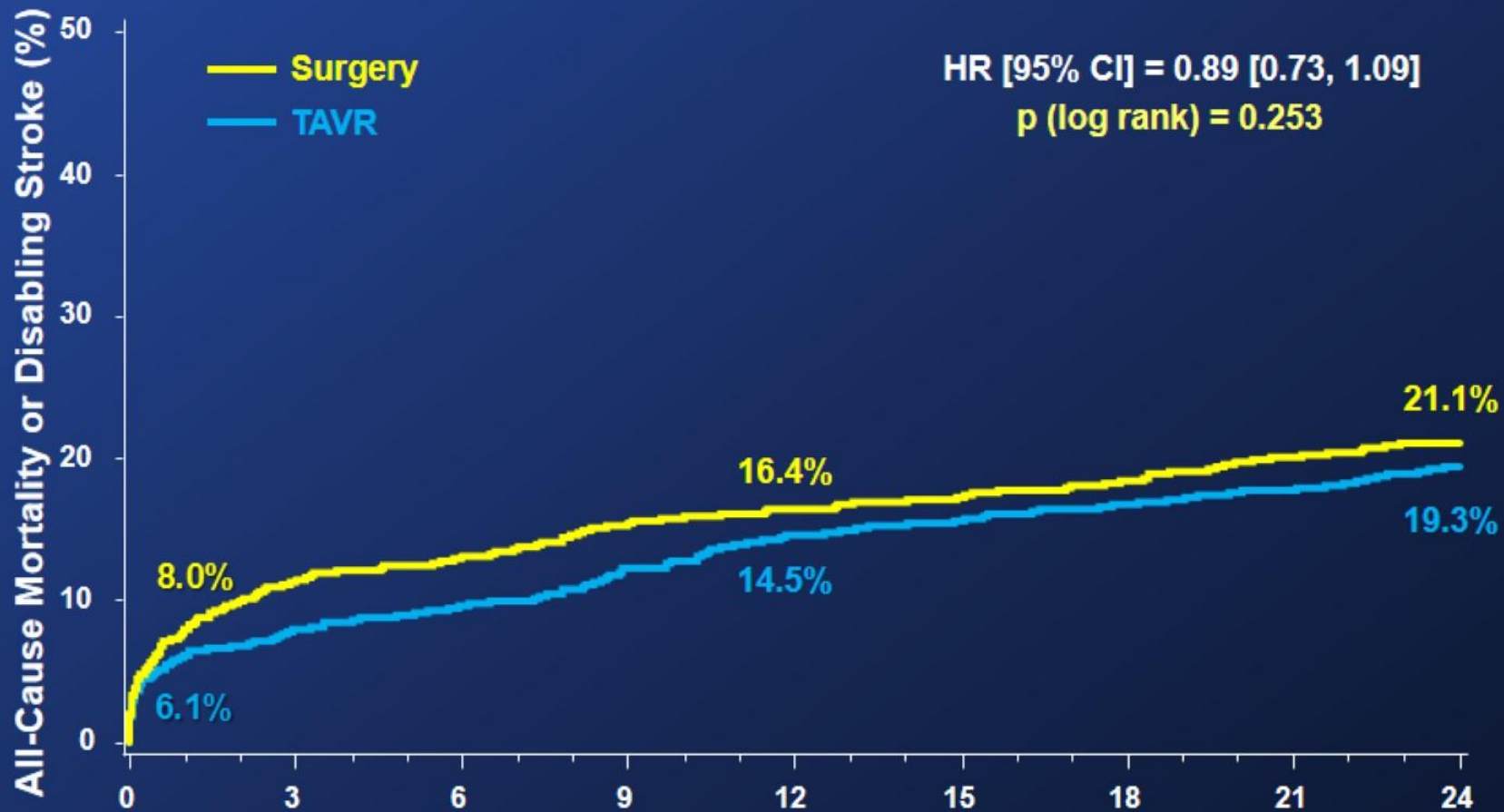
Inclusion Criteria



- **Severe AS:** Echo-derived AVA $\leq 0.8 \text{ cm}^2$ (or AVA index $< 0.5 \text{ cm}^2/\text{m}^2$) and mean AVG $> 40 \text{ mm Hg}$ or peak jet velocity $> 4.0 \text{ m/s}$
- **Cardiac Symptoms:** NYHA Functional Class $\geq \text{II}$
- **Intermediate Risk:**
 1. Determined by the multi-disciplinary Heart Team
 2. Using a guideline STS $\geq 4\%$, and
 3. Adjudicated by case review committee

Primary Endpoint (ITT)

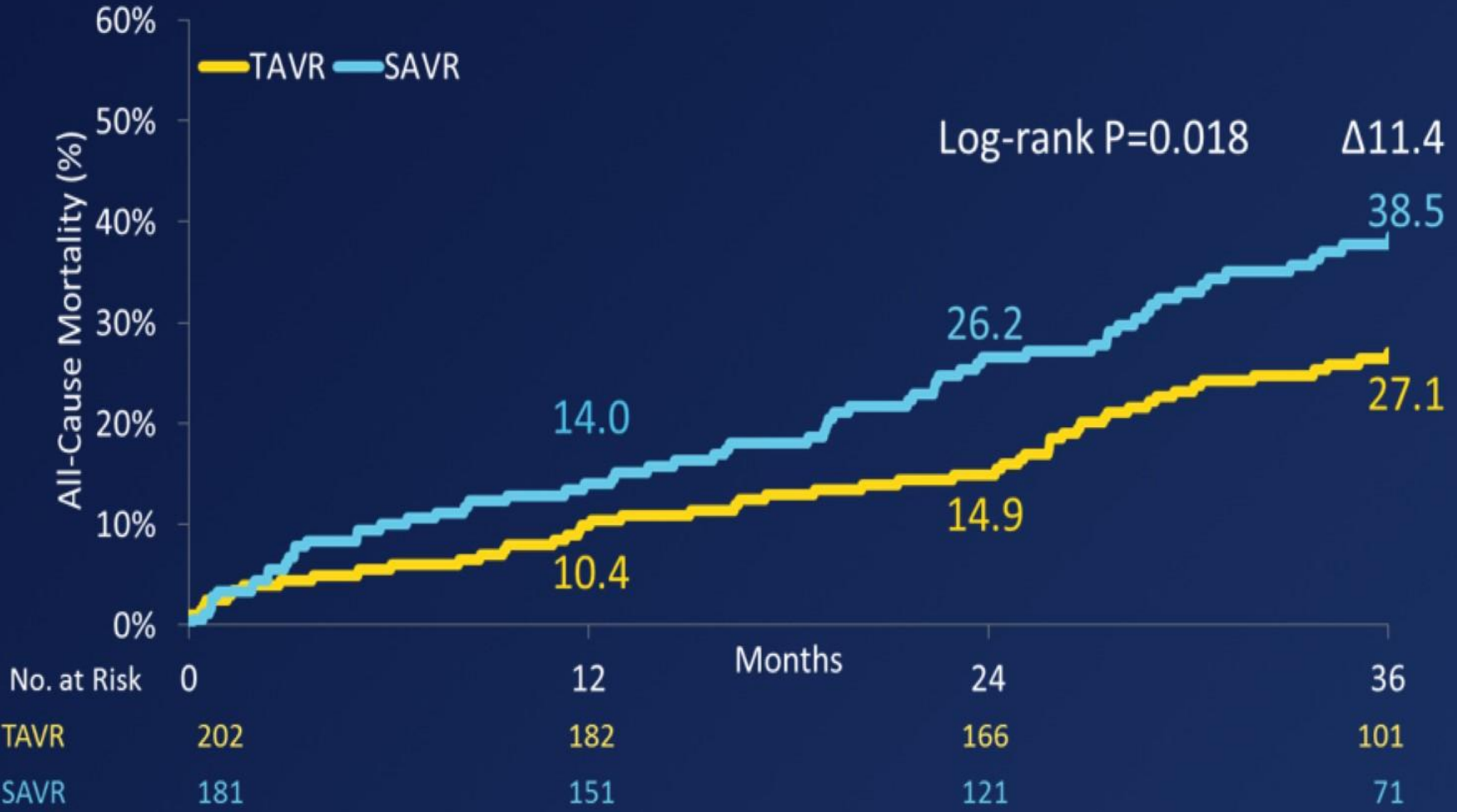
All-Cause Mortality or Disabling Stroke



Number at risk:

