KOMPLEXNÍ KARDIO VASKULÁRNÍ CENTRUM VFN Praha

Nové horizonty v léčby trikuspidální regurgitace

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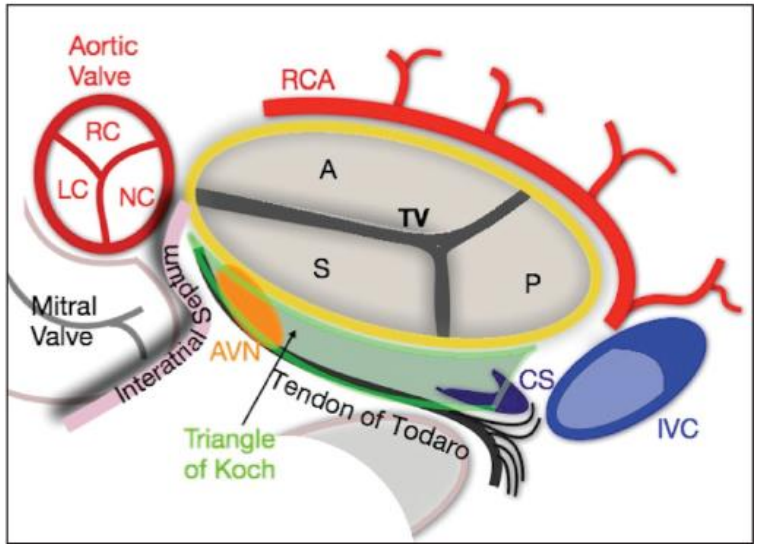
VŠEOBECNÁ FAKULTNÍ NEMOCNICE V PRAZE

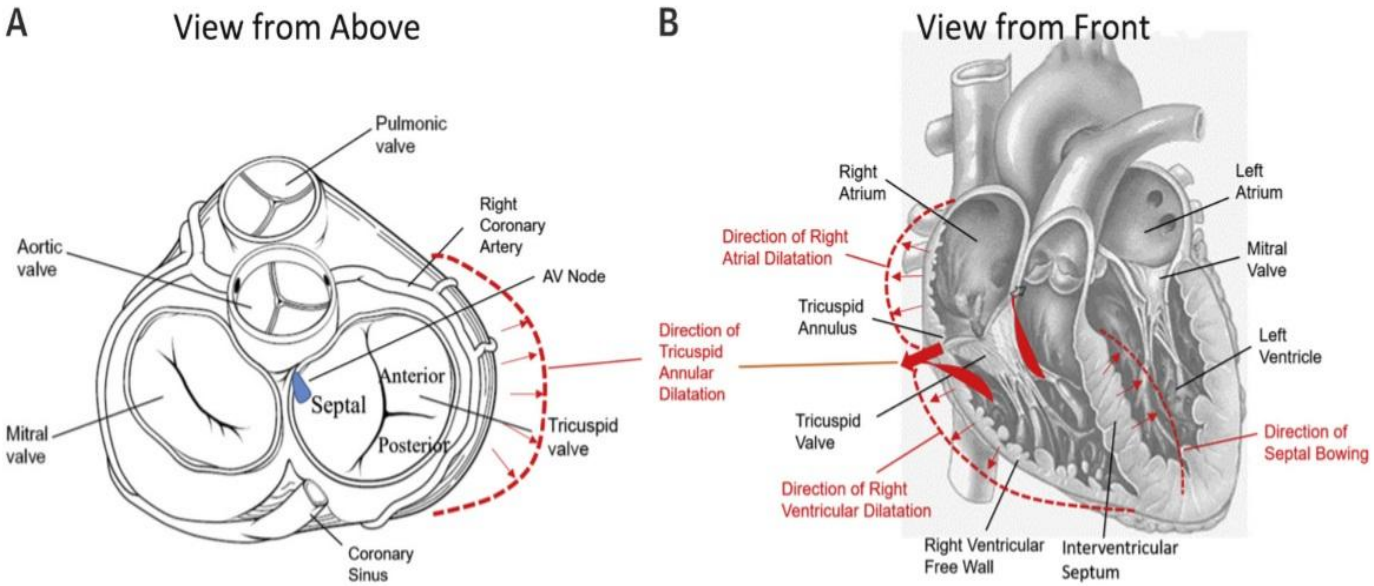
Trikuspidální regurgitace

Není zapomenutá chlopenní vada

- Komplexní struktura chlopně ve srovnání s ostatními
- Obtížné klinické hodnocení symptomů
- Obtížná kvantifikace (výrazně volum dependentní)
- Obtížně zobrazení z TEE
- Obtížné hodnocení funkce pravé komory



Kinno M et al. Cardiac Intervention Today 2018



Dahou, A. et al. J Am Coll Cardiol Img. 2019;12(3):458-68.

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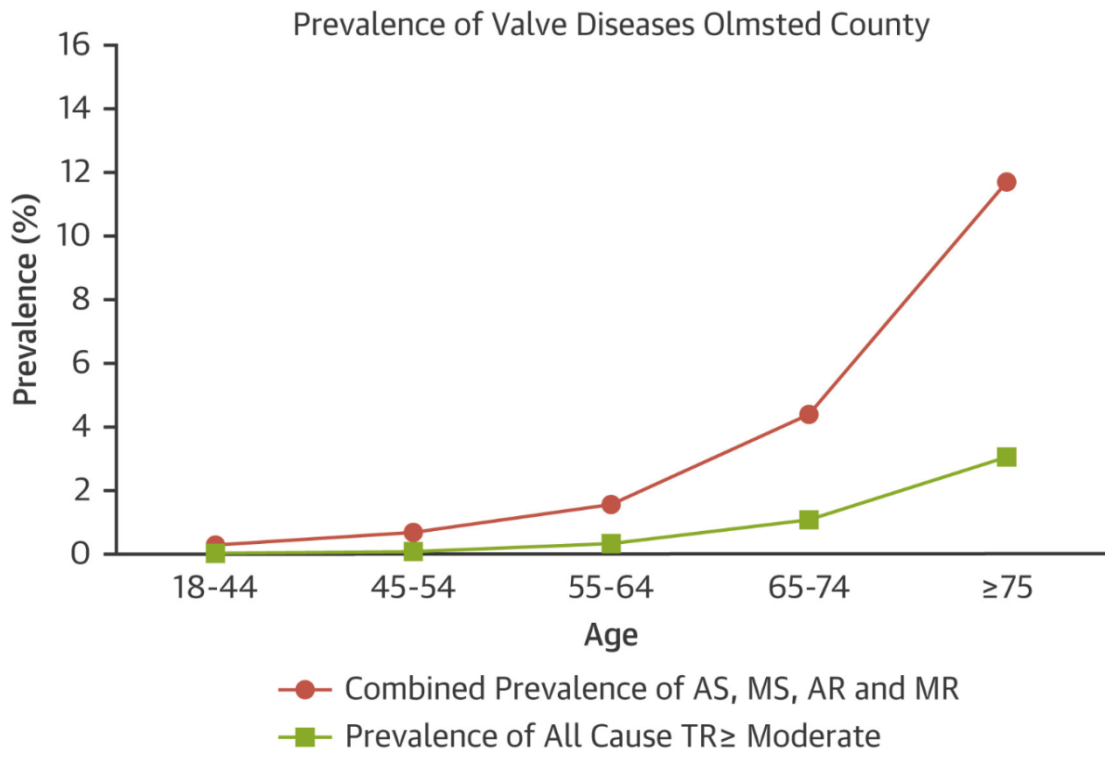
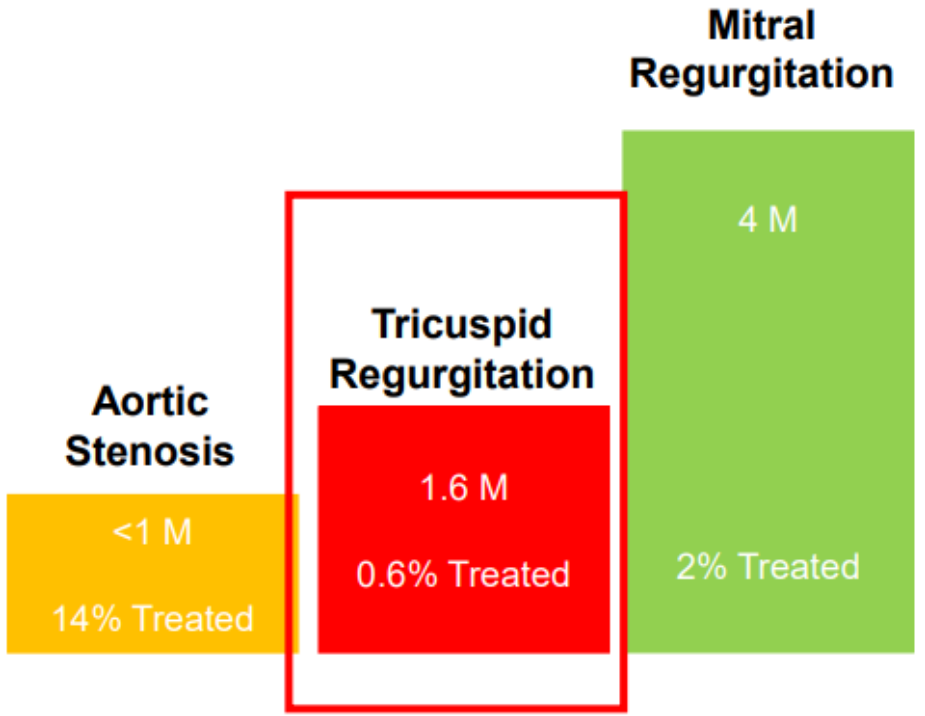
Prevalence trikuspidální regurgitace



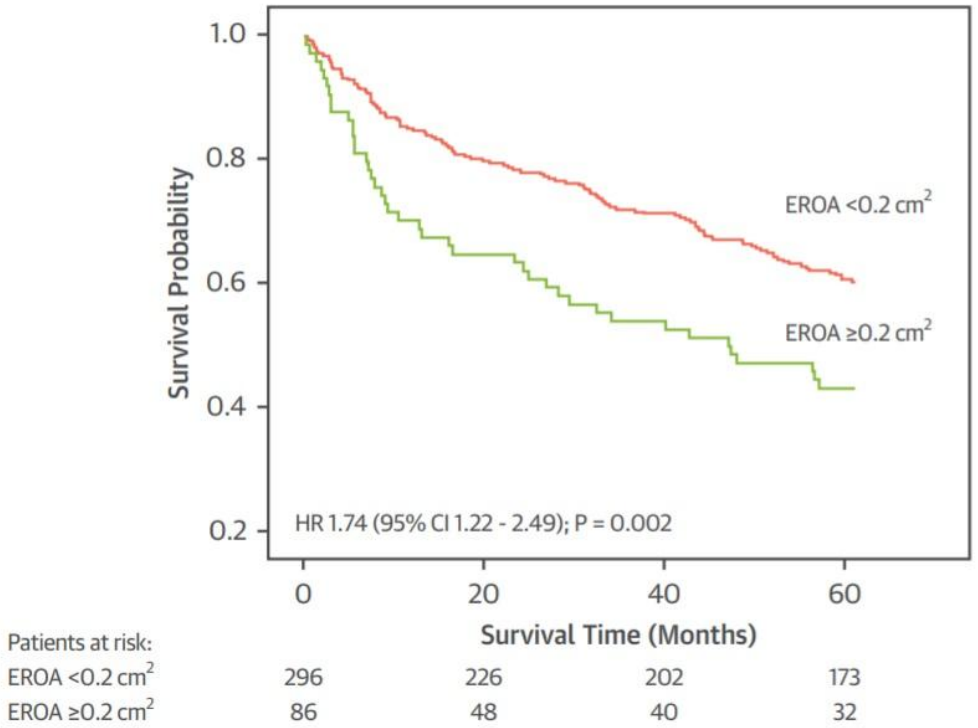
Topilsky Y et al. JACC: Cardiovasc Imag 2019



