KOMPLEXNÍ KARDIO VASKULÁRNÍ CENTRUM VFN Praha

# Katetrizační plastika mitrální a trikuspidální chlopně – co je nového?

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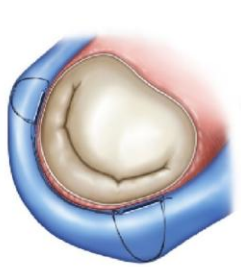
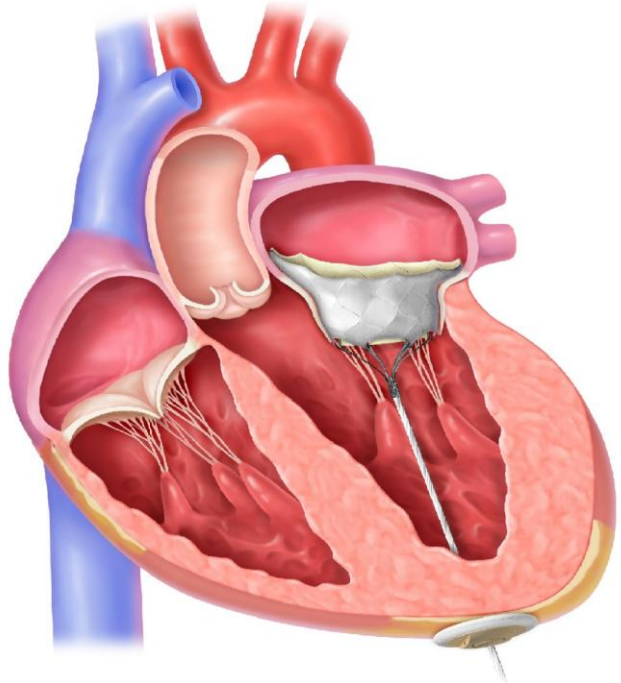
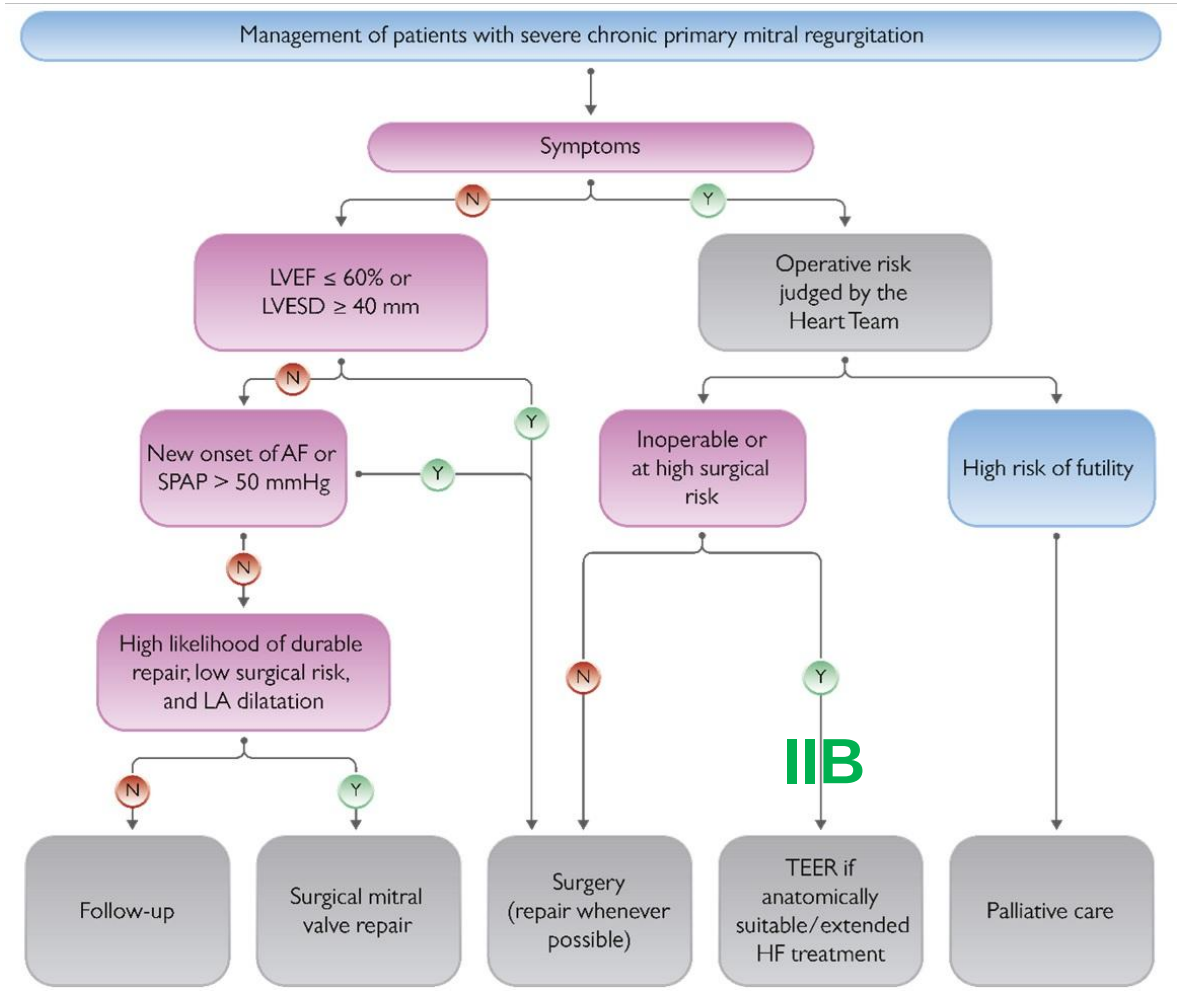
# Transkatétrová intervence mitrální chlopně (TMVI)