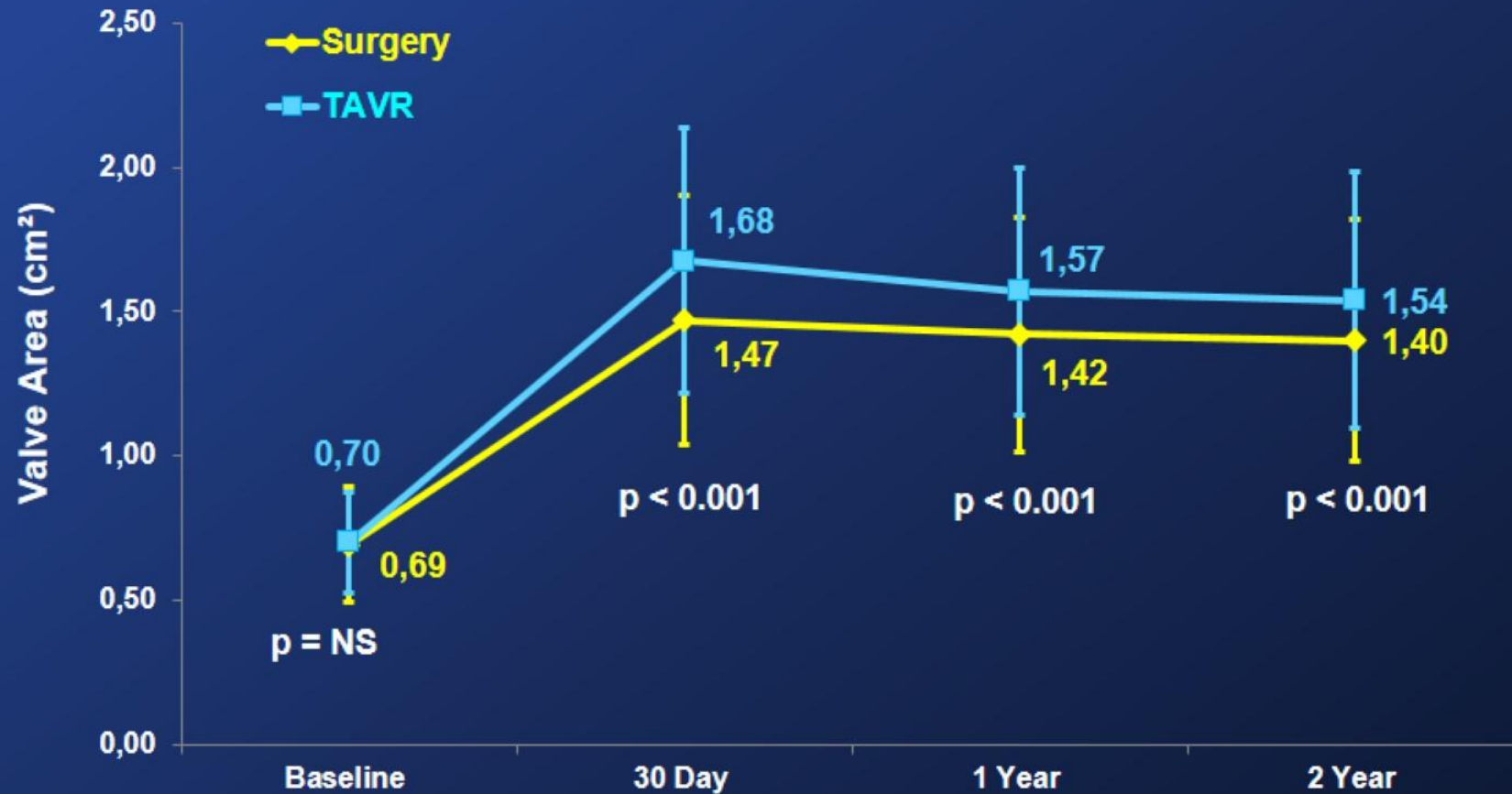
	0	3	6	9	12	15	18	21	24
Surgery	1021	838	812	783	770	747	735	717	695
TAVR	1011	918	901	870	842	825	811	801	774

All-Cause Mortality – STS ≤ 7%



Echocardiography Findings (VI)

