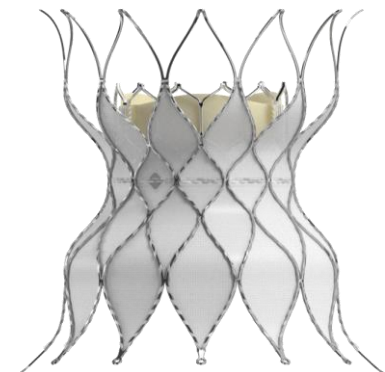


TAVI – nové přístupy v léčbě chlopenních vad

Michael Želízko



Symposium 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)

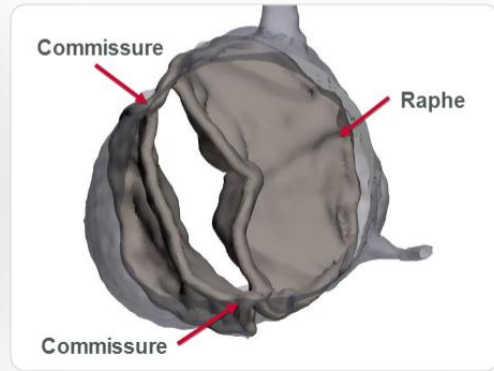
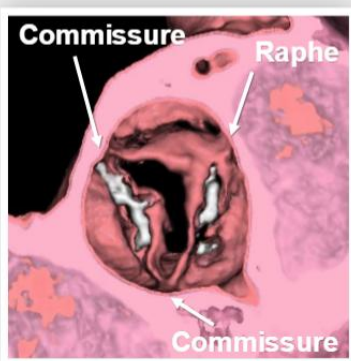
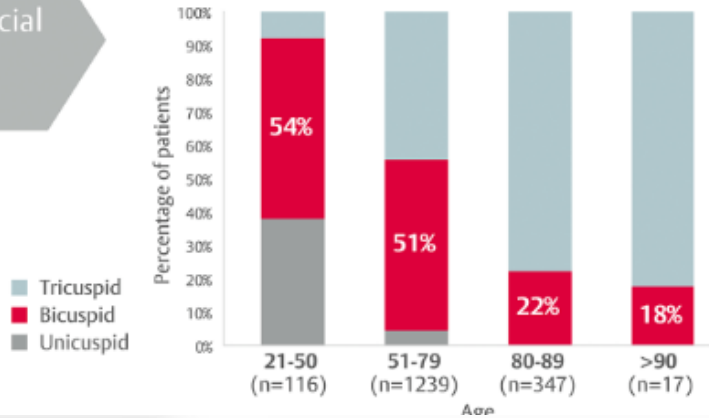
- THV-in-THV

Bikuspidní aortální chlopeň

Congenital bicuspid aortic valve disease is more prevalent in younger patients requiring AVR³

Careful lifetime planning is crucial for bicuspid patients

Aortic Valve Replacement by Valve Type



Epidemiology of Bicuspid Aortic Valve Disease

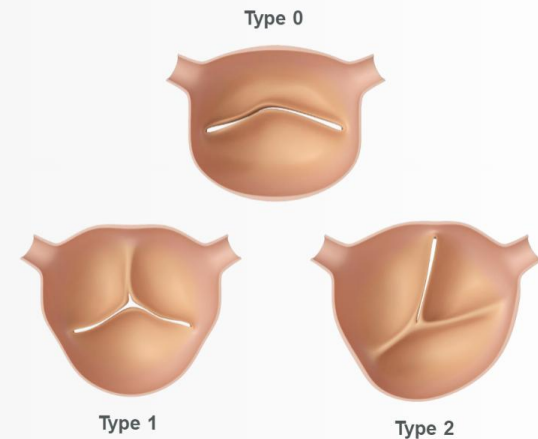
- Most frequent congenital heart disease, occurring in 1 to 2% of the population¹
- BAV can be inherited, with 6.4% in first-degree relatives of individuals with the condition²
- Prevalence of bicuspid aortic valves is uniform across the world²
- 10% of patients undergoing TAVR have a bicuspid aortic valve¹



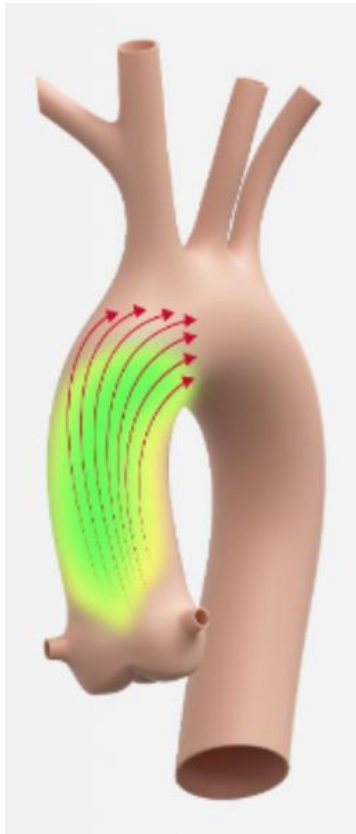
Sievers et al provide a systematic classification of BAV

Classifies three types of bicuspid valve morphologies:

- Type 0 (no raphe)
- Type 1 (one raphe)
- Type 2 (two raphes)

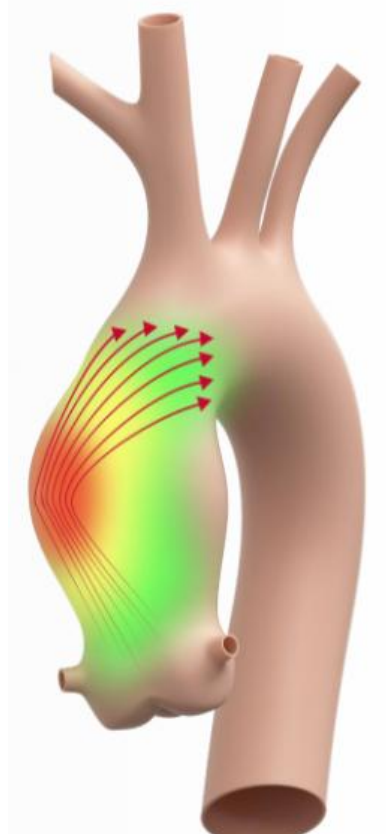


BAV – TAVI pouze u nemocných bez aortopatie

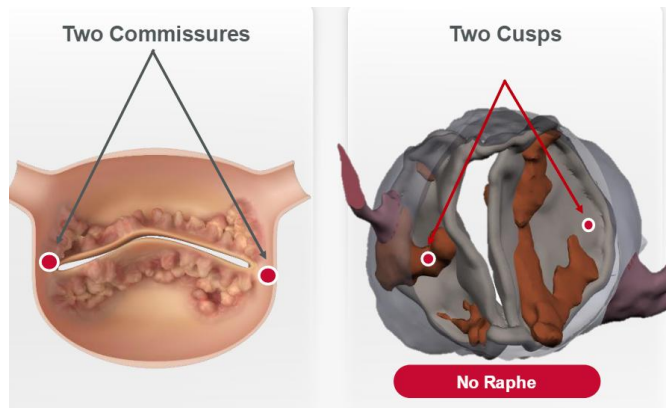


Bicuspid Aortic Valve characteristics

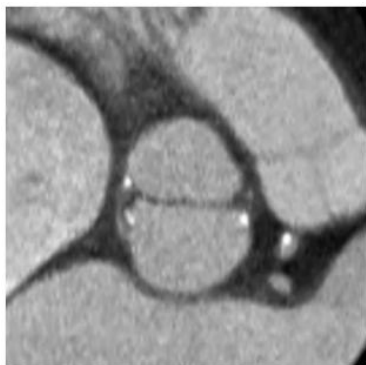
- Aortopathy manifested as dilatation of the thoracic aorta occurs in 40-70% of BAV patients dependent on population studied and definition of dilation¹
- 2020 ACC/AHA recommends surgical replacement of the ascending aorta is indicated in patients with a BAV if the diameter of the aortic sinuses or ascending aorta is $\geq 55\text{mm}^2$
- 2021 ESC/EACTS guidelines include the indication for surgery when aortic diameter is $\geq 50\text{mm}$ and additional risk factors or coarctation are present³



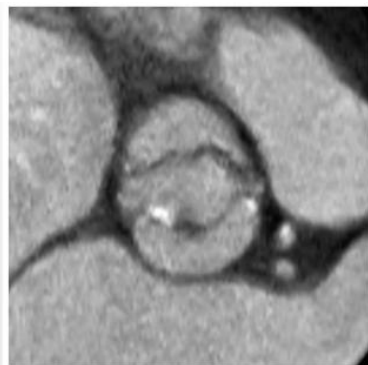
Typ 0 BAV



Cca 10% BAV = type 0
Supraannular sealing
Vyšší implantační pozice
Undersizing lepší nežli oversizing



