TAVI – nové přístupy v léčbě chlopenních vad

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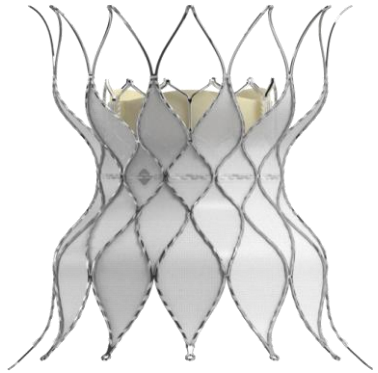
Sympozium Edwards Lifesciences Czech Republic s.r.o.
Nové perspektivy v léčbě chlopenních vad

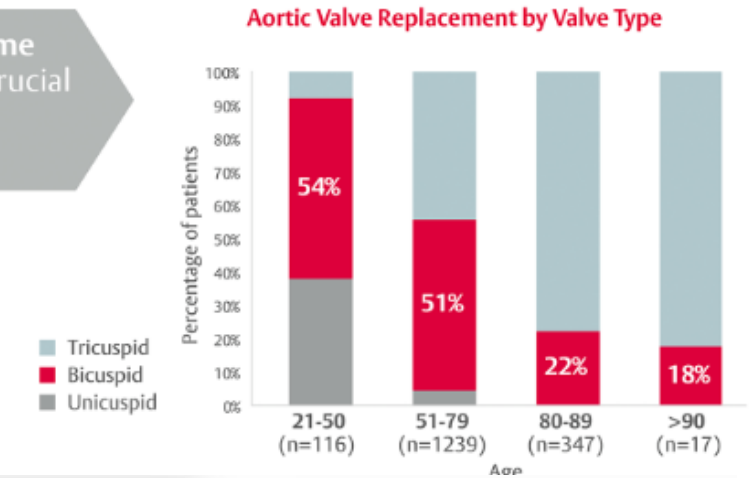


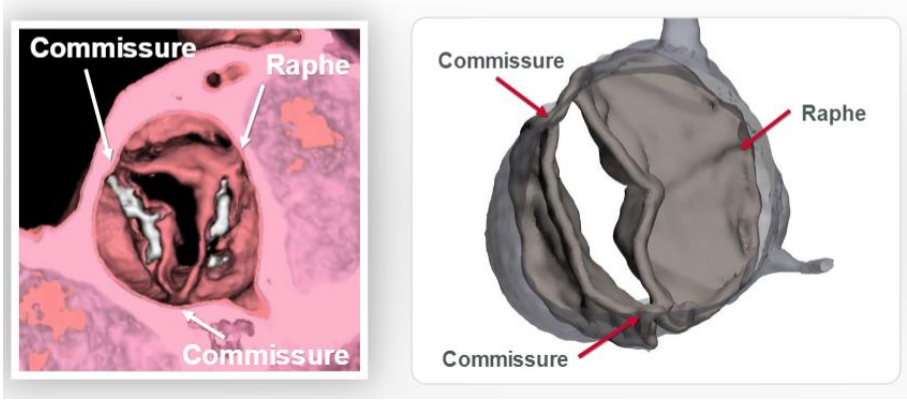
- **Bikuspidní aortální chlopeň**
- Valve-in-valve:
  - Aortic
  - Mitral
  - Pulmonary
  - Tricuspid (off label)
- THV-in-THV

Bikuspidní aortální chlopeň

Congenital bicuspid aortic valve disease is more prevalent in younger patients requiring AVR[3]

Careful **lifetime planning** is crucial for bicuspid patients

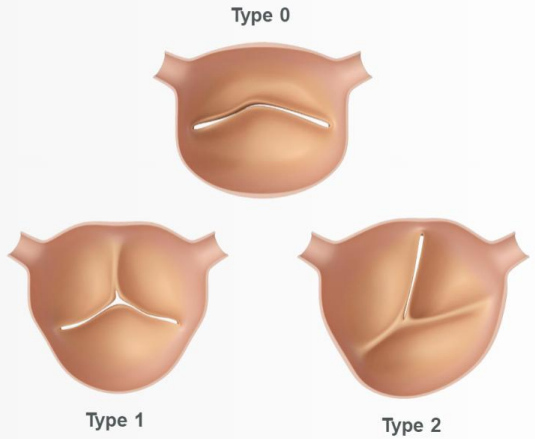




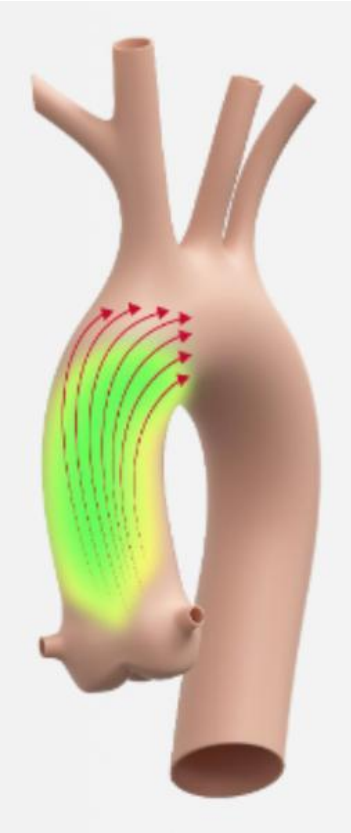
Epidemiology of Bicuspid Aortic Valve Disease

- Most frequent congenital heart disease, occurring in 1 to 2% of the population[1]
- BAV can be inherited, with 6.4% in first-degree relatives of individuals with the condition[2]
- Prevalence of bicuspid aortic valves is uniform across the world[2]
- 10% of patients undergoing TAVR have a bicuspid aortic valve[1]

- Sievers et al provide a systematic classification of BAV
- Classifies three types of bicuspid valve morphologies:
  - Type 0 (no raphe)
  - Type 1 (one raphe)
  - Type 2 (two raphes)

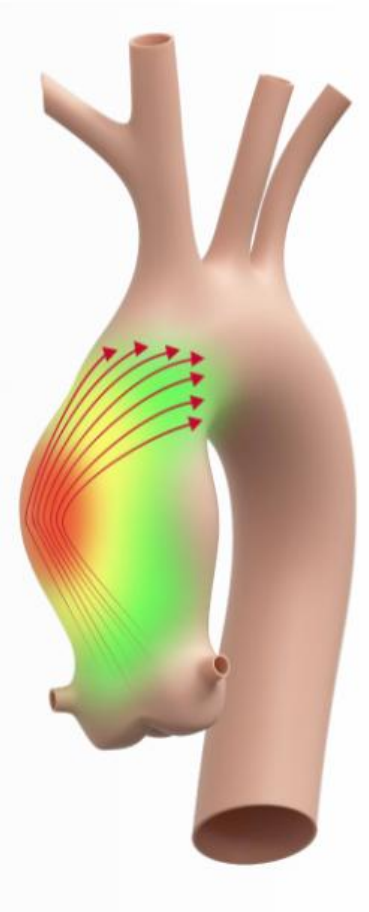


BAV – TAVI pouze u nemocných bez aortopatie

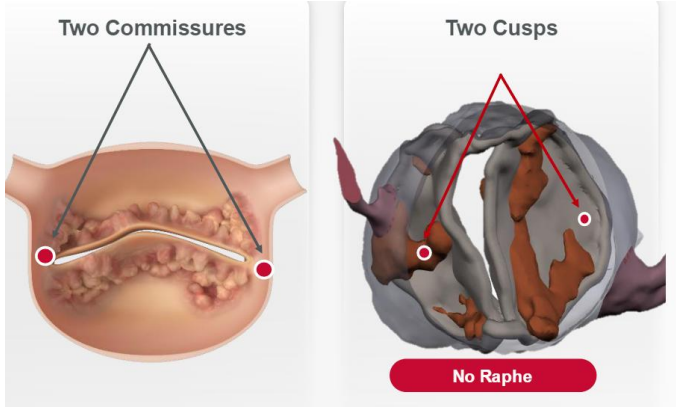


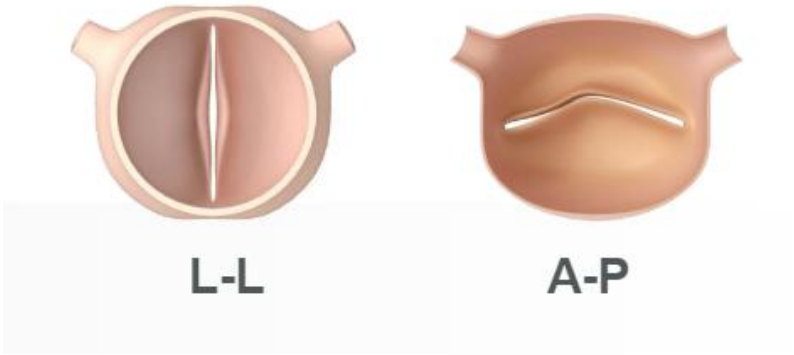
Bicuspid Aortic Valve characteristics

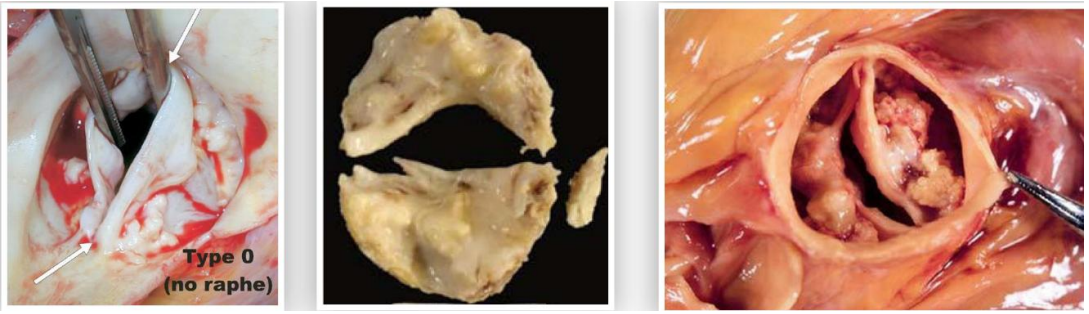
- Aortopathy manifested as dilatation of the thoracic aorta occurs in 40-70% of BAV patients dependent on population studied and definition of dilation[1]
- 2020 ACC/AHA recommends surgical replacement of the ascending aorta is indicated in patients with a BAV if the diameter of the aortic sinuses or ascending aorta is ≥55mm[2]
- 2021 ESC/EACTS guidelines include the indication for surgery when aortic diameter is ≥ 50mm and additional risk factors or coarctation are present[3]