Aortic Valve Area



No. of Echos

Surgery

861

727

590

488

TAVR

899

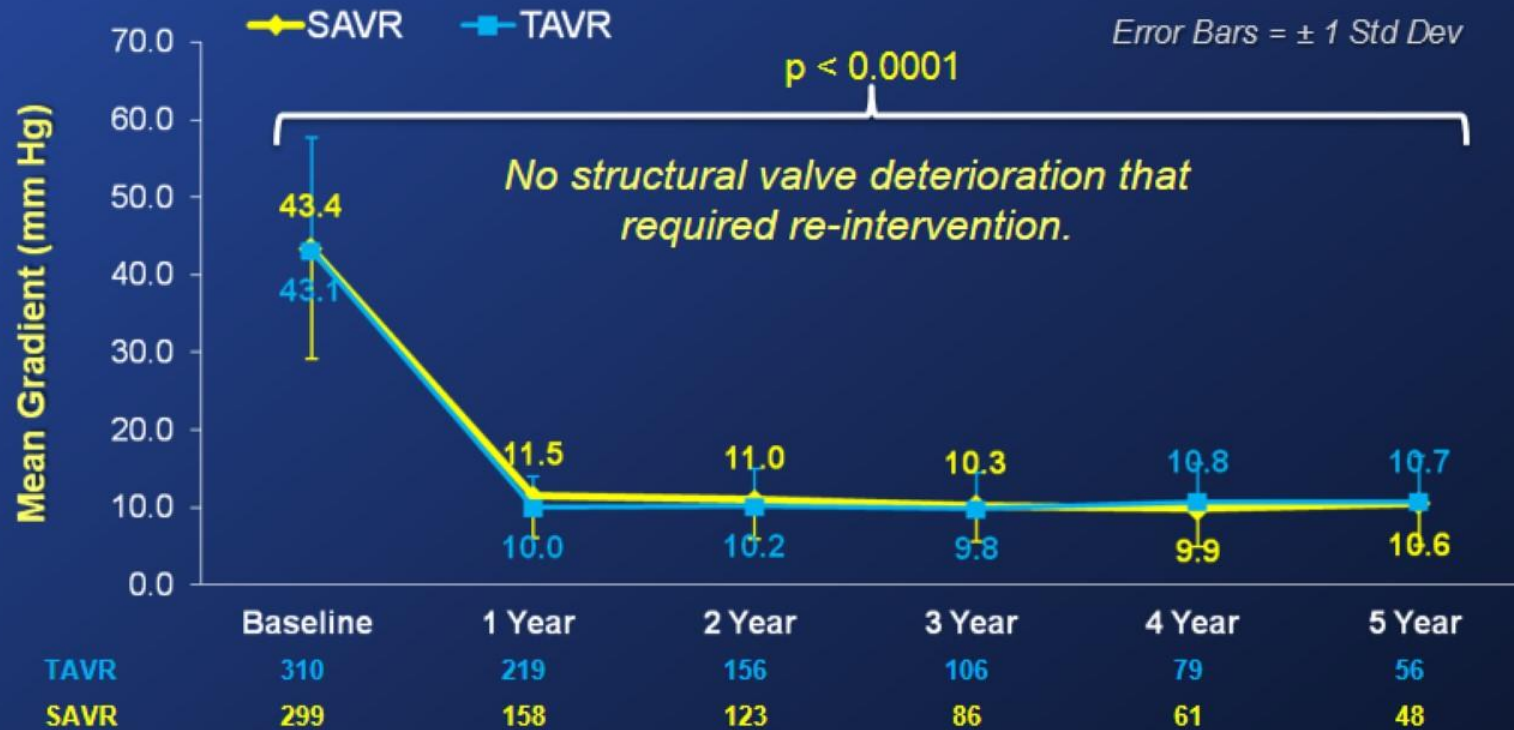
829

695

567

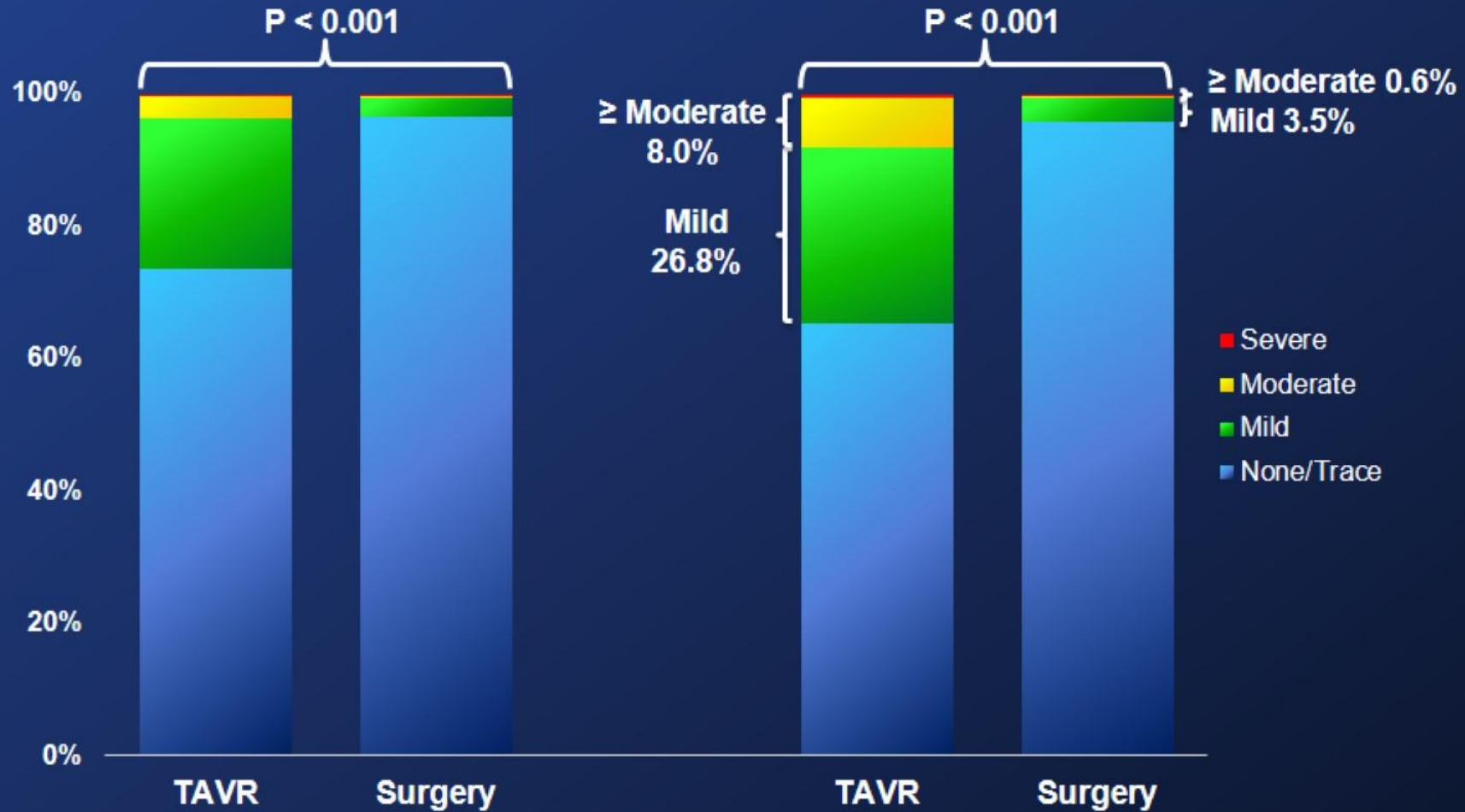
Error bars represent \pm Standard Deviation

Aortic Valve Mean Gradient



Paravalvular Regurgitation (VI)