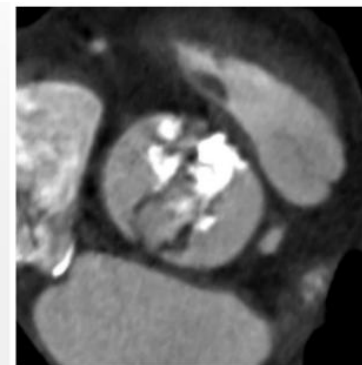
Diastole



Systole

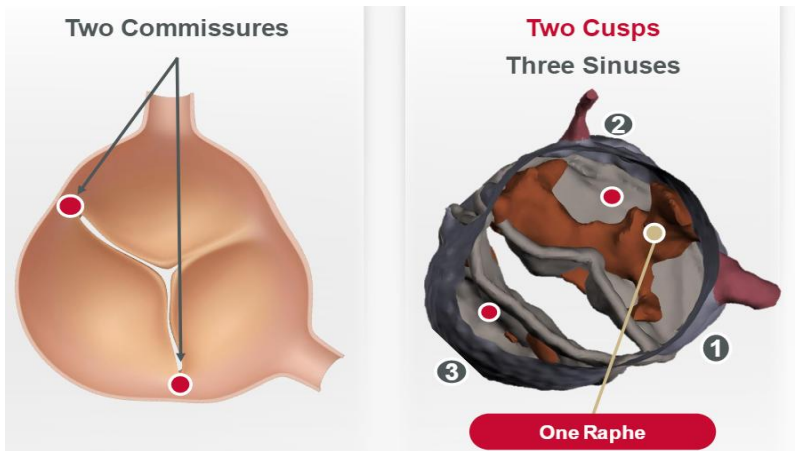


Diastole



Systole

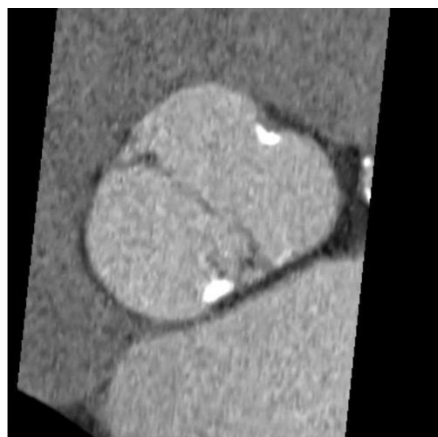
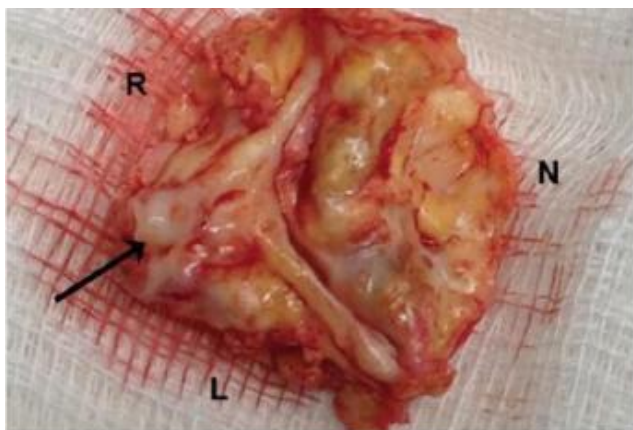
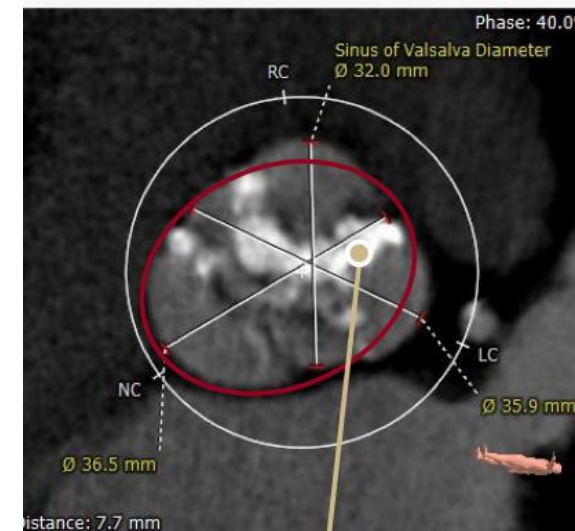
Typ 1 BAV



- 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%

May be elliptical in shape



Diastole



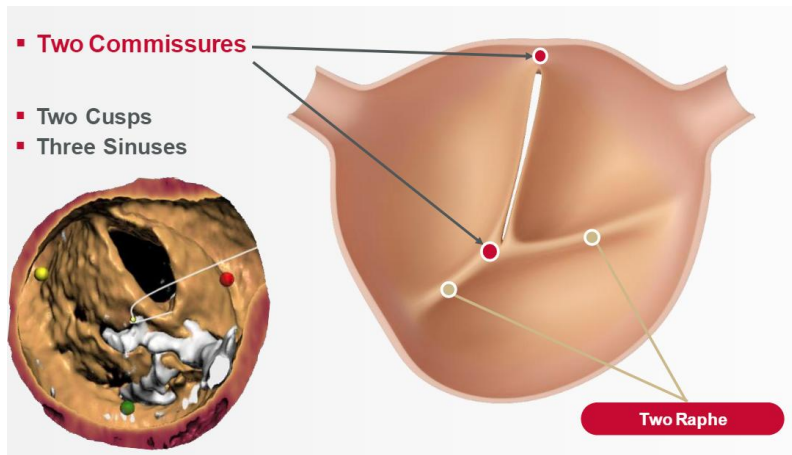
Systole

Kalcifikované raphe

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

Typ 2

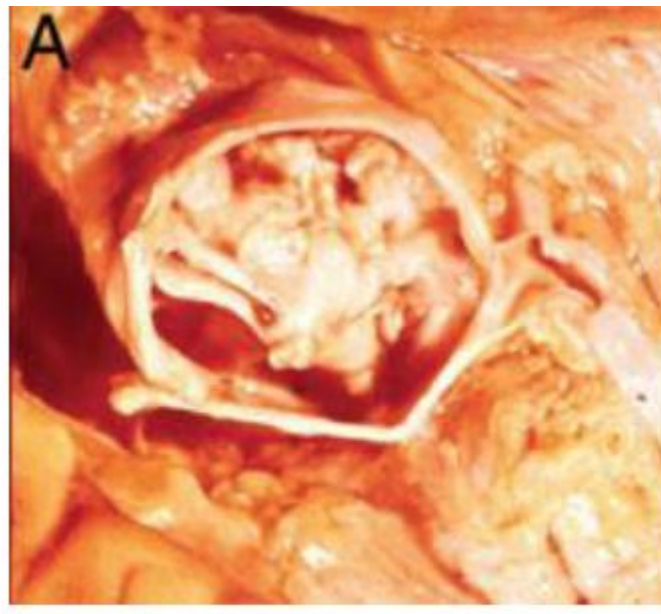
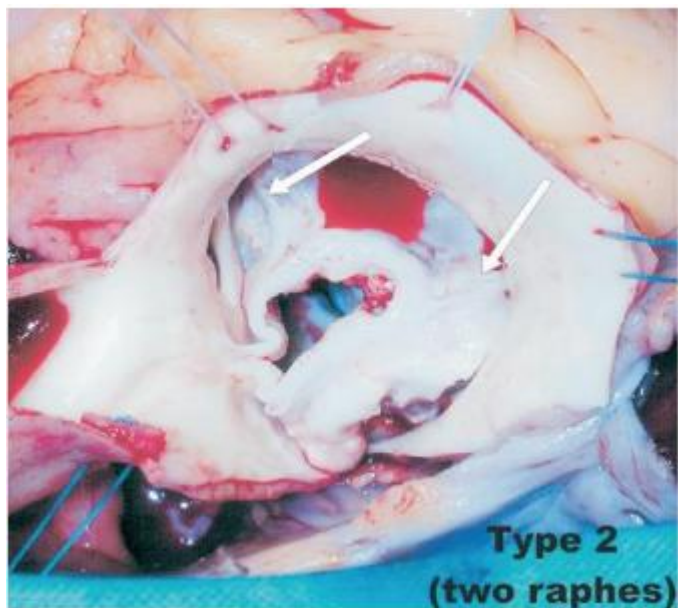
1-5% BAV
Nejčastěji aneurysma asc. aorty