Nishimura RA al. AHA/ACC guideline for management the patient of valvular heart disease. 2014

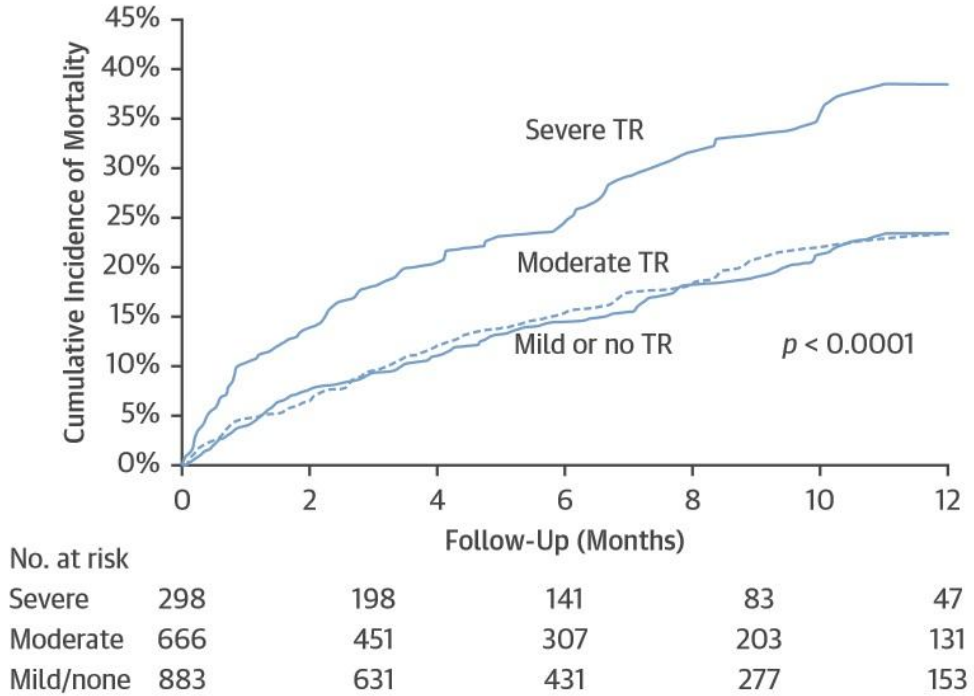
Trikuspidální regurgitace a prognóza

U srdečního selhání HFrEF



Bartko PE et al. JACC Imag 2017

Po katetrizační plastice Mi chlopně



Sorajja P et al. JACC 2017

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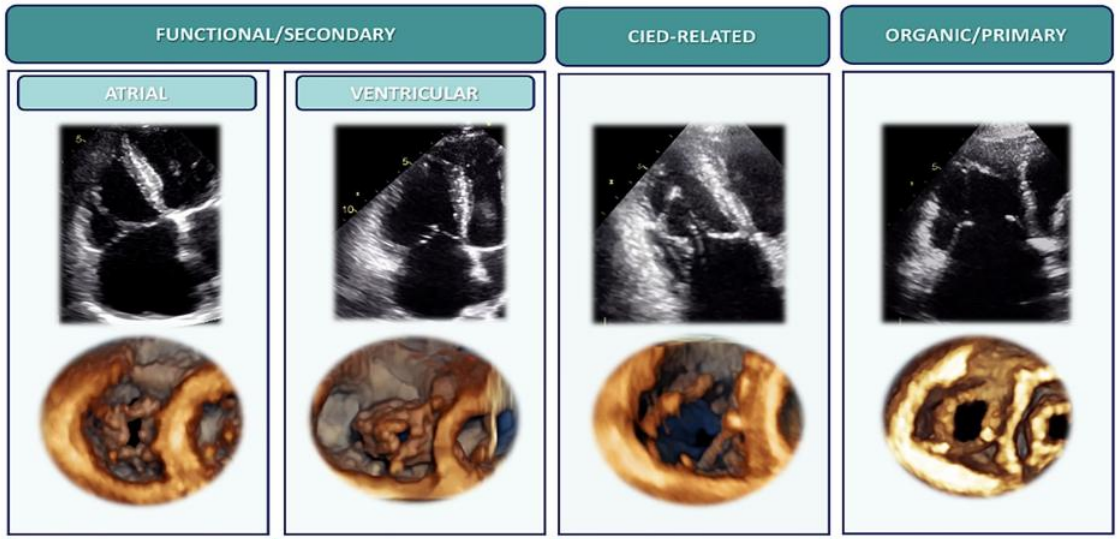
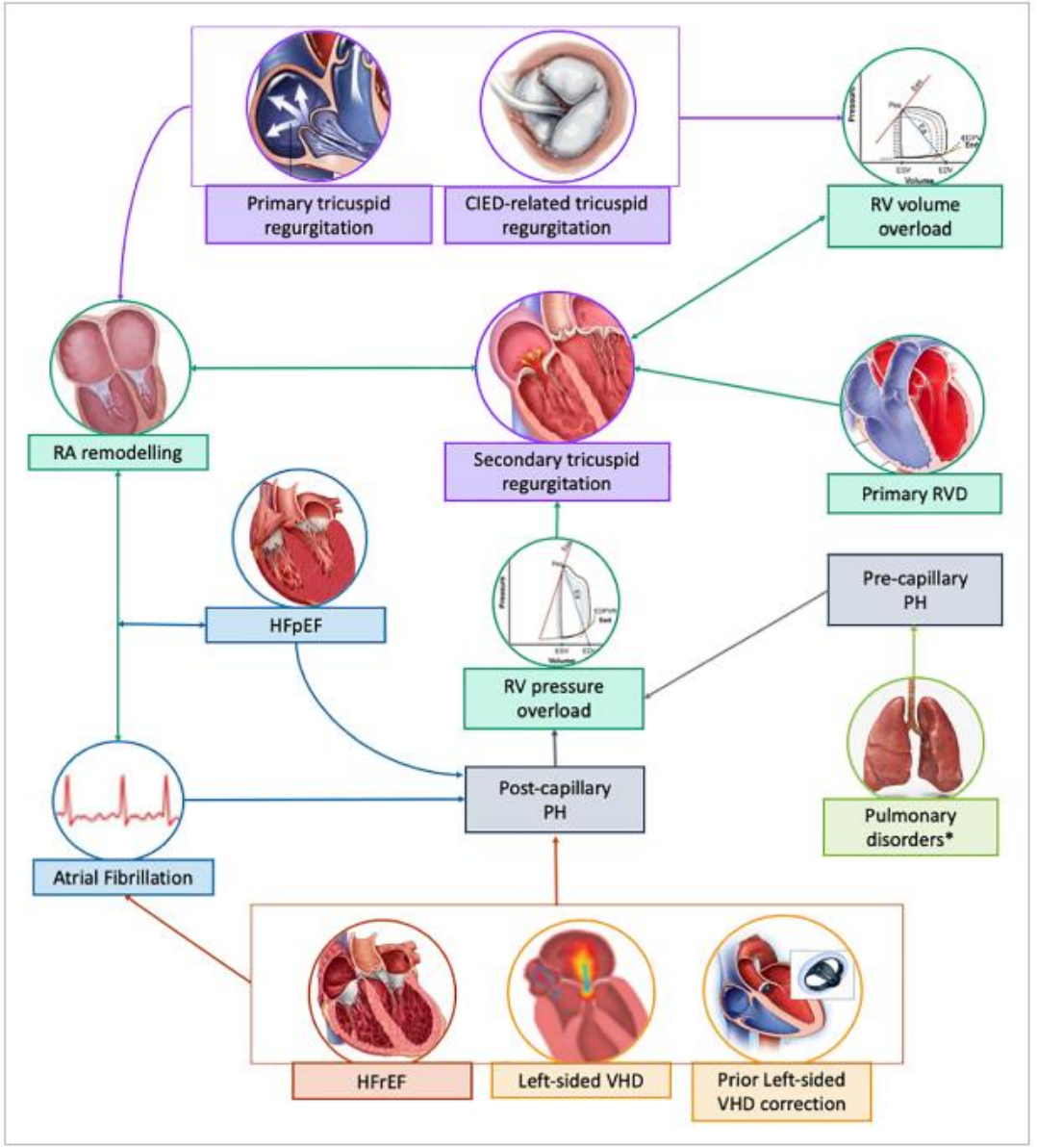
Etiologie a patofyziologie trikuspidální regurgitace



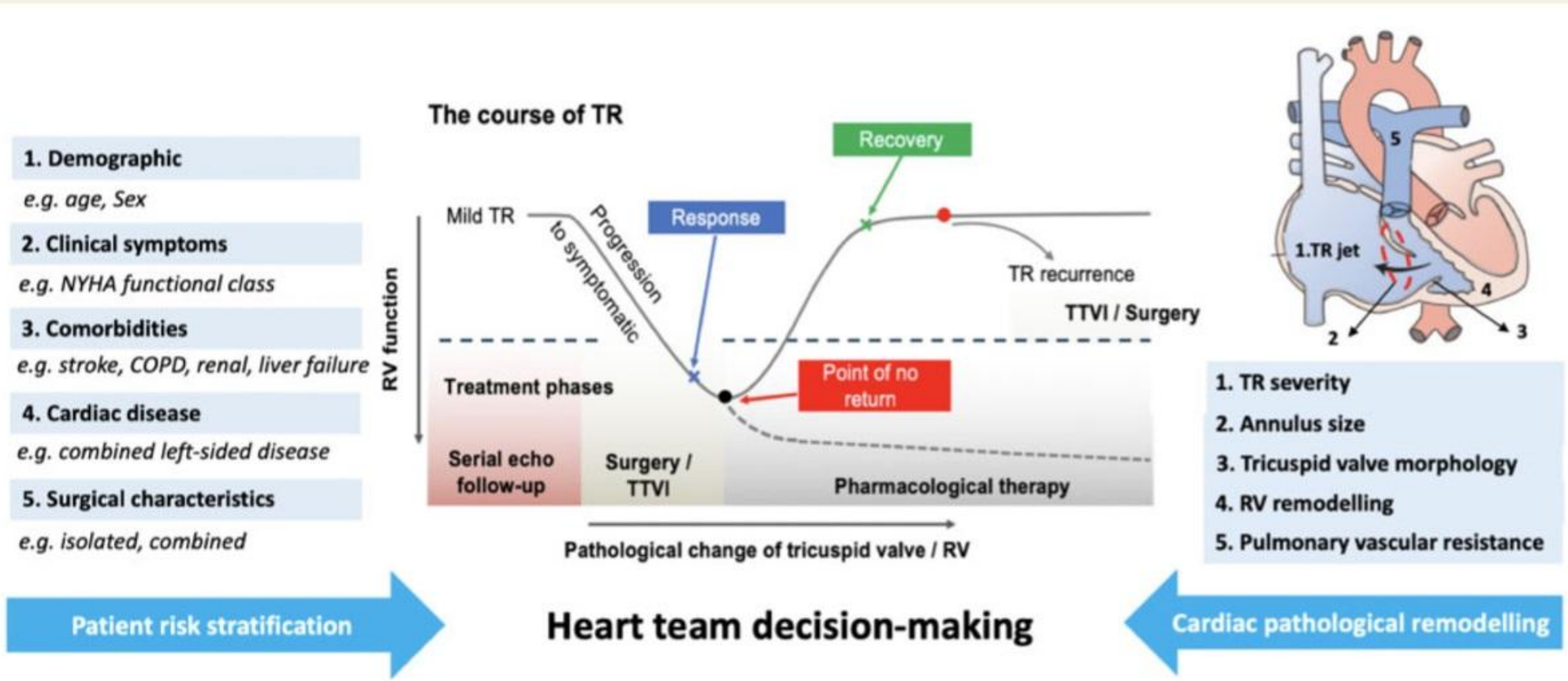
Parameter	Atrial FTR	Ventricular FTR	CIED-Related	Primary TR	
				Prolapse (I)	RHD (IIIA)
Leaflet Tethering	-	+++	++	-	-
Leaflet Restriction	-	Systole	Systole/Diastole	-	Diastole
RA/TA Dilatation	+++	++	+/-	++	++
RV Dilatation	+/-	+++	+/-	+/-	+/-
RV Dysfunction	+/-	+++	+/-	+/-	+/-

Hahn R et al. EHJ Cardiovasc Imaging 2022



Adamo M et al. Eur J Hear Failure 2024

Strategie léčby trikuspidální regurgitace

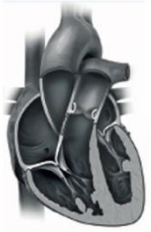
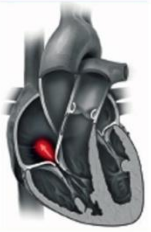
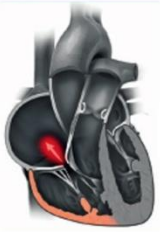
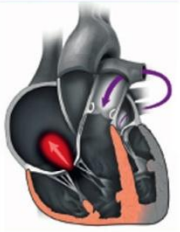
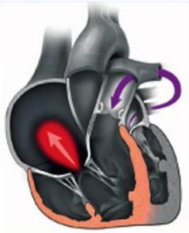


Take home figure Heart team decision-making for treatment of tricuspid regurgitation. COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association; RV, right ventricle; TR, tricuspid regurgitation; TTVI, transcatheter tricuspid valve intervention.

