

Trikuspidální regurgitace

- katetrizační možnosti léčby

David Zemánek

II. interní klinika

kardiologie a angiologie

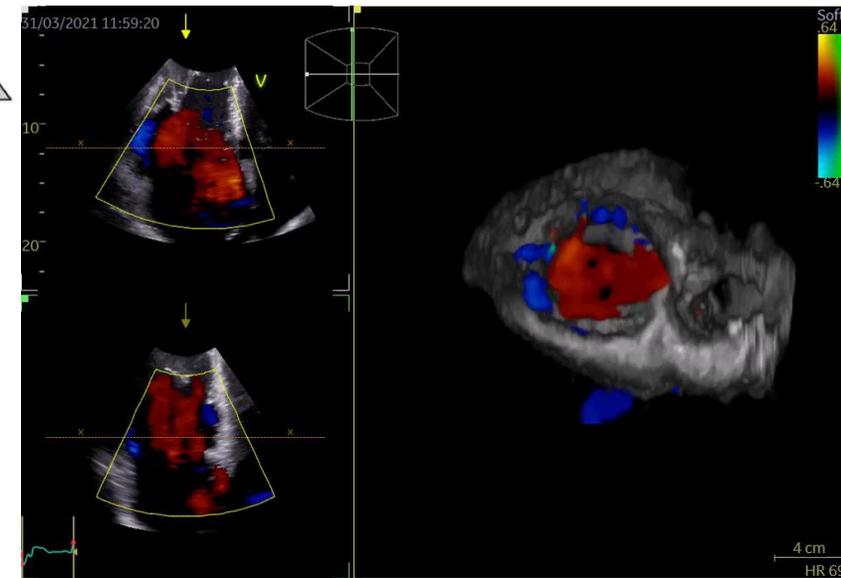
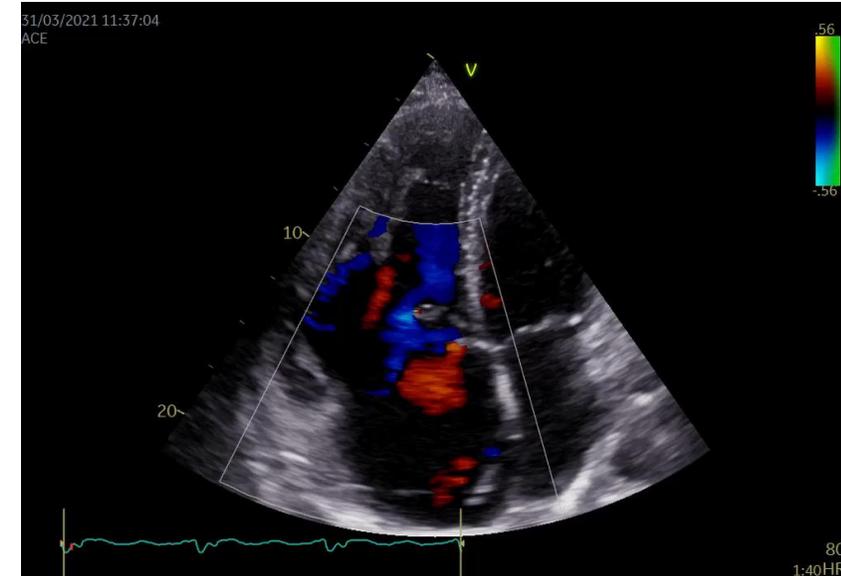
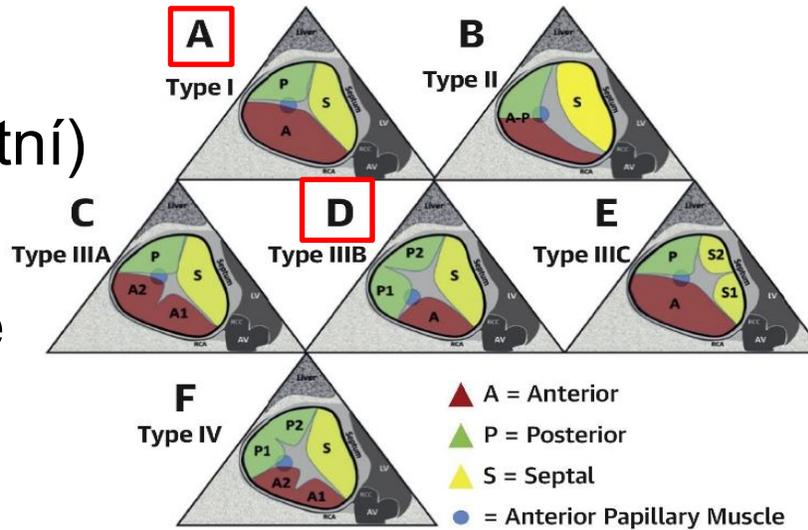
Komplexní kardiovaskulární centrum

VFN a 1. LF UK Praha



Trikuspidální regurgitace

- Obtížné klinické hodnocení symptomů
- Obtížná kvantifikace (výrazně volum dependentní)
- Obtížně zobrazení z TEE
- Obtížné hodnocení funkce pravé komory
- Variabilní anatomie
- Prstenec je neplanární struktura