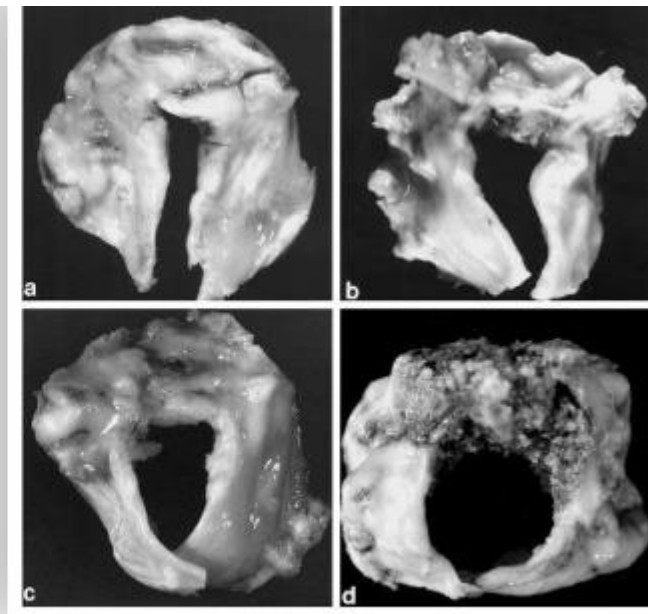
Diastole



Systole

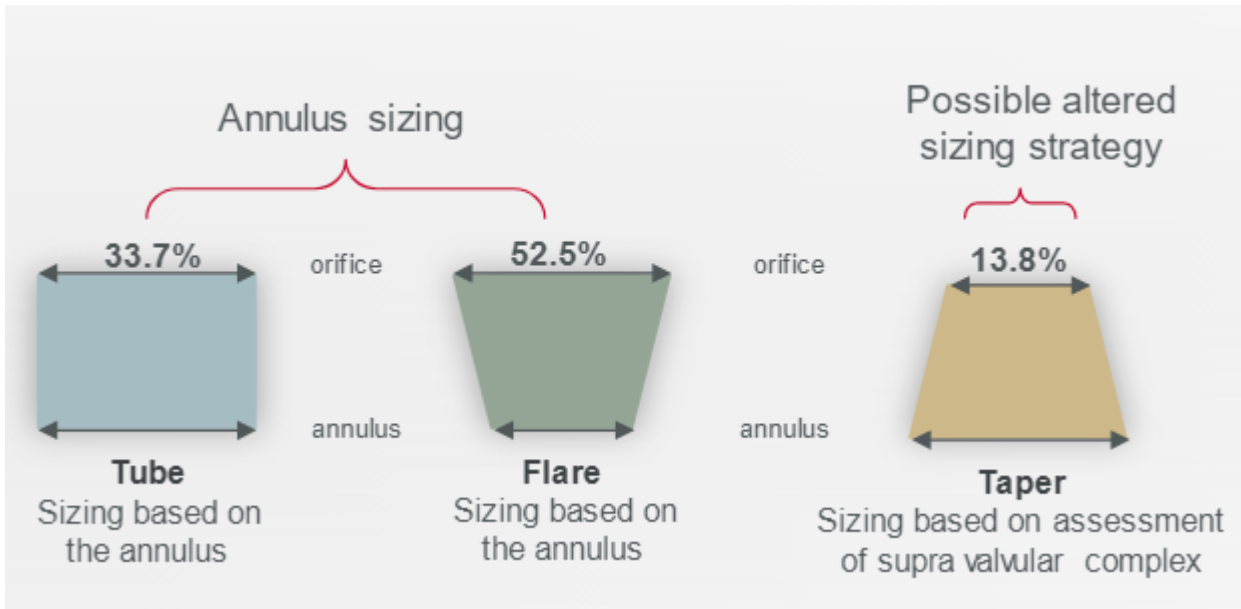


(Bax et al., 2014, p. 2631)



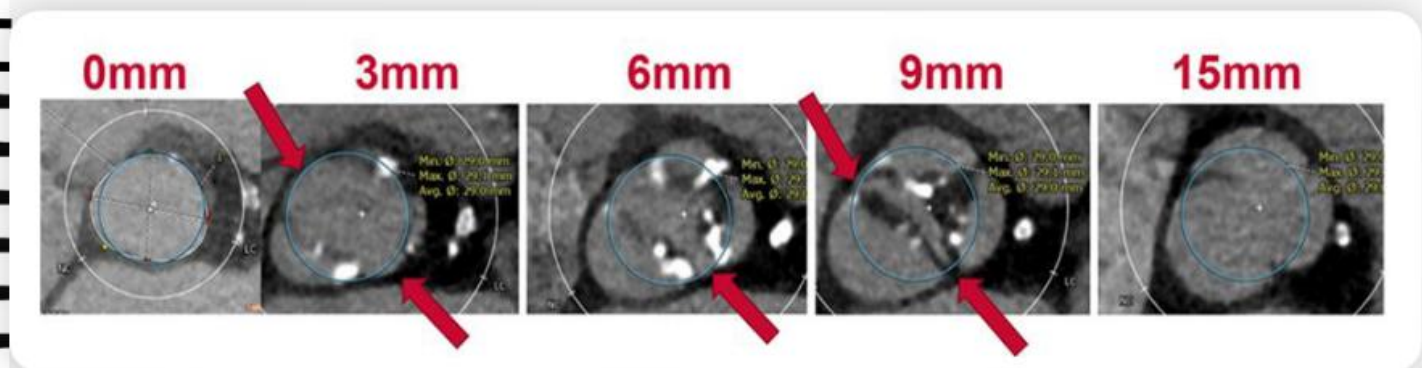
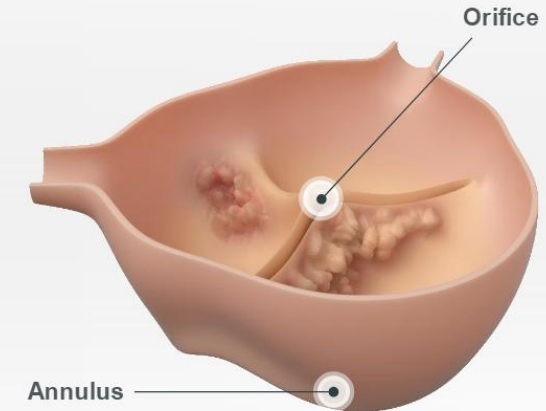
(Roberts & Ko, 2005, p. 921)

CT analýza – „circle method“



Annulus to orifice mismatch:

The diameter of the annulus is smaller or larger than the orifice diameter



Circle method: prevence komplikací

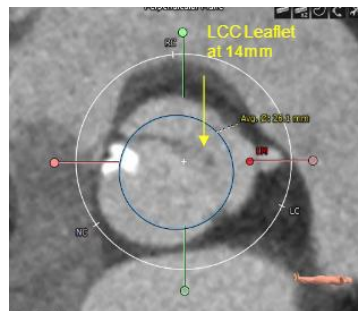
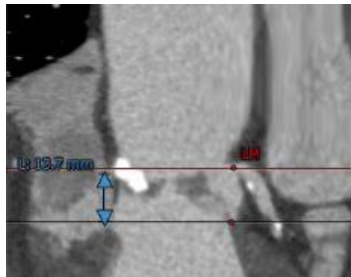
Circles at 12 – to STJ height
Simulate the relation of deployed valve to the
Left Main Artery (LM) and Right Coronary Artery (RCA)

And can identify:

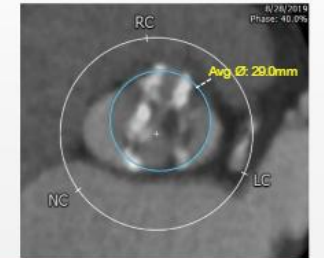
Leaflet height and leaflet calcium
SOV width
Risk for sinus sequestration



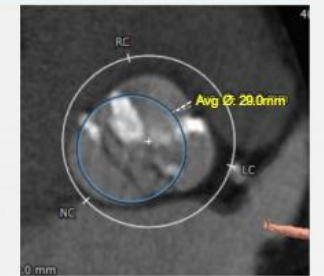
Vales. Cardiol Ther. 2021 June 3.



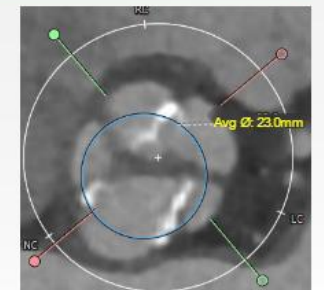
1. **The circle is too large** it extends beyond the commissures, with a potential risk of commissure rupture



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

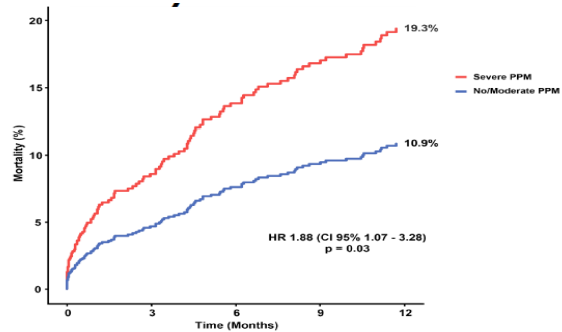


- Bikuspidní aortální chlopeň
- **Valve-in-valve:**
 - **Aortic**
 - Mitral
 - Pulmonary
 - Tricuspid (off label)
- THV-in-THV

TAVI: valve-in-valve implantace

Degenerované chirurgické bioprotézy:

- Riziko „patient-prosthesis mismatch“ (ppm)
- Riziko obstrukce koronárních tepen