3-Class Grading Scheme



No. of echos

30 Days

2 Years

TAVR

872

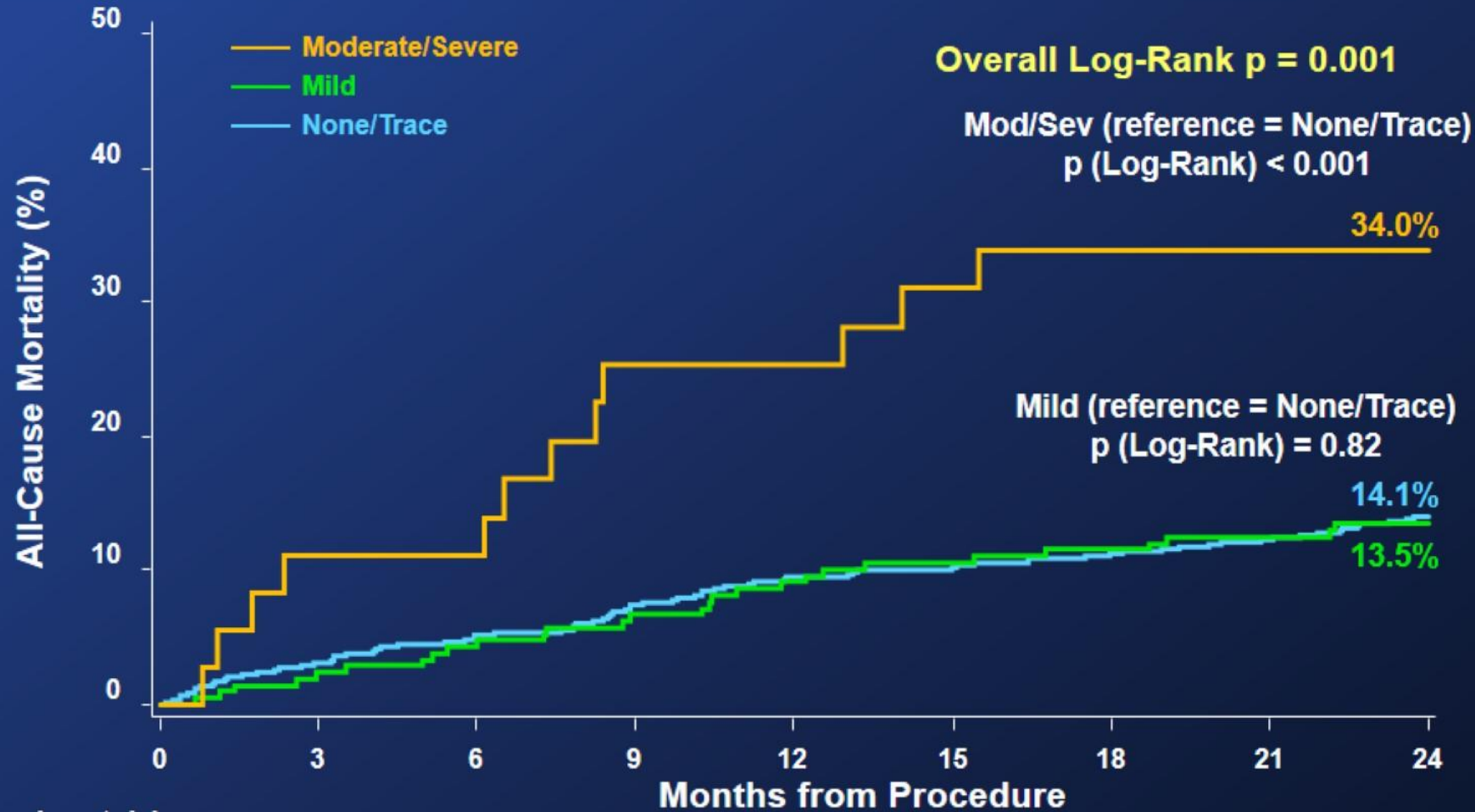
600

Surgery

757

514

Severity of PVR at 30 Days and All-cause Mortality at 2 Years (VI)



Number at risk:

Moderate/Sev	36	32	32	26	26	24	22	22	21
Mild	210	204	199	194	188	184	182	180	175
None/Trace	701	678	664	647	628	621	612	605	585

Stratifikace rizika:

STS nebo EuroSCORE II

logistické EuroSCORE I

- ▶ Nízké < 4%
- ▶ Střední 4-8%
- ▶ Vysoké > 8%

- < 10%
- 10-20%
- > 20%

STS calculator



Home Calculate Support

Procedure Type

CAB Only

AV Replacement

MV Replacement Only

MV Repair

AV Replacement + CAB

MV Replacement + CAB

MV Repair + CAB

Patient Age

Sex

Male Female

Risk Model and Variables - STS Adult Cardiac Surgery Database Version 2.81

RISK SCORES

[About the STS Risk Calculator](#)

Procedure: AV Replacement

Risk of Mortality: 4.137%

Morbidity or Mortality: 18.056%

Long Length of Stay: 10.328%

Short Length of Stay: 21.741%

Permanent Stroke: 1.687%

Prolonged Ventilation: 9.021%


DSW Infection: 0.412%

Renal Failure: 4.514%

Reoperation: 9.507%

EuroSCORE II

Important: The previous additive ¹ and logistic ² EuroSCORE models are out of date. A new model has been prepared from fresh data and is launched at the 2011 EACTS meeting in Lisbon. The model is called EuroSCORE II ³ - this online calculator has been updated to use this new model. If you need to calculate the older "additive" or "logistic" EuroSCORE please visit the old calculator by [clicking here](#).

Patient related factors		Cardiac related factors			
Age ¹ (years)	<input type="text" value="0"/>	<input type="text" value="0"/>	NYHA	<input type="text" value="select"/>	<input type="text" value="0"/>
Gender	<input type="text" value="select"/>	<input type="text" value="0"/>	CCS class 4 angina ⁸	<input type="text" value="no"/>	<input type="text" value="0"/>
Renal impairment ² <small>See calculator below for creatinine clearance</small>	<input type="text" value="normal (CC >85ml/min)"/>	<input type="text" value="0"/>	LV function	<input type="text" value="select"/>	<input type="text" value="0"/>
Extracardiac arteriopathy ³	<input type="text" value="no"/>	<input type="text" value="0"/>	Recent MI ⁹	<input type="text" value="no"/>	<input type="text" value="0"/>
Poor mobility ⁴	<input type="text" value="no"/>	<input type="text" value="0"/>	Pulmonary hypertension ¹⁰	<input type="text" value="no"/>	<input type="text" value="0"/>
Previous cardiac surgery	<input type="text" value="no"/>	<input type="text" value="0"/>	Operation related factors		
Chronic lung disease ⁵	<input type="text" value="no"/>	<input type="text" value="0"/>	Urgency ¹¹	<input type="text" value="elective"/>	<input type="text" value="0"/>
Active endocarditis ⁶	<input type="text" value="no"/>	<input type="text" value="0"/>	Weight of the intervention ¹²	<input type="text" value="isolated CABG"/>	<input type="text" value="0"/>
Critical preoperative state ⁷	<input type="text" value="no"/>	<input type="text" value="0"/>	Surgery on thoracic aorta	<input type="text" value="no"/>	<input type="text" value="0"/>
Diabetes on insulin	<input type="text" value="no"/>	<input type="text" value="0"/>			
EuroSCORE II <input type="text" value="EuroSCORE II"/>		<input type="text" value="0"/>			
 <small>Note: This is the 2011 EuroSCORE II</small>		<input type="button" value="Calculate"/> <input type="button" value="Clear"/>			

Notes about euroSCORE II

Age - in completed years. Some of the weighting for age is now incorporated into the renal impairment risk factor, so it is important that all risk factors are entered to give reliable risk estimations - see note [2]. Of over 20,000 patients in the EuroSCORE database, only 21 patients were aged over 90 - therefore the risk model may not be accurate in these patients. Please exercise clinical discretion in interpreting the score. The oldest patient in the EuroSCORE database was 95 - EuroSCORE is not validated in patients over this age.

Logistické EuroSCORE I



Important: The previous additive and logistic EuroSCORE models are out of date. A new model has been prepared from fresh data and is launched at the 2011 EACTS meeting in Lisbon. The model is called EuroSCORE II - we strongly advise that you use this model - [available here](#). If you really wish to calculate the older "additive" or "logistic" EuroSCORE you can use it below.