Chang Ch et al. Eur Heart J 2019

Trikuspidální regurgitace - indikace

- Evidence ve srovnání s dalšími chlopenními vadami je velmi malá
- Existují indikace k chirurgické léčbě při současné operaci srdce nebo v případě symptomatické primární regurgitace
- Jednoznačná klinická evidence o prospěchu chirurgické léčby u izolované sekundární trikuspidální regurgitace chybí
- Pacienti stadia 2-5 jsou v současné době předmětem řady studií
  - Symptomatická TriR přes diuretickou léčbu
  - Symptomatická TriR s nutností hospitalizace pro srdeční selhání
  - TriR se současnou dilatací a případně nově vznikou dysfunkcí PK

	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
					
Symptoms	None	None*	None-vague*	Current or previous episodes of RHF	Overt RHF and/or end-organ damage due to chronic RV volume overload#
TR grade	Less than moderate	>Moderate	Severe	Severe	Torrential
Annular remodeling	Normal	Normal or mildly remodeled	Present	Moderate-severe	Severe
Leaflet coaptation	Normal	Mildly abnormal	Abnormal	Coaptation gap	Large coaptation gap
Tethering	None	None or mildly abnormal (<8 mm)	Abnormal (usually <8 mm)	Significantly abnormal with varying degree of tethering	Significantly abnormal (usually >8 mm)
RV function and remodeling	Normal	Normal function Absent or mild remodeling	Mild RV dysfunction and/or remodeling	>Moderate dysfunction and remodeling	Severe RV dysfunction and remodeling
Medical	No treatment but regular clinical and echo follow-up in patients with high likelihood of developing TR progression such as those in Table 1	None or low-dose diuretics	Diuretics	Moderate to high-dose diuretics and/or requirement for IV diuretics	Multiple admissions for RHF. Frequent need for IV diuretics and/or high-dose combination diuretics
Surgical treatment	No	Consider TV surgery (preferably repair) at time of left-sided surgery	TV surgery (preferably repair) at time of left-sided surgery. Isolated TV surgery (preferably repair) in presence of symptoms or progressive RV remodeling and comorbidities	Isolated TV surgery (repair or replacement) either isolated or at time of left-sided surgery in the absence of severe pulmonary hypertension and severe comorbidities. High risk of perioperative RV dysfunction.	Prohibitive intra- and peri-operative risk
Percutaneous treatment	No	Potential future target for percutaneous options as minimally invasive option could change natural history with minimal risk	Potential candidates for isolated TR surgery who could be enrolled in upcoming IDE RCTs	Current group of patients being treated in EFS if high-risk for surgery. May require combination of annuloplasty and leaflet device or TVR	Prohibitive risk and potentially futile. (Palliative procedures can be considered in highly selected patients)

Taramasso M et al. JACC Cardiovasc Imag 2019

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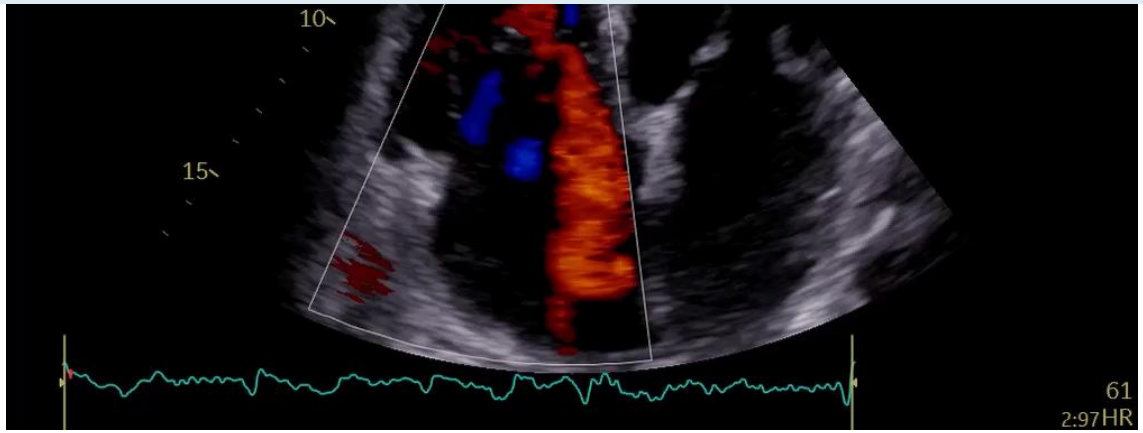
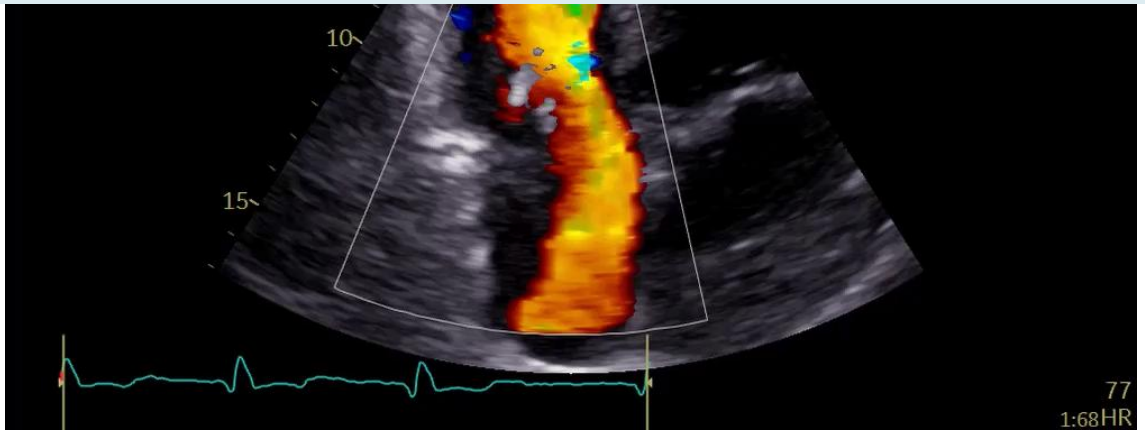
„Nová klasifikace trikuspidální regurgitace“

Table I **Proposed expansion of the ‘Severe’ grade**

Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7–13 mm	14–20 mm	≥21 mm
EROA (PISA)	<20 mm^2	20–39 mm^2	40–59 mm^2	60–79 mm^2	≥80 mm^2
3D VCA or quantitative EROA[a]			75–94 mm^2	95–114 mm^2	≥115 mm^2

VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.
[a]3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.





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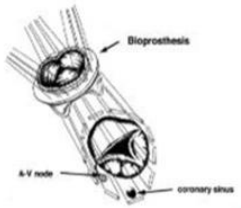
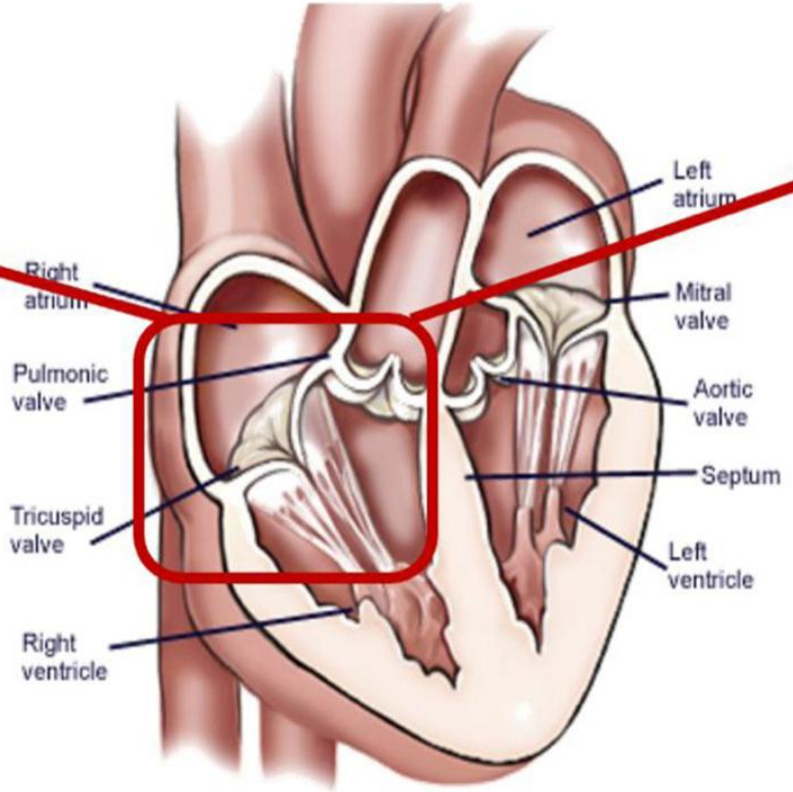
Možnosti léčby trikuspidální regurgitace

Surgical treatment

Severe isolated TR
- Mild symptomatology
- Mild RV dysfunction/remodeling
- No pulmonary hypertension
- No end-organ involvement
- Low-dose diuretic therapy

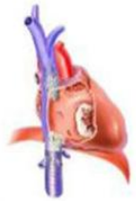
Mild-moderate TR
- Concomitant to left-sided valve surgery
- Annular dilation