Typ 0 BAV





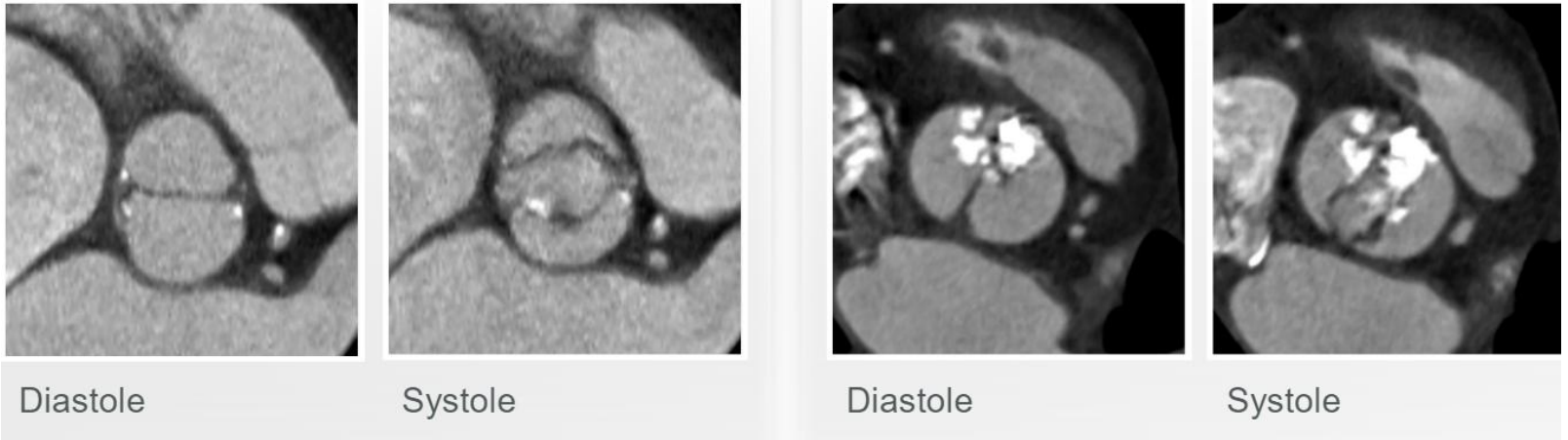


Cca 10% BAV = type 0

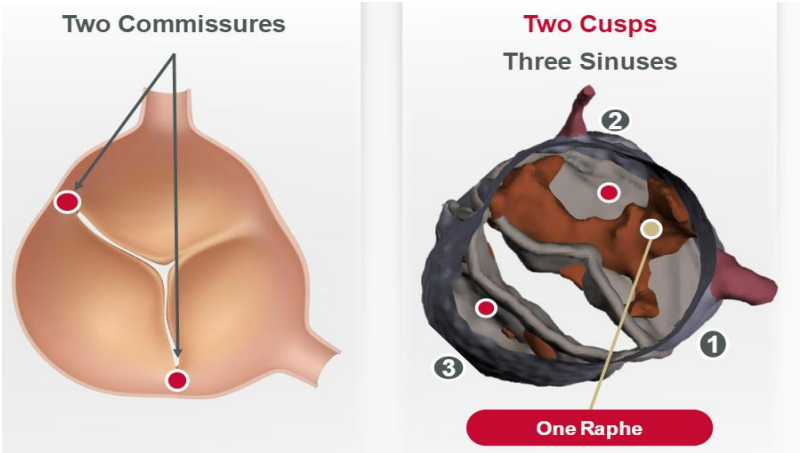
Supraannular sealing

Vyšší implantační pozice

Undersizing lepší nežli oversizing

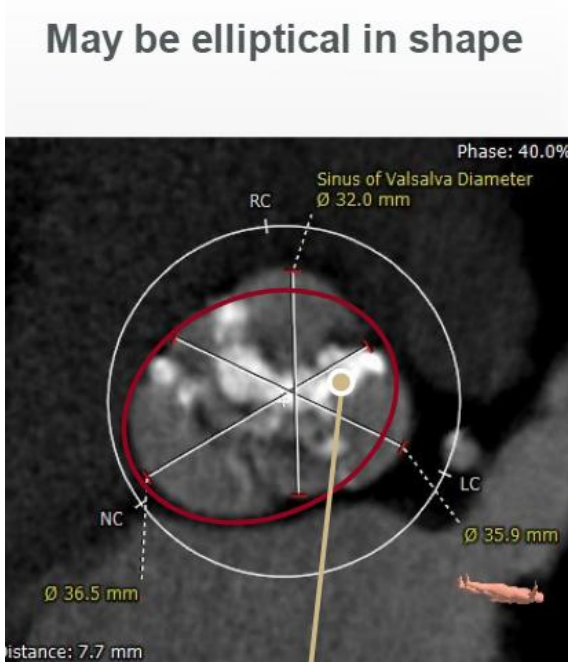


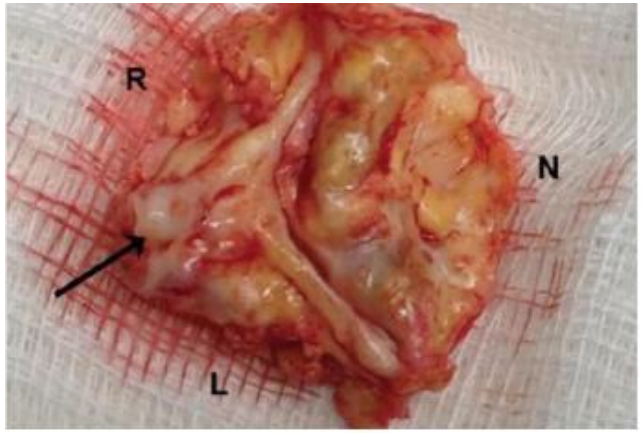
Typ 1 BAV

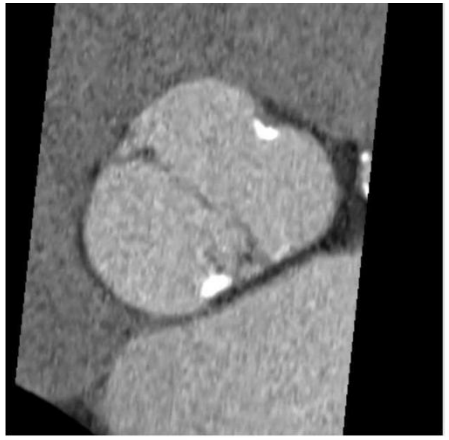


- 2 cusps are conjoined with 1 raphe
- Most common type of BAV ~ 89%

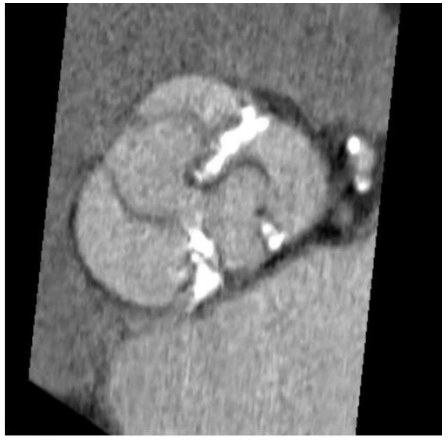
	European	Asian
LCC & RCC fusion	80.1%	72.0%
RCC & NCC fusion	16.0%	21.2%
LCC & NCC fusion	3.3%	6.5%







Diastole



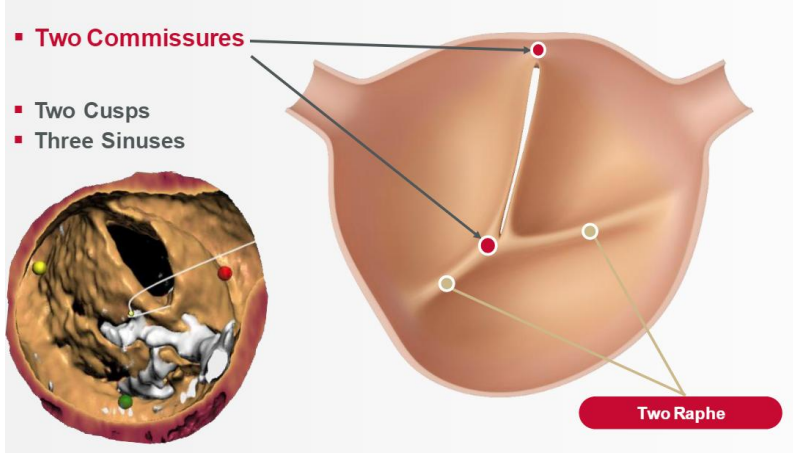
Systole

<u>Kalcifikované raphe</u>

- TAVI s vysokou radiální silou
- Elipticita nebo „under-deployment“= potencionálně kratší životnost chlopně

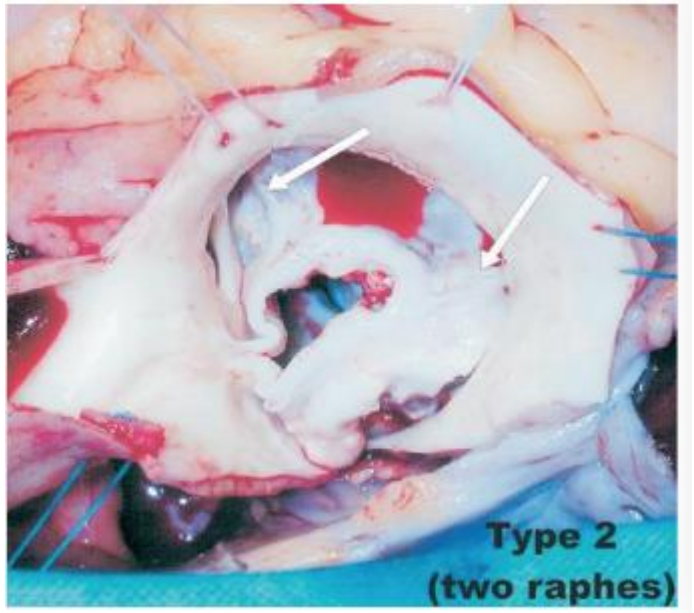
Typ 2

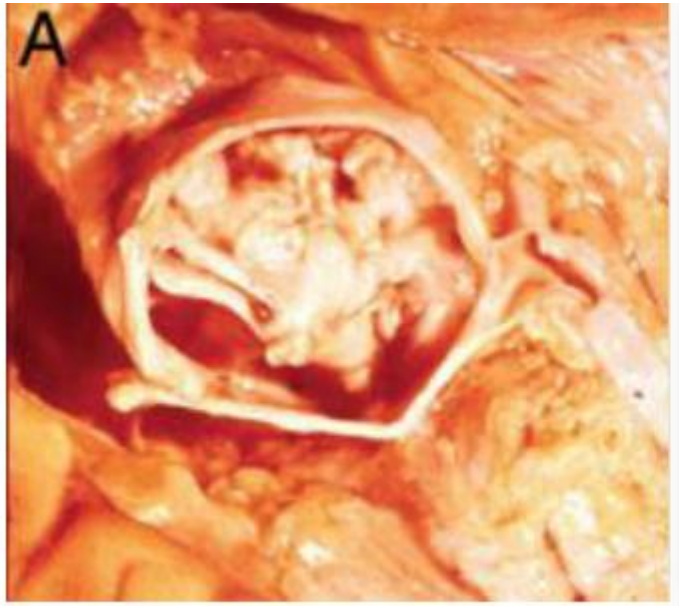
1-5% BAV
Nejčastěji aneurysma asc. aorty