z obrazového archívu VFN



Nová klasifikace trikuspidální regurgitace

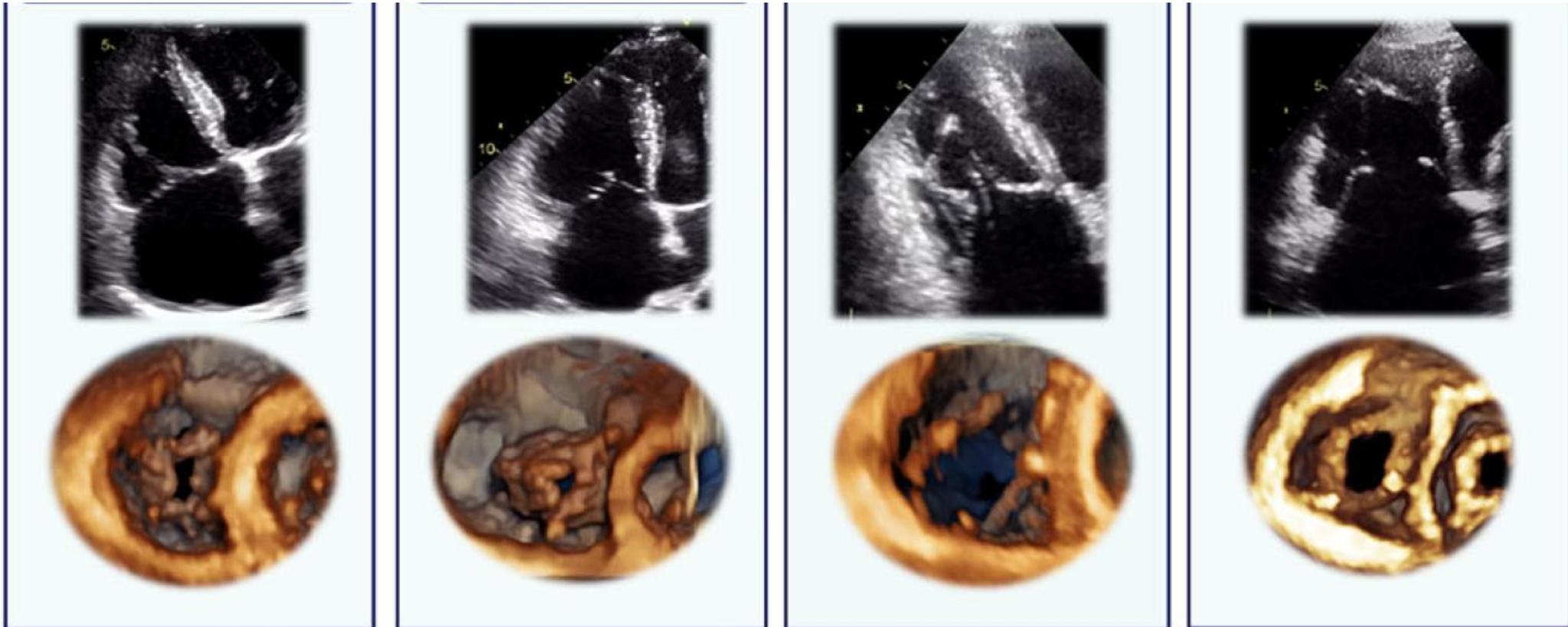
Sekundární/funkční

CIED asociovaná

Primární/organická

Atriální

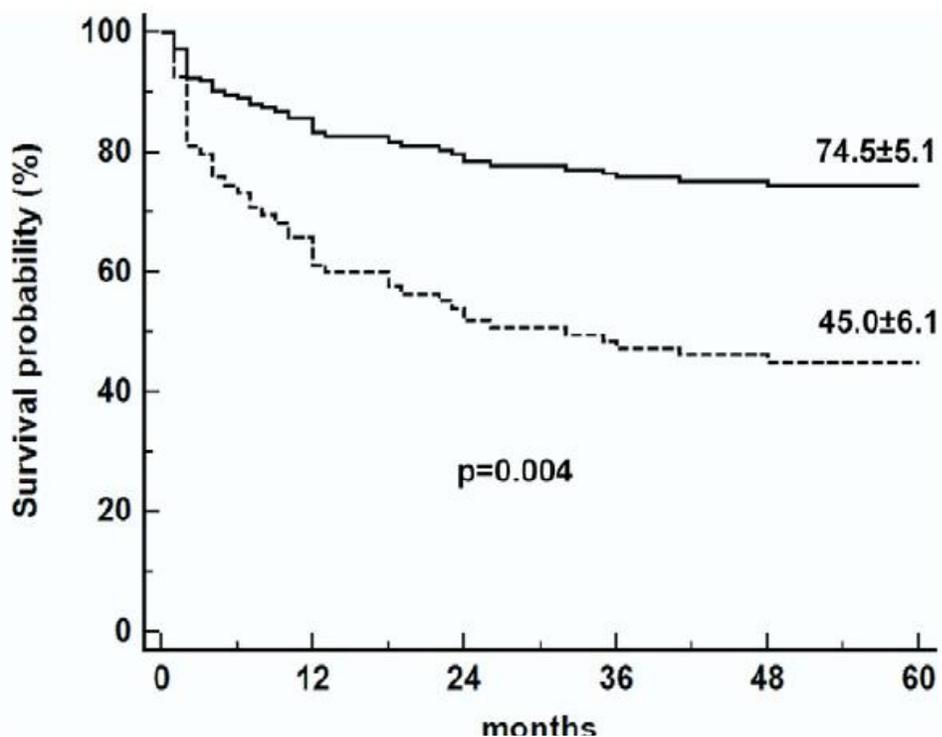
Ventrikulární



Praz F. Eurointervention 2021; 17: 791-808
Hahn R. EHJ – CVI 2022 ; 23: 913-929

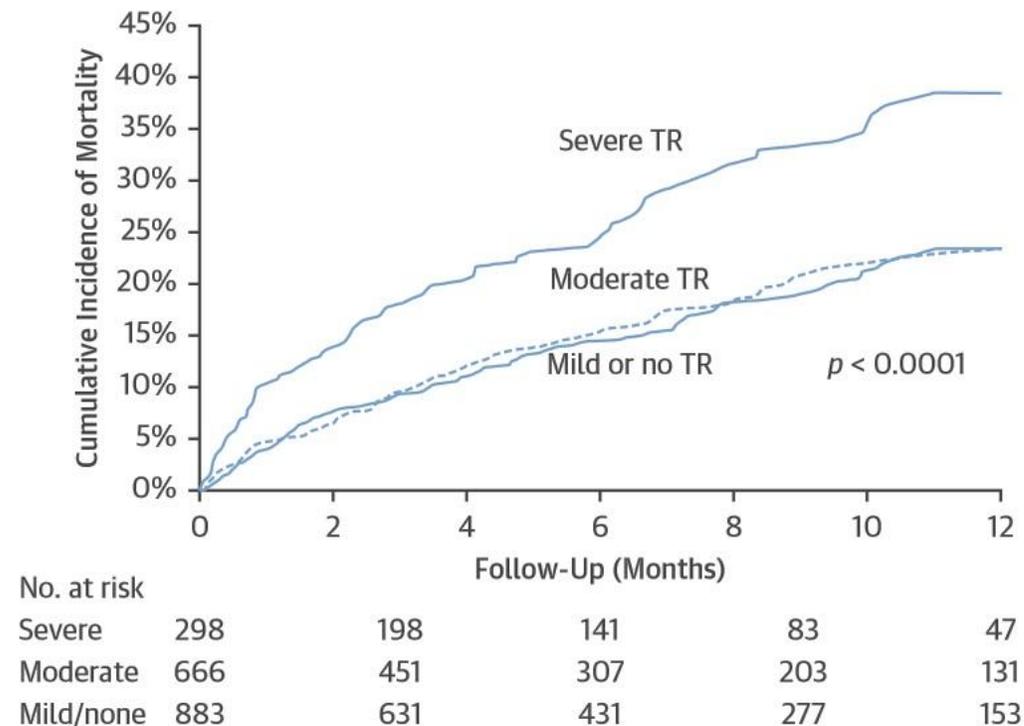
Trikuspidální regurgitace a prognóza

Po KCH výkonu na mitrální chlopi



Calafiore A et al. Ann Thorac Surg 2009

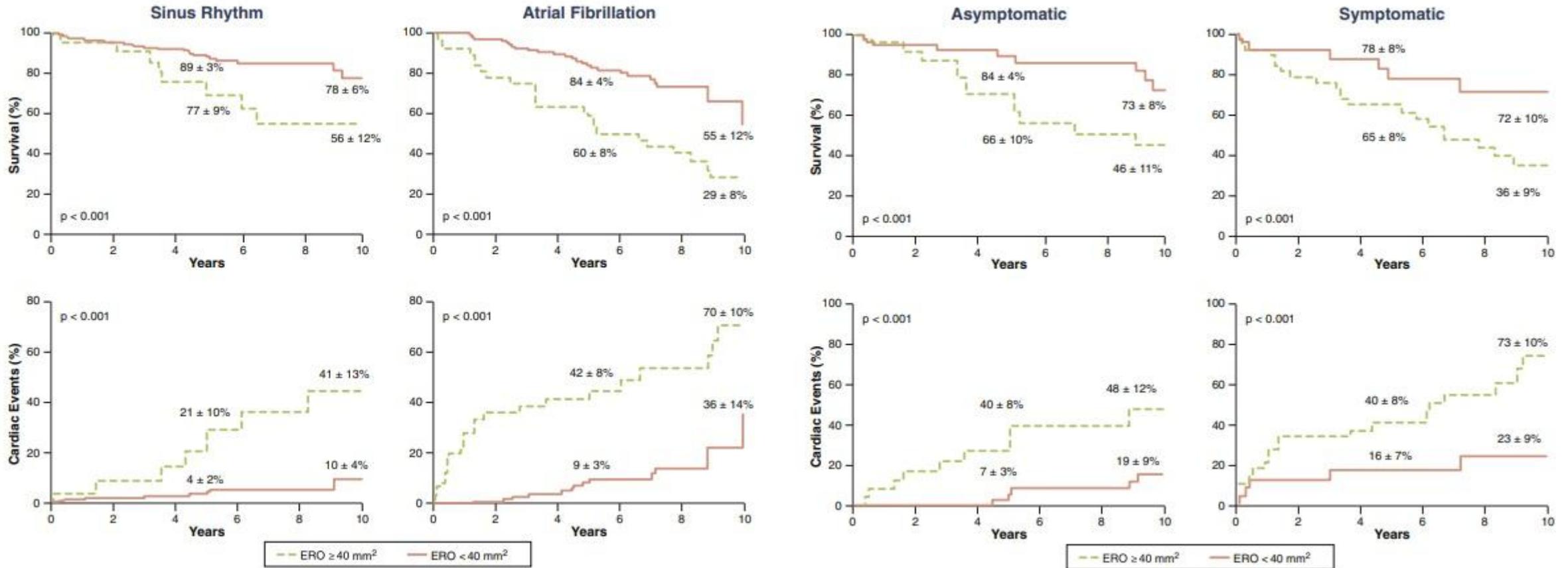
Po katetrizační plastice Mi chlopně



Sorajja P et al. JACC 2017



Izolovaná trikuspidální regurgitace a prognóza

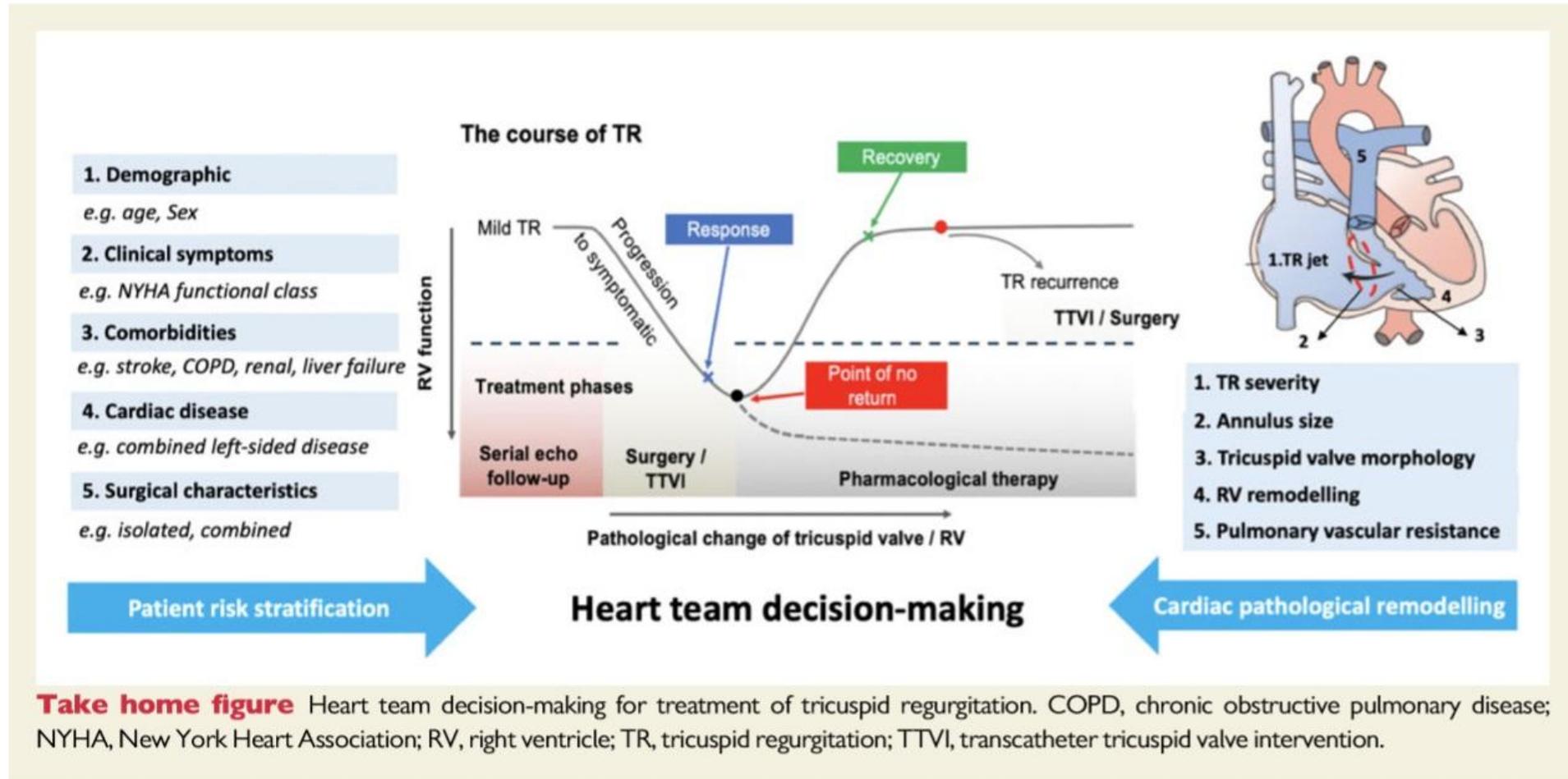


Začarovaný kruh trikuspidální regurgitace

- Významná pozdní TR po operaci levostranné vady
 - konzervativní postup, medikamentózní léčba
- rozvoj symptomů srdečního selhání + dysfunkce PK + orgánové postižení
 - indikace k operačnímu řešení – vysoké operační riziko
 - špatné chirurgické výsledky
 - ještě pozdější reference k operaci
- časté odmítnutí operace pro pokročilost stavu



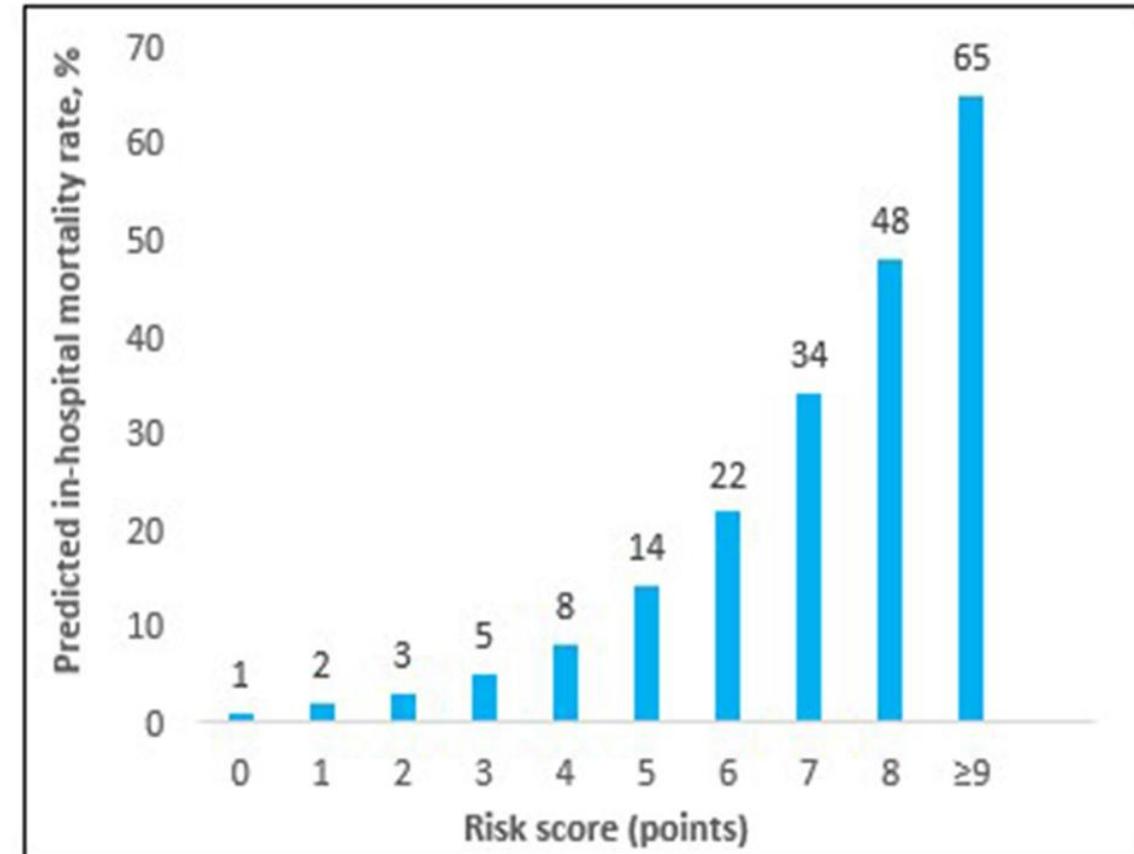
Strategie léčby trikuspidální regurgitace



Tri-Score – odhad časné mortality operace izolované TR

Časná operační mortalita podle Tri-Score

Risk factors (final model from multivariate analysis)	Scoring
Age \geq 70 years	1
NYHA functional class III-IV	1
Right-sided heart failure signs	2
Daily dose of furosemide \geq 125mg	2
Glomerular filtration rate $<$ 30 ml/min	2
Elevated total bilirubin	2
Left ventricular ejection fraction $<$ 60%	1
Moderate/severe right ventricular dysfunction	1
Total	12



Dreyfus G. EHJ 2022, 43 (7): 654–662

TRIGISTRY: multicenter registry (33 centers - 10 countries)
2,413 patients with severe isolated functional tricuspid regurgitation

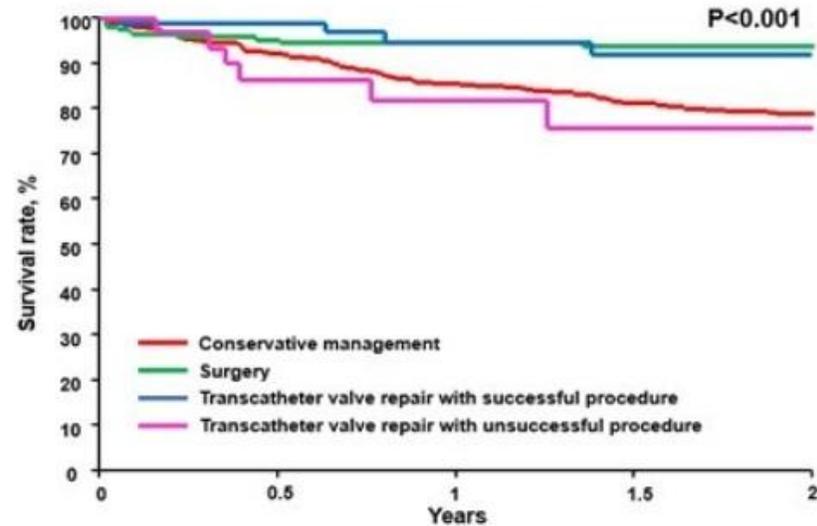
Comparison of the survival rates at 2 years between the different treatment modalities according to the TRI-SCORE category (low, intermediate and high).