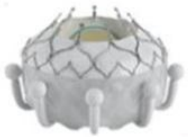




Transcatheter treatment

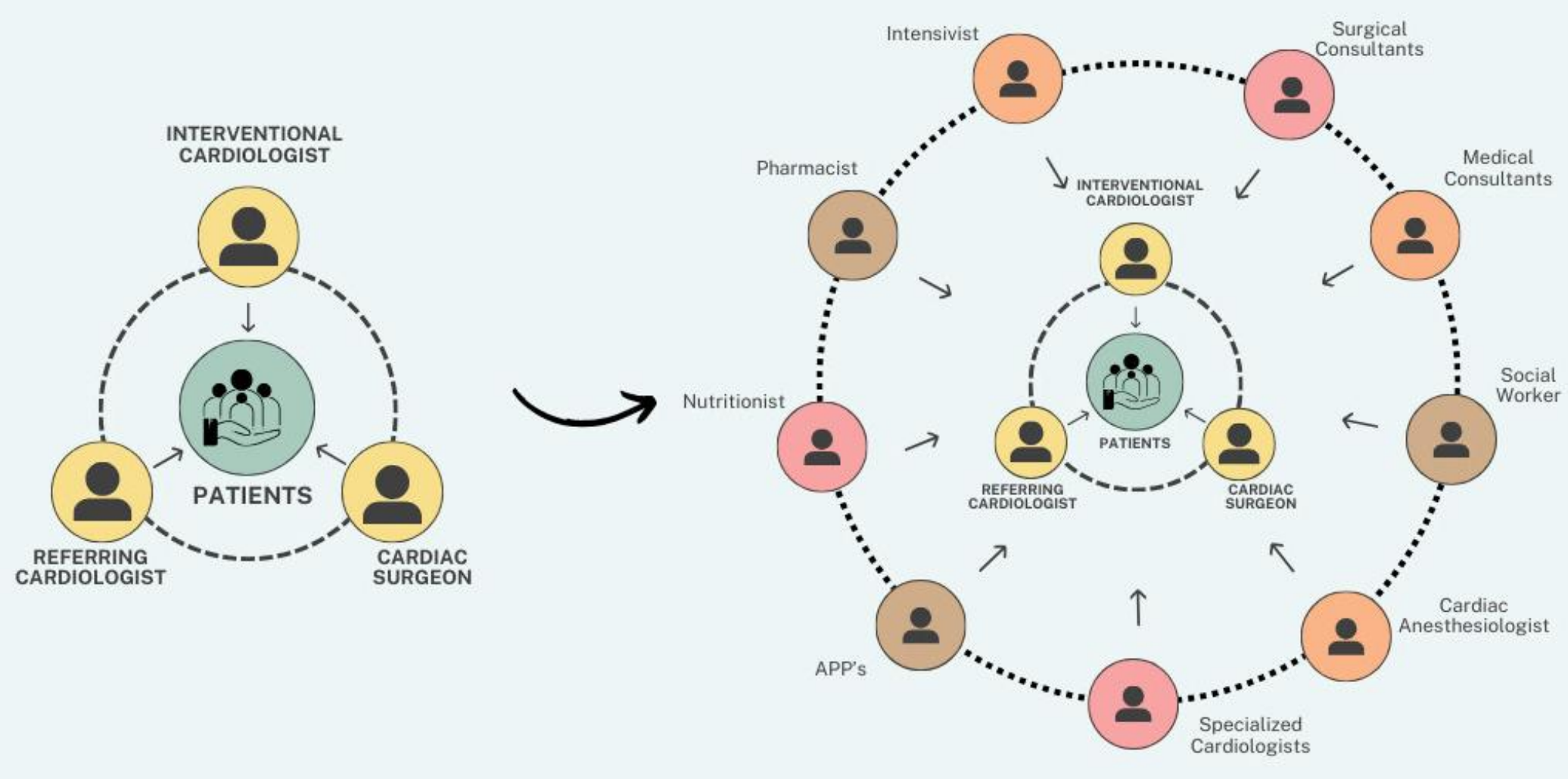
Severe TR
- Marked symptomatology
- Moderate RV dyfunction/remodeling
- No pulmonary hypertension
- Mild end-organ involvement
- Optimal medical therapy
- Concomitant to transcatheter mitral valve repair procedures





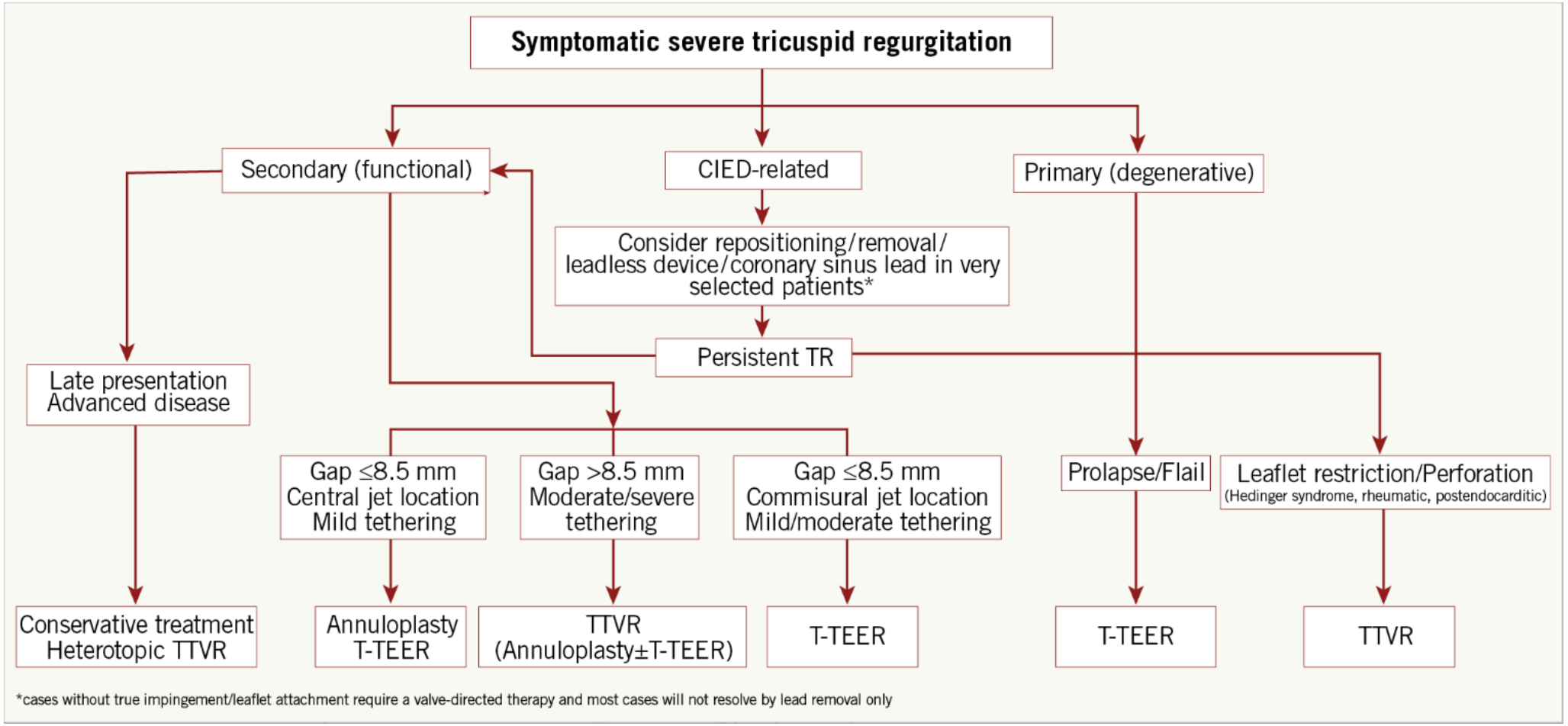
Sala A et al. J Soc CV Angio and Interv 2023

Heart team - rozhodnutí o způsobu léčby



Riojas RA et al. Vessel Plus 2024

Algoritmus katetrizační léčby trikuspidální regurgitace

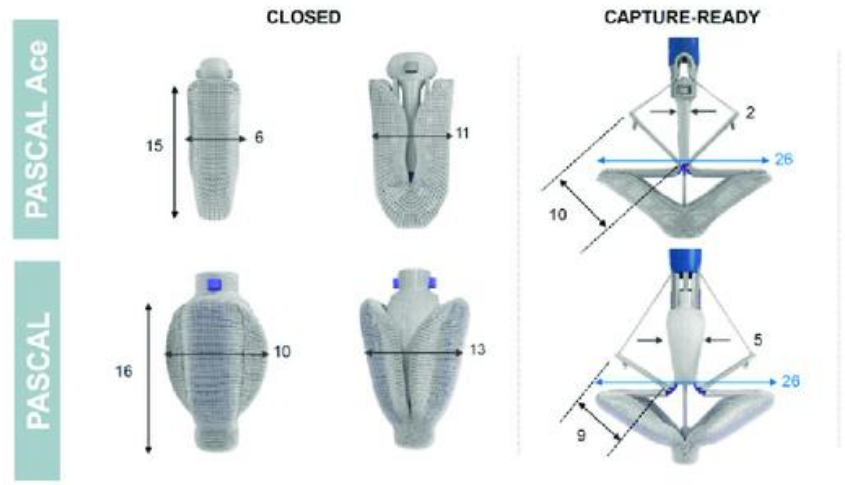


Praz F et al. EuroIntervention 2021

Katetrizační plastika cípů (TEER)

- **Nejběžnější způsob katetrizační léčby trikuspidální chlopně**
- Princip podobný jako u ošetření mitrální chlopně (klipy většinou do antero-septální a postero-septální komisury)
- TriClip (Abbott) – mírně upravený zaváděcí systém MitraClip – 2 klipy (4)
- Pascal (Edwards Lifesciences) – stejný systém, klip ACE
- **Nevýhody:**
  - závislý na kvalitě zobrazení
  - nevhodný pro pacienty s velkou ztrátou koaptace (gap ≥ 8,5 mm)

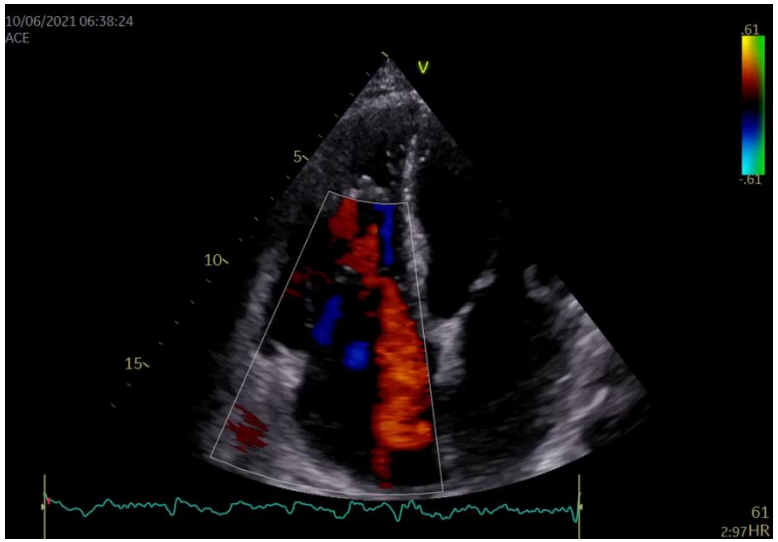
zdroj Abbott

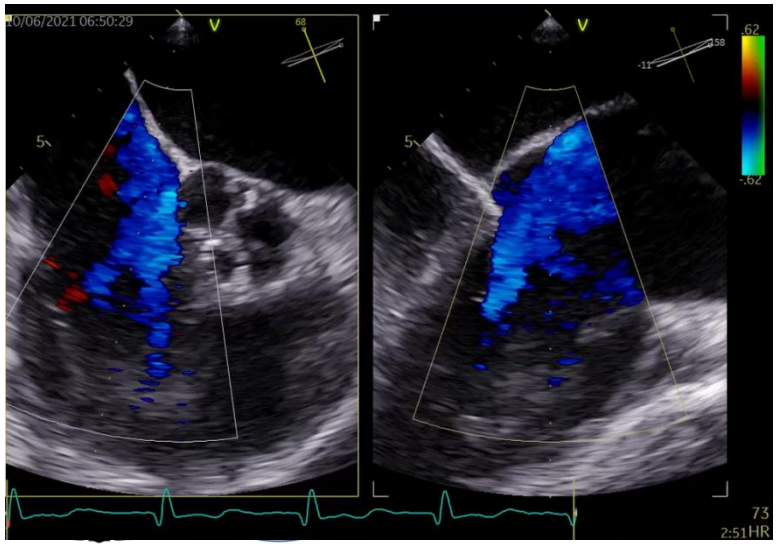


zdroj Edwards Lifesciences

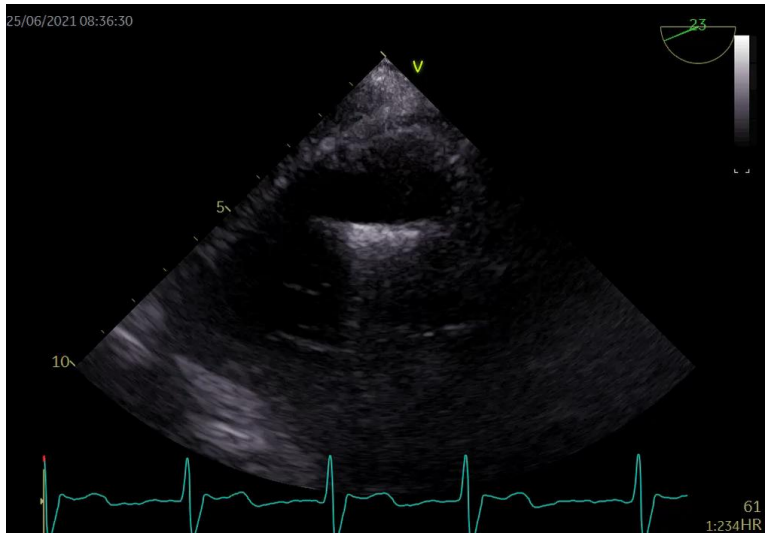
Plastika cípů trikuspidální chlopně pomocí Pascal