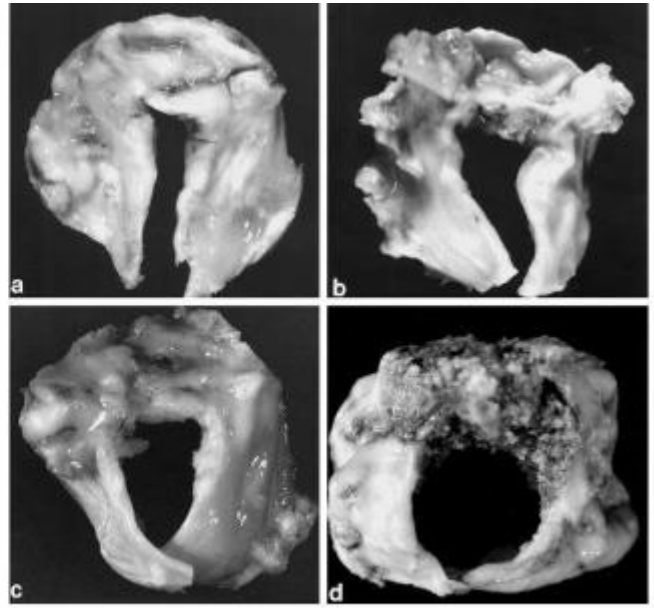
Diastole

Systole



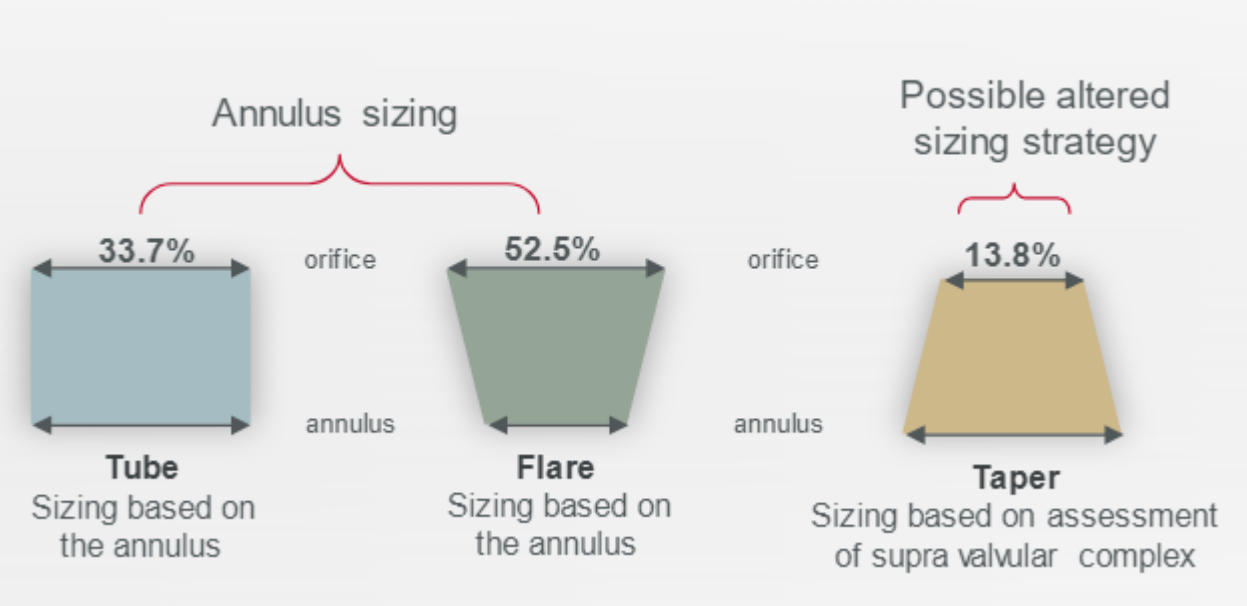


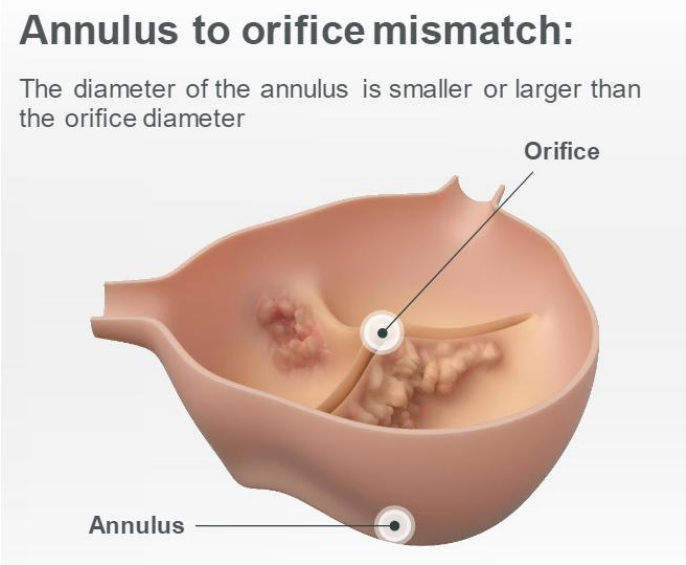
(Bax et al., 2014, p. 2631)

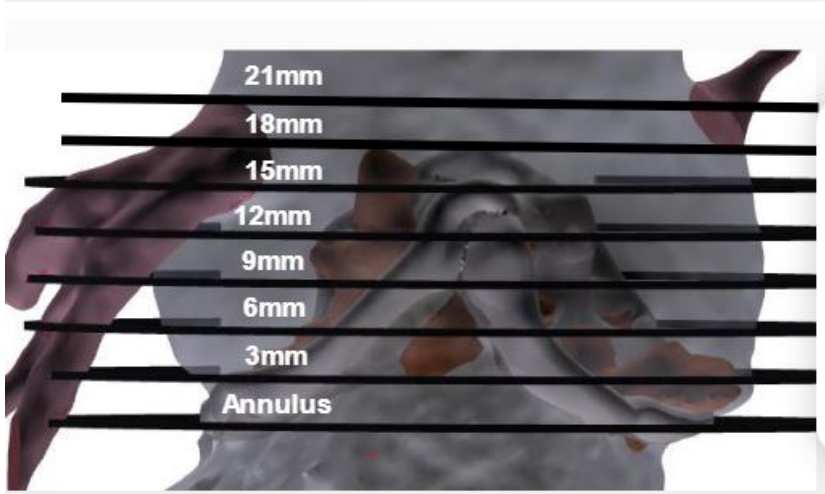


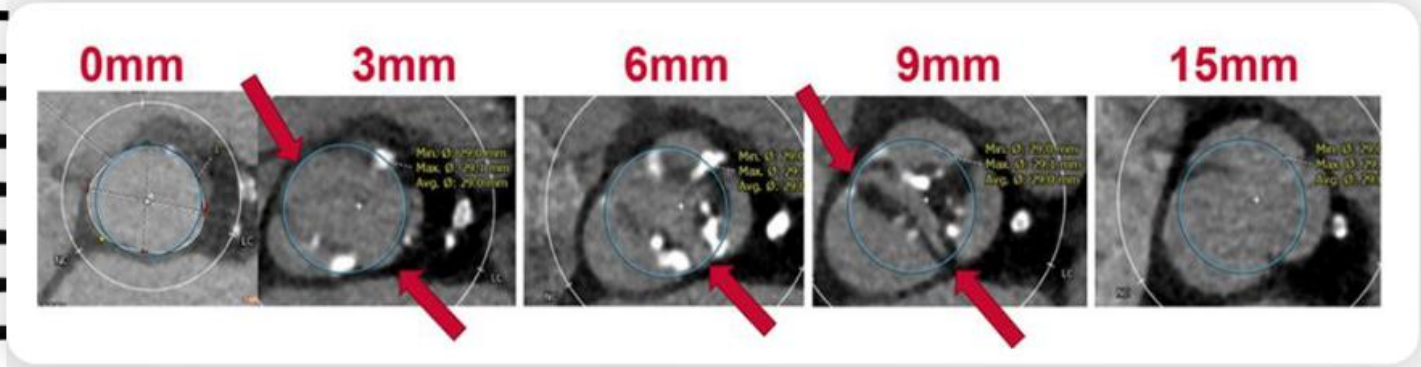
(Roberts & Ko, 2005, p. 921)

CT analýza – „circle method“





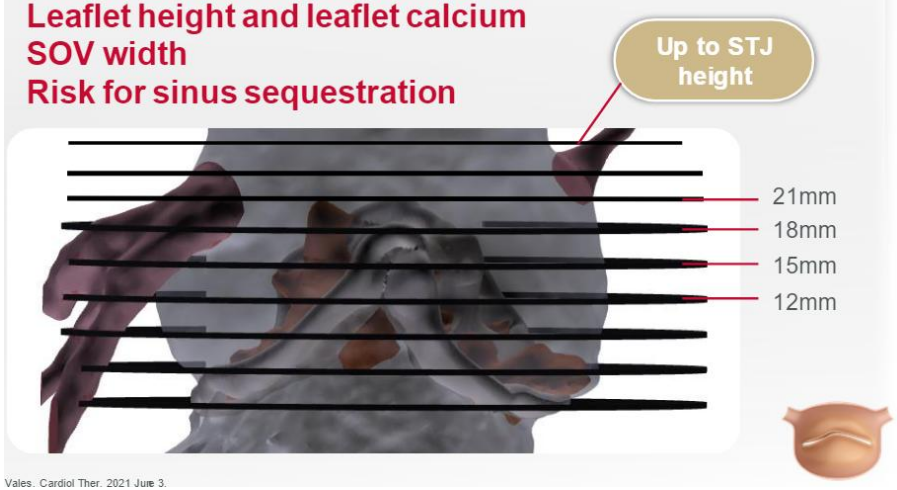




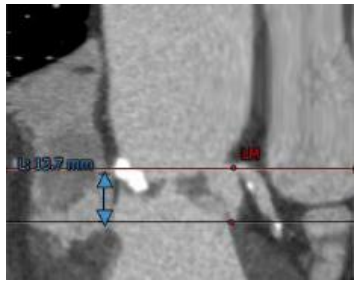
Circle method: prevence komplikací, velký annulus

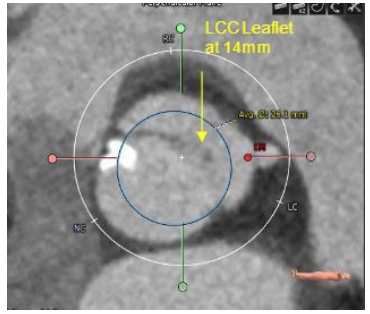
Circles at 12 – to STJ height
Simulate the relation of deployed valve to the
Left Main Artery (LM) and Right Coronary Artery (RCA)

And can identify:
Leaflet height and leaflet calcium
SOV width
Risk for sinus sequestration

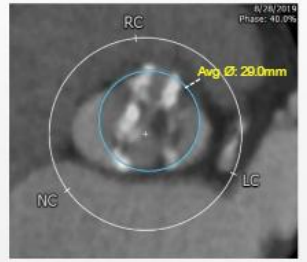


Vales. Cardiol Ther. 2021 June 3.

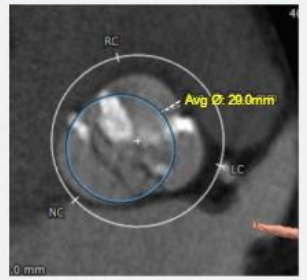




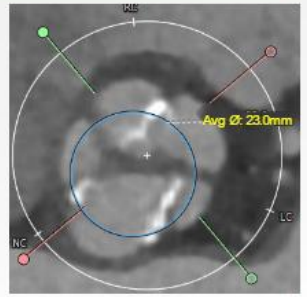
1. **The circle is too large** it extends beyond the commissures, with a potential risk of commissure rupture



2. **If the circle is large enough to touch the commissures**, then sealing is expected



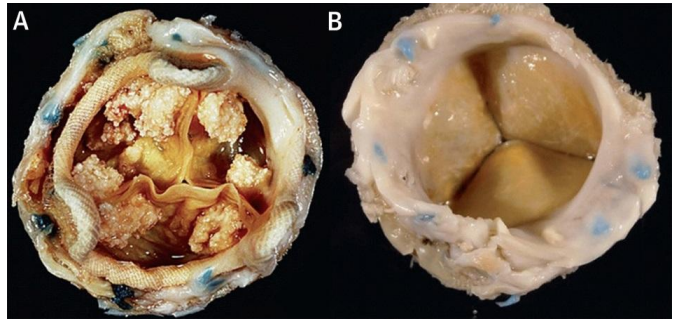
3. **If the circle is undersized**, and does not touch the commissures, there is a risk of paravalvular leak (PVL) or valve embolization



Large annulus 800-900 mm2 – S3 29 mm + 4-8 cc
Very large annulus (>900 mm^2) – pouze v přítomnosti kalcia

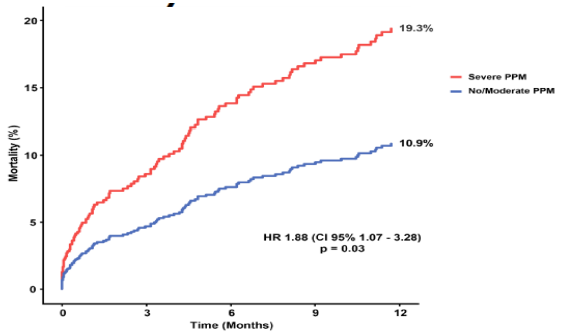
- Bikuspidní aortální chlopeň
- **Valve-in-valve:**
  - **Aortic**
  - Mitral
  - Pulmonary
  - Tricuspid (off label)
- THV-in-THV

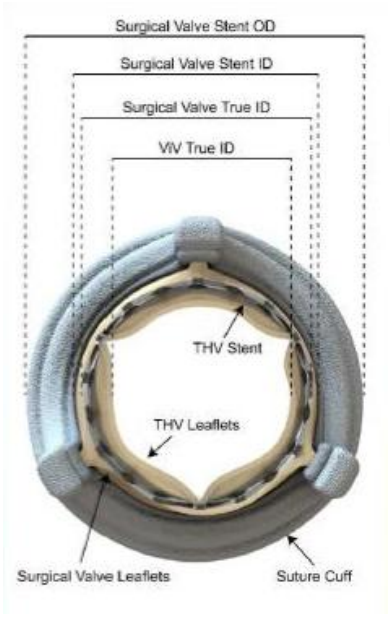
TAVI: valve-in-valve implantace



Degenerované chirurgické bioprotézy:

- Riziko „patient-prosthesis missmatch” (ppm)
- Riziko obstrukce koronárních tepen
- **Malý annulus = preference TAVI nad SAVR**

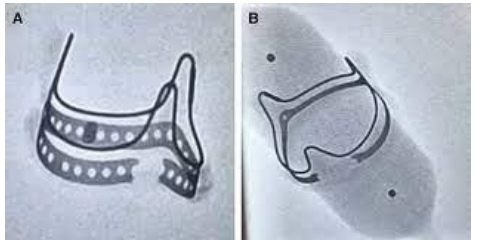




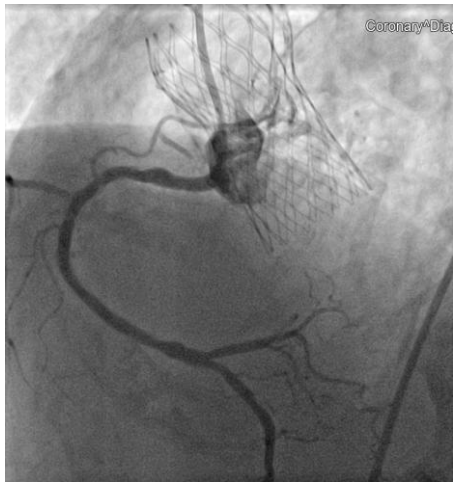
Riziko patient-prosthesis missmatch:

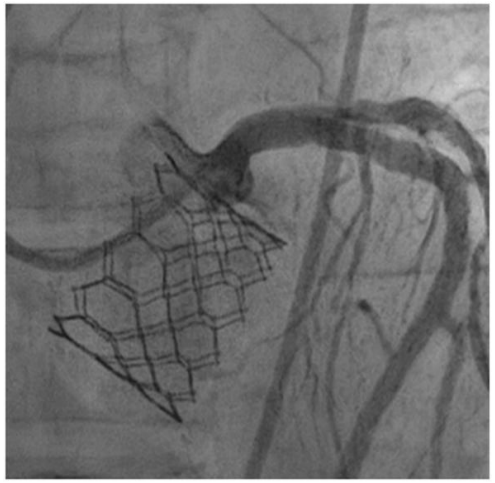
Surgical labeled size < 23 mm
PPM = residual mean gradient ≥ 20 mmHg
PPM = iEOA < 0,65 cm^2/m^2
mild PPM = iEOA < 0,85 cm^2/m^2

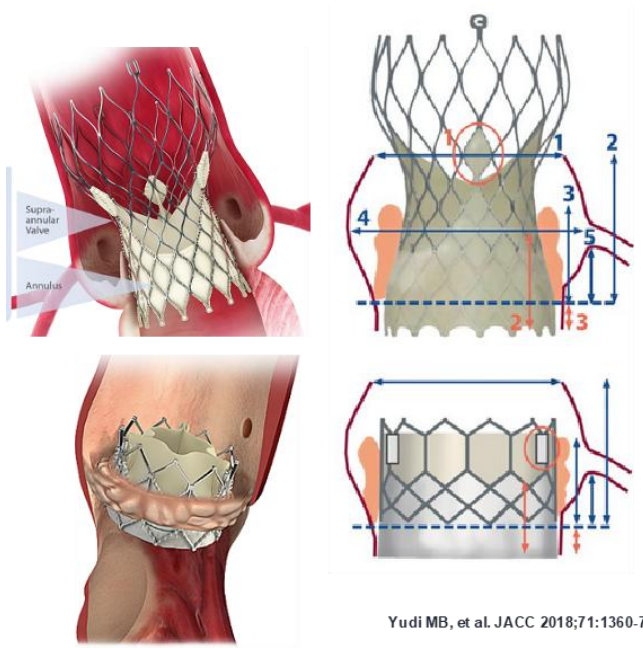
Valve fracture – noncompliant balonek



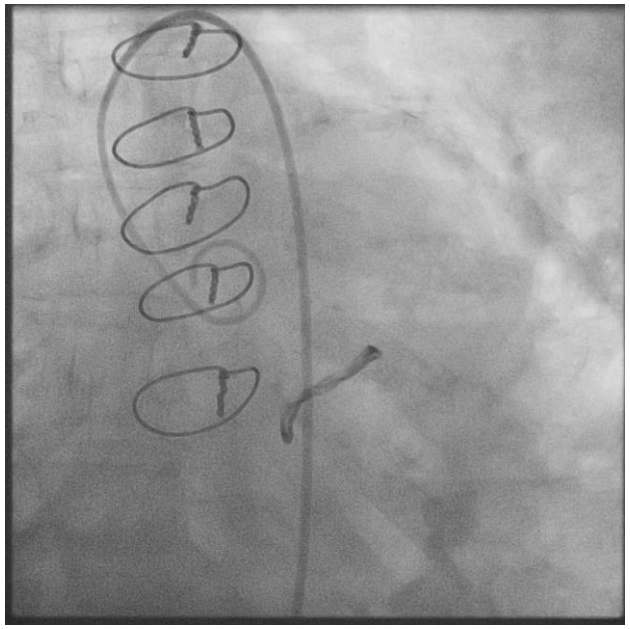
Přístup ke koronárním tepnám

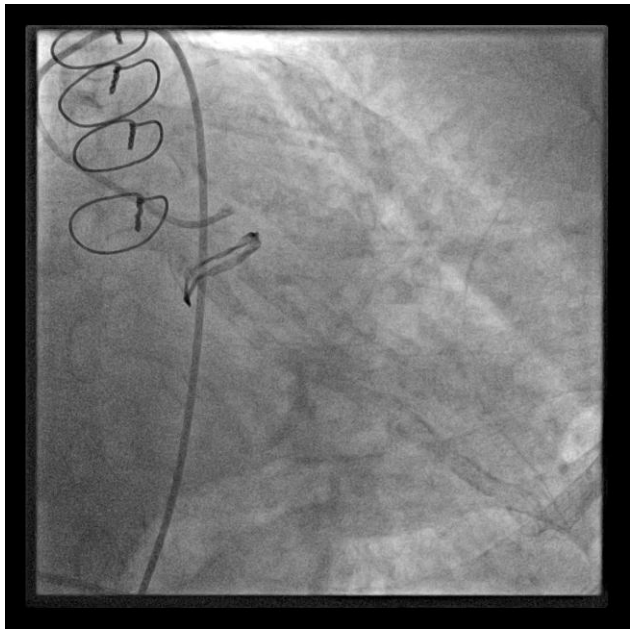






Yudi MB, et al. JACC 2018;71:1360-78





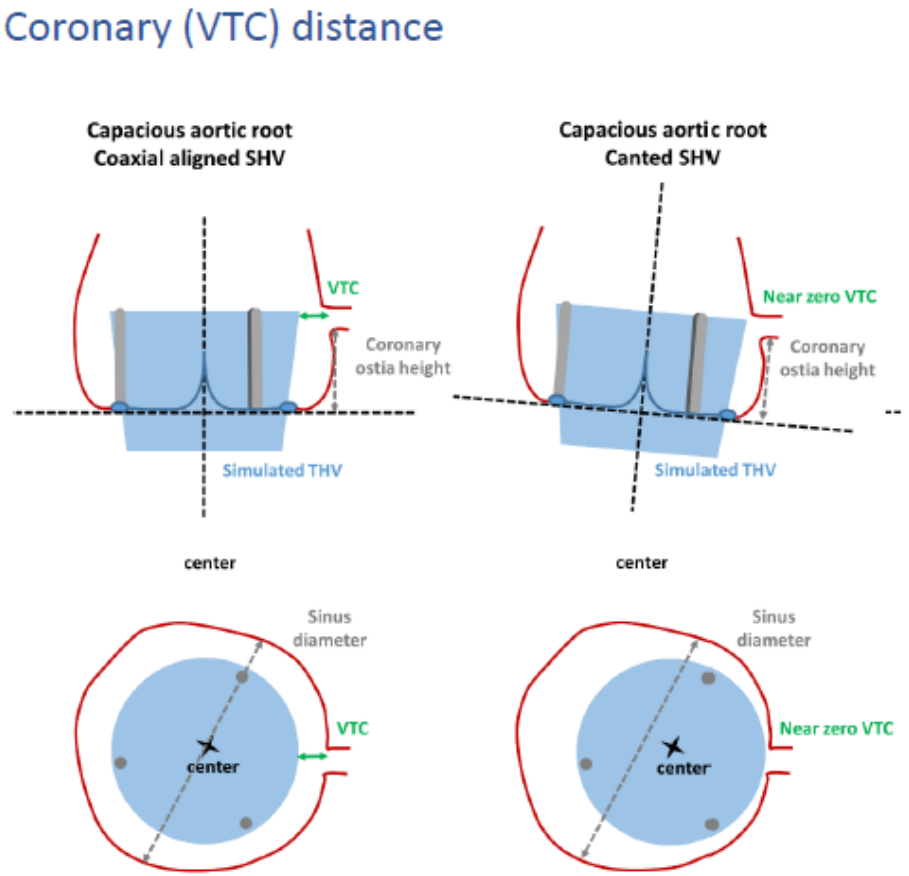
Jak predikovat koronární obstrukci u ViV?

Výška a typ bioprotézy
(Mitroflow, Trifecta jsou nejhorší)

Výška STJ

Šířka SOV (odstup LCA)

Úhel anulus bioprotézy/aorta



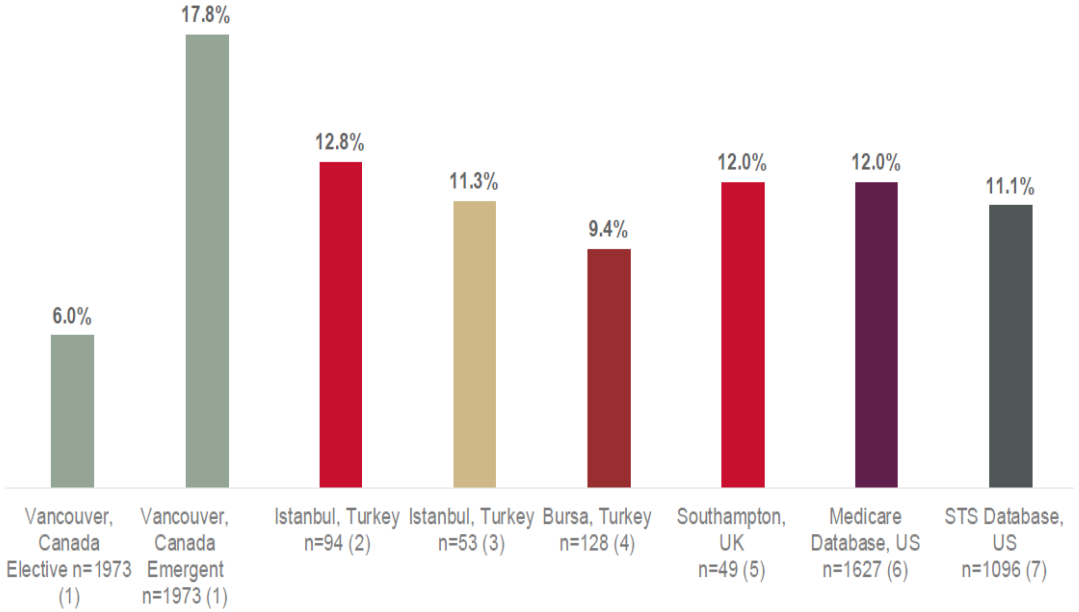
VTC!