Patient-related factors			Cardiac-related factors		
Age (years)	<input type="text" value="0"/>	<input type="text" value="0"/>	Unstable angina ⁶	<input type="text" value="No"/>	<input type="text" value="0"/>
Gender	<input type="text" value="Select"/>	<input type="text" value="0"/>	LV function	<input type="text" value="Select"/>	<input type="text" value="0"/>
Chronic pulmonary disease ¹	<input type="text" value="No"/>	<input type="text" value="0"/>	Recent MI ⁷	<input type="text" value="No"/>	<input type="text" value="0"/>
Extracardiac arteriopathy ²	<input type="text" value="No"/>	<input type="text" value="0"/>	Pulmonary hypertension ⁸	<input type="text" value="No"/>	<input type="text" value="0"/>
Neurological dysfunction ³	<input type="text" value="No"/>	<input type="text" value="0"/>	Operation-related factors		
Previous Cardiac Surgery	<input type="text" value="No"/>	<input type="text" value="0"/>	Emergency ⁹	<input type="text" value="No"/>	<input type="text" value="0"/>
Creatinine > 200 µmol/ L	<input type="text" value="No"/>	<input type="text" value="0"/>	Other than isolated CABG	<input type="text" value="No"/>	<input type="text" value="0"/>
Active endocarditis ⁴	<input type="text" value="No"/>	<input type="text" value="0"/>	Surgery on thoracic aorta	<input type="text" value="No"/>	<input type="text" value="0"/>
Critical preoperative state ⁵	<input type="text" value="No"/>	<input type="text" value="0"/>	Post infarct septal rupture	<input type="text" value="No"/>	<input type="text" value="0"/>

Logistic <input type="text" value="EuroSCORE"/>	<input type="text" value="0"/>	
	Note: Logistic is now default calculator	<input type="button" value="Calculate"/> <input type="button" value="Clear"/>

Frailty – křehkost, chatrnost:

- ▶ Biologický sy snížené rezervy a odolnosti vůči stresorům vyplývající z kumulace snížené funkční rezervy různých fyziologických systémů a způsobující zranitelnost při působení zevních vlivů...

Frailty index (1-7)

- ▶ Každodenní aktivity:
 - péče o osobní hygienu
 - stravování
 - oblékání
- ▶ Fenotyp křehkosti, zranitelnosti:
 - fyzická aktivita
 - mentální aktivita
- ▶ Test fyzické zdatnosti:
 - síla stisku ruky
 - postavení ze sedu
 - 5 m chůze
- ▶ Laboratorní hodnoty:
 - A, FEV1, CrCl, BNP

How do you define debility or frailty ?



• *Same age (90) and predicted risk (12%)*

• *Frailty Index*

7 (Severely frail)

1 (Very fit)

Balloon-expandable devices

Sapien XT



Sapien 3



Self-expanding devices

Evolut R



Acurate Neo



Portico

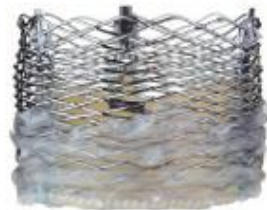


Allegra



Mechanically-expandable devices

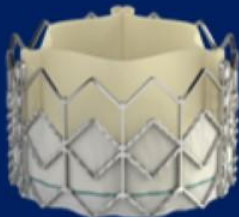
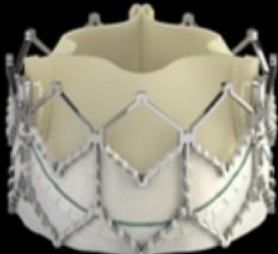