Těžká trikuspidální regurgitace





Umístění klipu v P-S komisuře



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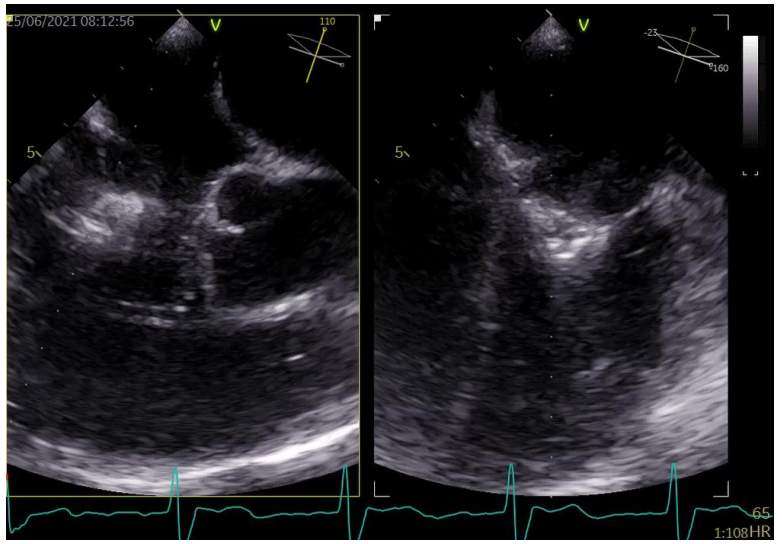
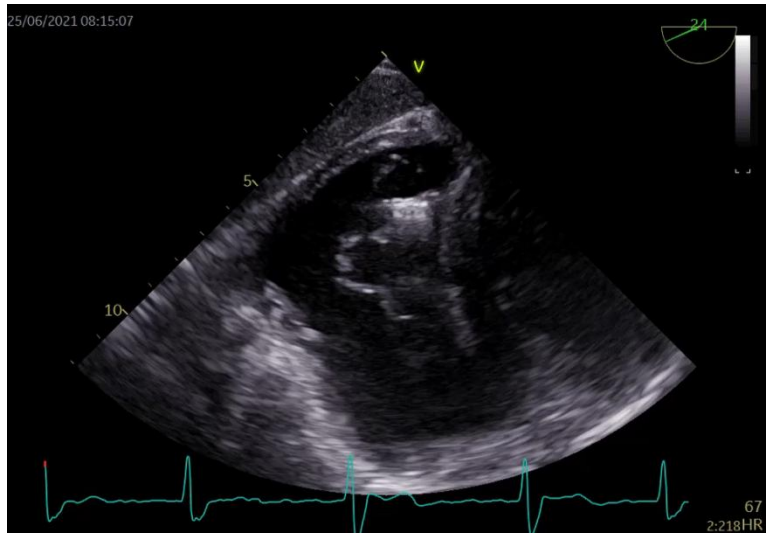
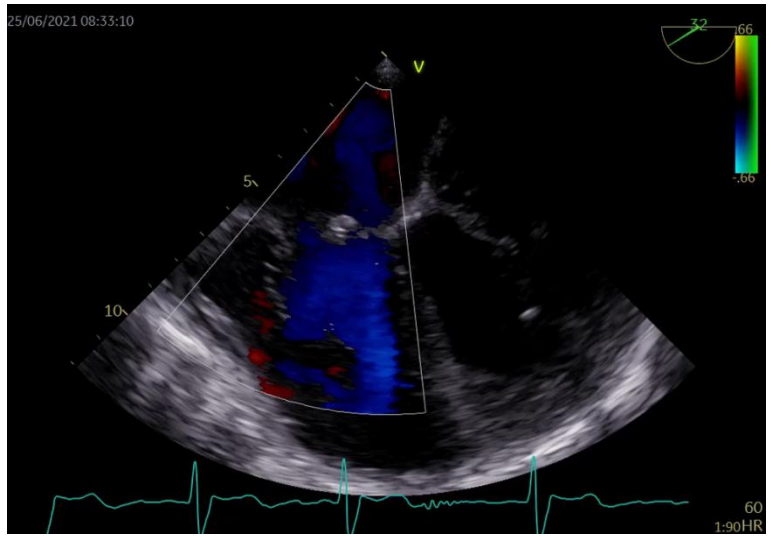


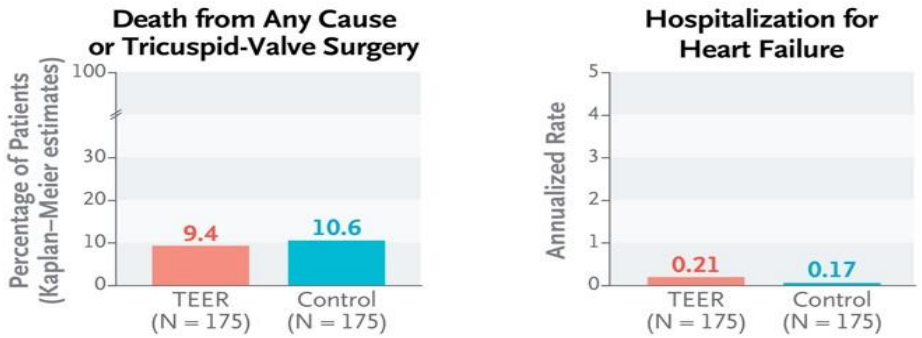
Finální výsledek

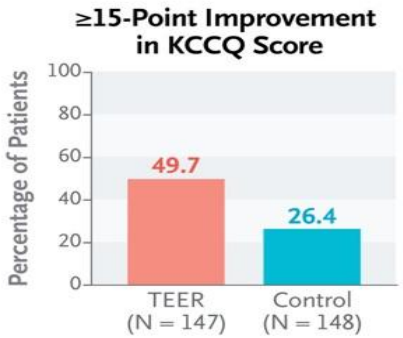




TRILUMINATE study

	TEER Group (N = 175)	Control Group (N = 175)
Hierarchical composite — no. of wins	11,348	7643





BACKGROUND

Severe tricuspid regurgitation is a debilitating condition that is associated with substantial morbidity and often with poor quality of life. Decreasing tricuspid regurgitation may reduce symptoms and improve clinical outcomes in patients with this disease.

METHODS

We conducted a prospective randomized trial of percutaneous tricuspid transcatheter edge-to-edge repair (TEER) for severe tricuspid regurgitation. Patients with symptomatic severe tricuspid regurgitation were enrolled at 65 centers in the United States, Canada, and Europe and were randomly assigned in a 1:1 ratio to receive either TEER or medical therapy (control). The primary end point was a hierarchical composite that included death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and an improvement in quality of life as measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ), with an improvement defined as an increase of at least 15 points in the KCCQ score (range, 0 to 100, with higher scores indicating better quality of life) at the 1-year follow-up. The severity of tricuspid regurgitation and safety were also assessed.

RESULTS

A total of 350 patients were enrolled; 175 were assigned to each group. The mean age of the patients was 78 years, and 54.9% were women. The results for the primary end point favored the TEER group (win ratio, 1.48; 95% confidence interval, 1.06 to 2.13; P=0.02). The incidence of death or tricuspid-valve surgery and the rate of hospitalization for heart failure did not appear to differ between the groups. The KCCQ quality-of-life score changed by a mean (±SD) of 12.3±1.8 points in the TEER group, as compared with 0.6±1.8 points in the control group (P<0.001). At 30 days, 87.0% of the patients in the TEER group and 4.8% of those in the control group had tricuspid regurgitation of no greater than moderate severity (P<0.001). TEER was found to be safe; 98.3% of the patients who underwent the procedure were free from major adverse events at 30 days.

CONCLUSIONS

Tricuspid TEER was safe for patients with severe tricuspid regurgitation, reduced the severity of tricuspid regurgitation, and was associated with an improvement in quality of life. (Funded by Abbott; TRILUMINATE Pivotal ClinicalTrials.gov number, NCT03904147.)

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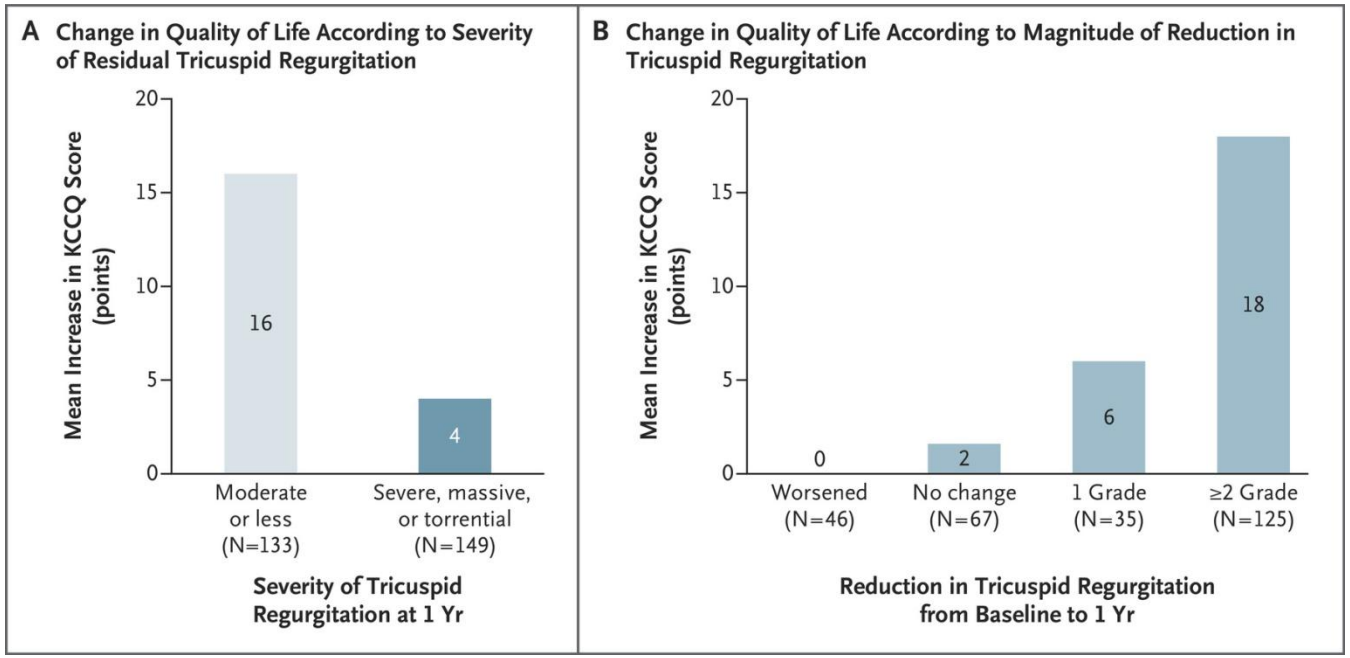
Sorajja P et al. NEJM 2023