1217 patients conservatively managed

551 underwent an isolated tricuspid valve surgery

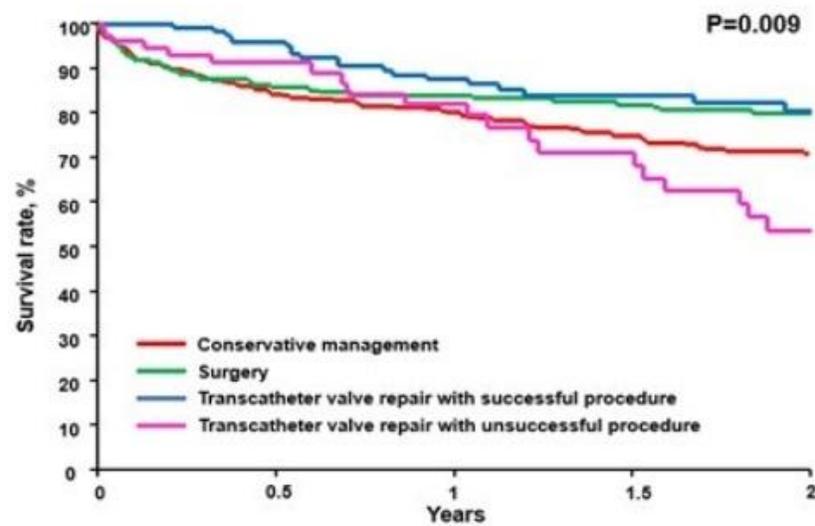
645 underwent a transcatheter valve repair

LOW TRI-SCORE (≤ 3)



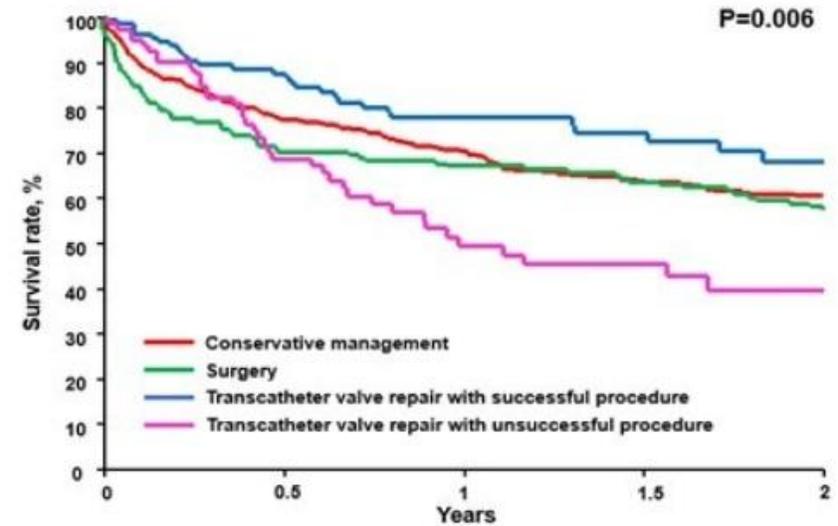
Patients at risk			
Conservative management	433	349	286
Surgery	183	139	119
Transcatheter valve repair with successful procedure	100	41	20
Transcatheter valve repair with unsuccessful procedure	45	17	6

INTERMEDIATE TRI-SCORE (4-5)



Patients at risk			
Conservative management	359	256	194
Surgery	185	130	109
Transcatheter valve repair with successful procedure	172	79	36
Transcatheter valve repair with unsuccessful procedure	83	36	14

HIGH TRI-SCORE (≥ 6)

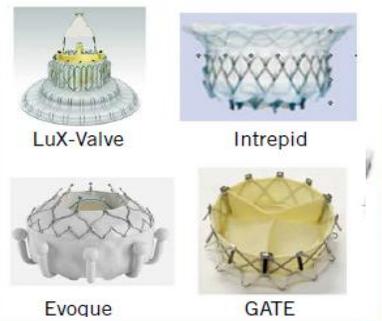


Patients at risk			
Conservative management	425	241	168
Surgery	183	106	80
Transcatheter valve repair with successful procedure	141	59	24
Transcatheter valve repair with unsuccessful procedure	94	27	11

Katetrizační výkony na trikuspidální chlopi (TTVI)

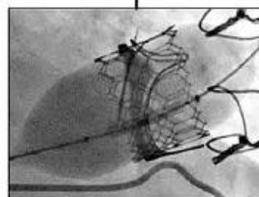
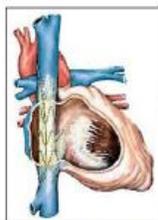
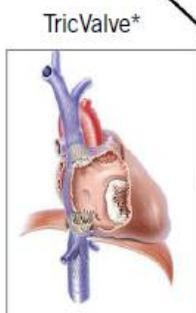
Katetrizační náhrada

Gate
Evoque
Vdyne



Heterotopická implantace protězy

TricValve
Tricento



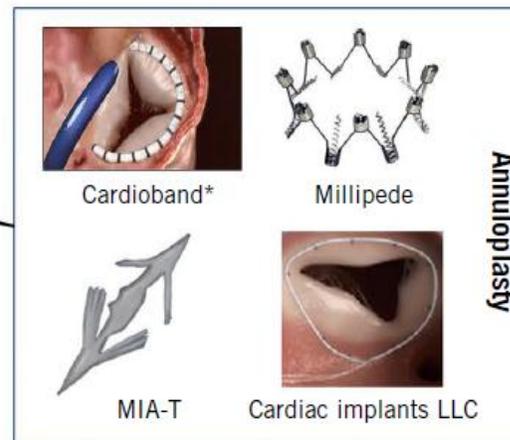
Zlepšení koaptace - TEER

Triclip
Pascal
Forma



Katetrizační anuloplastiky

Cardioband



Valve-in-valve

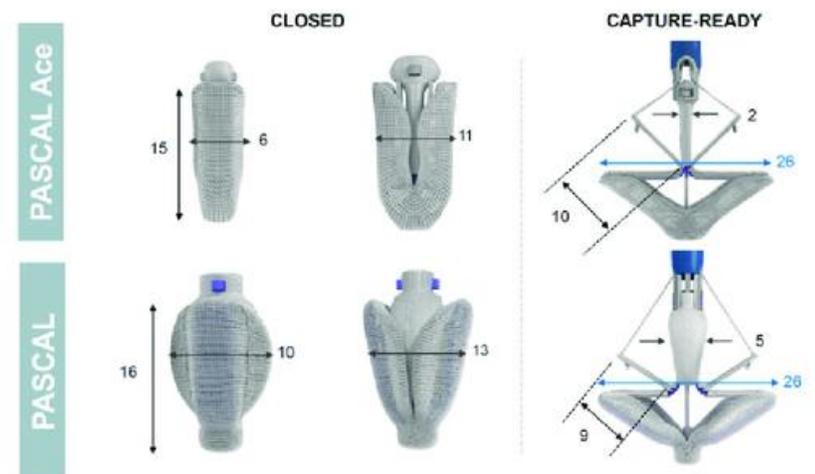
Sapien 3, XT

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 $\geq 8,5$ mm)



zdroj Abbott

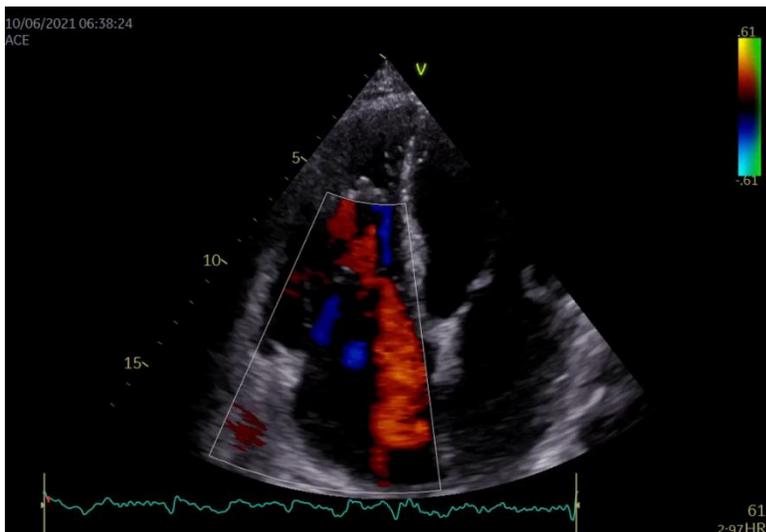


zdroj Edwards Lifesciences

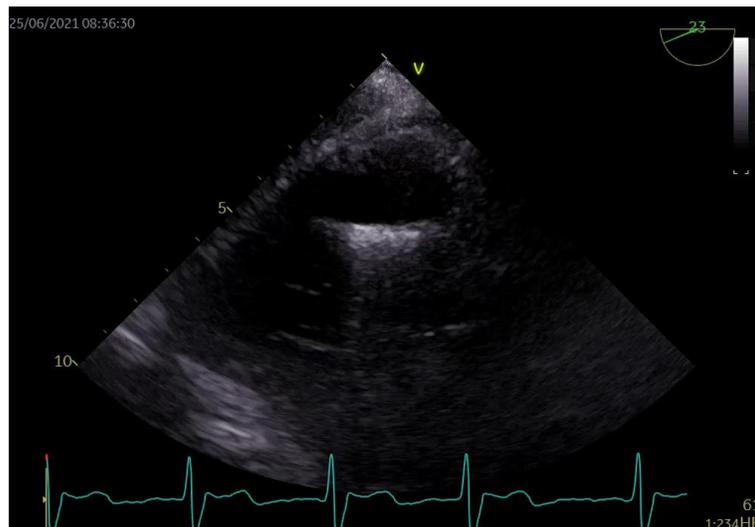


Plastika cípů trikuspidální chlopně pomocí Pascal

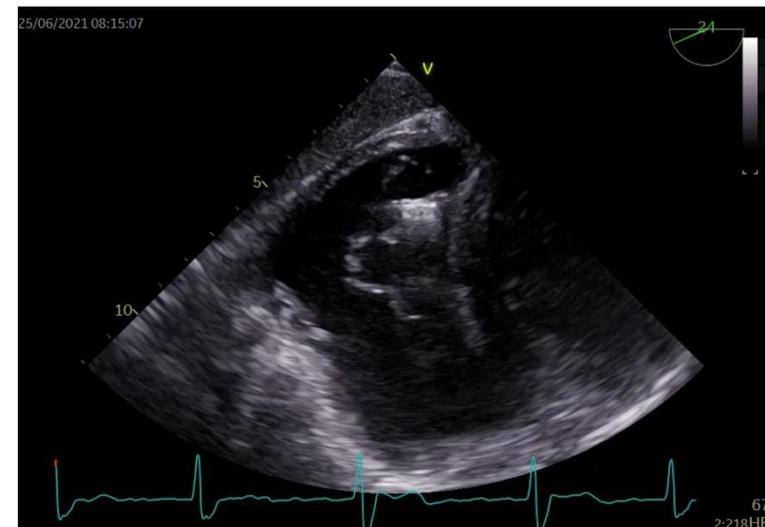
Těžká trikuspidální regurgitace



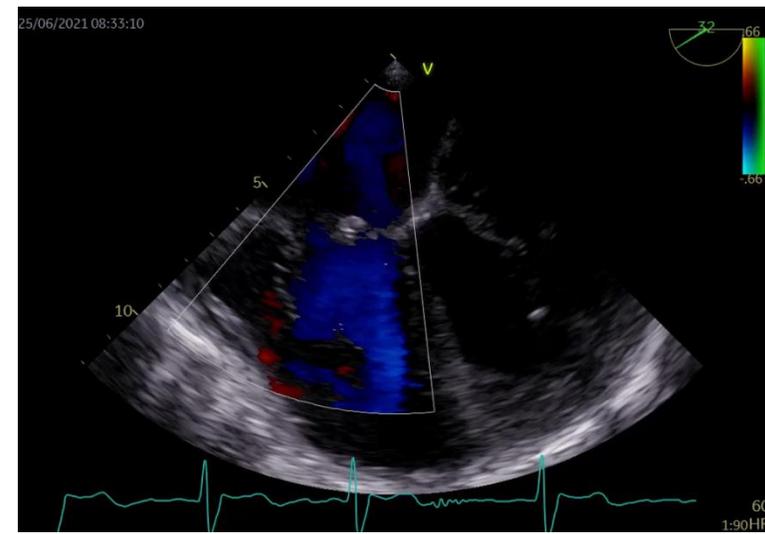
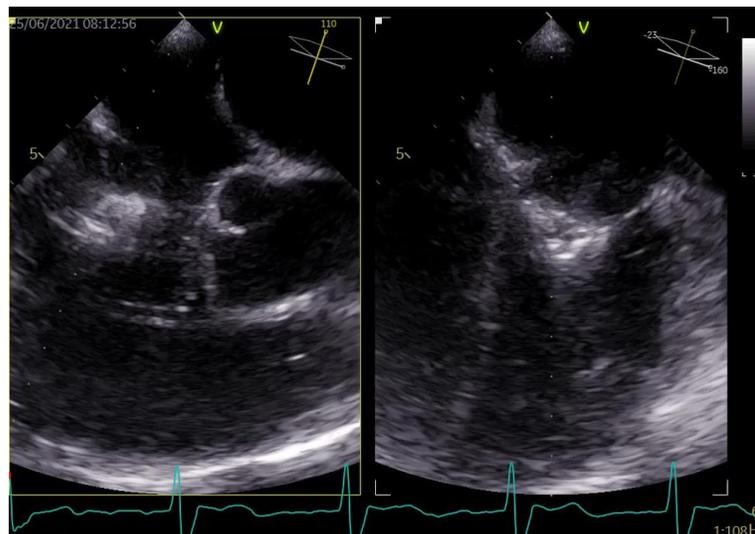
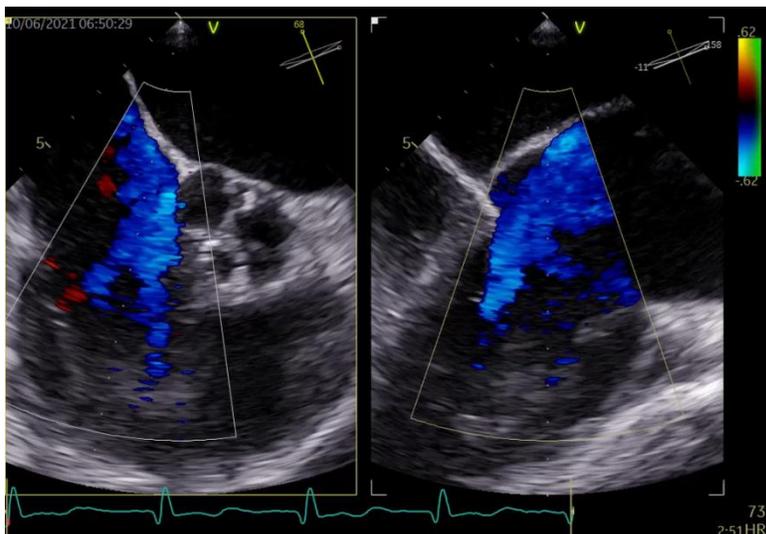
Umístění klipu v P-S komisuře