Lotus



PARTNER SAPIEN Platforms

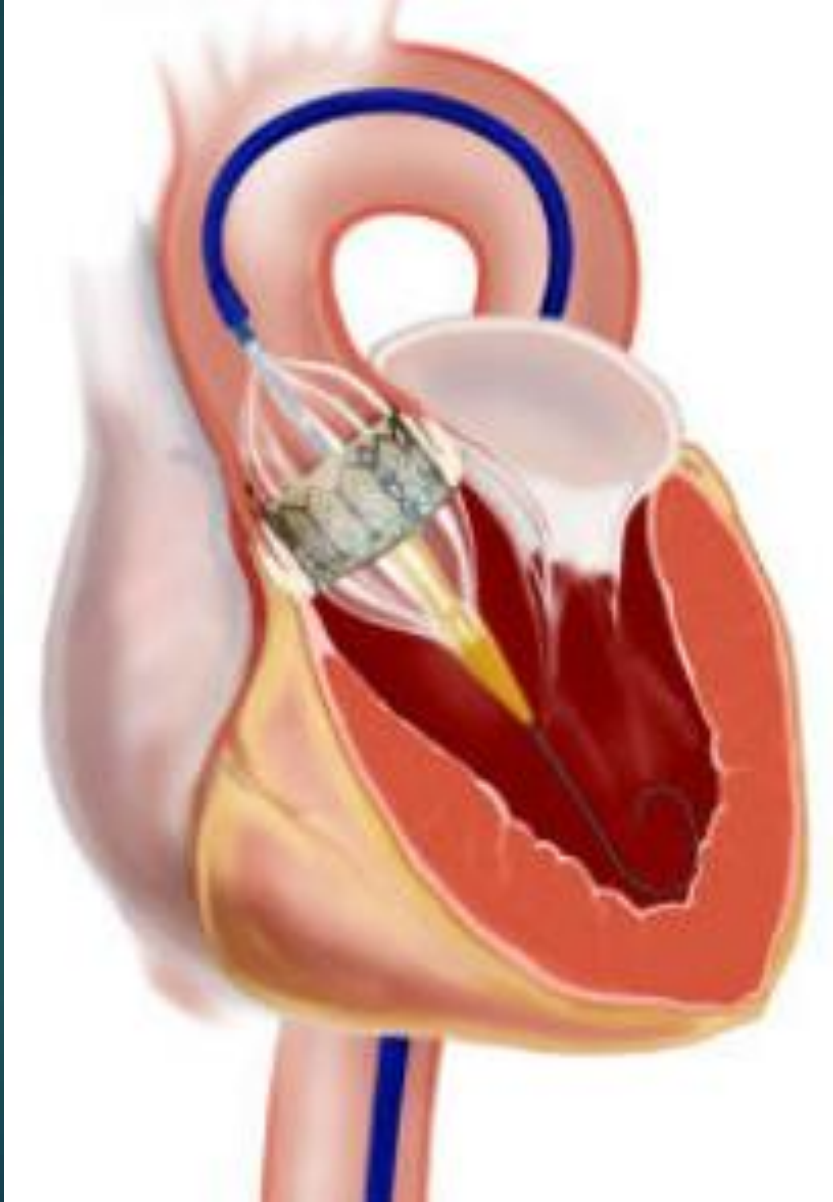
Device Evolution



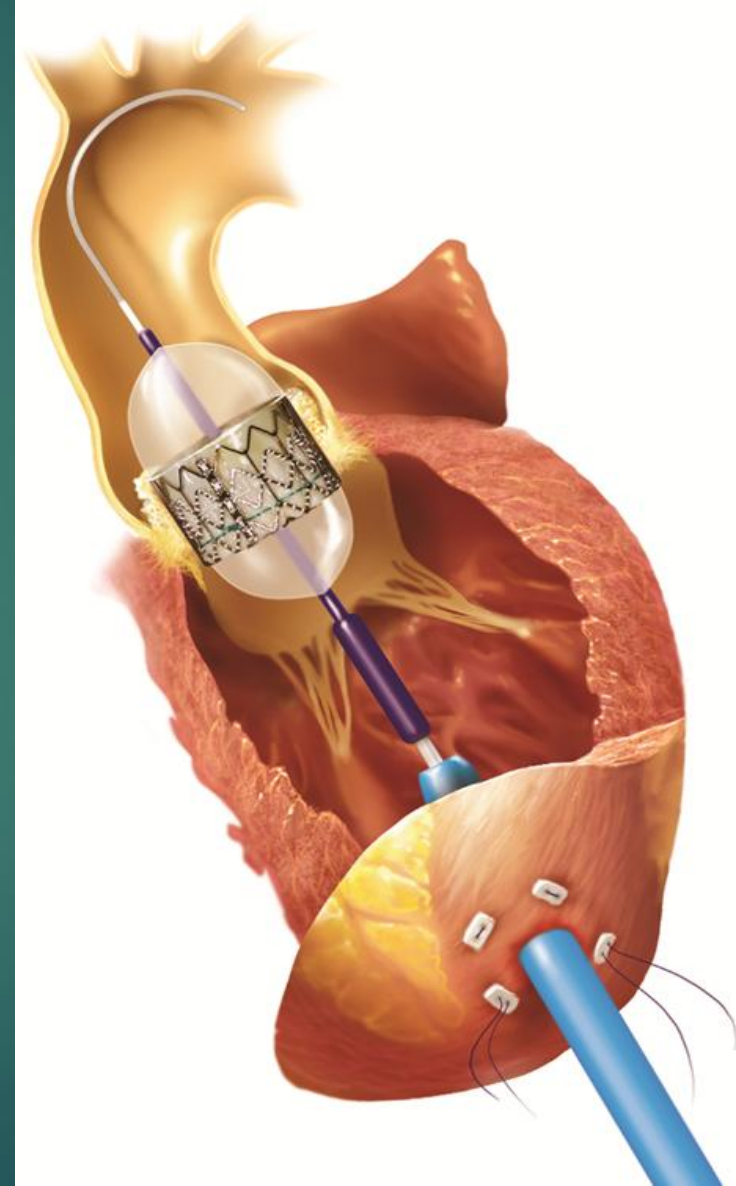
	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility			
Available Valve Sizes	 23 mm  26 mm	 23mm  26mm  29mm*	 20 mm  23 mm  26 mm  29 mm

***First Implant Oct 30, 2012**

TF implantace



TA implantace



Number of enrolled patients by centers

TAVI

Center	2009	2010	2011	2012	2013	2014	2015	2016	2017*	Total
CKTCH Brno	11	19	18	14	19	28	47	53	22	231
České Budějovice	4	4	10	2	17	10	14	43	13	117
FN Olomouc	0	6	4	4	3	4	33	49	29	132
FN Plzeň	0	0	0	2	10	17	20	18	0	67
FNHK	12	26	17	19	17	26	38	36	29	220
FNKV Praha	13	24	18	19	24	33	41	28	0	200
IKEM Praha	24	19	18	24	30	35	44	25	3	222
Nemocnice Na Homolce	0	2	2	0	8	19	26	26	16	99
Třinec	13	35	50	53	73	80	89	98	54	545
Ústí nad Labem	4	4	7	10	8	6	9	13	0	61
VFN Praha	0	0	4	3	5	10	9	14	2	47
Total	81	139	148	150	214	268	370	403	168	1941

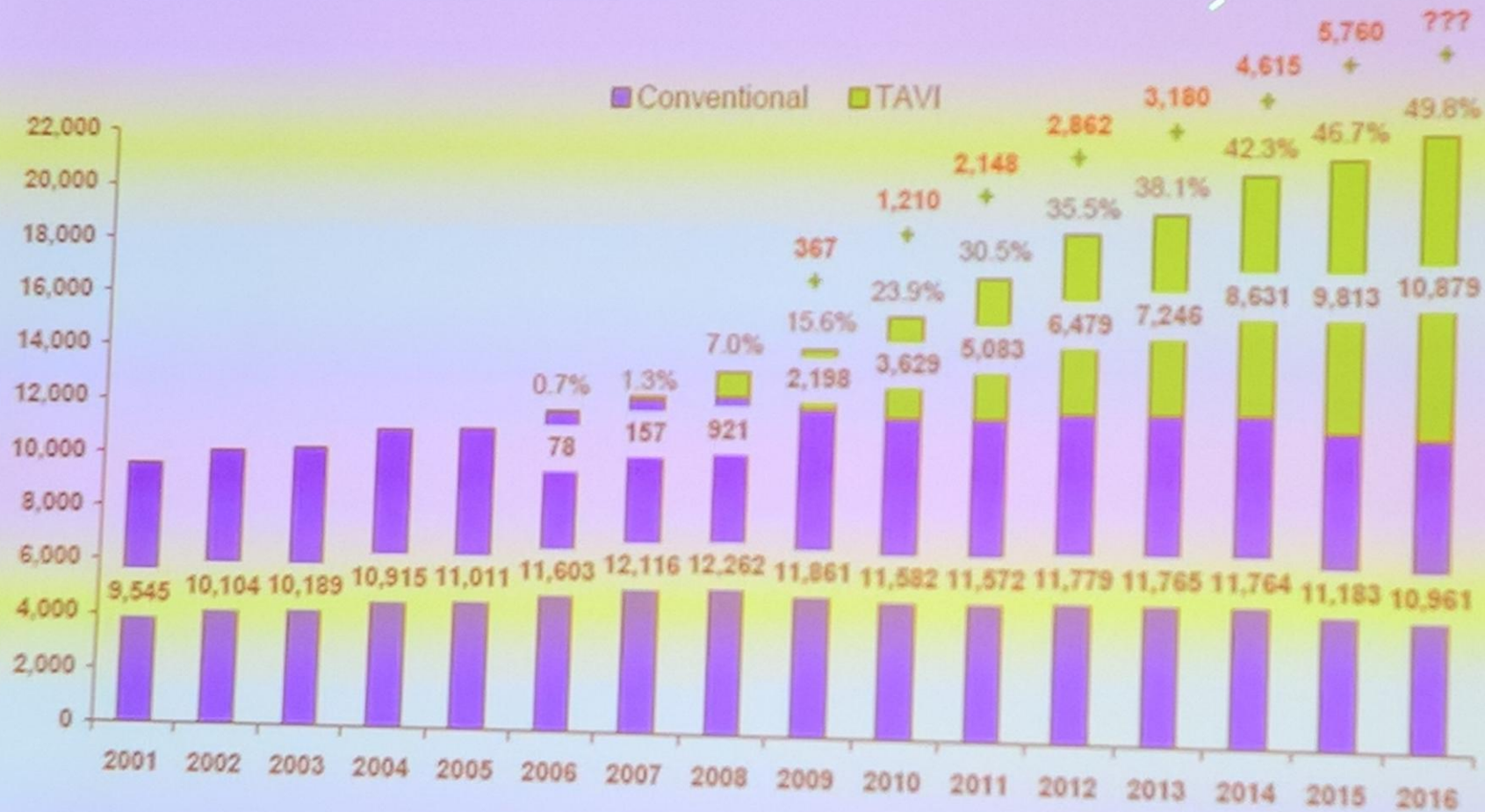
*Patients enrolled between January and June.