TRILUMINATE study

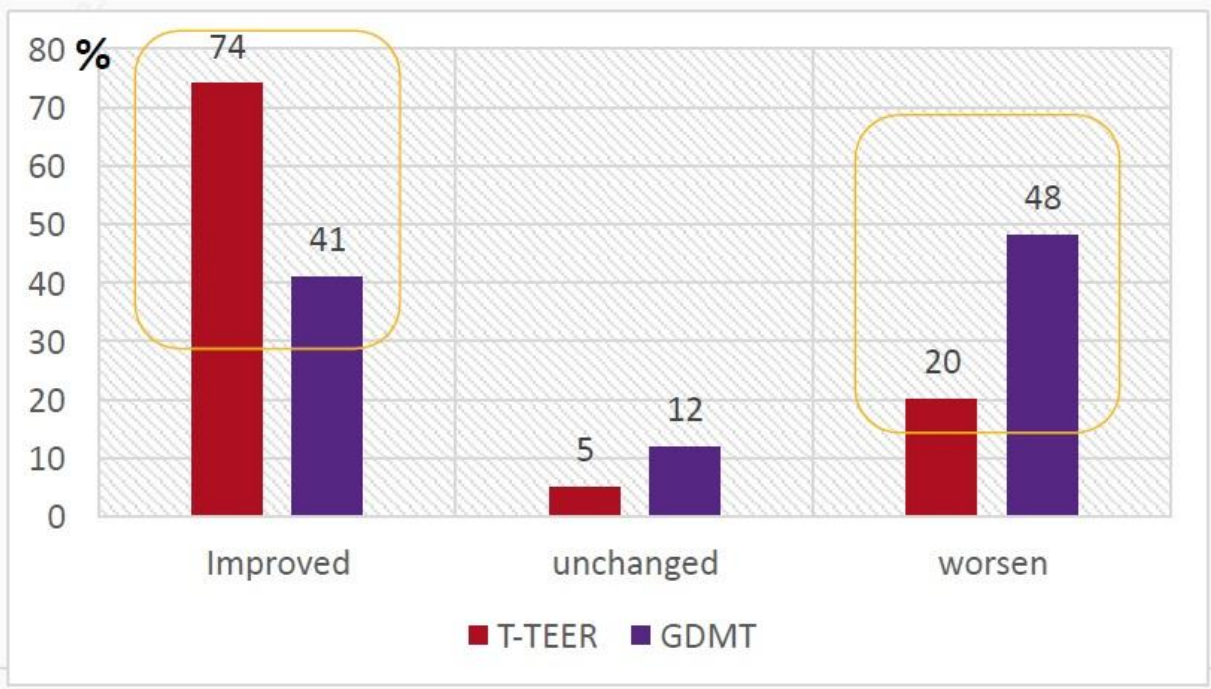


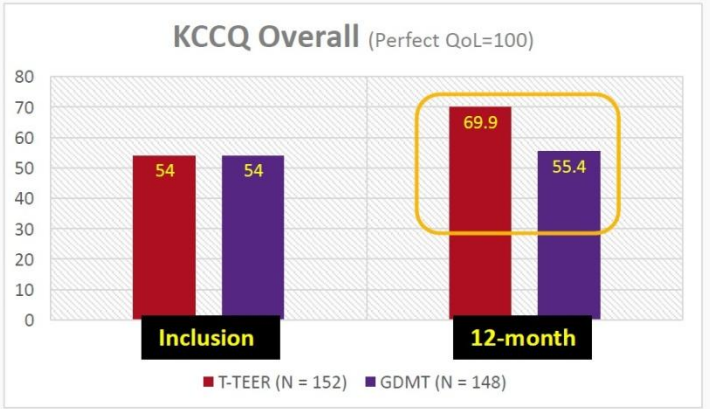
Subgroup	No. of Patients	TEER Group	Control Group	Odds Ratio (95% Confidence Interval)
		patients with ≥15-point improvement in KCCQ/total no. (%)		
All Patients	295	73/147 (49.7)	39/148 (26.4)	2.76 (1.69–4.49)
Age				
<78 yr	140	37/71 (52.1)	13/69 (18.8)	4.69 (2.19–10.05)
≥78 yr	155	36/76 (47.4)	26/79 (32.9)	1.83 (0.96–3.52)
Sex				
Male	126	24/60 (40.0)	11/66 (16.7)	3.33 (1.46–7.63)
Female	169	49/87 (56.3)	28/82 (34.1)	2.49 (1.33–4.64)
Tricuspid regurgitation severity				
Grade 3	85	22/40 (55.0)	10/45 (22.2)	4.28 (1.67–10.94)
Grade 4	56	13/33 (39.4)	5/23 (21.7)	2.34 (0.70–7.86)
Grade 5	139	36/69 (52.2)	18/70 (25.7)	3.15 (1.54–6.44)
New York Heart Association class				
I or II	138	23/68 (33.8)	12/70 (17.1)	2.47 (1.11–5.49)
III or IV	157	50/79 (63.3)	27/78 (34.6)	3.26 (1.69–6.26)
Hospitalization for heart failure within the past year				
No	230	54/117 (46.2)	28/113 (24.8)	2.60 (1.49–4.56)
Yes	65	19/30 (63.3)	11/35 (31.4)	3.77 (1.35–10.56)
Kidney disease				
No	199	53/101 (52.5)	25/98 (25.5)	3.22 (1.77–5.87)
Yes	96	20/46 (43.5)	14/50 (28.0)	1.98 (0.85–4.62)
Previous mitral or aortic intervention				
No	189	45/90 (50.0)	26/99 (26.3)	2.81 (1.53–5.16)
Yes	106	28/57 (49.1)	13/49 (26.5)	2.67 (1.18–6.07)
KCCQ				
<50	118	42/53 (79.2)	28/65 (43.1)	5.05 (2.21–11.52)
≥50	177	31/94 (33.0)	11/83 (13.3)	3.22 (1.50–6.93)
6-min walk distance				
<240 m	121	33/61 (54.1)	22/60 (36.7)	2.04 (0.98–4.21)
≥240 m	164	37/79 (46.8)	14/85 (16.5)	4.47 (2.17–9.21)
Left ventricular ejection fraction				
<50%	33	12/19 (63.2)	4/14 (28.6)	4.29 (0.97–18.97)
≥50%	234	55/118 (46.6)	30/116 (25.9)	2.50 (1.44–4.34)
Right ventricular end-diastolic dimension				
<5 cm	133	37/71 (52.1)	18/62 (29.0)	2.66 (1.30–5.46)
≥5 cm	156	35/75 (46.7)	18/81 (22.2)	3.06 (1.53–6.12)
Right atrial volume				
<150 ml	186	50/101 (49.5)	24/85 (28.2)	2.49 (1.35–4.60)
≥150 ml	103	22/45 (48.9)	12/58 (20.7)	3.67 (1.55–8.69)
Tricuspid annular plane systolic excursion				
<1.7 cm	151	36/72 (50.0)	21/79 (26.6)	2.76 (1.40–5.45)
≥1.7 cm	134	36/74 (48.6)	13/60 (21.7)	3.43 (1.59–7.36)
Central venous pressure				
<10 mm Hg	66	17/35 (48.6)	6/31 (19.4)	3.94 (1.30–11.95)
≥10 mm Hg	99	22/44 (50.0)	17/55 (30.9)	2.24 (0.98–5.09)
Mean pulmonary artery pressure				
<25 mm Hg	138	34/74 (45.9)	11/64 (17.2)	4.10 (1.85–9.06)
≥25 mm Hg	157	39/73 (53.4)	28/84 (33.3)	2.29 (1.20–4.38)
Cardiac output				
<4 liters/min	96	26/44 (59.1)	14/52 (26.9)	3.92 (1.66–9.25)
≥4 liters/min	198	47/103 (45.6)	24/95 (25.3)	2.48 (1.36–4.54)

Sorajja P et al. NEJM 2023

Tri.Fr study

Randomizovaná studie srovnávající T-TEER a optimální farmakologickou léčbu u pacientů se těžkou trikuspidální regurgitací (300 pacientů, 1:1)

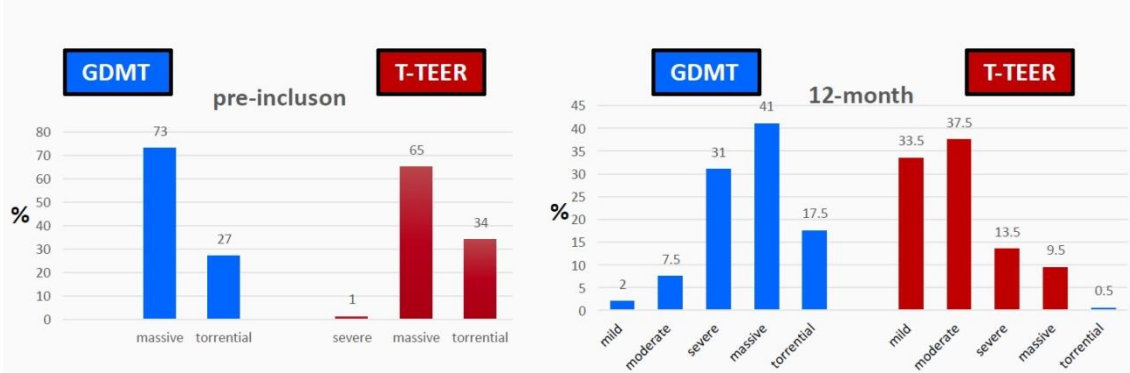




Overall KCCQ Summary Score at the 1-year follow-up:

T-TEER (69.9 ± 25.5) vs. control group (55.4 ± 28.8)

Absolute difference = 14.5±27.2, p<0.001



Donal E et al. JAMA 2025

Ortotopická implantace chlopně

Animace implantace chlopně Evoque

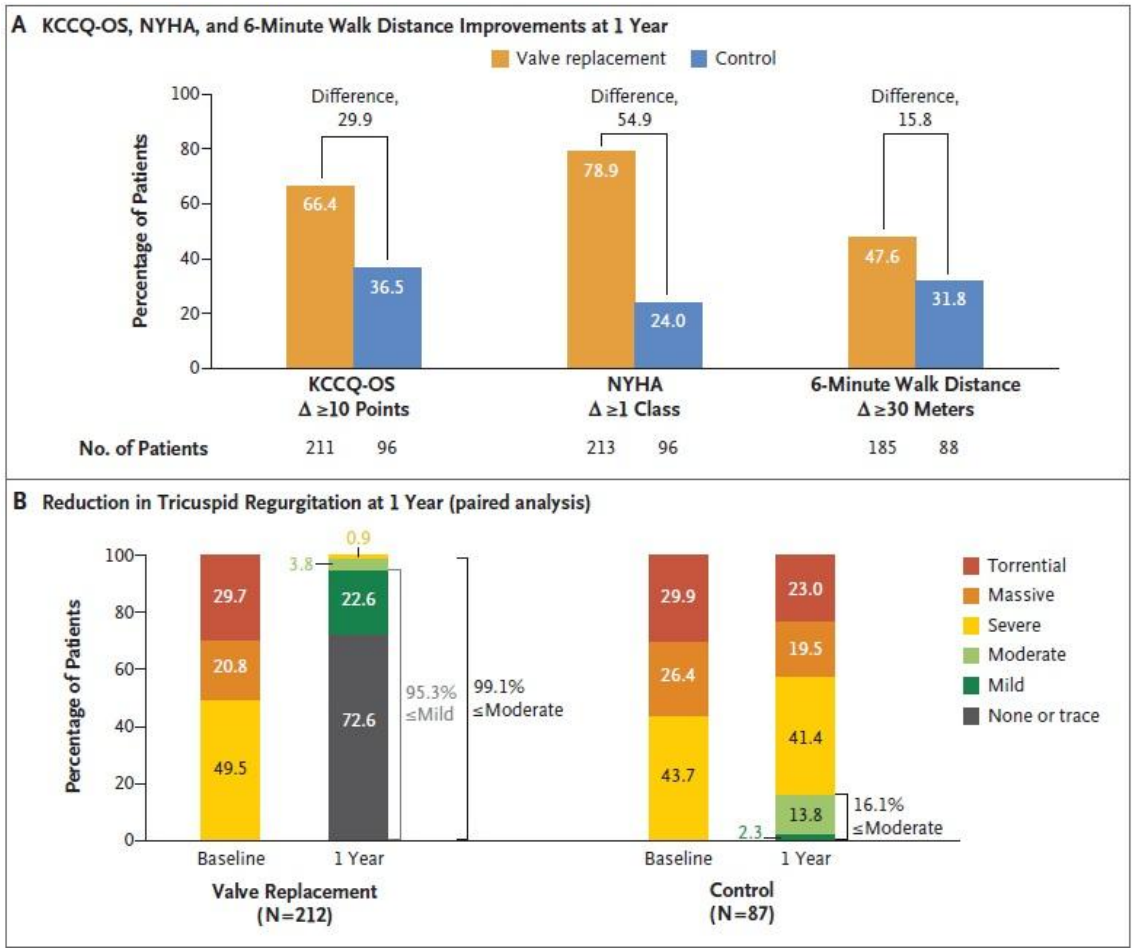
- **Výhody:**
  - fyziologické
  - prakticky bez regurgitace
- **Nevýhody:**
  - riziko AV bloku
  - degenerace bioprotézy, trombóza
  - selhání pravé komory
- Specifická situtace – „valve-in-valve“ a „valve-in-ring“