Finální výsledek

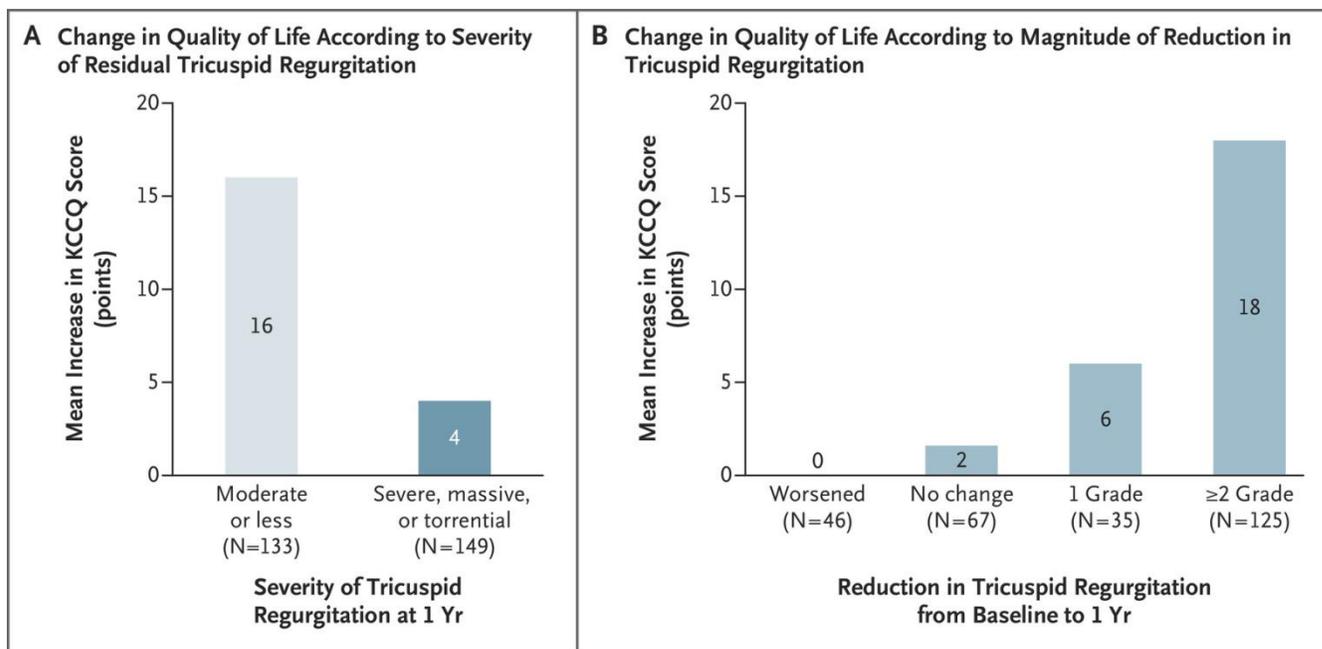


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TRILUMINATE study

Randomizovaná studie srovnávající T-TEER a optimální farmakologickou léčbu u pacientů se těžkou trikuspidální regurgitací (350 pacientů, 1:1)



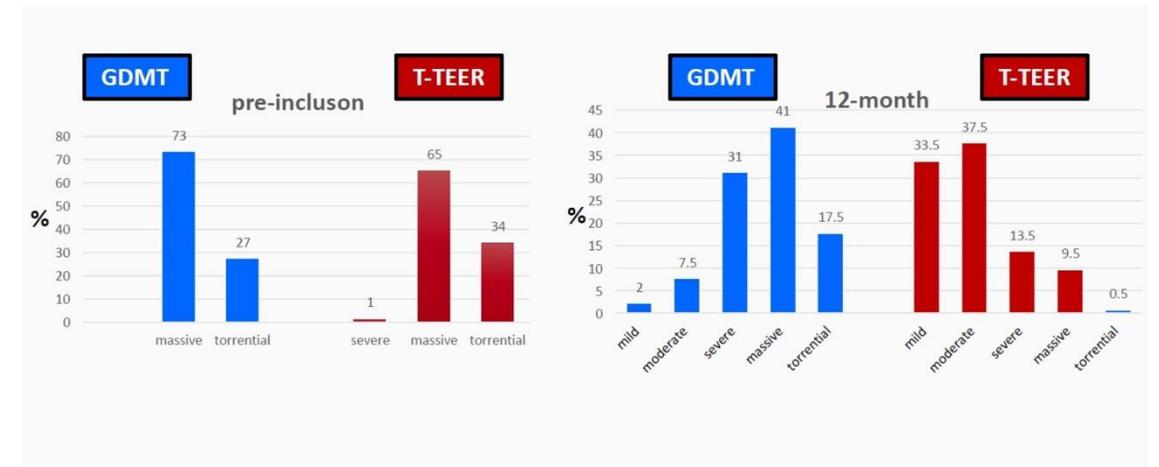
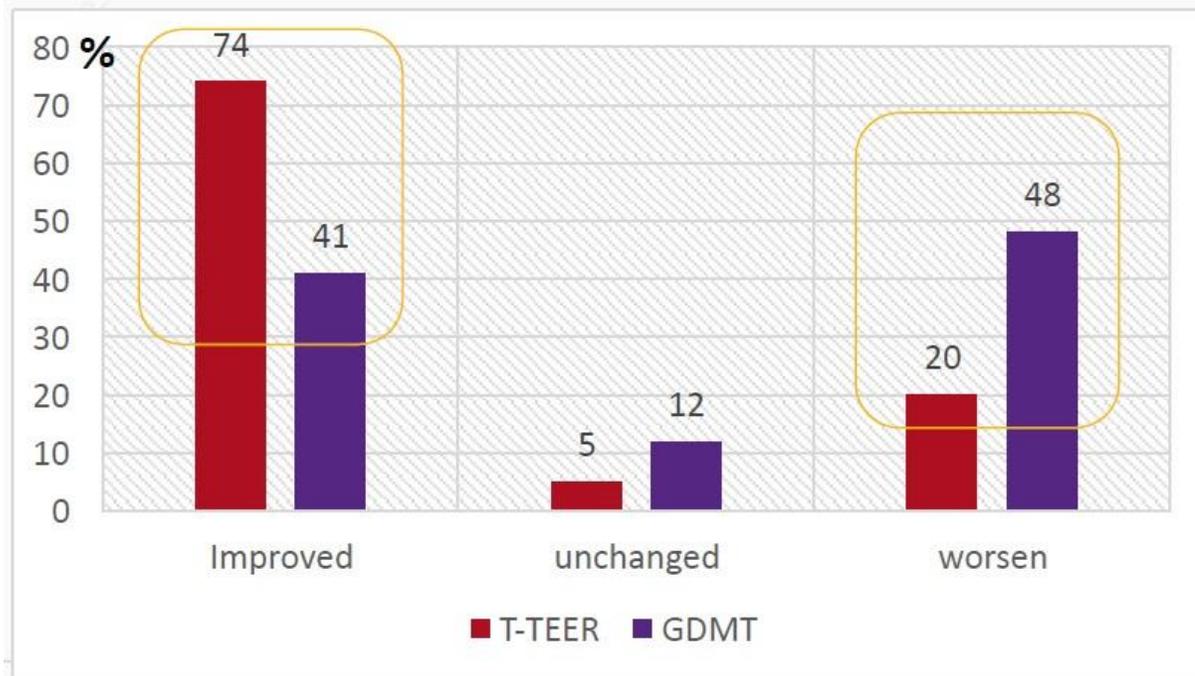
Sorajja P et al. NEJM 2023



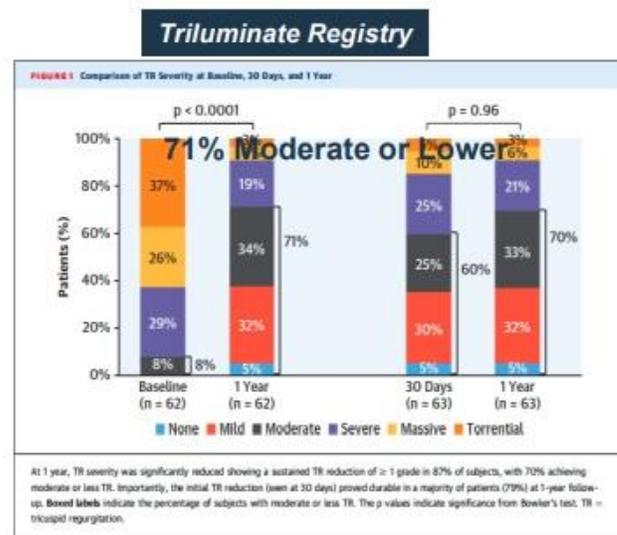
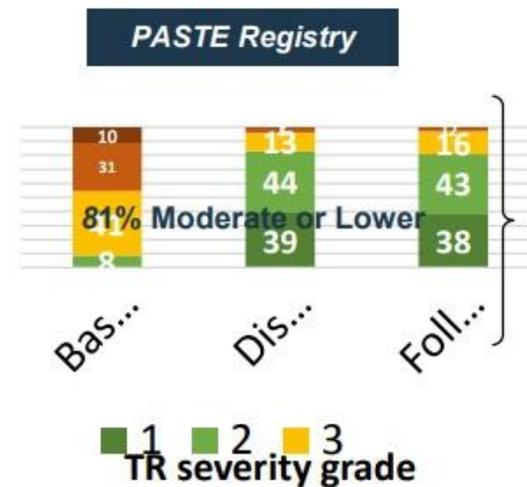
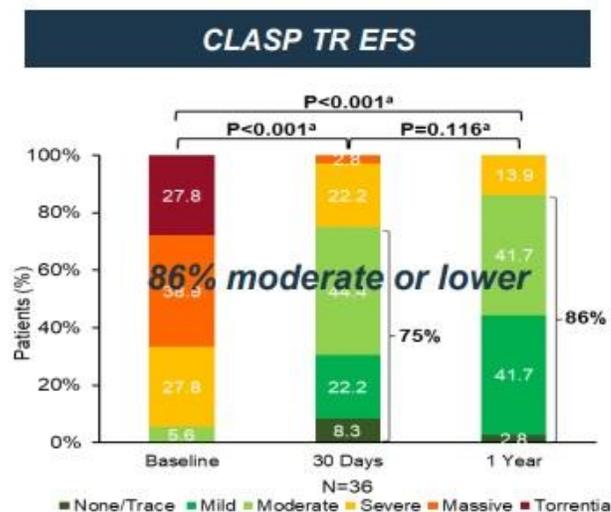
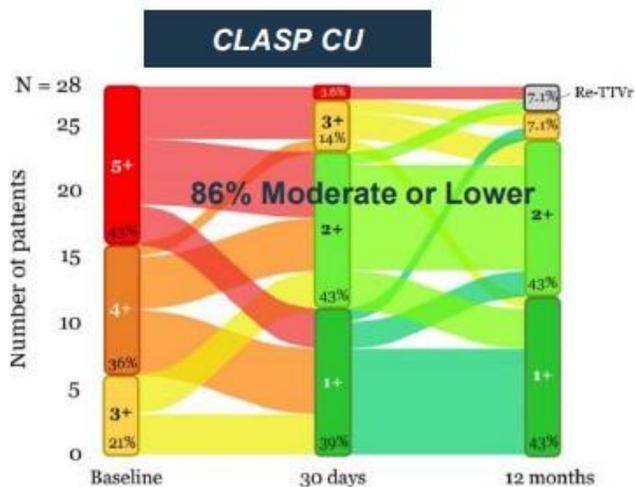
Subgroup	No. of Patients	TEER Group patients with ≥15-point improvement in KCCQ/total no. (%)	Control Group patients with ≥15-point improvement in KCCQ/total no. (%)	Odds Ratio (95% Confidence Interval)
All Patients	295	73/147 (49.7)	39/148 (26.4)	2.76 (1.69–4.49)
Age				
<78 yr	140	37/71 (52.1)	13/69 (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)

Tri.Fr study

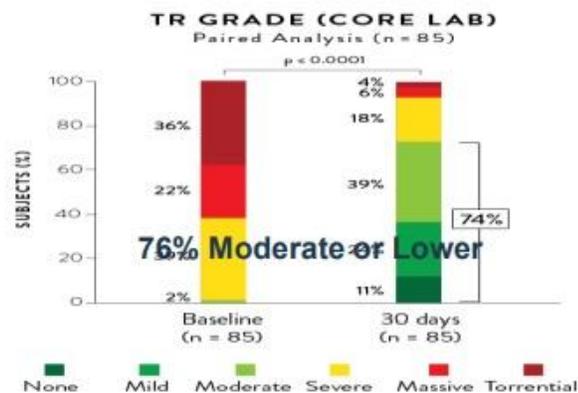
Randomizovaná studie srovnávající T-TEER a optimální farmakologickou léčbu u pacientů se těžkou trikuspidální regurgitací (300 pacientů, 1:1)