Cut-off 3-4 mm

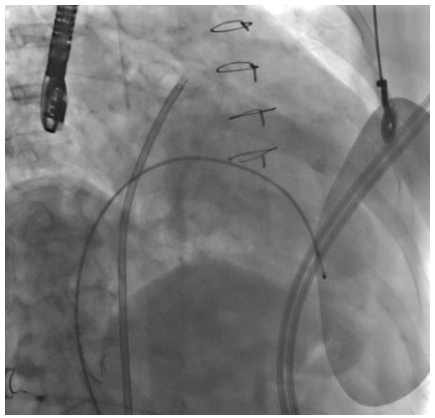
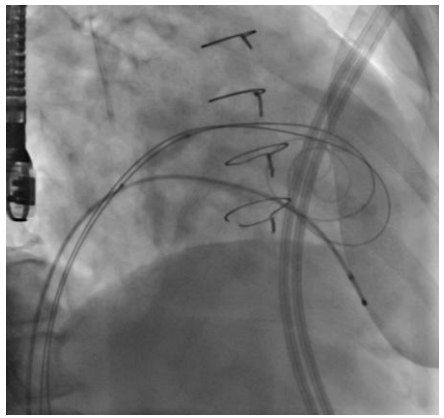
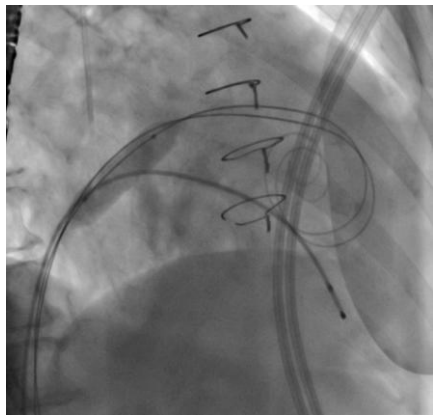
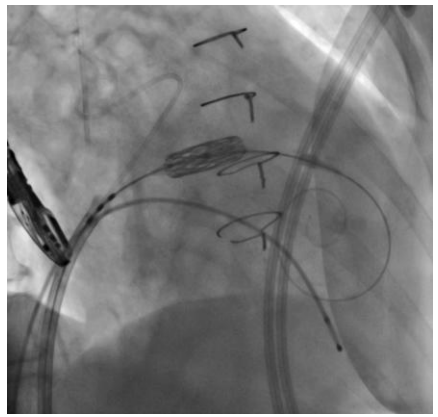
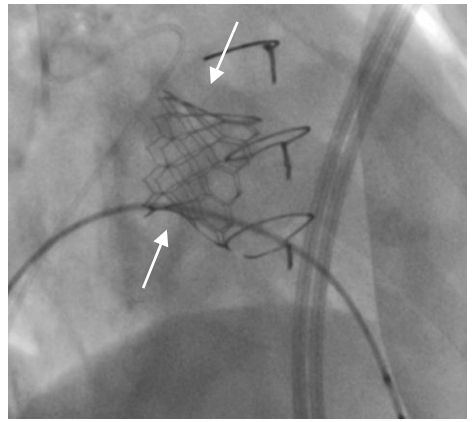
Blanke, 2016

- Bikuspidní aortální chlopeň
- **Valve-in-valve:**
  - Aortic
  - **Mitral**
  - Pulmonary
  - Tricuspid (off label)
- THV-in-THV

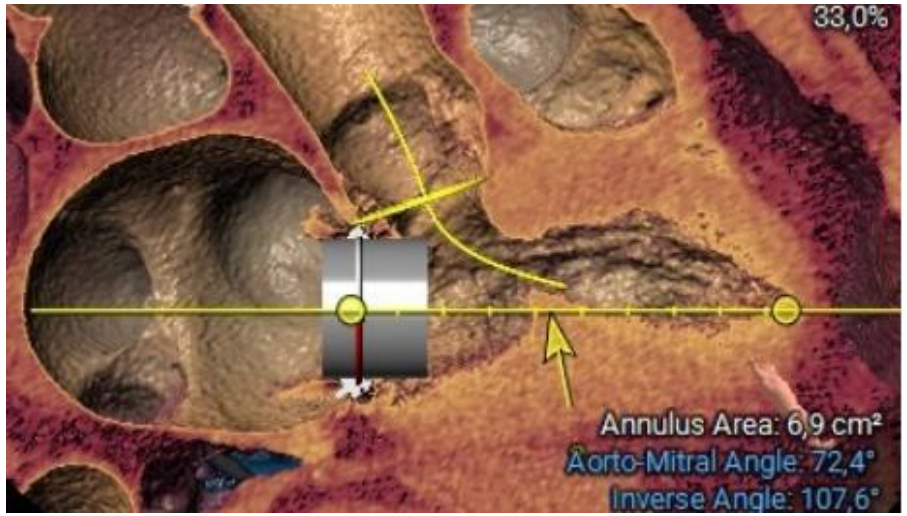
Transseptal mitral ViV vs Redo surgery



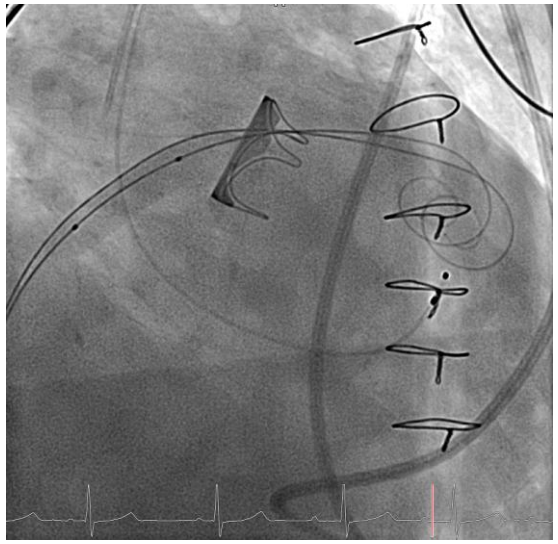
Transseptal mitral surgical ViV (n=1326)[1]	30 Days	1 Year
All-cause mortality	5%	15.8%
Cardiovascular mortality	2.1%	3.7%
Stroke	1.1%	3.3%
Mitral valve reintervention	0.4%	0.8%
New pacemaker	1.4%	2%
Device thrombosis	0.2%	0.3%
Mean MVG (mmHg)	7.4 (±2.75)	7.0 (±2.94)

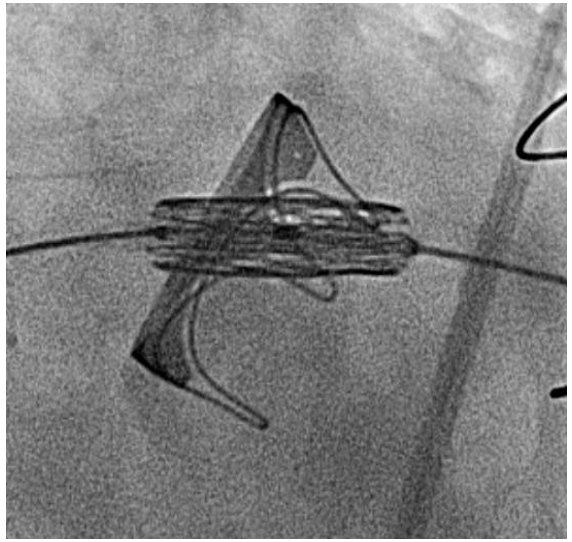






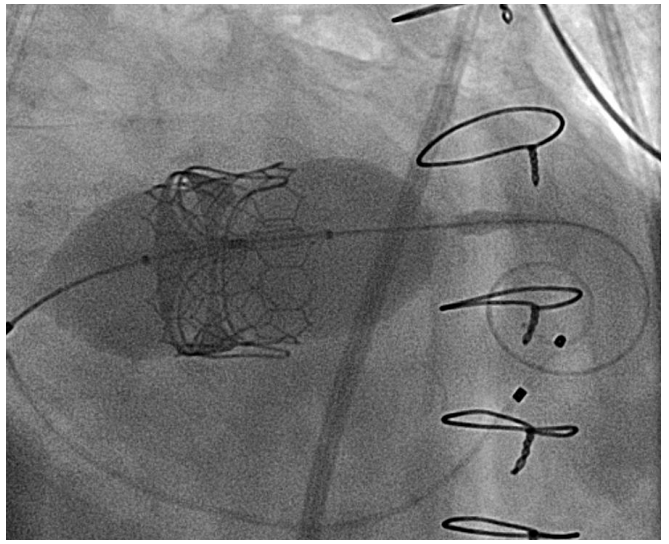
Valve-in-valve implantace do mitrální bioprotézy transseptálním přístupem



Muž 76 let
2012 emergentní MVR bio Magna 31 při ruptuře papilárního svalu + ECMO
2022 významná stenóza bioprotézy, NYHA III





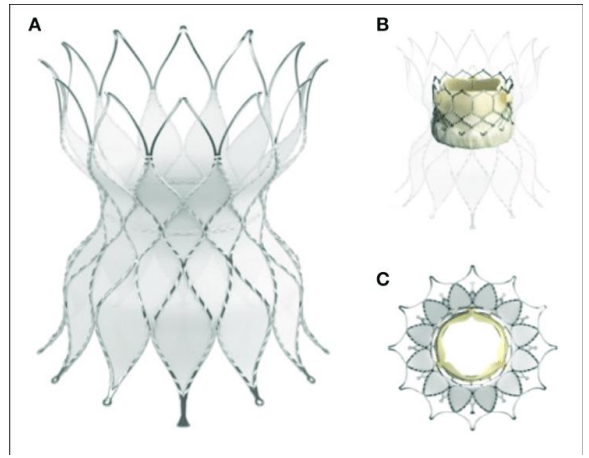


Transseptální punkce + dilatace septa – 2x stiff vodič do LK – zavedení chlopně – implantace při 170/min – finální pozice

- Bikuspidní aortální chlopeň
- **Valve-in-valve:**
  - Aortic
  - Mitral
  - **Pulmonary**
  - Tricuspid (off label)
- THV-in-THV

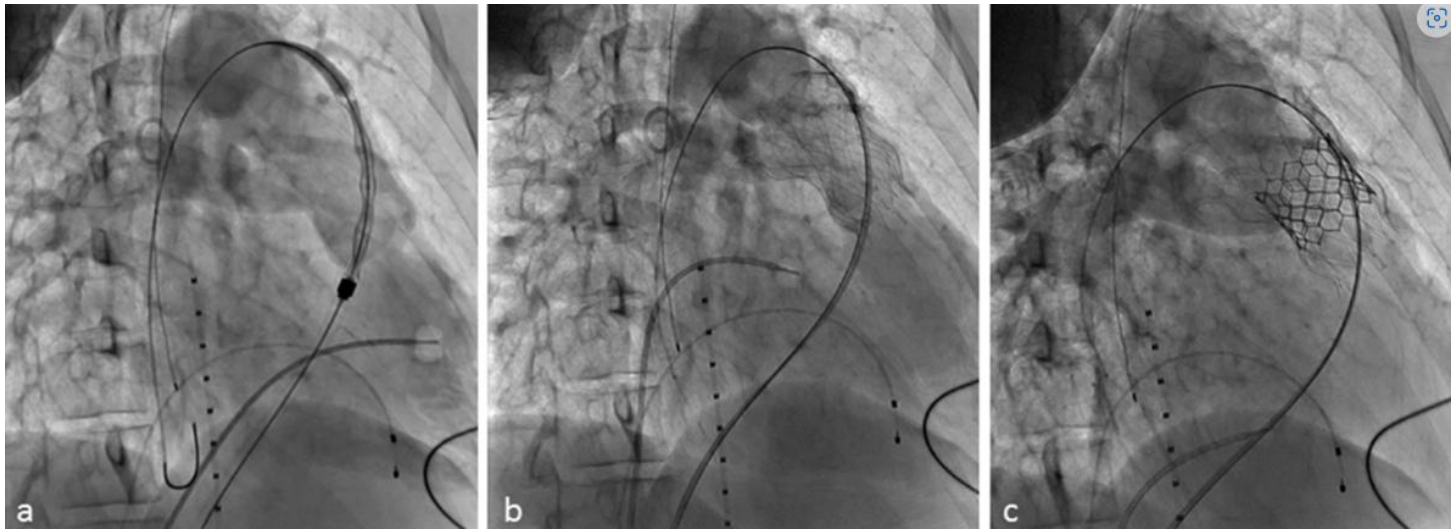
Dysfunkce RVOT konduitu nebo bioprotézy v pulmonální pozici (VVS)

- Indikace
  - Symptomy srdečního selhání
  - Gradient > 50/30 mmHg
  - RV EDV > 160 ml/m^2
  - EF RV < 40-45%



Alterra Sapien 3 THV

Melody valve (FDA 2010)



Harmony valve (Medtronic)

Retrospektivní registr + Compassion S3 trial: implantace S3

TAVI chlopně do dysfunkce RVOT konduitu /pulmonální bioprotézy (TPVI)

Study design

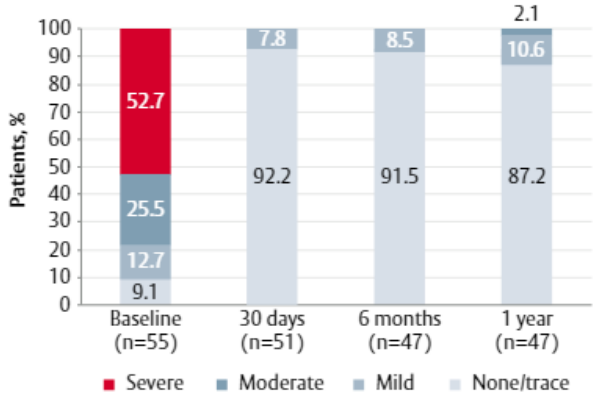
Retrospective, international, multicentre registry analysis; 23 centres overall.

n=774 patients who underwent TPVI with a SAPIEN XT valve or SAPIEN 3 valve between 1 January 2008 and 28 August 2019.