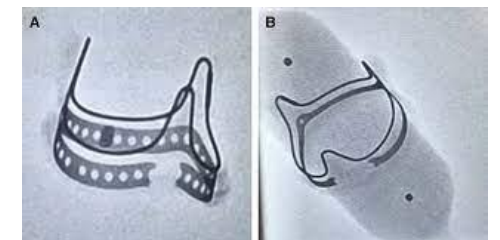
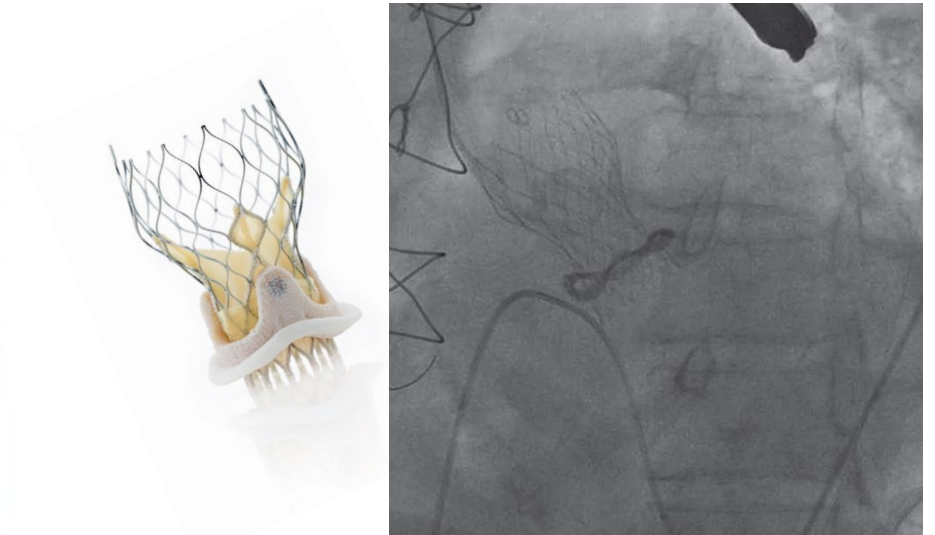
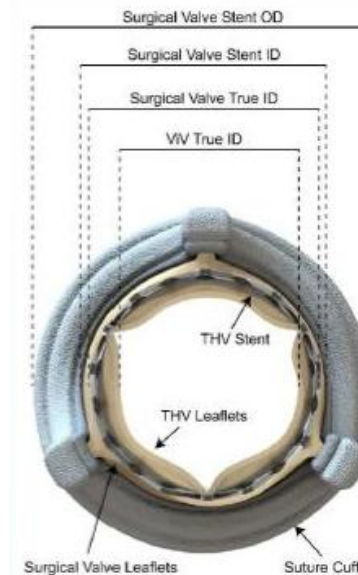
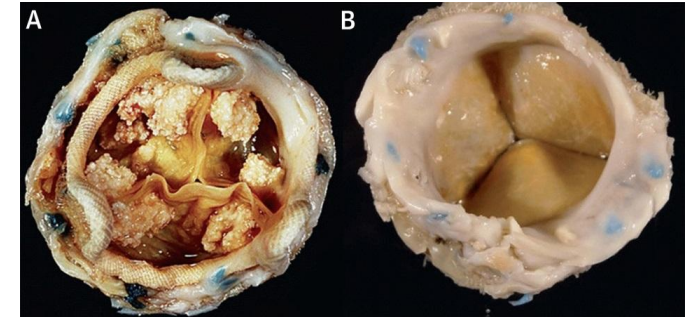
Riziko patient-prosthesis mismatch:

Surgical labeled size < 23 mm

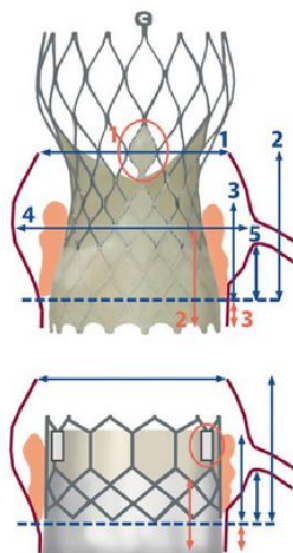
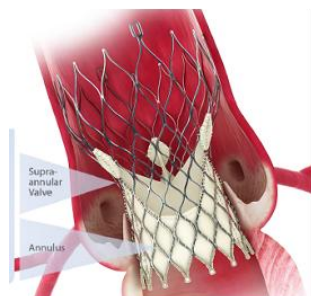
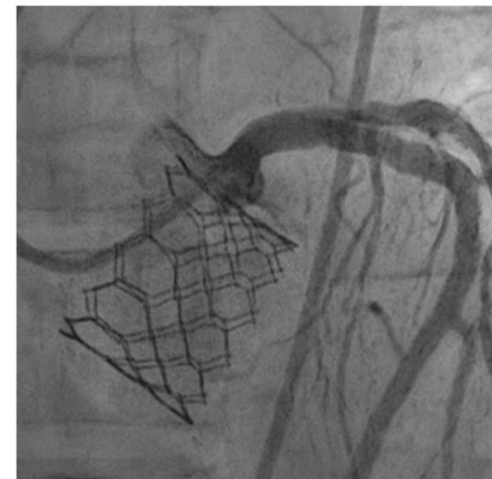
PPM = residual mean gradient ≥ 20 mmHg

PPM = iEOA < $0,65 \text{ cm}^2/\text{m}^2$

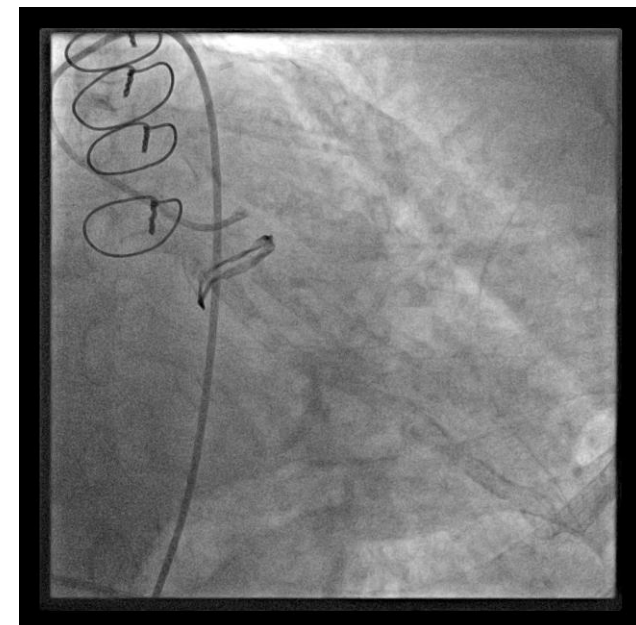
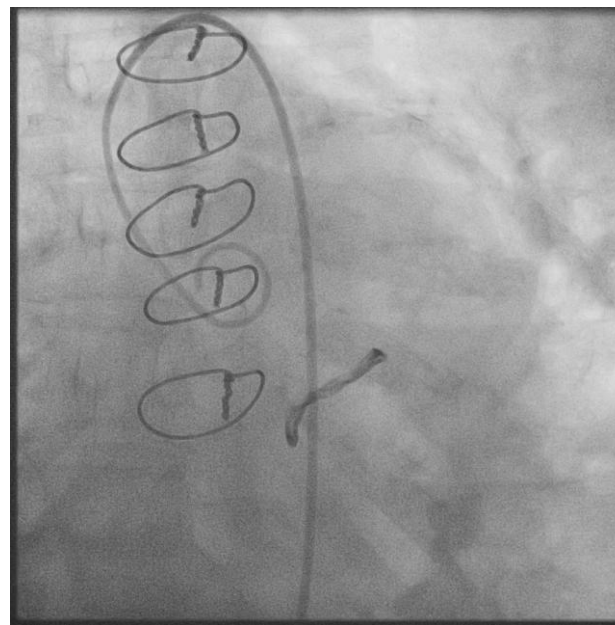
mild PPM = iEOA < $0,85 \text{ cm}^2/\text{m}^2$



Přístup ke koronárním tepnám



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



Jak predikovat koronární obstrukci u ViV?