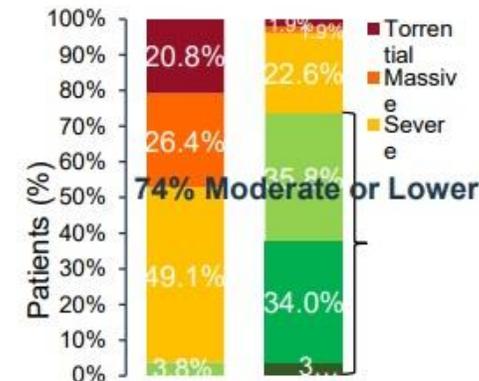
Efekt T-TEER je konzistentní



Triluminate Pivotal Roll In

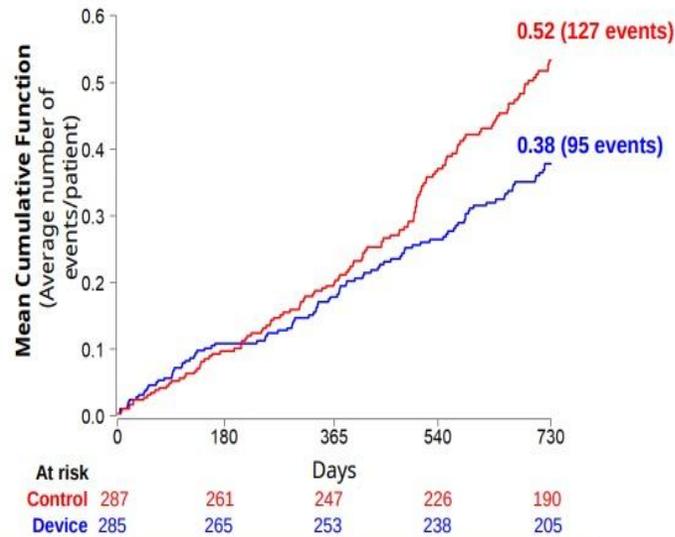
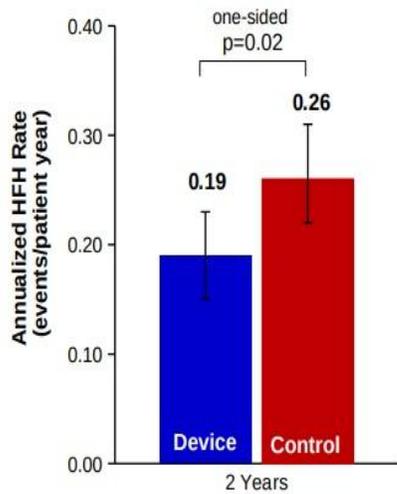


CLASP II TR Roll In

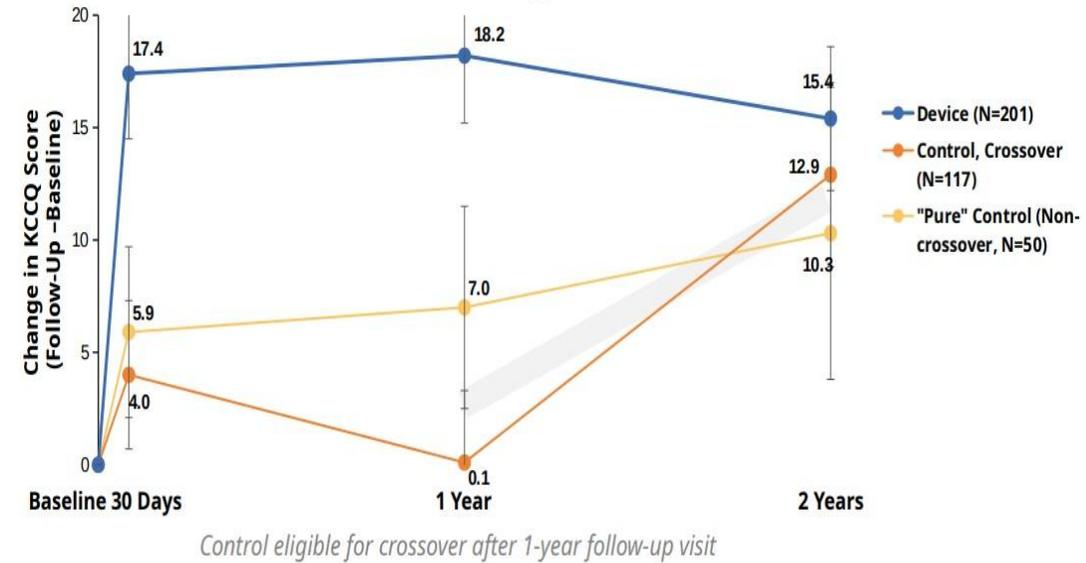


Takže žádná tvrdá data?

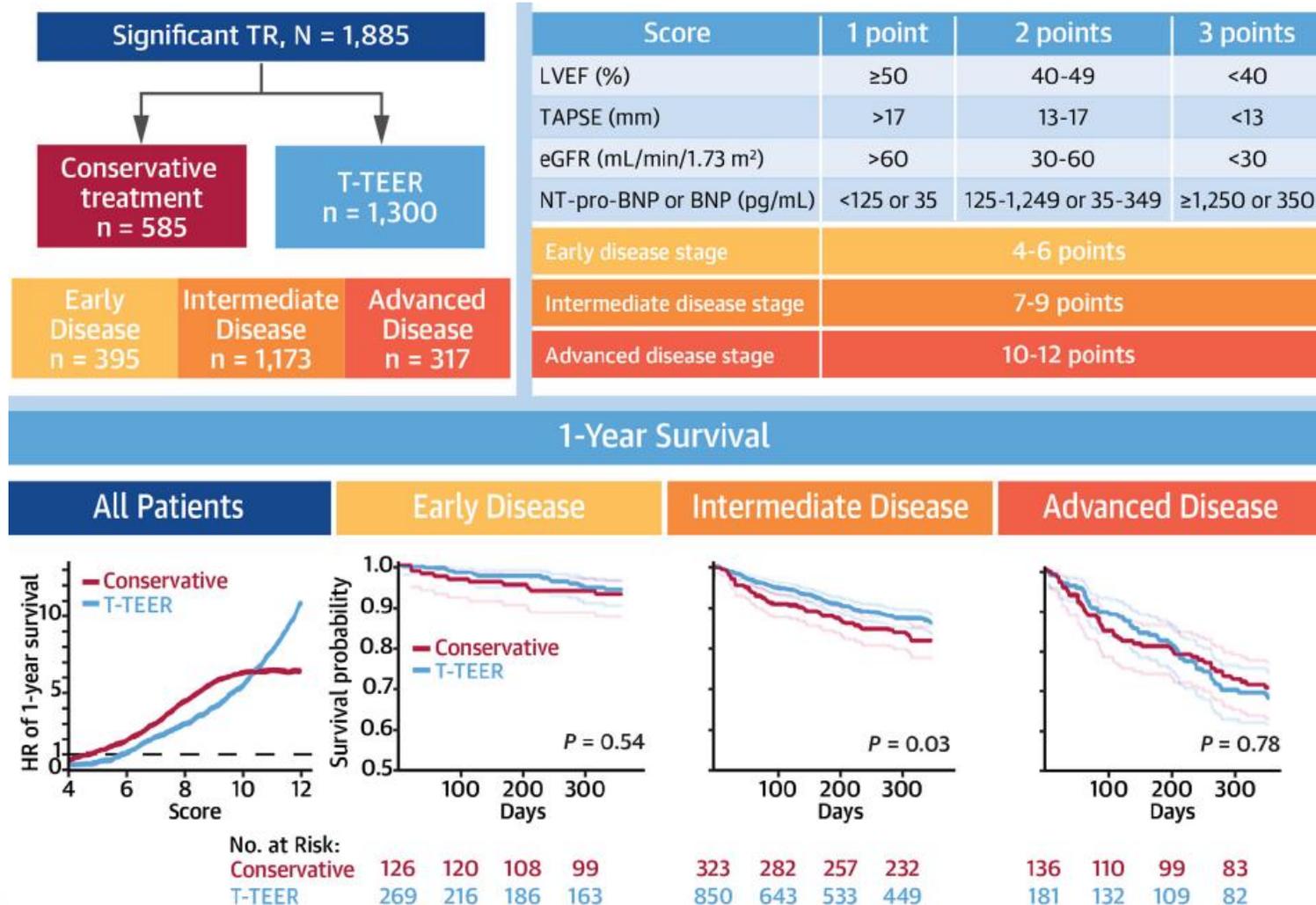
Hospitalizations



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

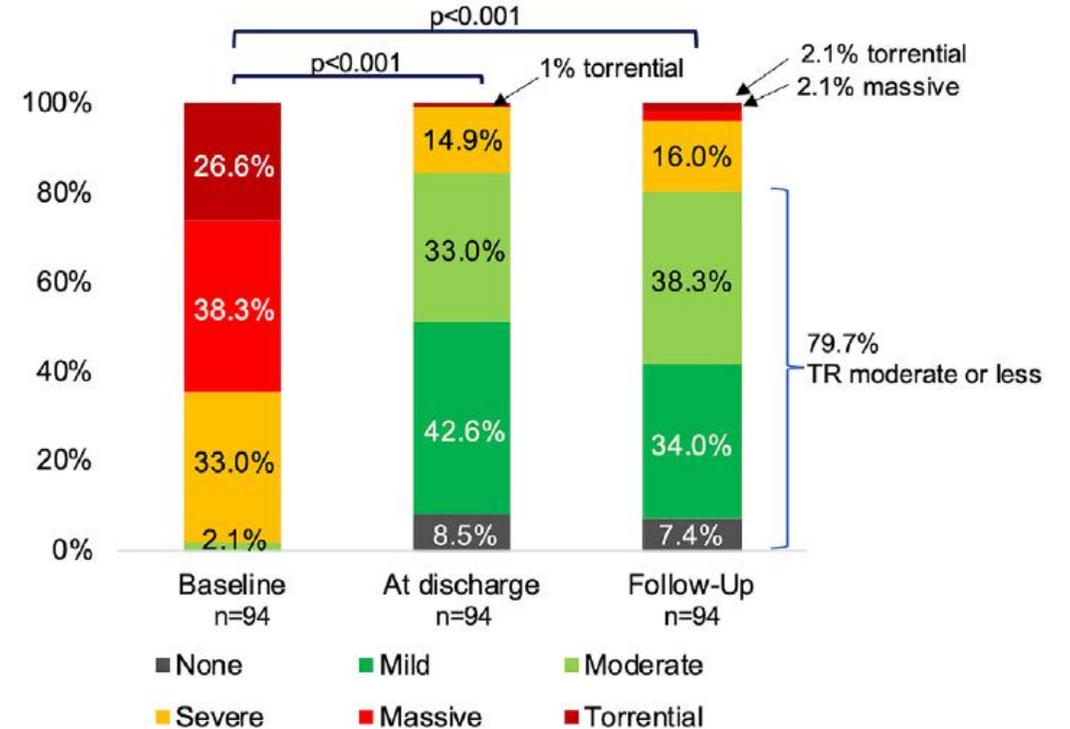
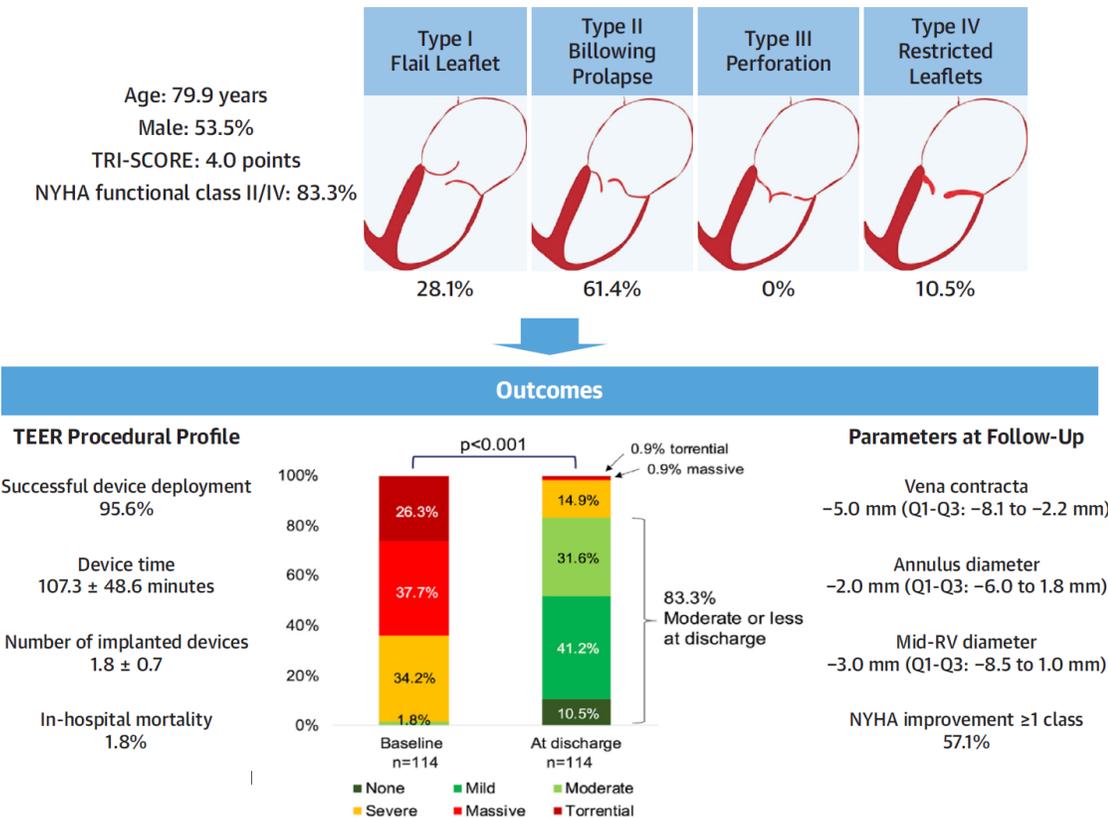