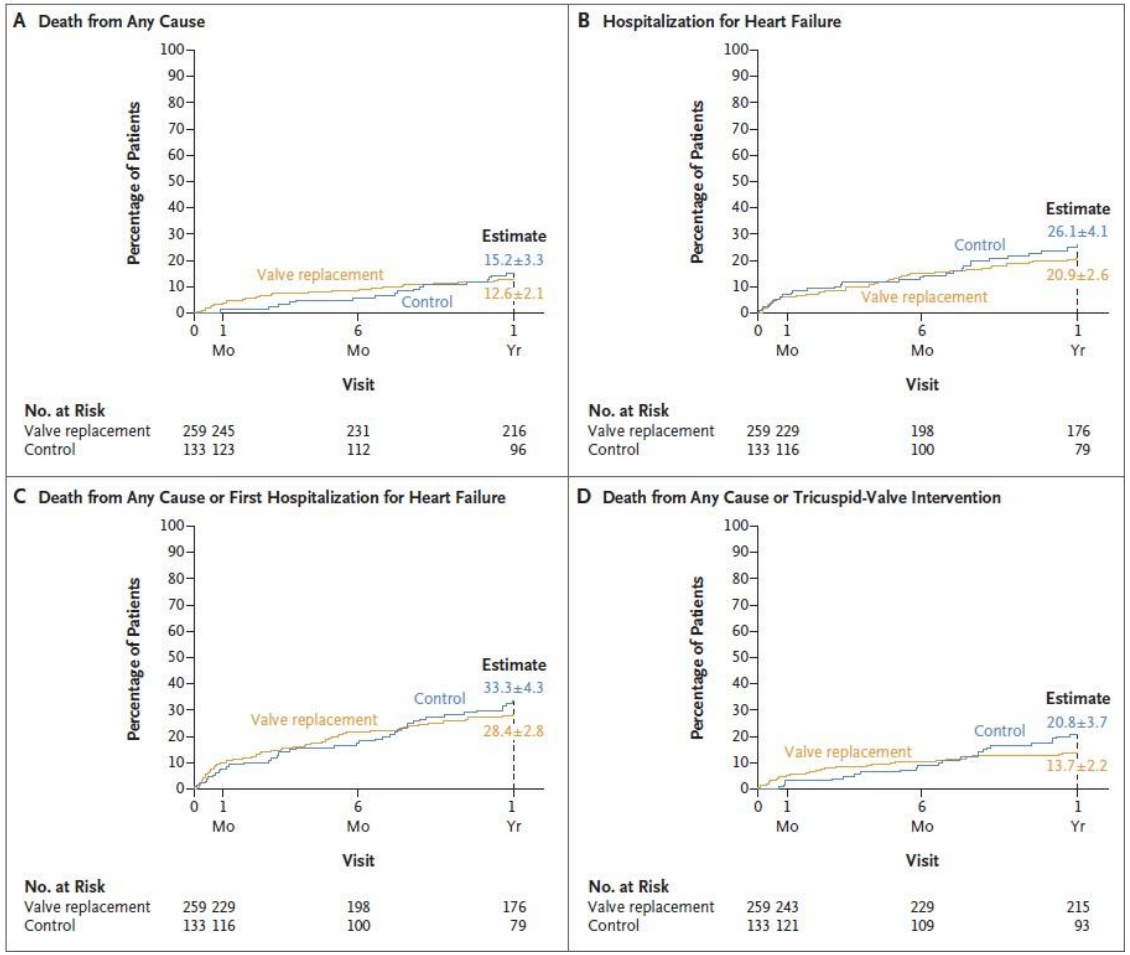
Edwards

zdroj Edwards Lifesciences

TRISCEND II study

Randomizovaná studie srovnávající TTVI a optimální farmakologickou léčbu u pacientů se těžkou trikuspidální regurgitací (400 pacientů, 2:1)



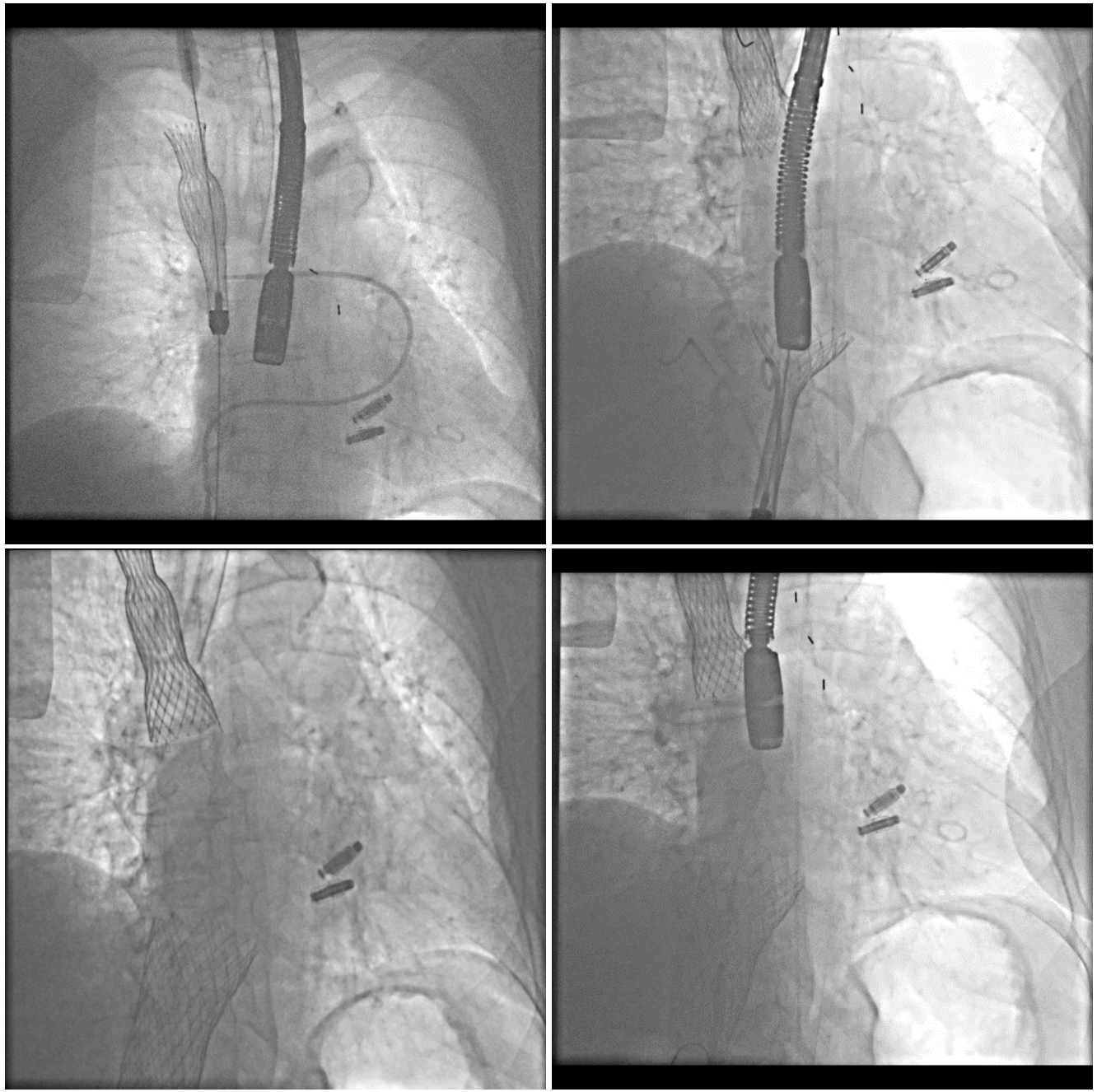


Hahn RT al. NEJM 2025

Heterotopická implantace chlopně

- **Výhody:**
  - není závislá na kvalitě zobrazení trikuspidální chlopně
  - může být zhoršená systolická funkce pravé komory (?)
- **Nevýhody:**
  - není to fyziologické
  - limitace rozměrem chlopní
  - nutnost antikoagulační léčby
  - limitovaná data

Implantace chlopně TricValve



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TRICUS study

ABSTRACT

BACKGROUND Several orthotopic transcatheter strategies have been developed to treat severe tricuspid regurgitation (TR); however, many patients are deemed unsuitable. Caval valve implantation with the TricValve system addresses this unmet need.

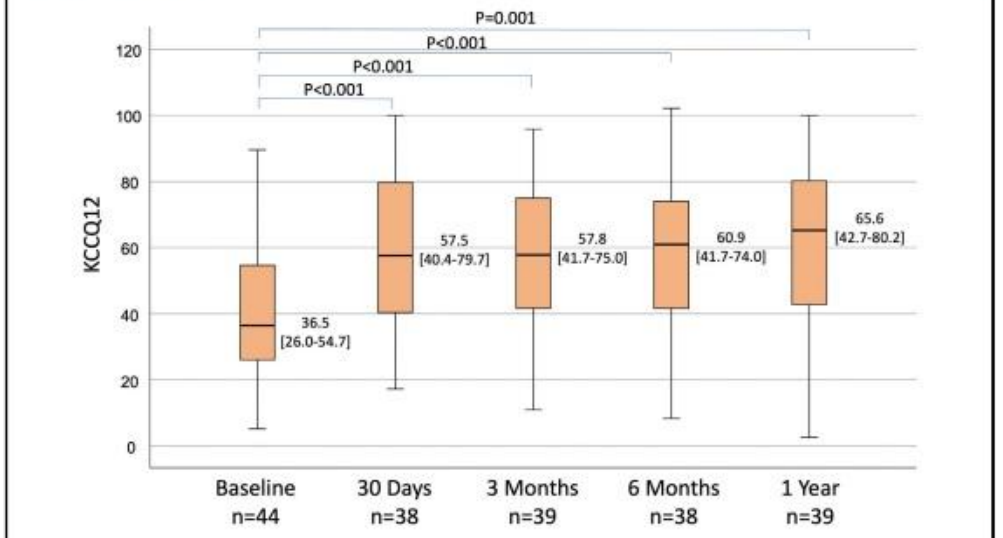
OBJECTIVES The study sought to determine the impact of TricValve on systemic congestion and quality of life (QOL) at 1 year.