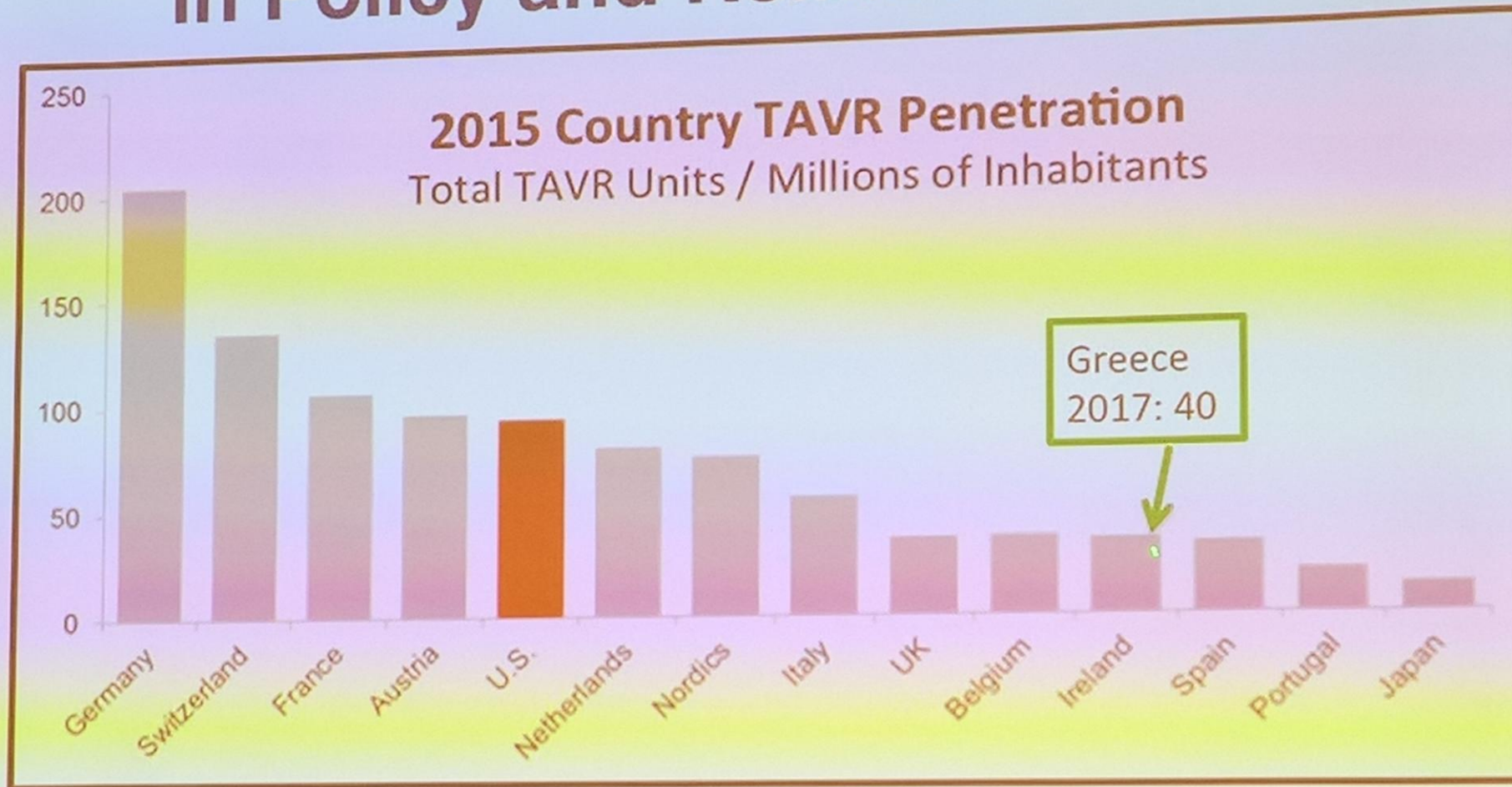
TAVI and TAVI 2 registries contain 1941 patients enrolled between January 2009 and June 2017.

isolated AVR / TAVI in Germany

2000 - 2016



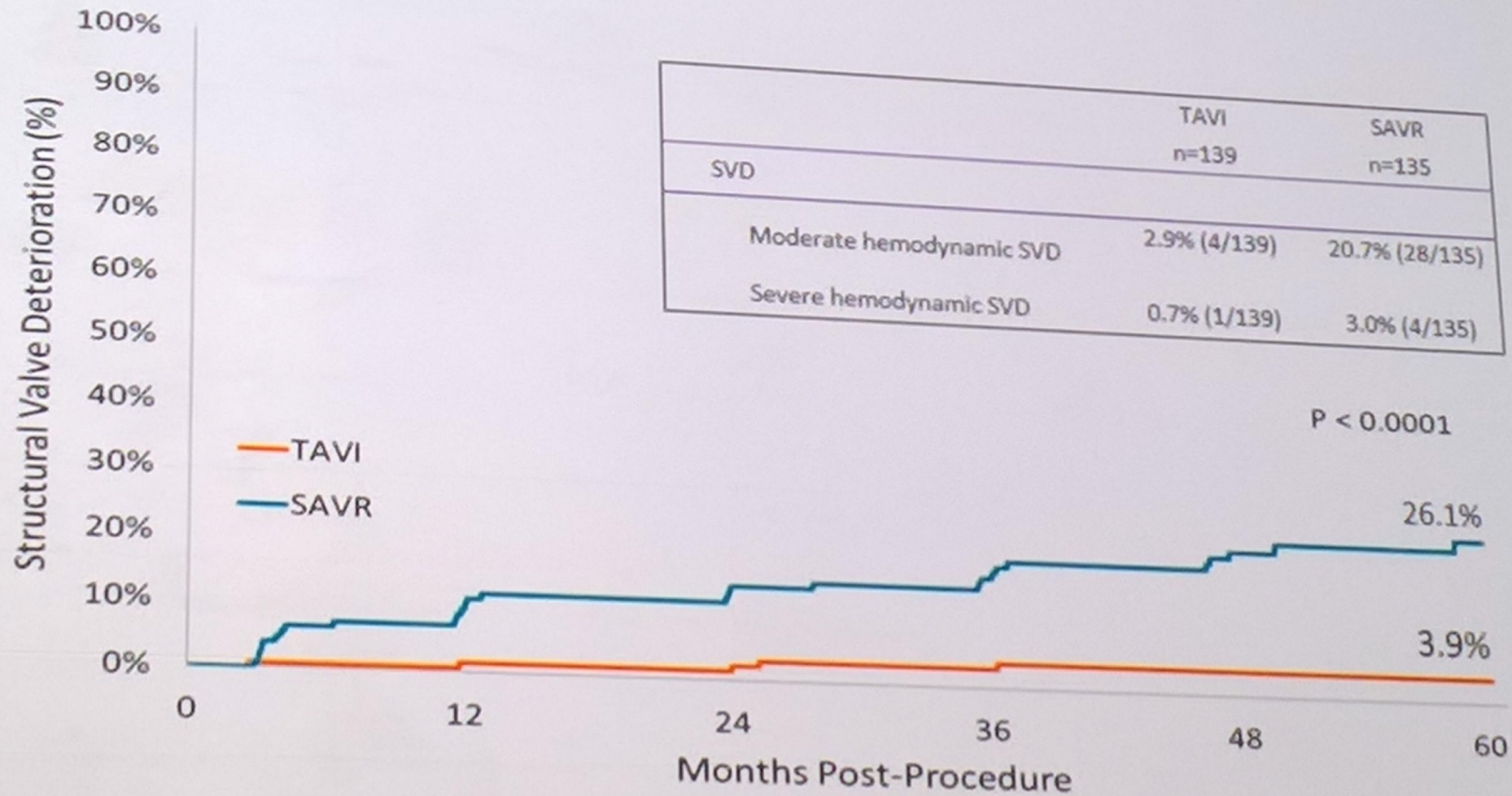
TAVR Utilization Driven by Variations in Policy and Reimbursement