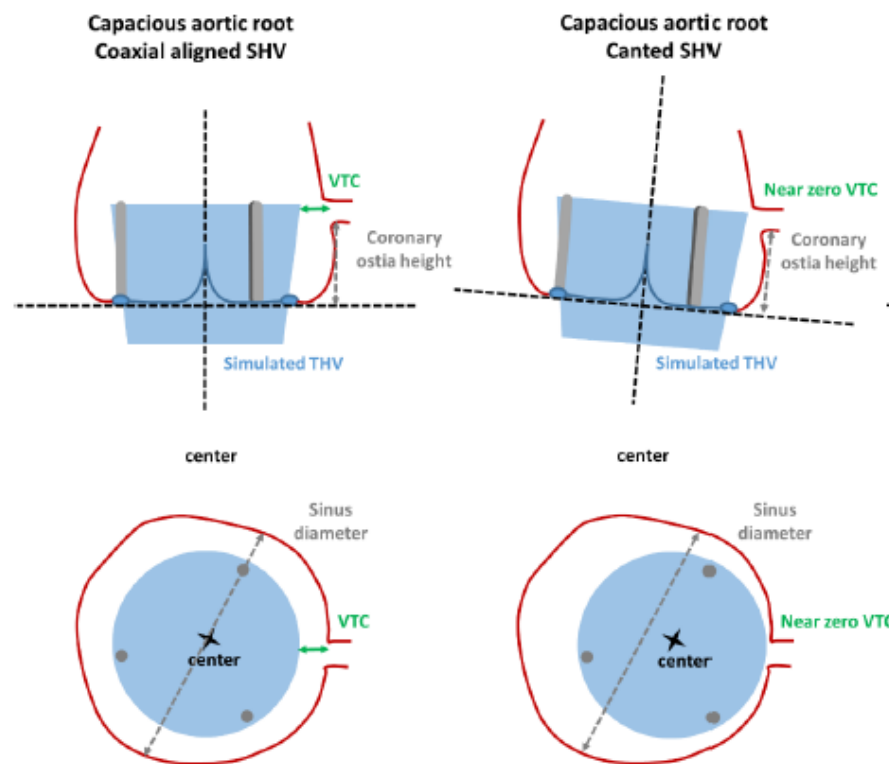
Virtual THV to Coronary (VTC) distance

Výška a typ bioprotézy
(*Mitroflow, Trifecta jsou nejhorší*)

Výška STJ

Šířka SOV (odstup LCA)

Úhel anulus bioprotézy/aorta



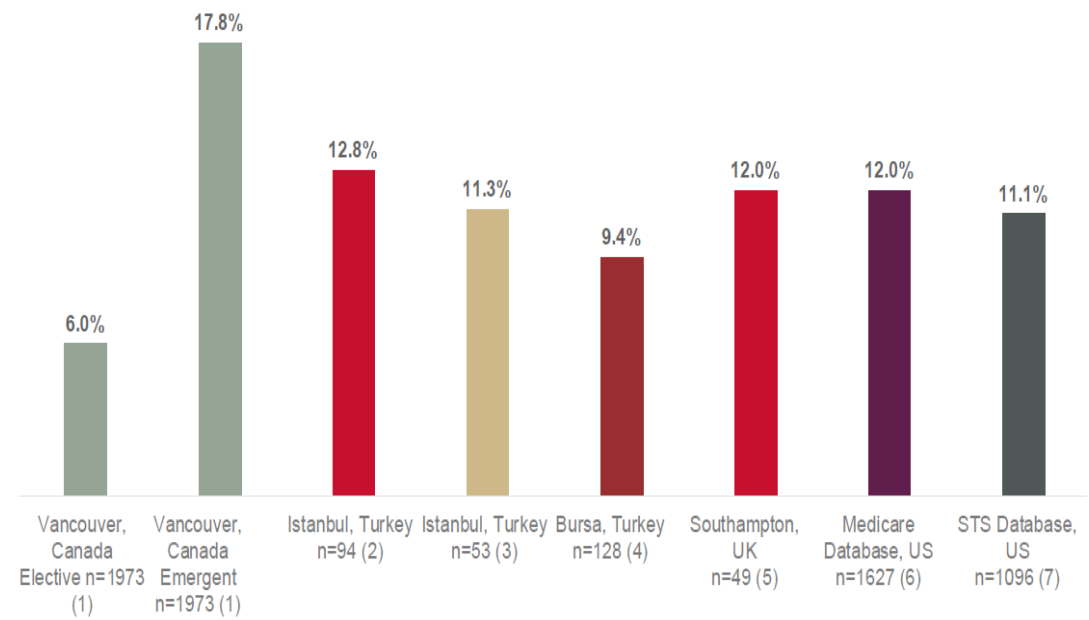
VTC!

Cut-off 3-4 mm

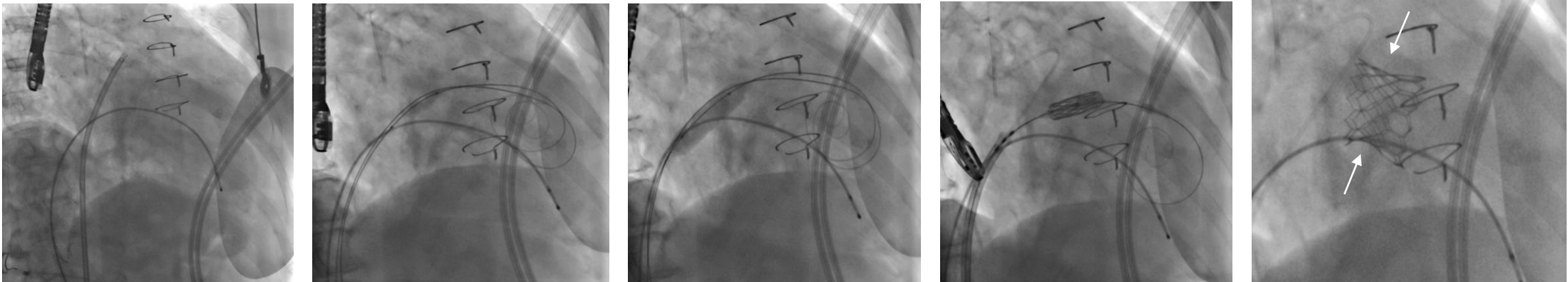
Blanke, 2016

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

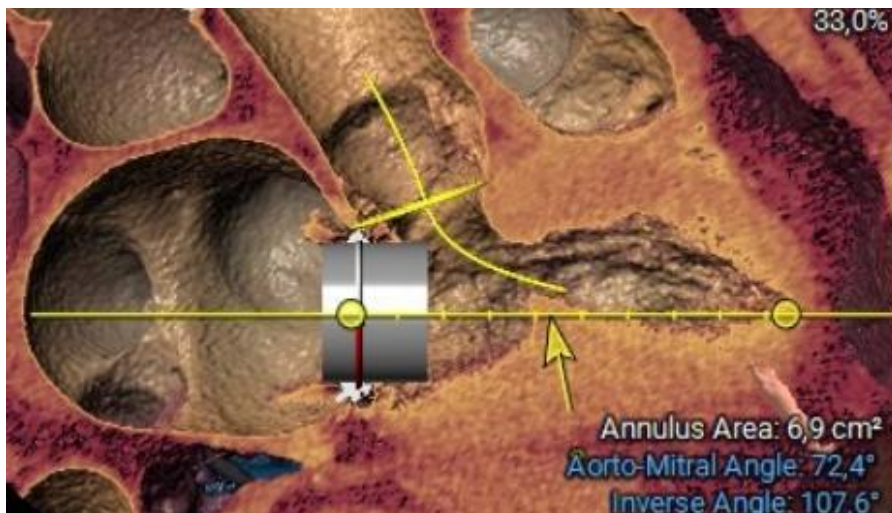
Transseptal mitral ViV vs Redo surgery



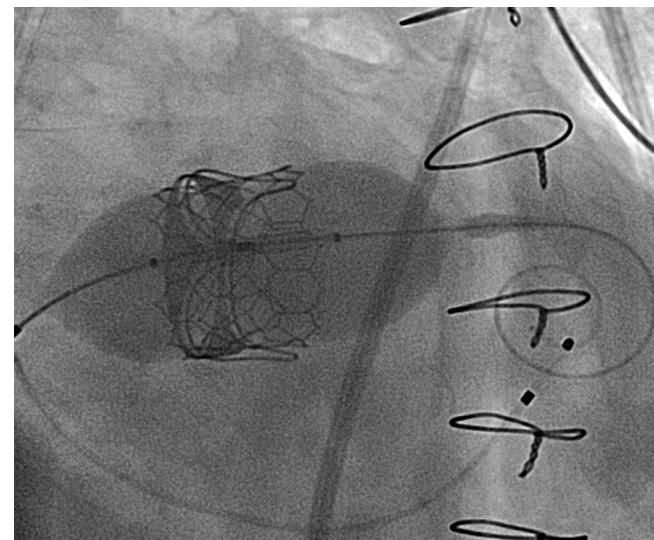
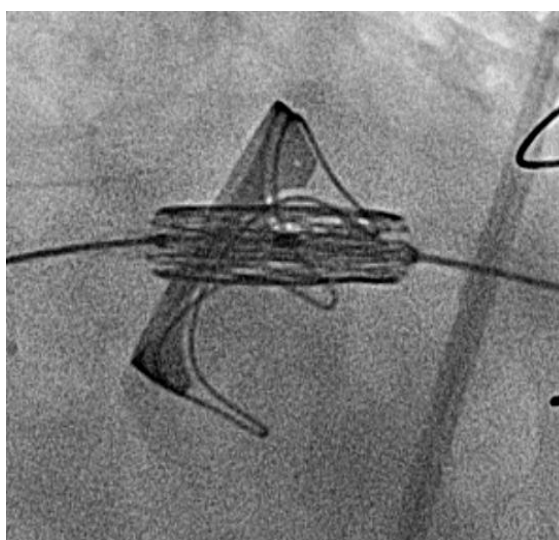
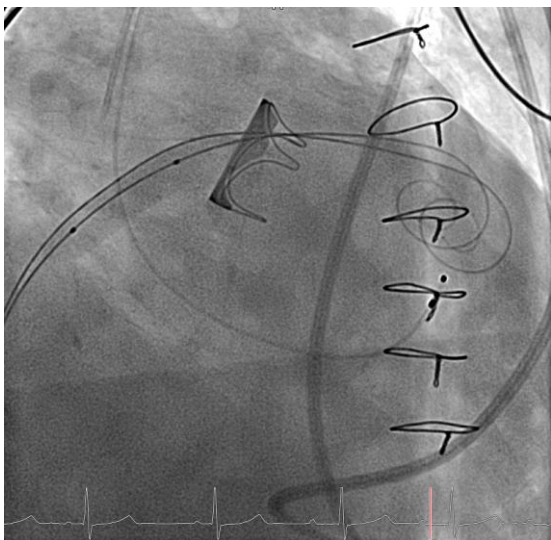
Transseptal mitral surgical ViV (n=1326) ¹	30 Days	1 Year
All-cause mortality	5%	15.8%
Cardiovascular mortality	2.1%	3.7%
Stroke	1.1%	3.3%
Mitral valve reintervention	0.4%	0.8%
New pacemaker	1.4%	2%
Device thrombosis	0.2%	0.3%
Mean MVG (mmHg)	7.4 (±2.75)	7.0 (±2.94)