	Native/patched (n=397)	Stented BPV (n=194)	Conduit (n=183)	All patients (n=774)
Valve type				
SAPIEN XT	83 (21)	44 (23)	46 (25)	173 (22)
SAPIEN 3	314 (79)	150 (77)	137 (75)	601 (78)
Early post-implantation echo				
Moderate or severe TR (n=712)	43 (12)	19 (10)	22 (13)	84 (12)
Moderate or severe PR (n=606)	17 (4.4)	3 (1.6)	2 (1.1)	22 (2.9)
RVOT gradient ≥40 mm Hg (n=686)	8 (2.4)	15 (8.9)	15 (8.3)	38 (4.9)
Serious procedural adverse event	36 (11)	12 (7.3)	19 (12)	67 (10)
Tricuspid valve injury	7/336 (2.1)	2/164 (1.2)	2/164 (1.2)	11/664 (1.7)
Valve or stent embolization or malposition	20/336 (6.0)	4/164 (2.4)	6/164 (3.7)	30/664 (4.5)

BPV: bioprosthetic valve; PR: pulmonary regurgitation; RVOT: right ventricular outflow tract; TR: tricuspid regurgitation

Figure 1. Total PR at 1 year in VI population



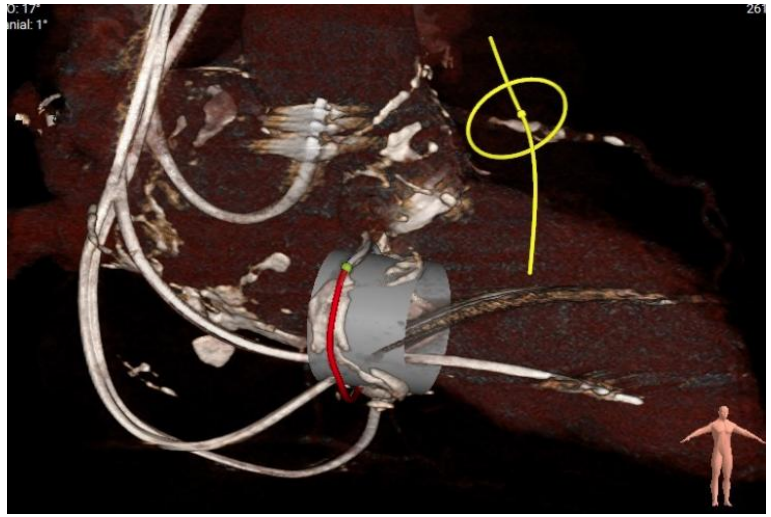
0%

- All-cause death at 1 year
- Endocarditis at 1 year
- Valve frame fracture at 6 months
- Implantation-related right heart injury

https://bit.ly/35nLnyA
50% homograft
35% chir. chlopeň

Shahanavaz, S et al. J Am Coll Cardiol. 2020

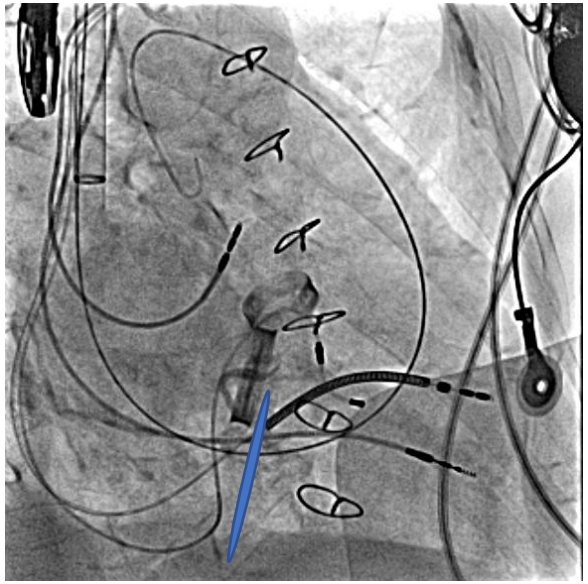
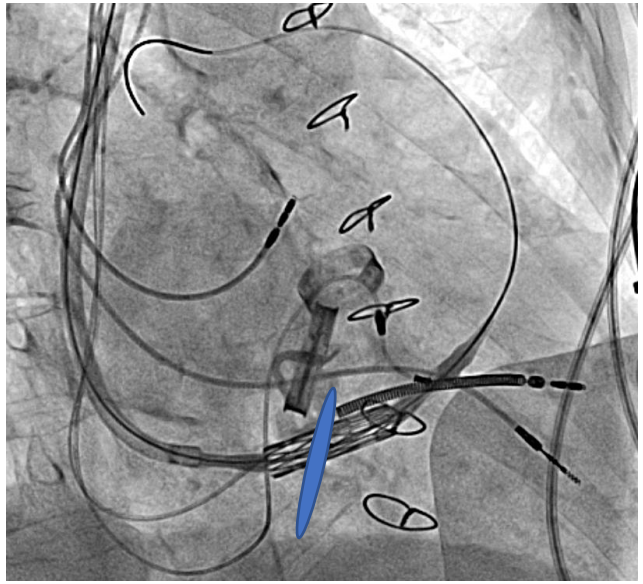
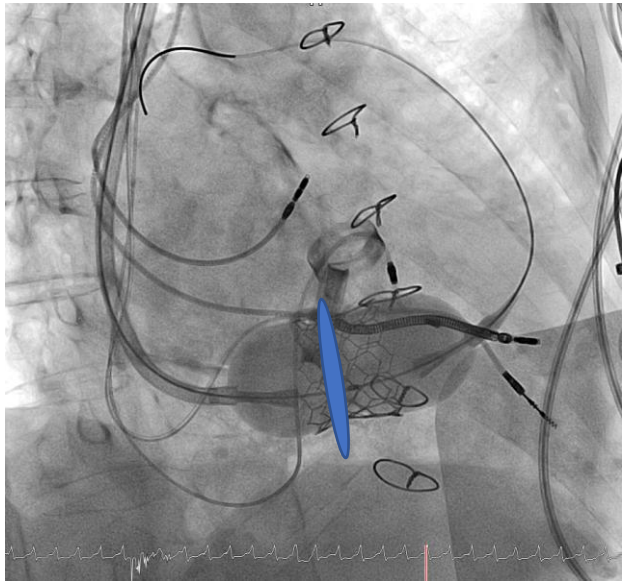
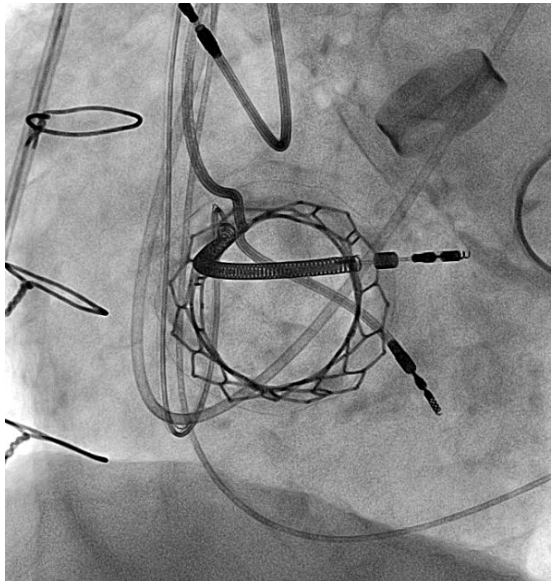
- Bikuspidní aortální chlopeň
- **Valve-in-valve:**
  - Aortic
  - Mitral
  - Pulmonary
  - **Tricuspid (off label)**
- THV-in-THV



TTVI – transkatetrová valve-in-valve implantace do trikuspidální bioprotézy
(CAVE: OFF-LABEL)

Žena, 79 let
- MVR mechanická M-H 27 v roce 1988
- AVR + náhrada trikuspidální chlopně SJM 35 mm v roce 1999
- CRT/D 2015, EF 35-40%

Těžká trikuspidální stenóza, jaterní cirhóza + hypersplenismus

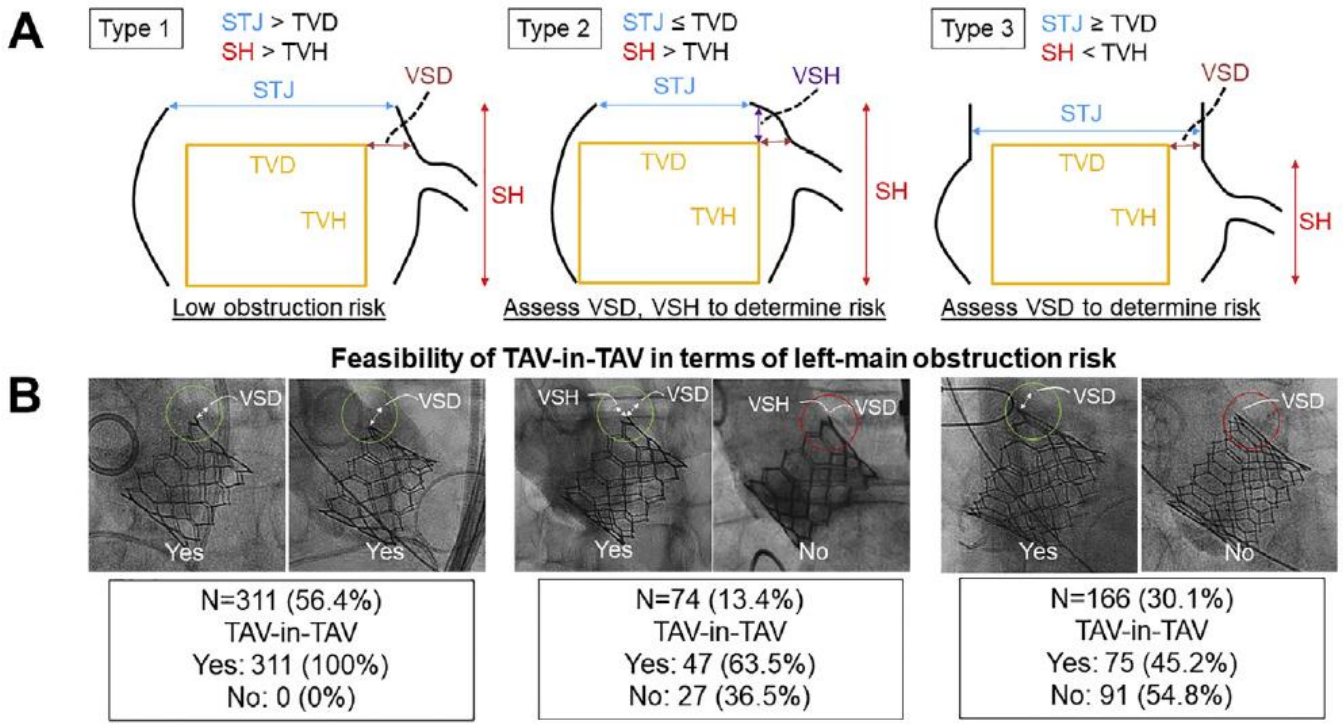





Sheath 21F přes vena jugularis – 2x Lunderquist do plicnice – ES 29 mm + 4 ccm + pace 150/min – finální pozice a expanze