Prognostické skóre pro T-TEER



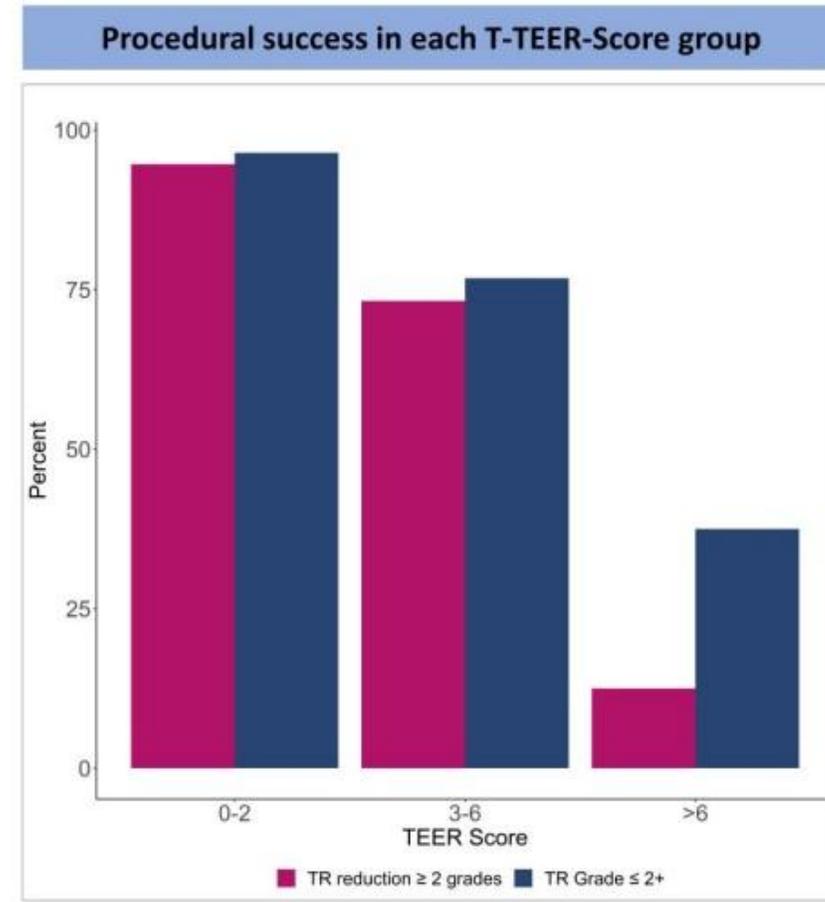
Primární trikuspidální regurgitace a T-TEER

T-TEER je efektivní a bezpečná léčba primární trikuspidální regurgitace



T-TEER prognostické skóre

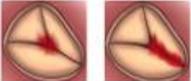
The Tricuspid TEER Scoring system			
Parameters	Straightforward (0 points)	Moderate (1 point)	Complex (2 points)
	0 - 2 mm	3 - 6 mm	> 6 mm
Septolateral Gap			
Septal Leaflet Mobility/Tethering	> 75 % ¹ 	25 - 75 % ¹ 	< 25 % ¹
Leaflet Number/Morphology	Type I-II 	Type III 	Type IV
Predominant Jet location	Anteroseptal 	Posteroseptal 	Anteroposterior
Shadowing/Image Quality	Good (0 points) 	Limited (1 point) 	
En-face TR Jet Morphology	oval/linear (0 points) 	star-shaped (1 point) 	



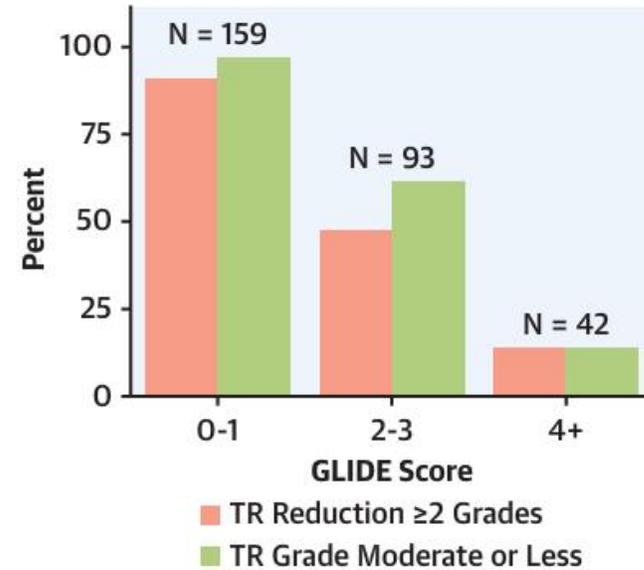
¹to the coaptation-line



Prognostické skóre pro T-TEER (GLIDE)

The GLIDE Scoring System		
Parameters	Straightforward (0 points)	Complex (1 point)
Septolateral Gap	0-5 mm 	≥6 mm 
Predominant Jet Location	Anteroseptal/ Central 	Posteroseptal/ Anteroposterior/Diffuse 
Image Quality	Good 	Limited 
Chordal Structure Density	Modest 	High 
En Face TR Jet Morphology	Oval/Linear 	Star-Shaped 

Procedural Success in Each GLIDE Score Group

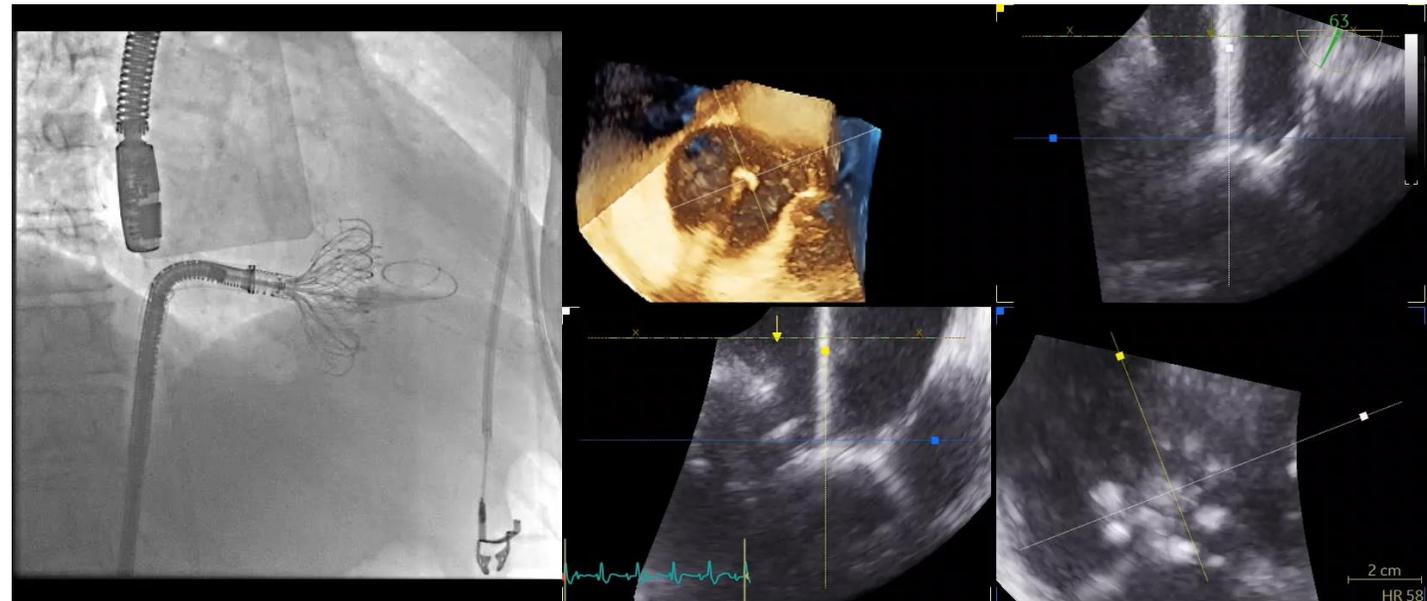


Ortotopická implantace chlopně

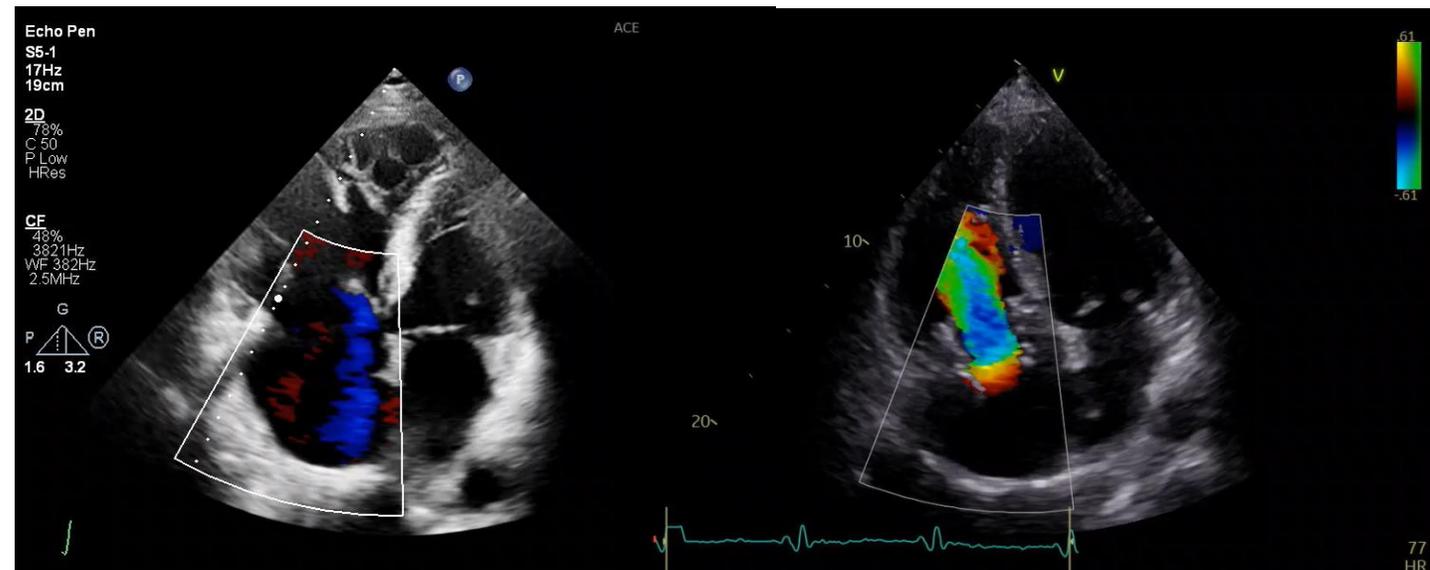
- **Výhody:**
 - fyziologické
 - prakticky bez regurgitace
- **Nevýhody:**
 - riziko AV bloku
 - degenerace bioprotézy, trombóza
 - selhání pravé komory
- Specifická situace:
- „valve-in-valve“ a „valve-in-ring“