METHODS The TRICUS (Safety and Efficacy of the TricValve® Transcatheter Bicaval Valves System in the Superior and Inferior Vena Cava in Patients With Severe Tricuspid Regurgitation) and TRICUS EURO studies were prospective, non-blinded, nonrandomized, single-arm trials representing the early-in-man experience of the TricValve system in NYHA functional class III or IV severe TR patients, optimally medicated and ineligible for open heart surgery, with significant caval backflow. The primary endpoint was QOL metrics and functional status. The 1-year results of the combined cohort are described here.

RESULTS Forty-four patients were included. Mean age was 76.2 ± 7.5 years, 81.0% were women, and the TRISCORE (risk score model for isolated tricuspid valve surgery) was 5.3 ± 1.3. Clinical improvement at 1 year was achieved in 42 (95.5%) patients, measured by (at least 1 of) an increase in ≥15 points from baseline in 12-item Kansas City Cardiomyopathy Questionnaire score, improvement to NYHA functional class to I or II, or an increase ≥40 m in the 6-minute walk test. There were 3 (6.8%) deaths at 1-year follow-up (1 cardiovascular), and the heart failure rehospitalization rate was 29.5%. Stent fracture, conduction system disturbances, or clinically significant leaflet thrombosis were not detected. Abolished hepatic vein backflow was achieved and persisted in 63.8% of the patients, contributing towards a reduction in congestive symptoms, N-terminal pro-B-type natriuretic peptide levels ($P = 0.032$), and diuretic treatment.

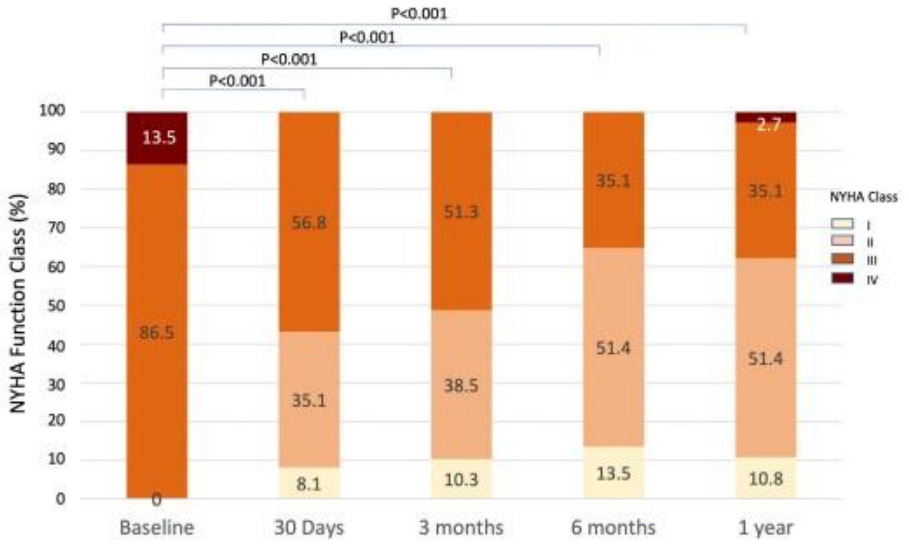
CONCLUSIONS Caval valve implantation with the TricValve system associated with meaningful 1-year clinical improvements in terms of QOL along with relatively low mortality rates. (TRICUS Study - Safety and Efficacy of the TricValve® Device; NCT03723239). (J Am Coll Cardiol Intv 2023;■:■-■) © 2023 by the American College of Cardiology Foundation.

FIGURE 1 KCCQ-12 Score



Baseline and 30-day, 3-month, 6-month, and 1-year follow-up in the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ-12) score. Values are median (Q1-Q3).

FIGURE 2 NYHA Functional Class



Baseline and 30-day, 3-month, 6-month, and 1-year follow-up in NYHA functional class. Data are presented as %.

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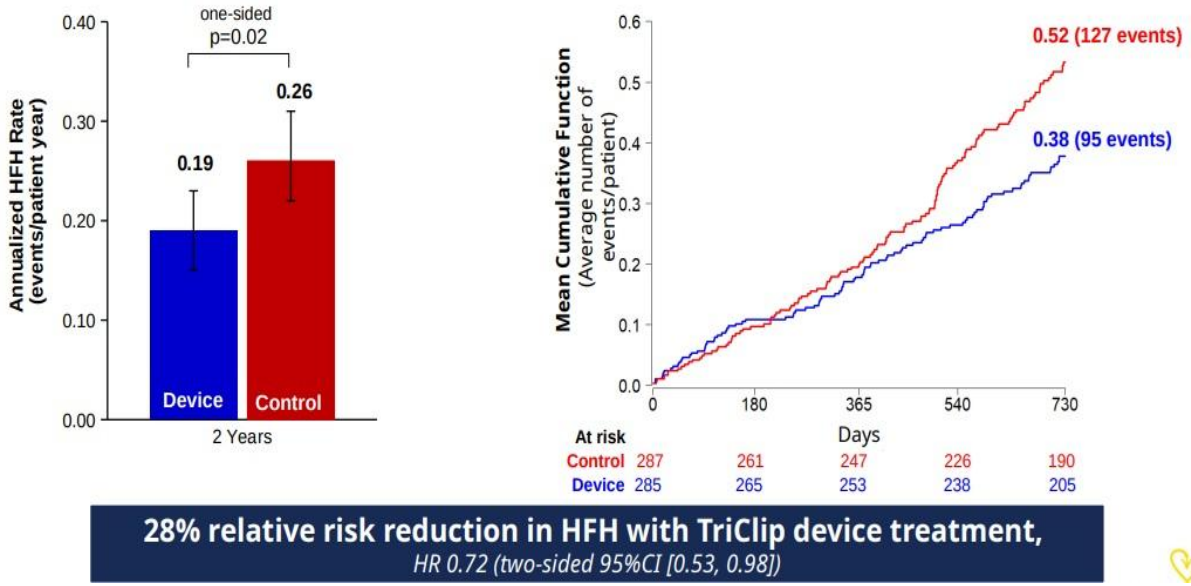
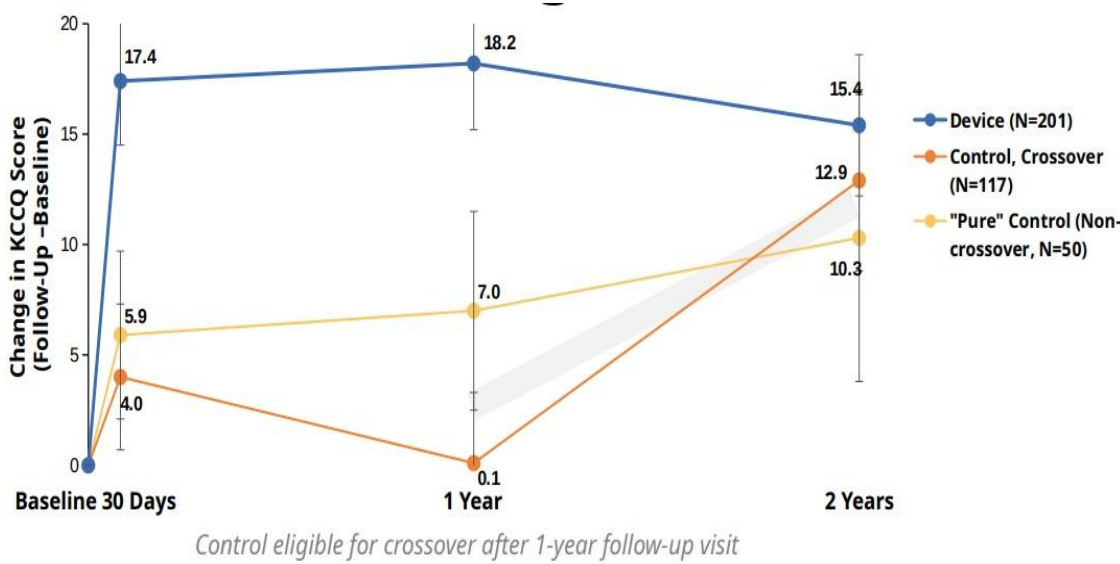
Blasco-Turrion S et al. JACC Interv 2024

Máme tvrdá data?

Hospitalizations



28% relative risk reduction in HFH with TriClip device treatment,
HR 0.72 (two-sided 95%CI [0.53, 0.98])



Control eligible for crossover after 1-year follow-up visit

TRILUMINATE PIVOTAL TRIAL

Kar S - ACC scientific sessions 2025

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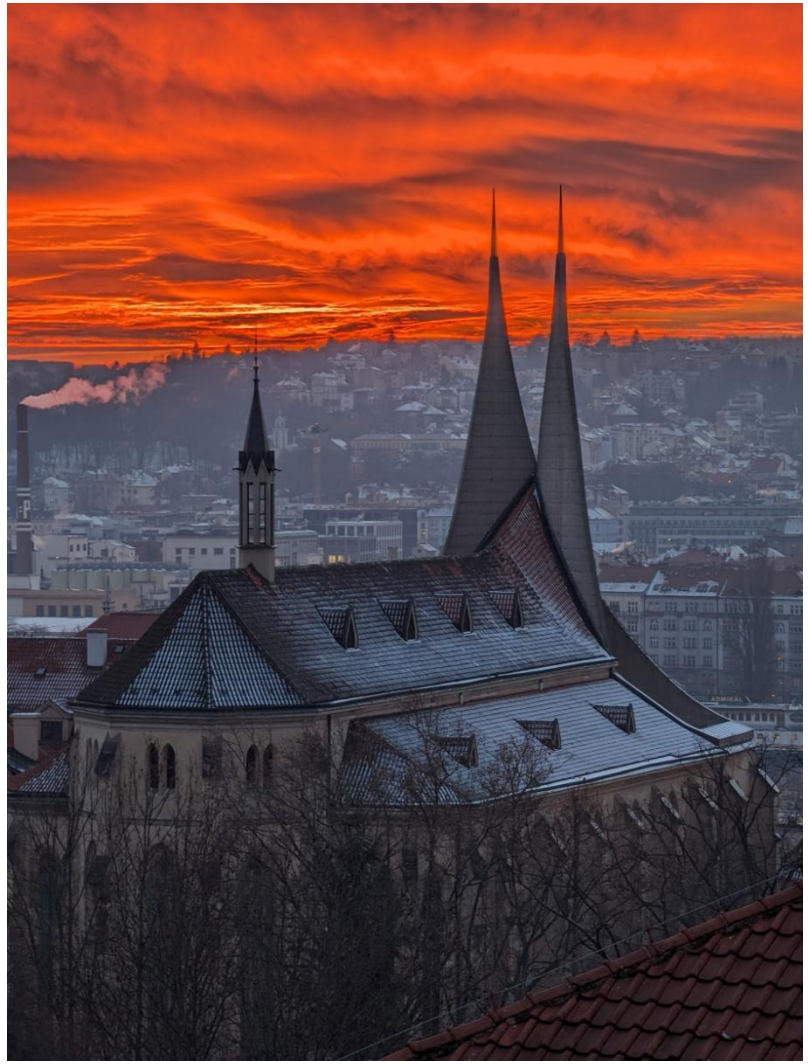
Závěr

- Trikuspidální regurgitace je jednou z nejčastějších chlopenních vad
- Etiologicky se jedná nejčastěji o sekundární postižení
- Je jednoznačně prokázáno, že její přítomnost je spojena s horší prognózou pacientů → pozornost věnovaná její léčbě
- Možnosti léčby dnes zahrnují, jak chirurgické možnosti (plastika a náhrada chlopně), tak celou řadu katetrizačních technik (**plastika cípů** nebo prstence, ortotopická a heterotopická **implantace chlopně**)
- Přesto zůstává řada otázek dosud nezodpovězena (především kdy a jakým způsobem léčit)

DĚKUJI ZA POZORNOST!



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