- Bikuspidní aortální chlopeň
- Valve-in-valve:
  - Aortic
  - Mitral
  - Pulmonary
  - Tricuspid (off label)
- **THV-in-THV**

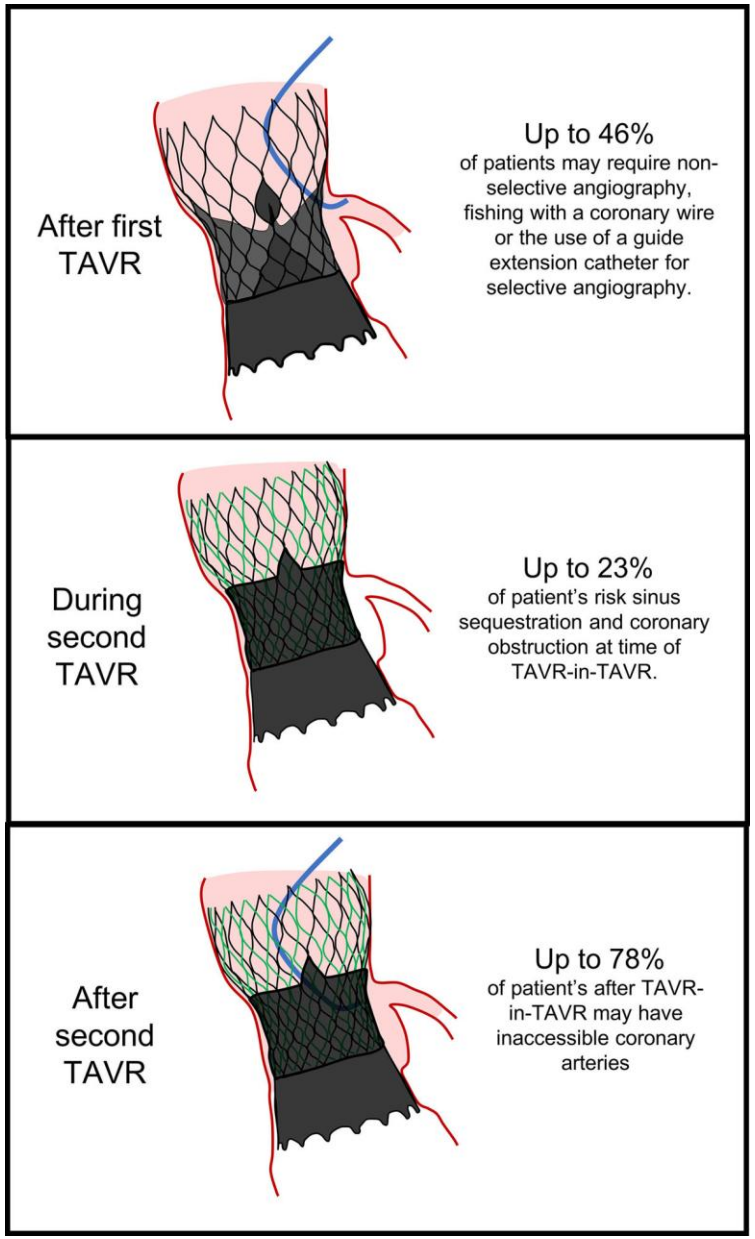
THV-in-THV (TAVI in TAVI)

20% risc of LMCA obstruction (Sapien)



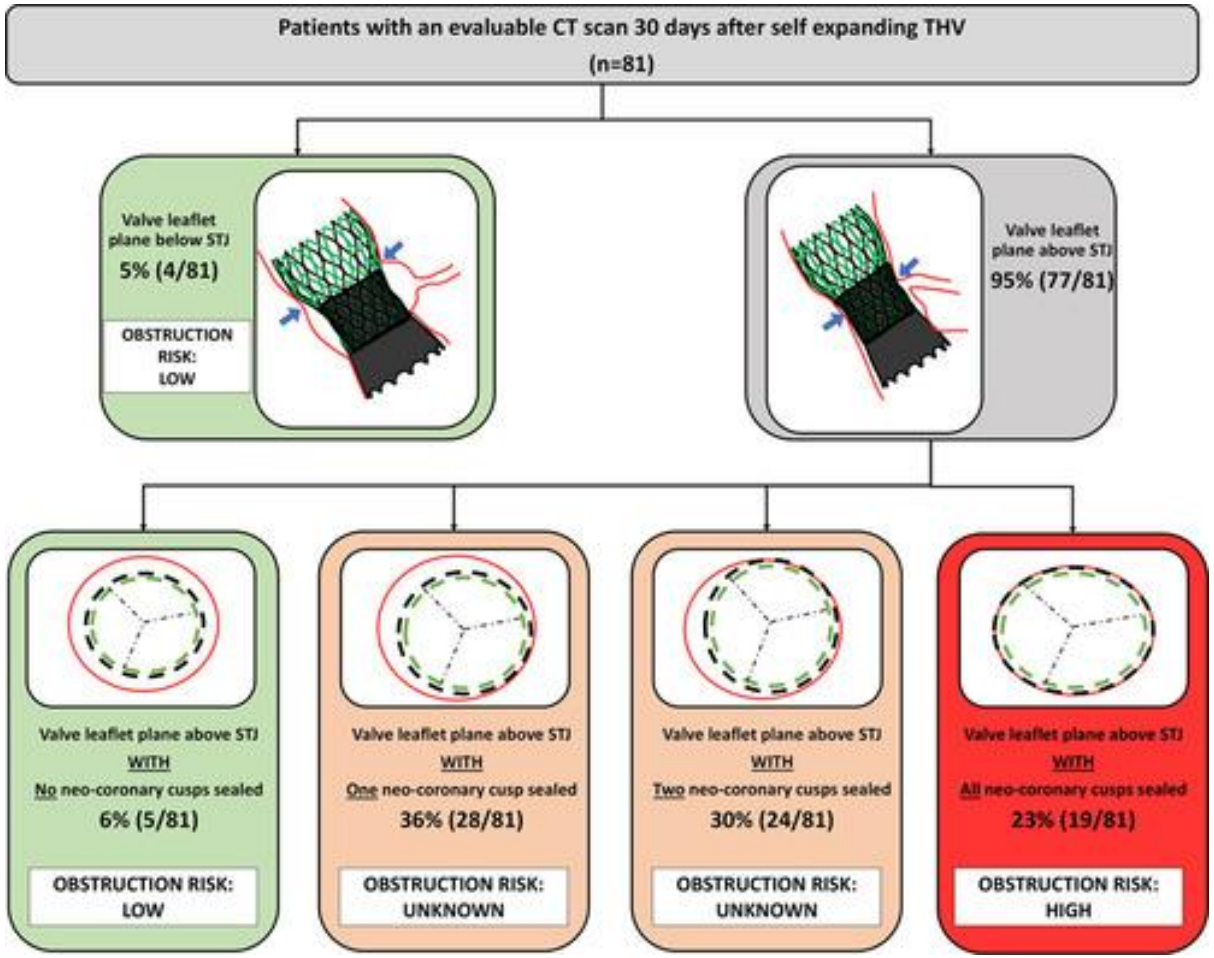
30-day outcomes for aortic THV-in-THV in high-risk or greater patients	TVT registry[1] (n=116)
All-cause Mortality	5.3%
Cardiac Mortality	2.6%
All Stroke	0.0%
Moderate/severe PVL	4.2%
AV gradient mean (mmHg)	15.4
Device Success	98.3%
Permanent Pacemaker Implantation	7.9%
Major vascular complications	0.0%
Device thrombosis	0.9%

Tang, JACC 2019



THV-in-THV (TAVI in TAVI)

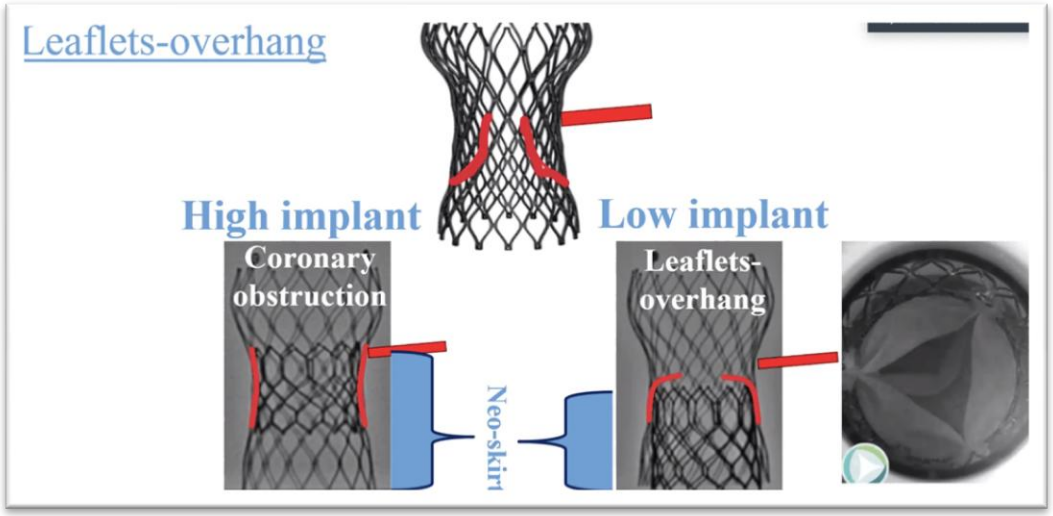
20-50% risc of LMCA obstruction (Evolut)