Implantace chlopně Evoque do trikuspidální chlopně



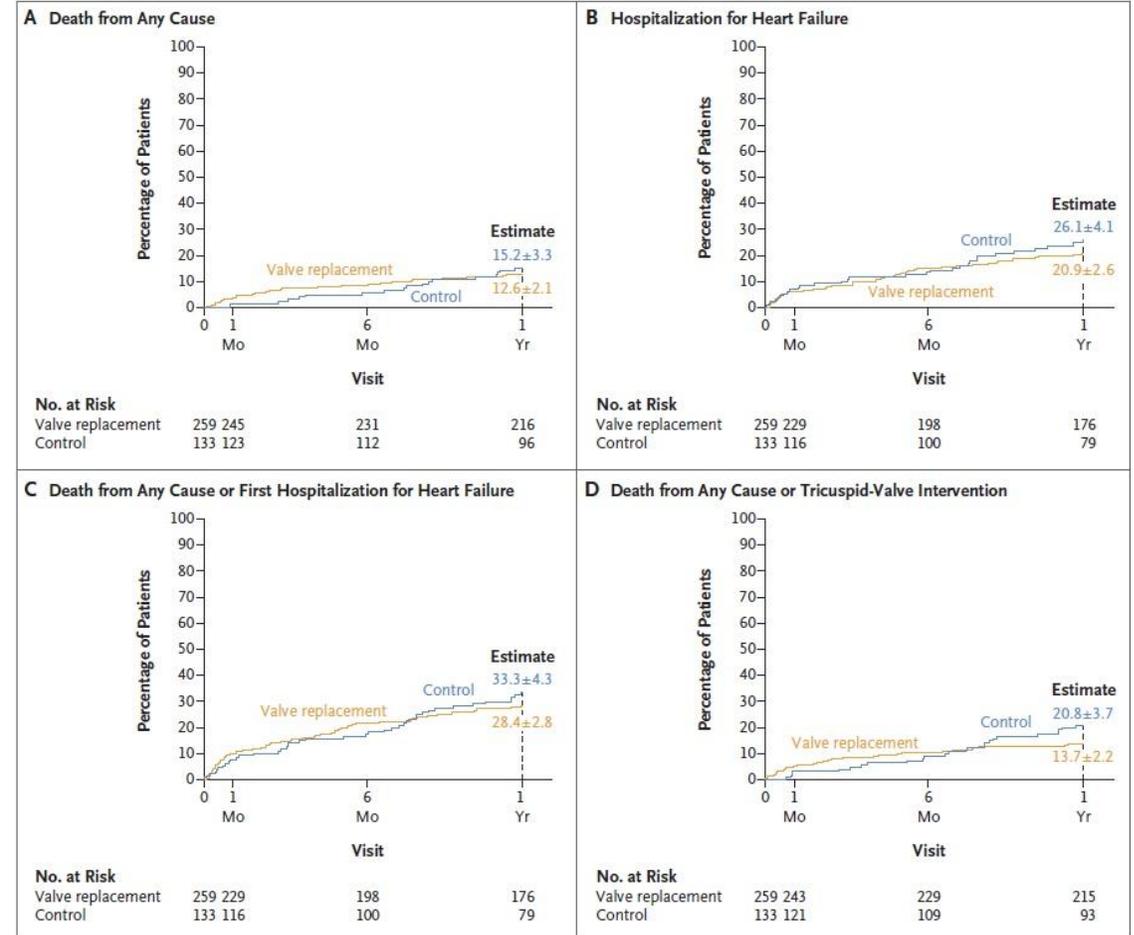
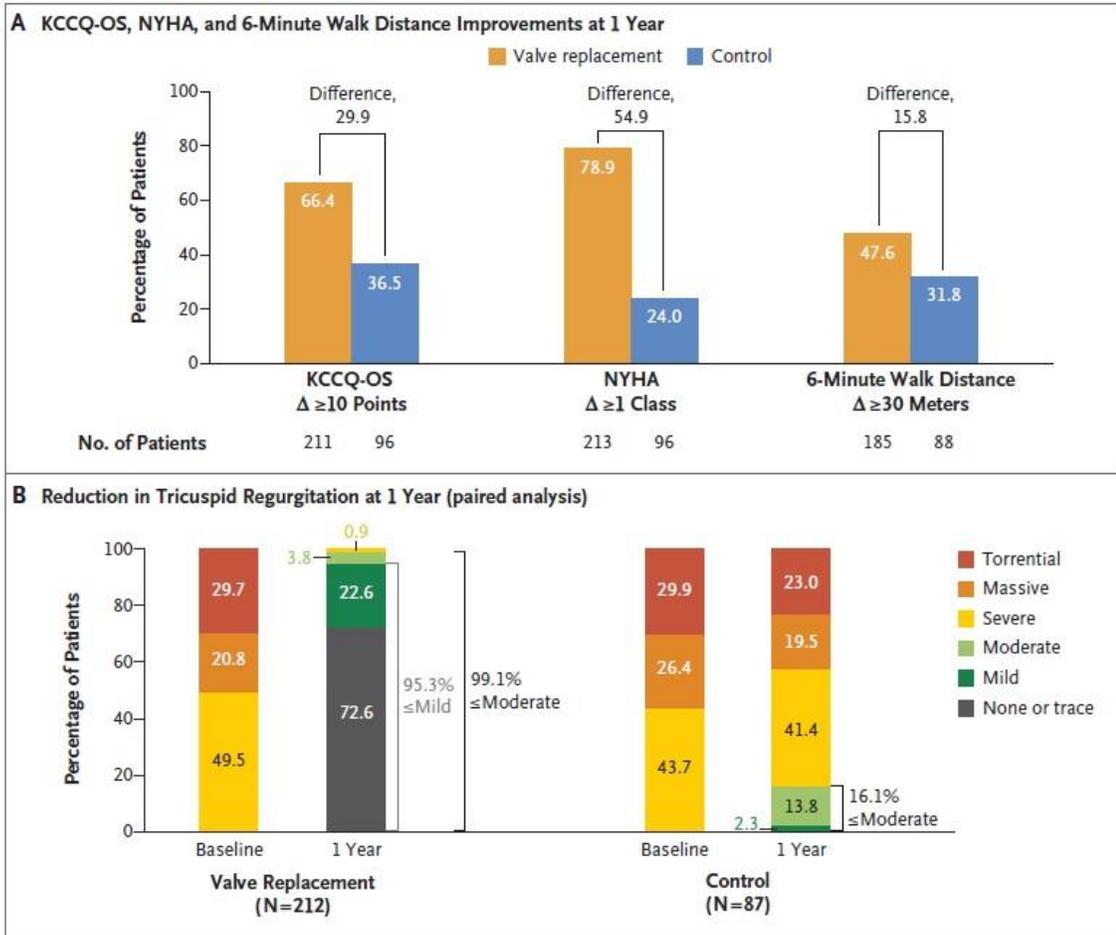
Echokardiografie před a po implantaci chlopně Evoque



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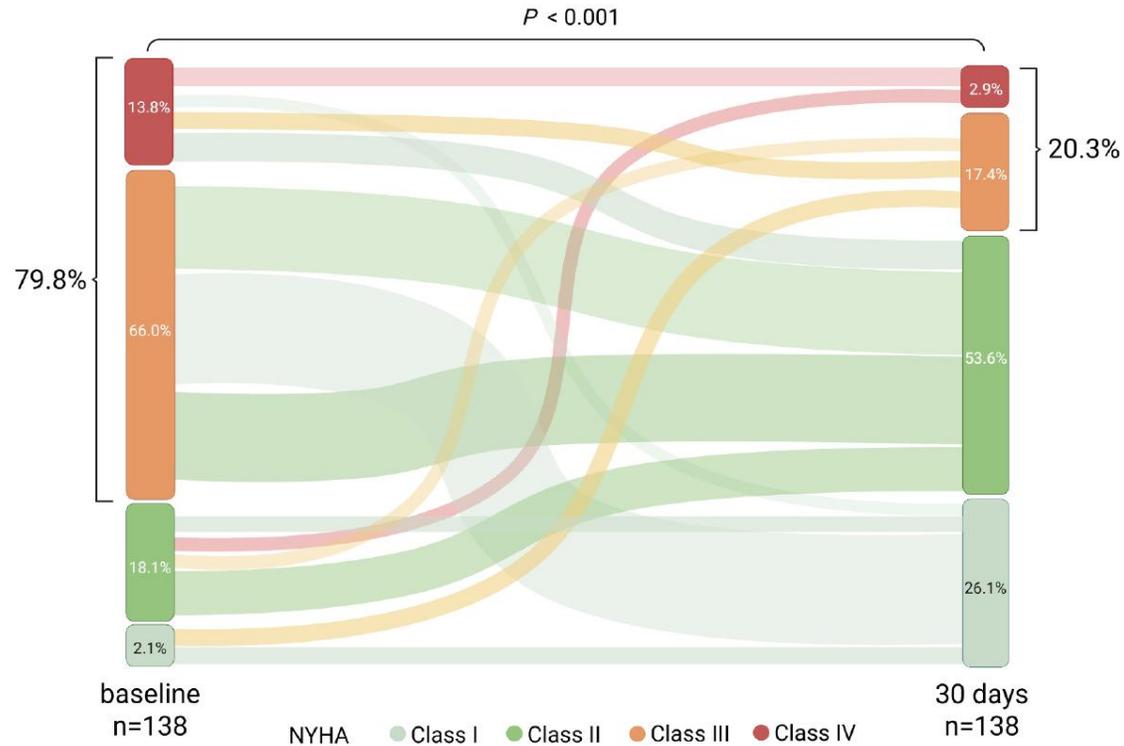
TRISCEND II study

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



EVOQUE registr

Registr zahrnující 176 pacientů implantovaných v 12 evropských centrech



30-Day Outcomes of Real-World TTVR With Evoque System in Europe, N = 176

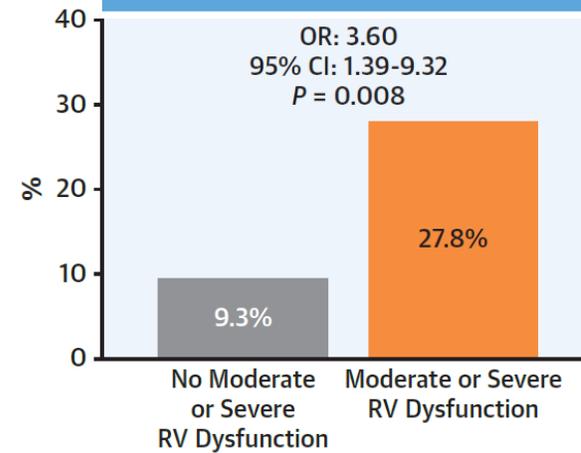
Patient Population

- Mean age 77.8 years
- 72% women
- Median TRI-SCORE 5 (IQR 2)
- Treated with the EVOQUE system October 2023 to February 2025
- 12 Heart Valve Centers

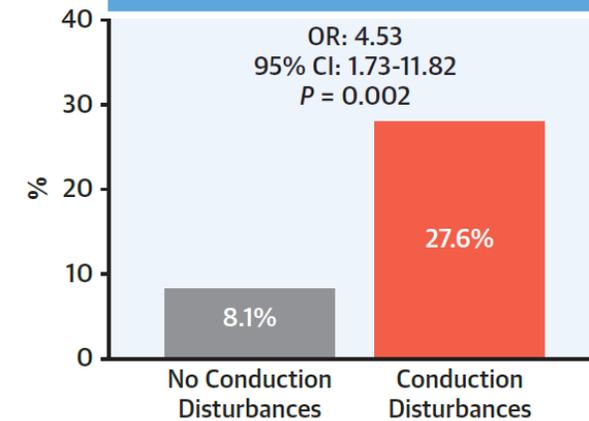
Outcomes at 30 Days

- T-VARC clinical success: 86.9%
- Improvement of ≥ 1 NYHA functional class: 71%
- Improvement in renal function: eGFR mean difference +6.7 mL/min/1.73 m², P < 0.001
- Reduction in bilirubin levels: mean difference -3.1 μ mol/mL, P < 0.001

Frequency of Clinical Failure



Frequency of PPM Implantation



- Successful TR reduction after TTVR was associated with significant improvements in functional status and hepato-renal function.
- Moderate or severe RV dysfunction at baseline (20.5%) predicted clinical failure.
- Conduction disturbances at baseline (32.4%) predicted PPM implantation.



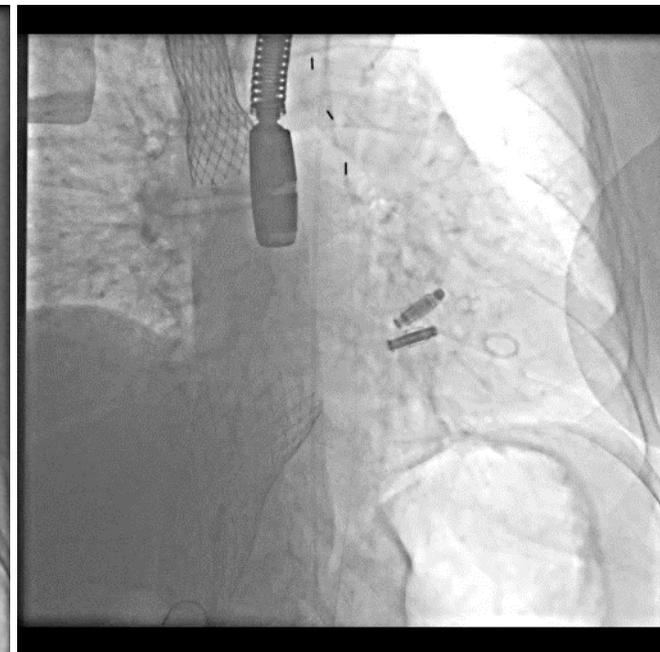
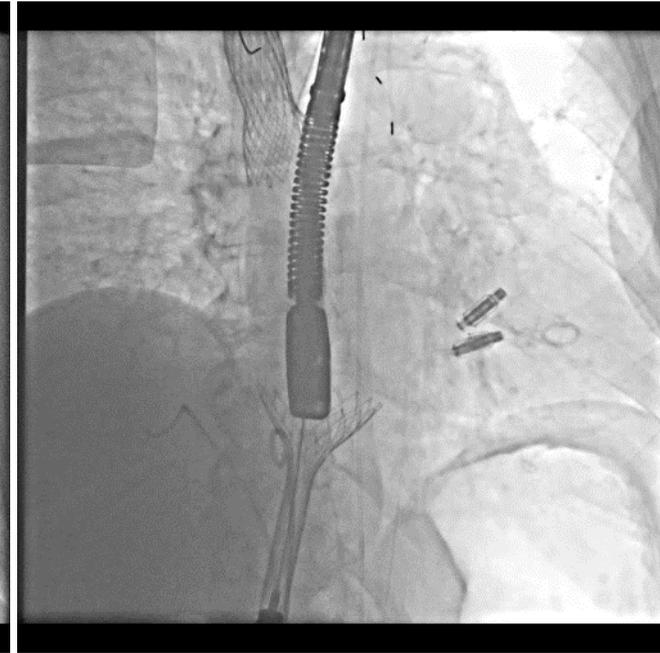
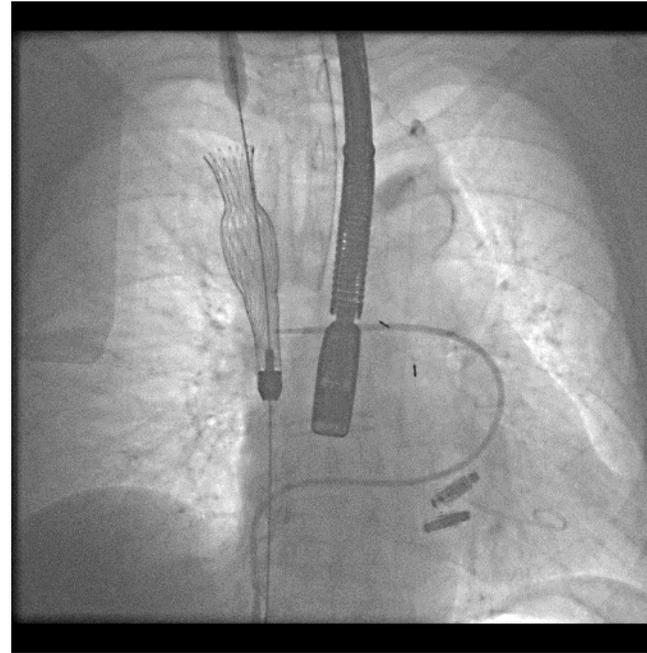
Heterotopická implantace chlopně

- **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



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.