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



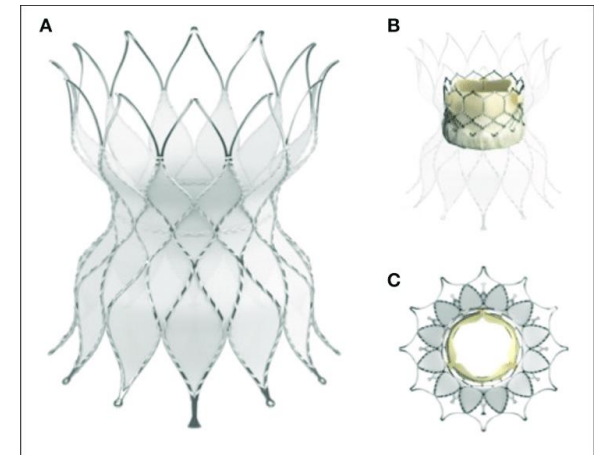
Transseptální punkce + dilatace septa – 2x stiff vodič do LK – zavedení chlopně – implantace při 170/min – finální pozice

- 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/m²
- EF RV $< 40-45\%$



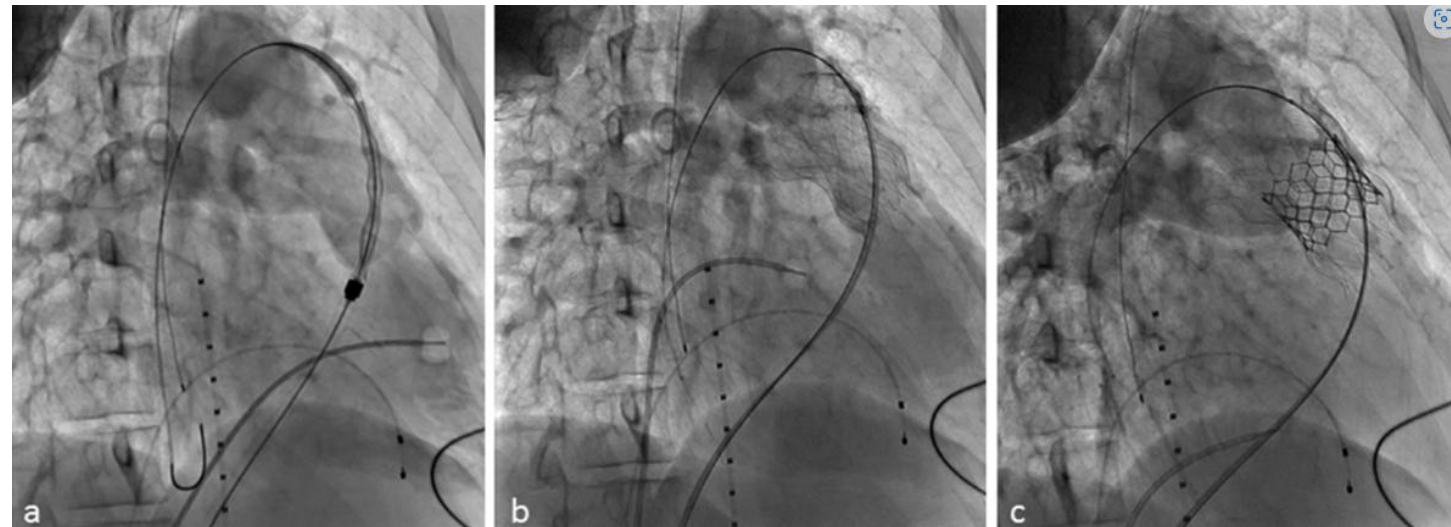
Alterra Sapien 3 THV



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.

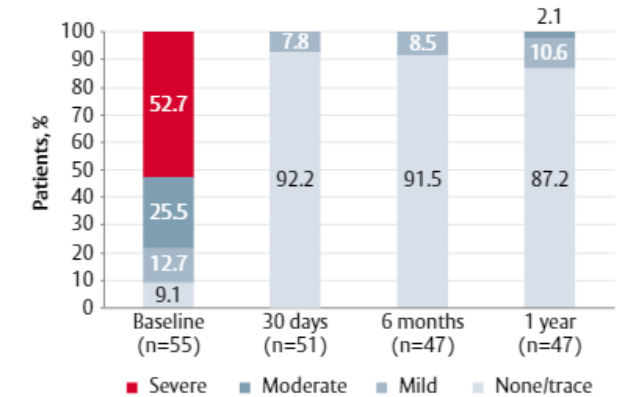


n=774 patients who underwent TPVI with a SAPIEN XT valve or SAPIEN 3 valve between 1 January 2008 and 28 August 2019.

	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				
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. chlopěň

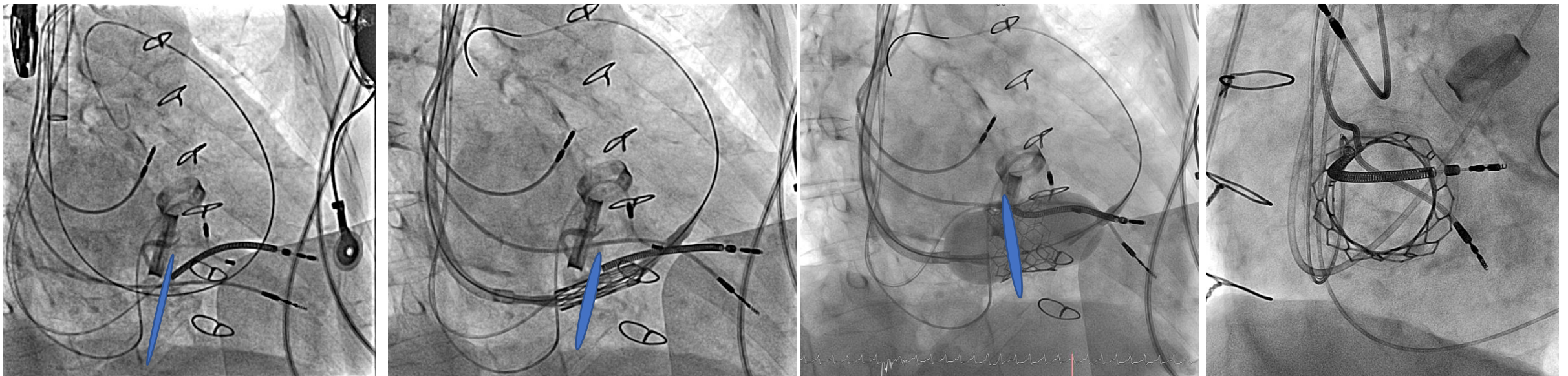
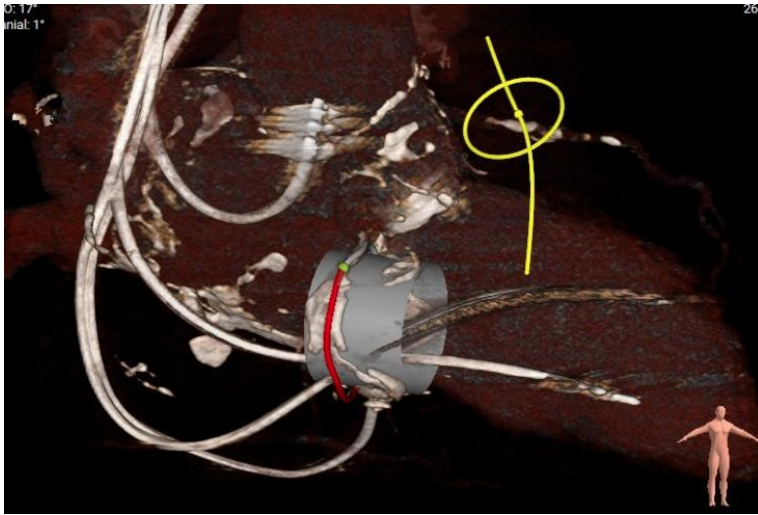
- Bikuspidní aortální chlopeň
- **Valve-in-valve:**
 - Aortic
 - Mitral
 - Pulmonary
 - **Tricuspid (off label)**
- THV-in-THV