SOURCE: Eurostat, U.S. Census Bureau, Industry estimates

The NOTION Trial

structural valve deterioration



The NOTION trial

Bioprosthetic valve failure

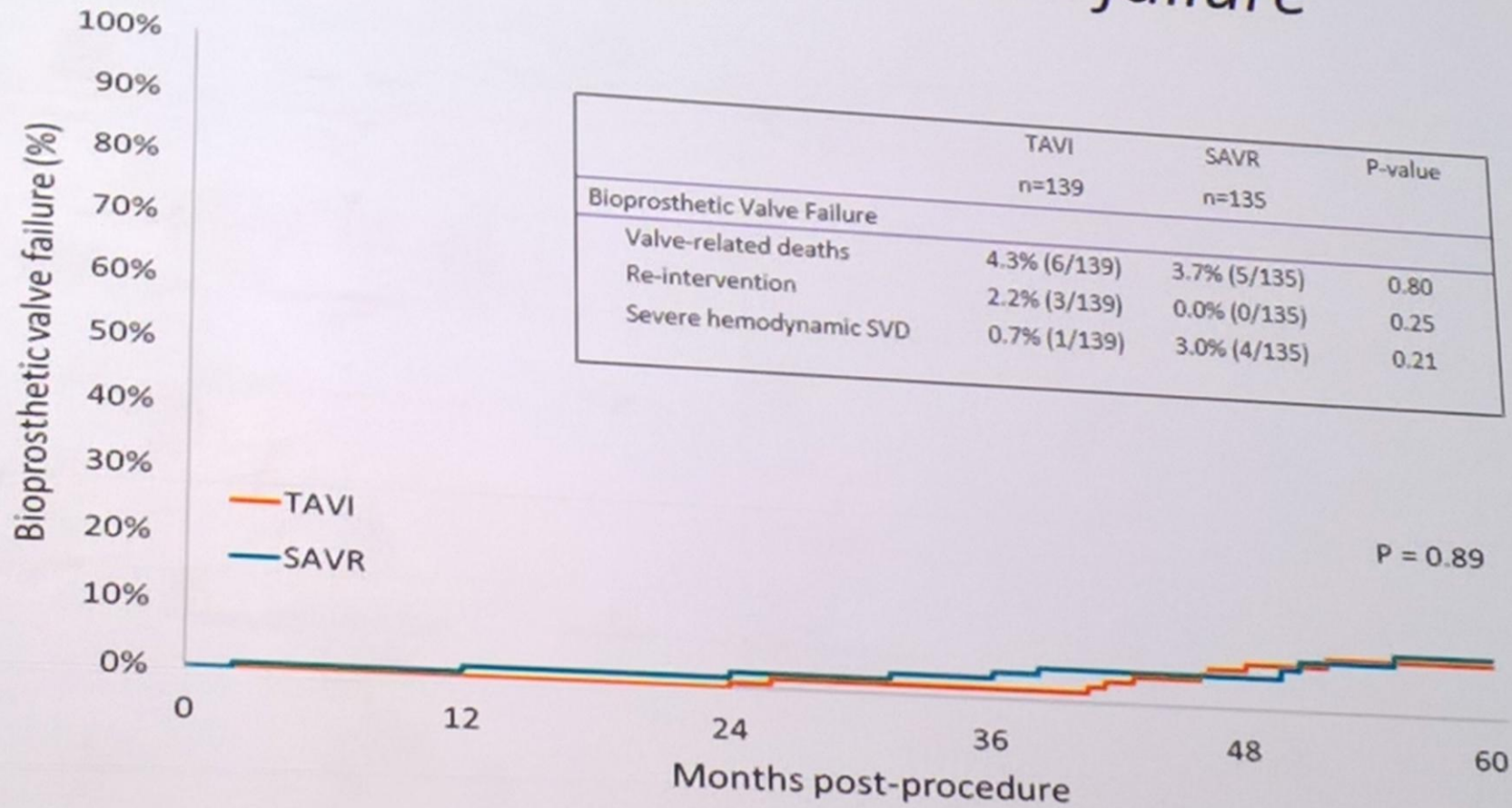


Table 7 Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk (see Table of Recommendations in section 5.2.)

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%) ^a		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%) ^a	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty ^b	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+

Baumgartner H. 2017
ESC/EACTS
Guidelines ...
European Heart Journal.
2017;38:2739–2786.

Linhartová K.
Summary prepared by the
Czech Society of Cardiology,
Cor Vasa. 2017;59:e562–
e591.

Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+

Baumgartner H. 2017
ESC/EACTS
Guidelines ...
European Heart
Journal.
2017;38:2739–2786.

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2017;59:e562–e591.

Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention

Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

©ESC 2017

CABG = coronary artery bypass grafting; CAD = coronary artery disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LV = left ventricle; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons; TAVI = transcatheter aortic valve implantation.

^aSTS score (calculator: <http://riskcalc.sts.org/stswebriskcalc/#/calculate>); EuroSCORE II (calculator: <http://www.euroscore.org/calc.html>); logistic EuroSCORE I (calculator: <http://www.euroscore.org/calcge.html>); scores have major limitations for practical use in this setting by insufficiently considering disease severity and not including major risk factors such as frailty, porcelain aorta, chest radiation etc.¹⁰³ EuroSCORE I markedly overestimates 30-day mortality and should therefore be replaced by the better performing EuroSCORE II with this regard; it is nevertheless provided here for comparison as it has been used in many TAVI studies/registries and may still be useful to identify the subgroups of patients for decision between intervention modalities and to predict 1-year mortality.

^bSee section 3.3, general comments, for frailty assessment.

Baumgartner H. 2017
ESC/EACTS
Guidelines ...
European Heart Journal.
2017;38:2739–2786.

Linhartová K.
Summary prepared by the
Czech Society of Cardiology,
Cor Vasa. 2017;59:e562–
e591.

Závěry (1):

- ▶ TAVI má u vysoce rizikových nemocných lepší klinické výsledky než chirurgická náhrada Ao chlopně (mortalita, CMP)
- ▶ U středně-rizikové populace jsou výsledky TAVI a SAVR srovnatelné, při TF přístupu nižší mortalita a výskyt CMP
- ▶ TAVI - nižší výskyt renálních insuf., FIS, nízkého minutového výdeje, významného krvácení s nutností reoperace, kratší pobyt na JIP, kratší hospitalizace
- ▶ TAVI – větší AVA po výkonu, nižší gradient, méně nemocných s PPM
- ▶ Chirurgie – méně vaskulárních komplikací, méně paravalvárních leaků, méně KS

Závěry (2):

► Indikace k chirurgii

- nemocní s nízkým rizikem (STS, EuroSCORE II < 4%)
- mladší pacienti (< 75 let)
- u nemocných s podezřením na inf. endokarditidu
- nepříznivá anatomie ilio-femorálního řečiště (TA, TAo, ...)
- nepříznivá anatomie aortálního anulu, Ao kořene nebo asc. Ao
- nepříznivá anatomie Ao chlopně (kalcifikace, bikusp. chlopeč)
- vysoké riziko tromboembolie (mobilní tromby v Ao, LK, ...)
- přidružená vada, vyžadující chirurgii (Mil, Trl, ICHS, ...)

Závěry (3):

▶ Indikace k TAVI

- starší pacienti (> 75 let)
- středně a vysoce rizikovní nemocní (STS/EuroSCORE II > 4%)
- závažné komorbidity, vysoký index křehkosti, omezená mobilita
- předchozí chirurgická intervence (průchodné bypassy)
- vhodná anatomie ilio-femorálního řečiště
- porcelánová aorta, po iradiaci, úzký anulus (PPM), kyfoskoliosa

Heart team !!!



Děkuji za pozornost!