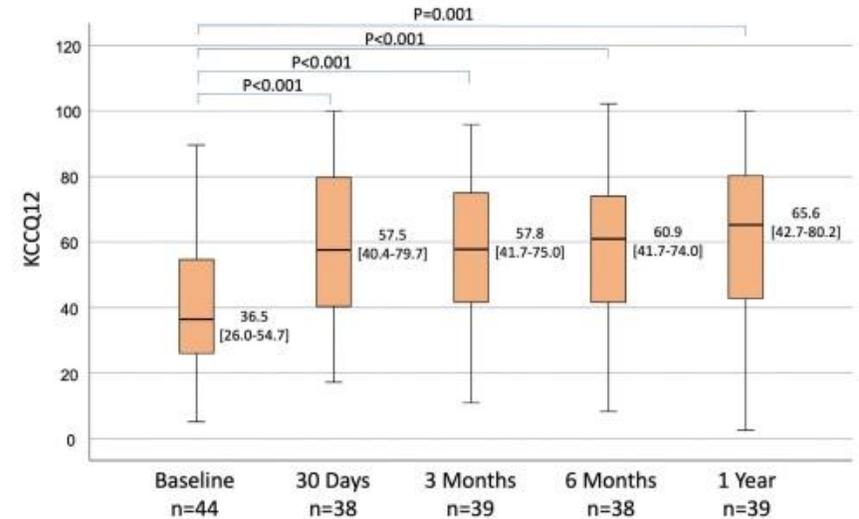
OBJECTIVES The study sought to determine the impact of TricValve on systemic congestion and quality of life (QOL) at 1 year.

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.

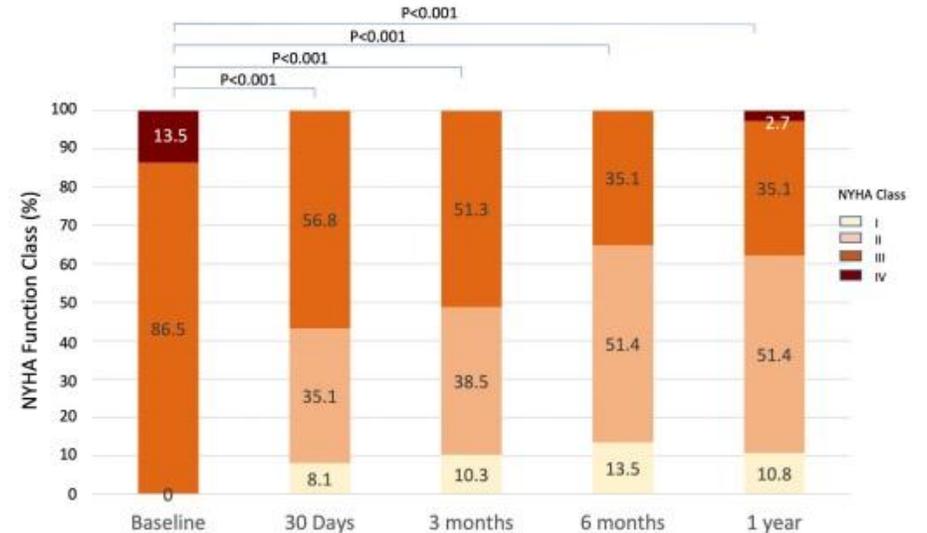
CONCLUSIONS Caval valve implantation with the TricValve system associated with meaningful 1-year clinical improvements in terms of QOL along with relatively low mortality rates. (TRICUS Study - Safety and Efficacy of the TricValve® Device; NCT03723239). (J Am Coll Cardiol Interv 2023; ■: ■-■) © 2023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



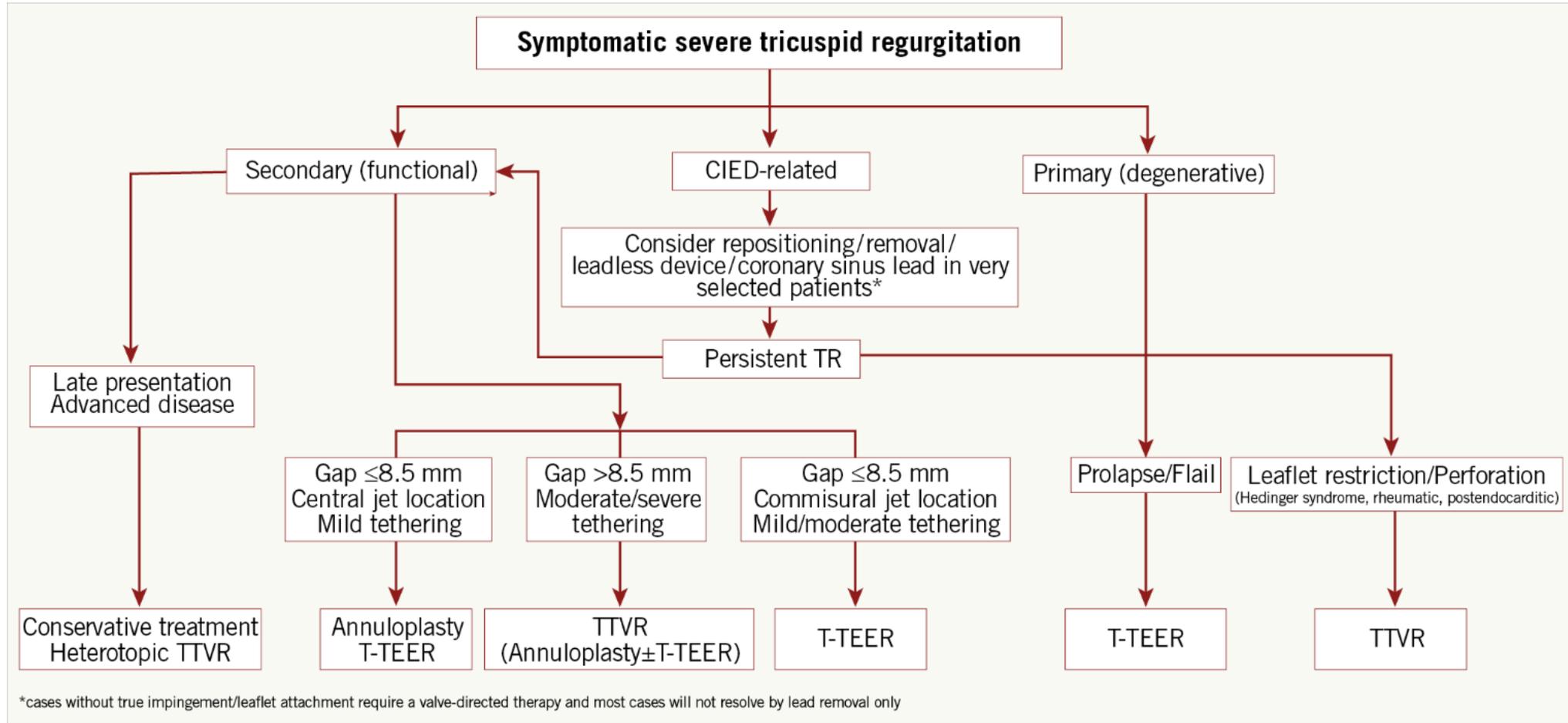
Současné možnosti katetrizační léčby

Device	TriClip	Pascal	Evoque	Cardioband	TricValve
Technique	Edge-to-edge	Edge-to-edge	Valve replacement	Direct annuloplasty	Heterotopic valve implantation
Advantages	<ul style="list-style-type: none"> - Wide choice of device - Usable in most anatomies 	<ul style="list-style-type: none"> - Possibility of contextual repair of mitral valve with the same device - Central spacer - Usable in most anatomies 	<ul style="list-style-type: none"> - Screening is not constrained by coaptation gap size, number of leaflets or jet location 	<ul style="list-style-type: none"> - Usable in very dilated annuli - Combined treatment (edge-to-edge) - Adaptable to the patient 	<ul style="list-style-type: none"> - Screening is not constrained by coaptation gap size, number of leaflets or jet location
Disadvantages	<ul style="list-style-type: none"> - Limited utility in large coaptation gaps 	<ul style="list-style-type: none"> - Limited utility in large coaptation gaps 	<ul style="list-style-type: none"> - Limited use in very dilated annuli - Necessity of pre-CT scan evaluation - Higher risk of conduction abnormalities 	<ul style="list-style-type: none"> - Complexity and duration of the procedure 	<ul style="list-style-type: none"> - Limited use in some anatomies - Necessity of pre-CT scan evaluation



Sorajja et al.	TRILUMINATE study	Randomized trial	350	Hierarchical composite (death, heart failure hospitalization, KCCQ score improvement)	87 % ≤ moderate TR at 30 days	Not significantly different	12.3 points improvement in KCCQ	Improvement in 74.9 % (p < 0.001)
Lurz et al.	bRIGHT study	Observational, real-world	511	1-year mortality, TR reduction, NYHA and KCCQ score changes	81 % ≤ moderate TR at 1 year	1-year mortality lower in the TR reduction group	19 ± 26-point improvement in KCCQ	75 % in NYHA I/II (p < 0.0001)
Donal et al.	Tri.Fr trial	Randomized trial	300	Composite clinical endpoint (NYHA change, major CV events)	6.8 % massive TR in T-TEER + OMT group	Not specified	69.9 vs 55.4 KCCQ score (P < 0.001)	74.1 % improved composite score
Kodali et al.	CLASP TR study	Prospective, single-arm	65	Safety and efficacy of PASCAL repair, KCCQ, and NYHA changes	86 % ≤ moderate TR at 1 year	87.9 % freedom from mortality	18 points KCCQ improvement (P < 0.001)	92 % in NYHA I/II (p < 0.001)
Wild, et al.	PASTE study	Observational, multicenter	1059	TR reduction, clinical success, NYHA class, and KCCQ changes	83 % ≤ moderate TR at 1 year	Not specified	Significant improvement in KCCQ score	66 % in NYHA I/II (p < 0.001)
Nickenig et al.	TRI-REPAIR study	Prospective, single-arm	30	Echocardiographic outcomes, KCCQ, 6MWT improvements	72 % ≤ moderate TR at 2 years	6.8 % mortality rate	14-point improvement in KCCQ	82 % in NYHA I/II (p < 0.002)
Nickenig et al.	TriBAND study	Prospective, single-arm	61	Safety and efficacy of Cardioband system, TR reduction and QoL	69 % ≤ moderate TR at 30 days	1.6 % mortality at 30 days	17-point improvement in KCCQ (P < 0.001)	74 % in NYHA I/II (p < 0.001)
Kodali et al.	TRISCEND study	Prospective, single-arm	176	Safety and efficacy of TV replacement, KCCQ, 6MWT improvements	97.6 % ≤ mild TR at 1 year	9.1 % mortality rate	25.7 points improvement in KCCQ (P < 0.001)	93.3 % in NYHA I/II (p < 0.001)
Hahn et al.	TRISCEND II study	Multicenter trial	400	Composite hierarchical outcome, including KCCQ, NYHA, 6MWT, heart failure events	95.3 % ≤ mild TR at 1 year 99.1 % ≤ moderate TR at 1 year	12.6 % mortality rate	23.1 % improvement in KCCQ (P < 0.001)	10.2 % improved NYHA class
Taramasso et al.	TriValve Registry	Observational, case-control	472	1-year mortality, rehospitalization, composite endpoint	Not specified	23 % vs 36 % mortality (TTVI vs control)	Not specified	Not specified
Blasco-Turrión et al.	TRICUS & TRICUS EURO studies	Prospective, single-arm	44	Impact on QoL and systemic congestion at 1 year	63.8 % abolished backflow, reduced TR	6.8 % mortality rate	Significant improvement in KCCQ score	95.5 % improved NYHA class

Algoritmus katetrizační léčby trikuspidální regurgitace



Závěr

- Trikuspidální regurgitace už dávno není považována za nevýznamnou chlopenní vadu
- Její přítomnost je jednoznačně spojena s horší prognózu pacientů
- Dnes máme důkazy o efektivitě a prospěšnosti katetrizační léčby v těchto indikacích (katetrizační plastika cípů trikuspidální chlopně a implantace chlopně)
- Přesto zůstává řada otázek dosud nezodpovězena (především kdy a jakým způsobem léčit)



DĚKUJI ZA POZORNOST!

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