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

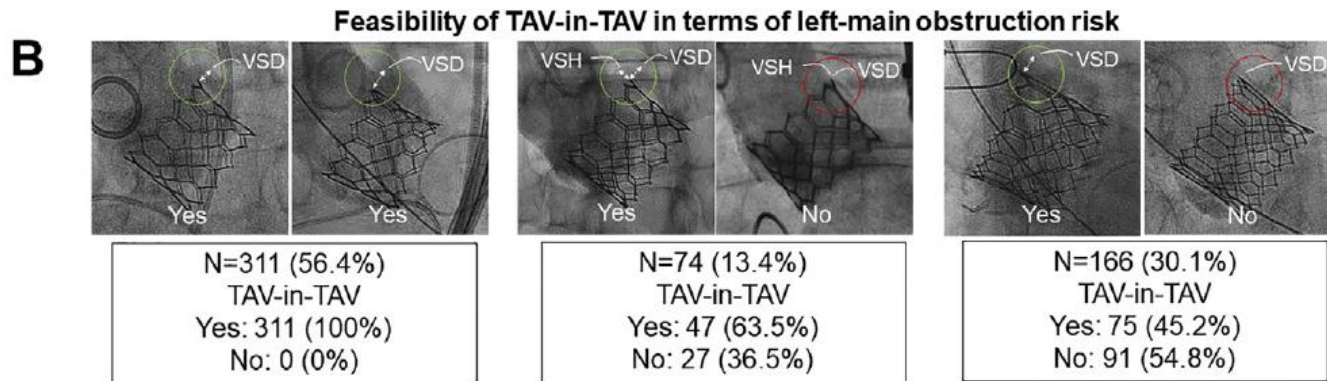
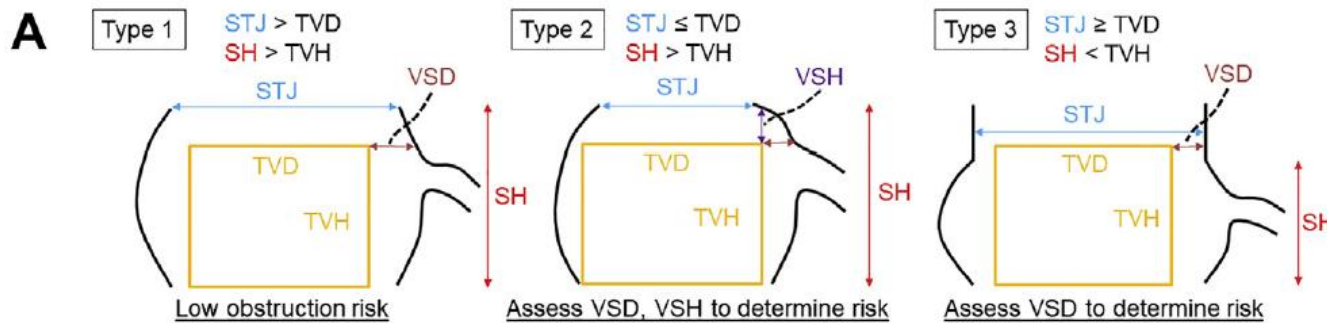


Sheath 21F přes vena jugularis – 2x Lunderquist do plicnice – ES 29 mm + 4 ccm + pace 150/min – finální pozice a expanze

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

THV-in-THV (TAVI in TAVI)

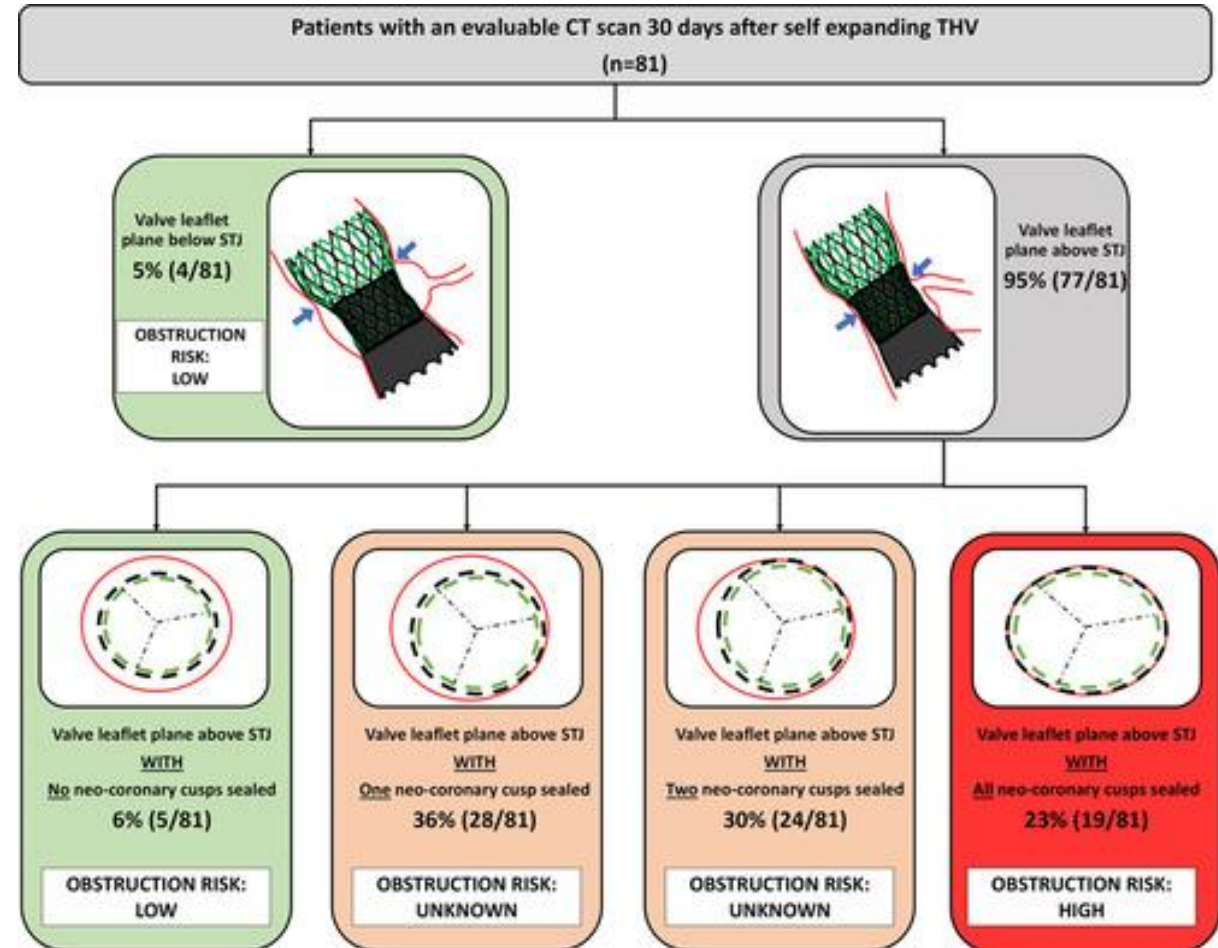
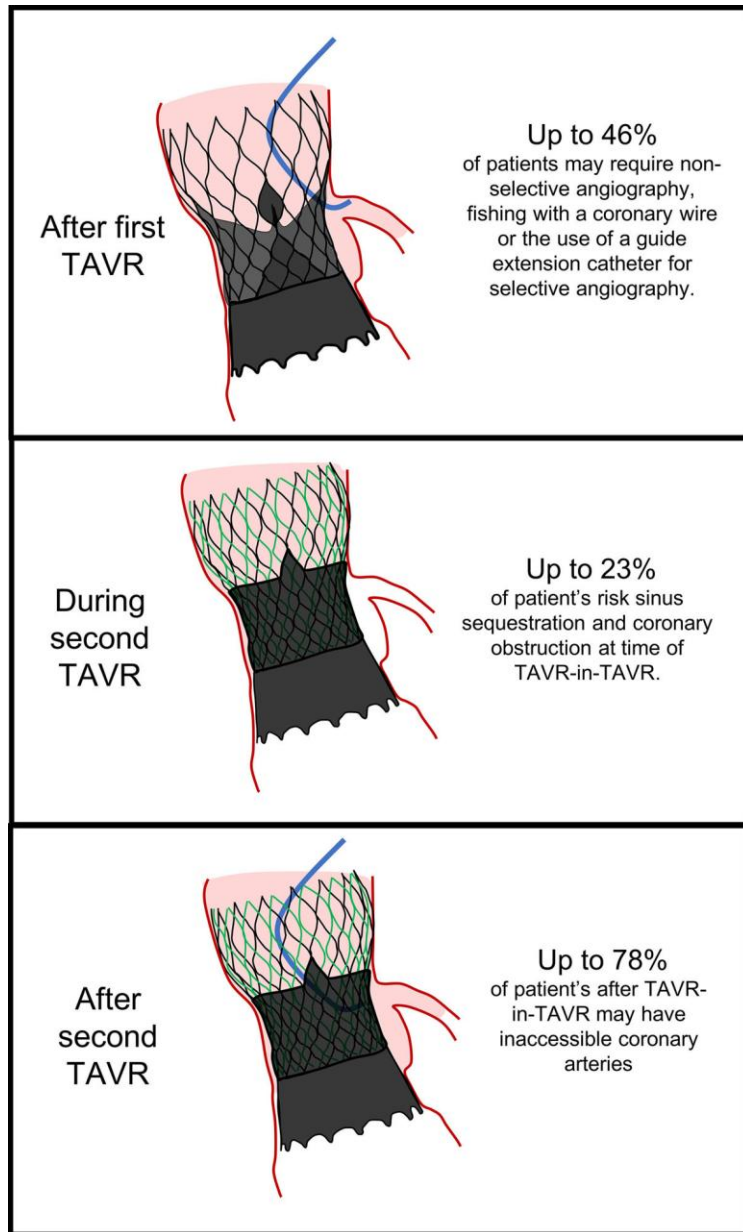
20% risc of LMCA obstruction (Sapien)