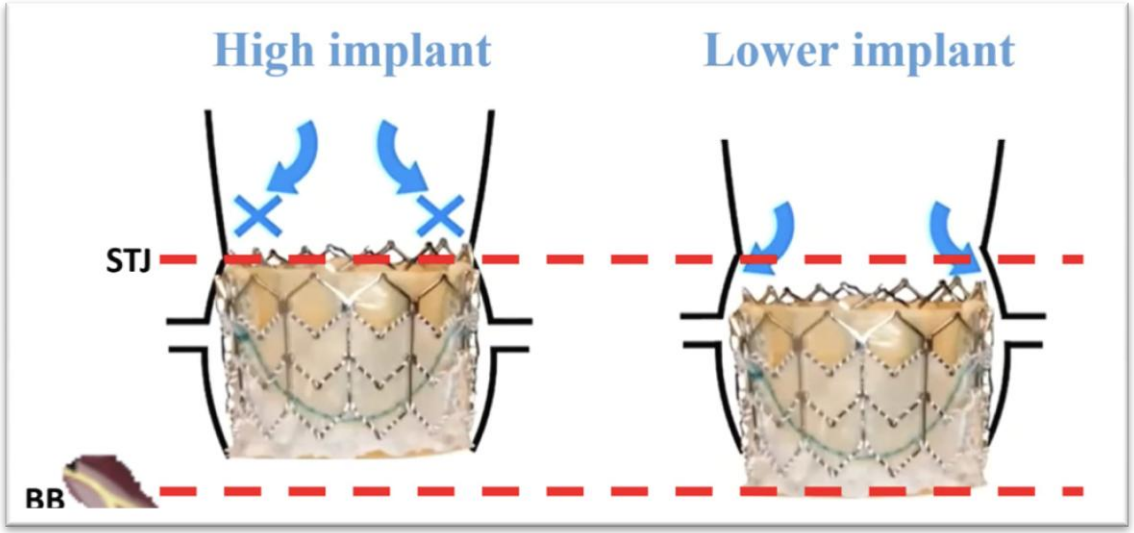
Brian, Circulation 2020

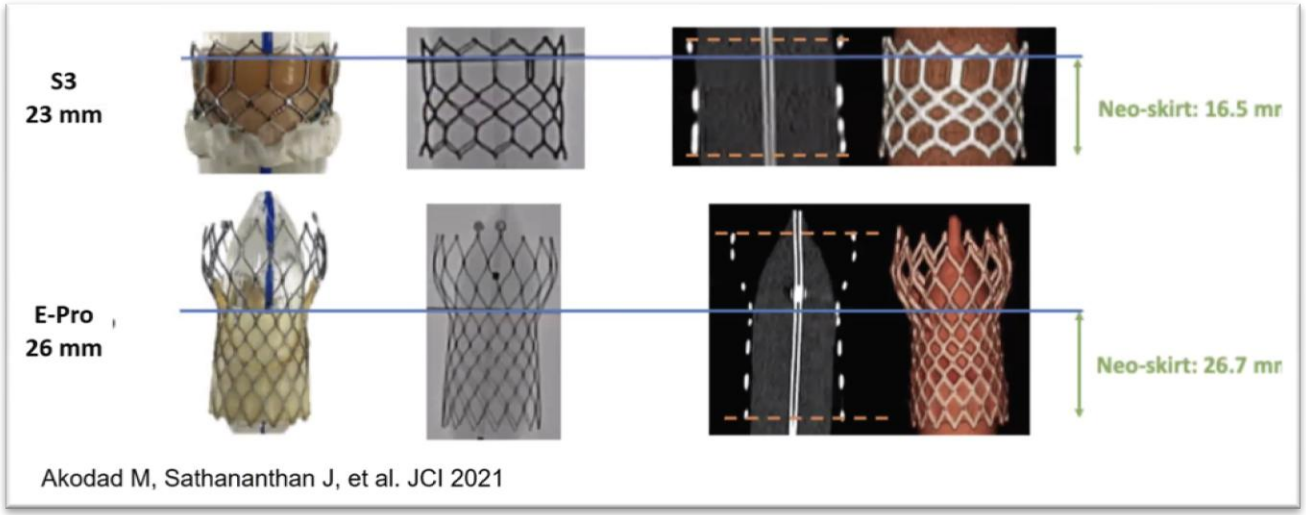
Problematika THV – in – THV implantací

Leaflets ovehang

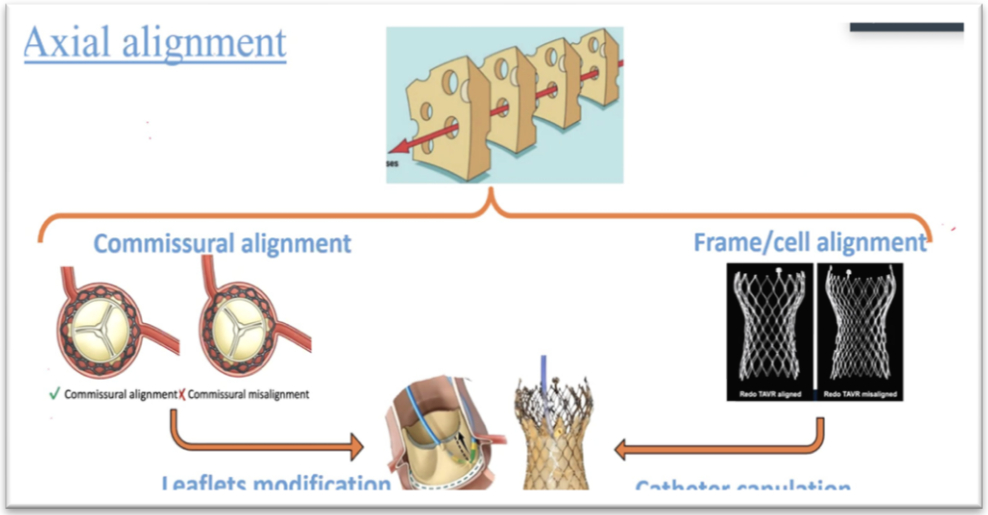


Sekvestrace sinů

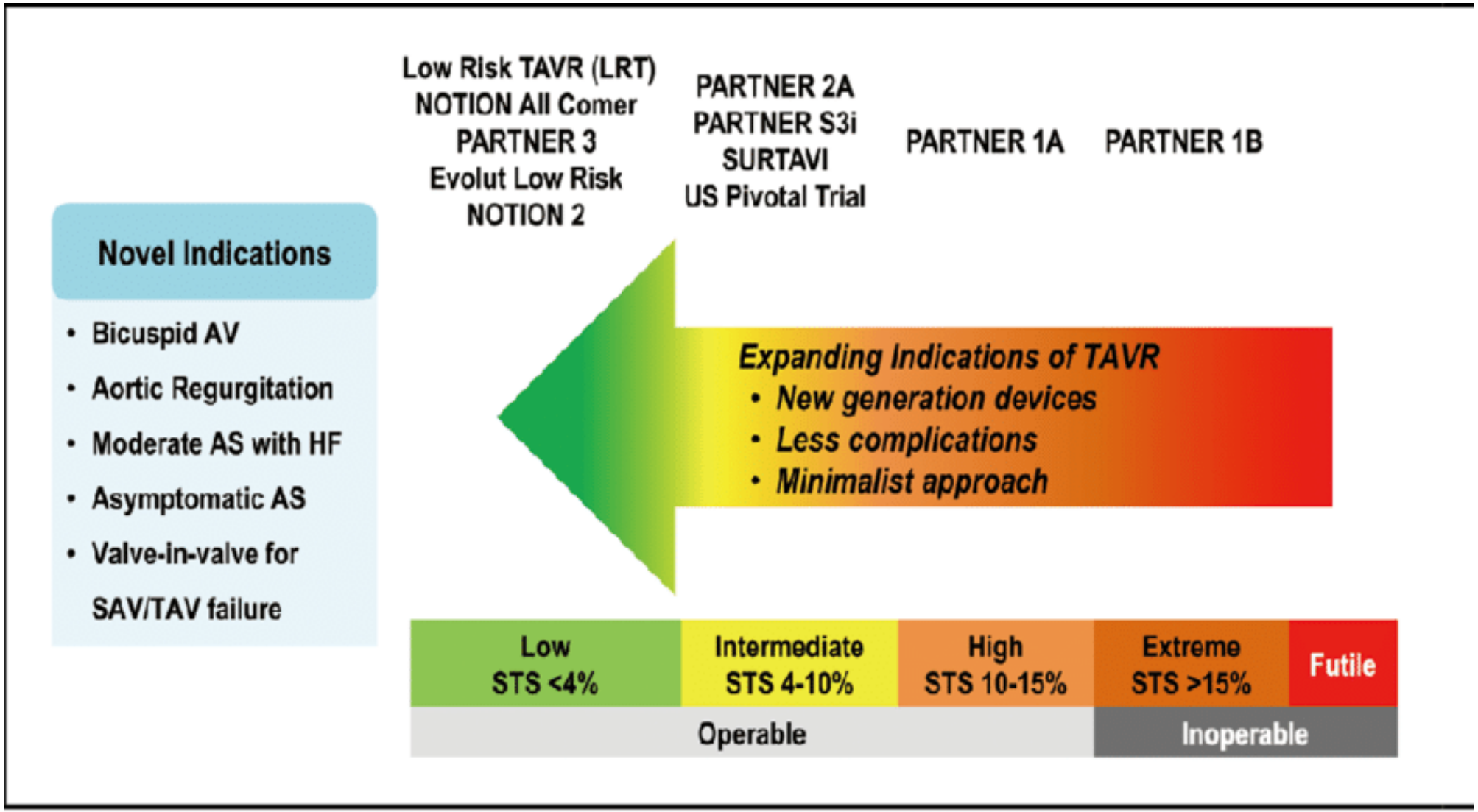




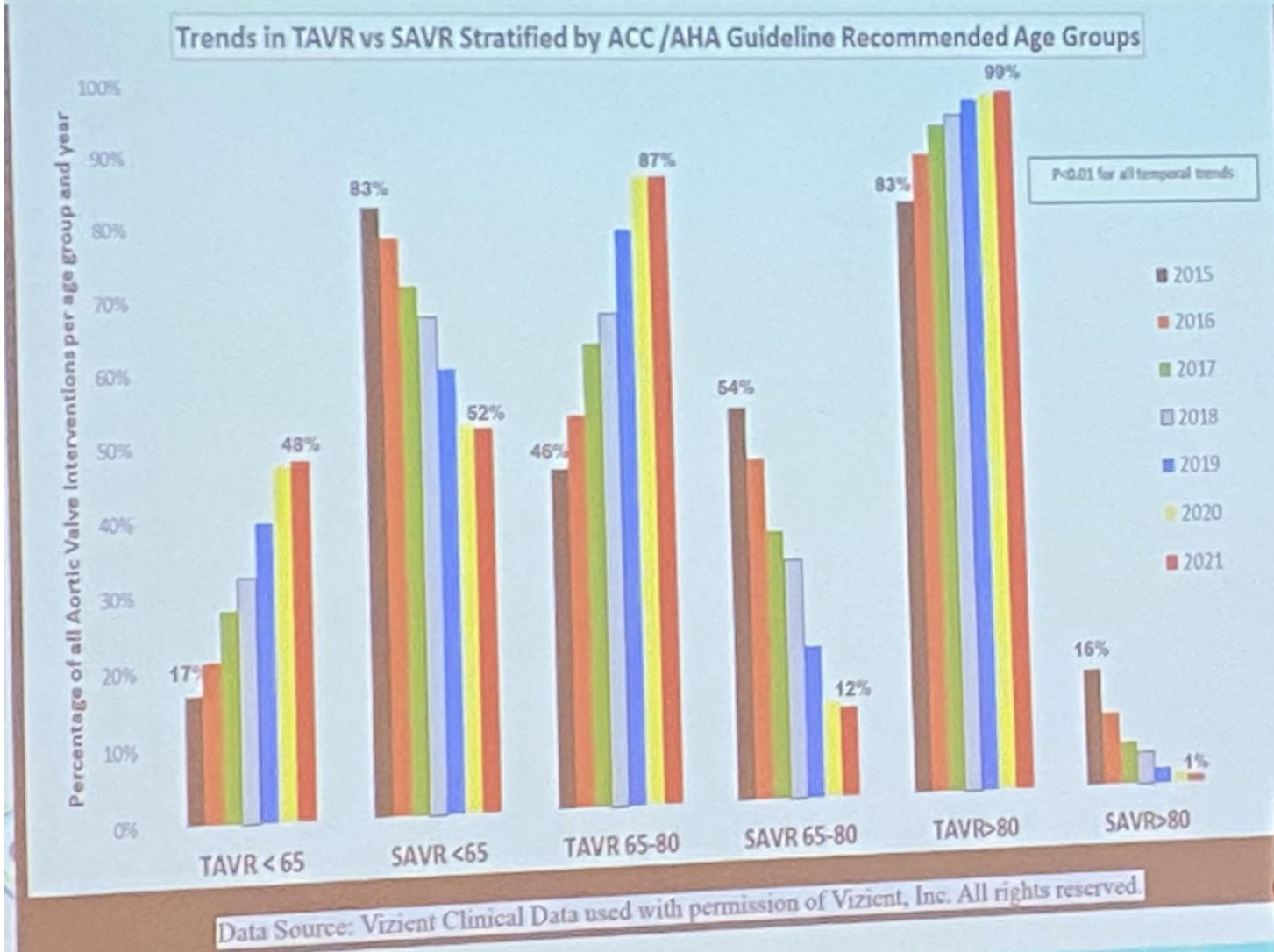
Neo-skirt + riziko obstrukce



Orientace neo-komisur


Low Risk TAVR (LRT)
NOTION All Comer
PARTNER 3
Evolut Low Risk
NOTION 2
PARTNER 2A
PARTNER S3i
SURTAVI
US Pivotal Trial
PARTNER 1A
PARTNER 1B
Novel Indications
• Bicuspid AV
• Aortic Regurgitation
• Moderate AS with HF
• Asymptomatic AS
• Valve-in-valve for SAV/TAV failure
Expanding Indications of TAVR
• New generation devices
• Less complications
• Minimalist approach
Low
STS <4%
Intermediate
STS 4-10%
High
STS 10-15%
Extreme
STS >15%
Futile
Operable
Inoperable

Current trends in TAVR vs SAVR in isolated AS (US perspective)



- 279,066 patients
- Patients <65 were 12.2% of all treated cases

Sharma et al. JACC