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%

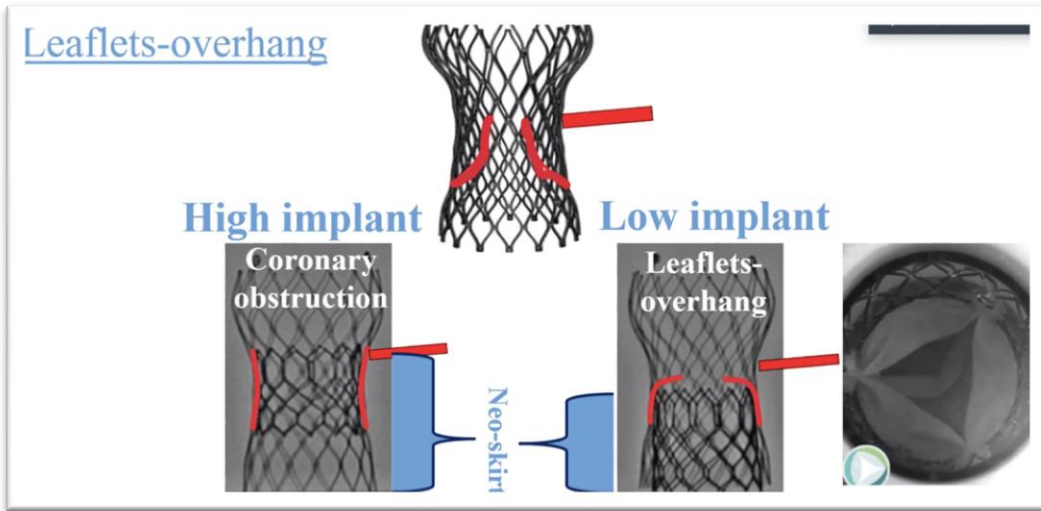
THV-in-THV (TAVI in TAVI)

20-50% risk of LMCA obstruction (Evolut)

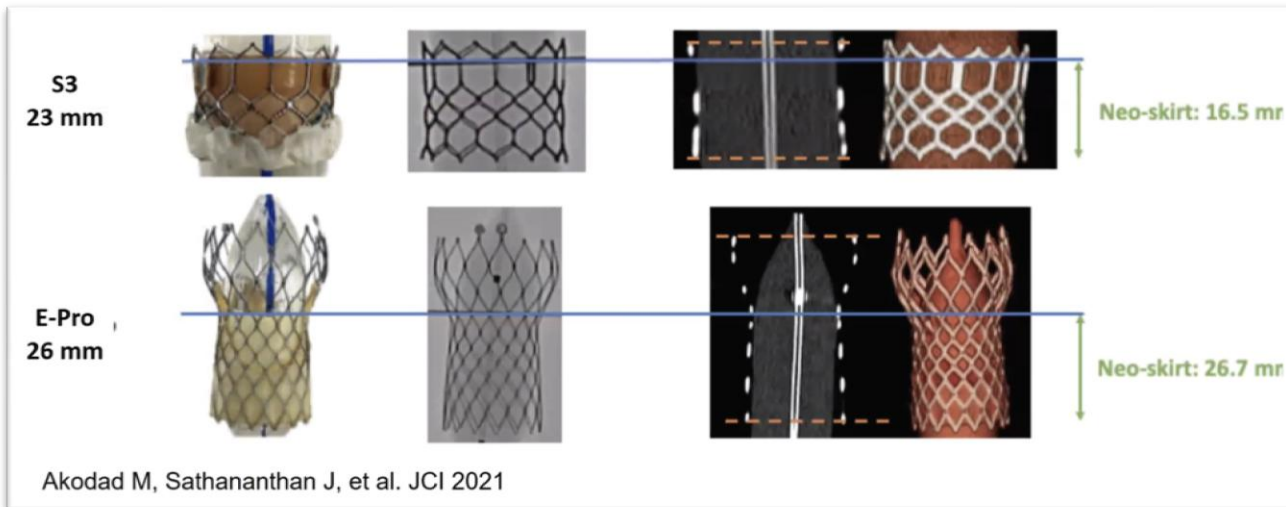
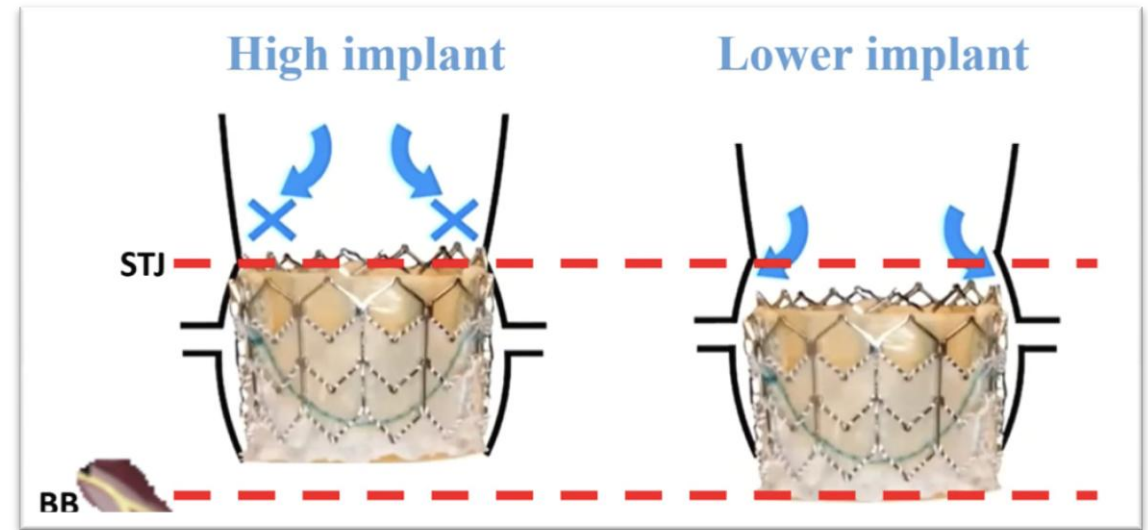


Problematika THV – in – THV implantací

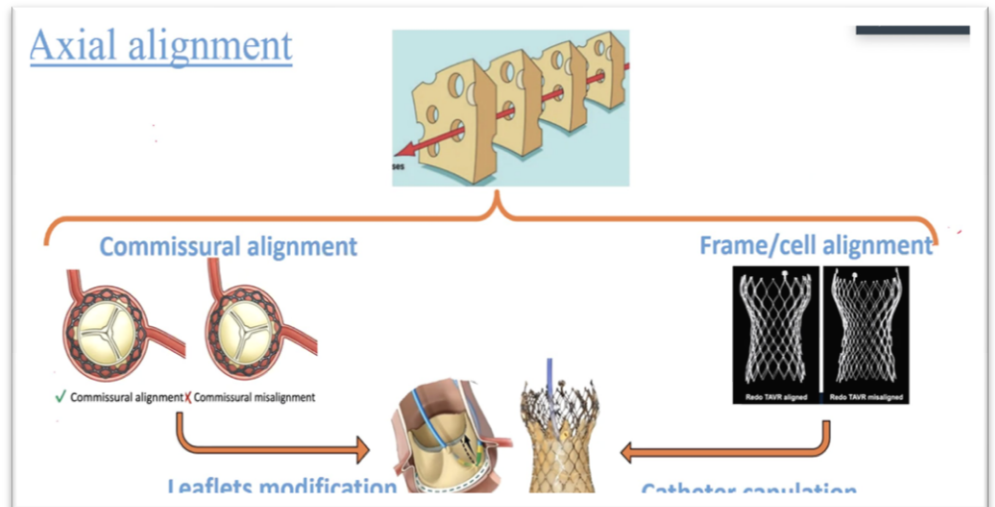
Leaflets overhang



Sekvestrace sinů



Neo-skirt + riziko obstrukce



Orientace neo-komisur

Novel Indications

- Bicuspid AV
- Aortic Regurgitation
- Moderate AS with HF
- Asymptomatic AS
- Valve-in-valve for SAV/TAV failure

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

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