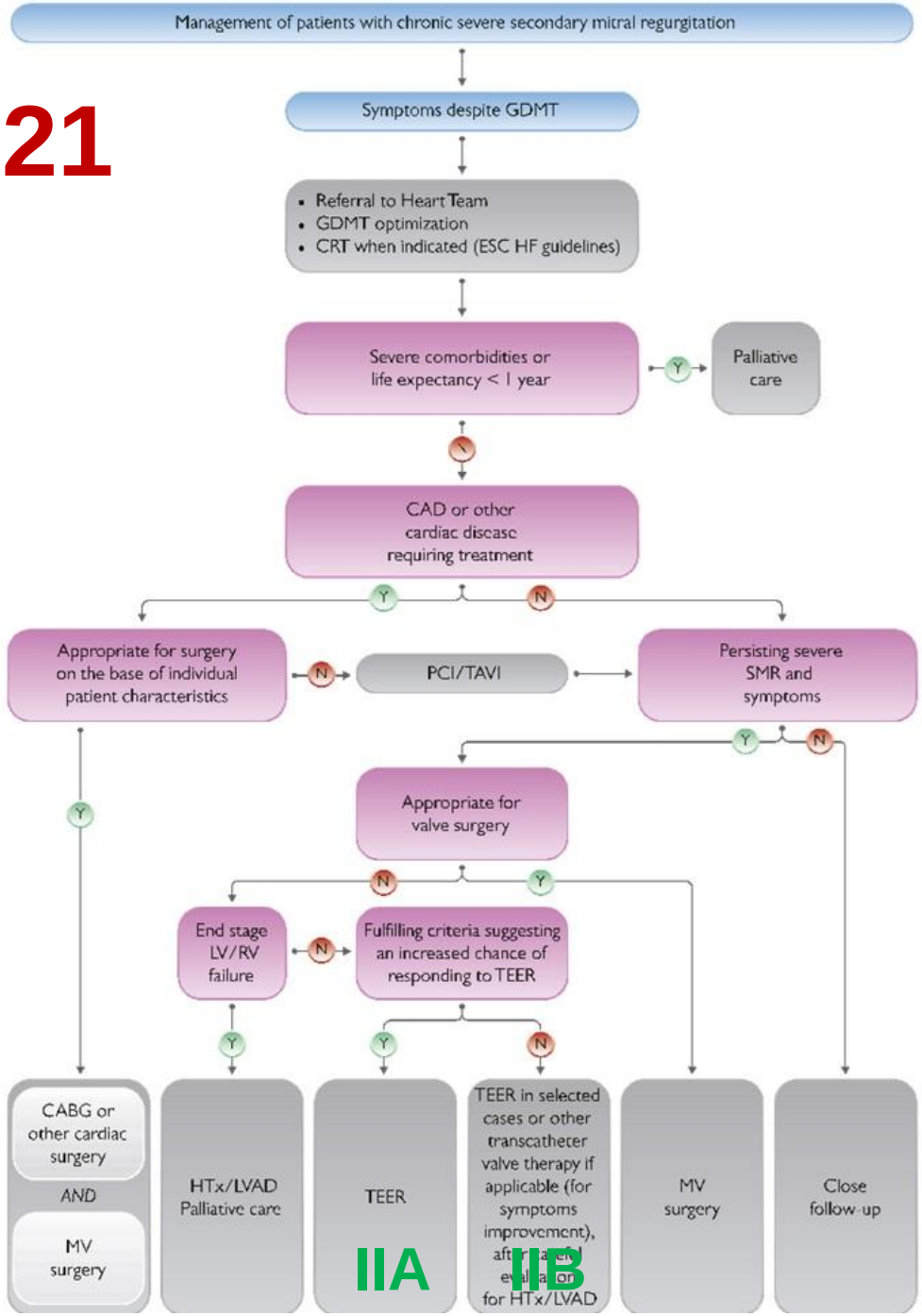


- Jsou pouze alternativou u chirurgicky rizikových pacientů (vysoké perioperační riziko), nebo nevhodných (srdeční selhání se sníženou systolickou funkcí, …)
- Focus Update ACC 2020 a ESC 2021
- Dělí se na:
  - **Záchovné výkony na mitrální chlopně**
    - Sutury cípů
    - Plastika prstence
    - Plastika závěsného aparátu
  - **Implantace bioprotézy (TMVR)**



# ESC valvular guidelines 2021

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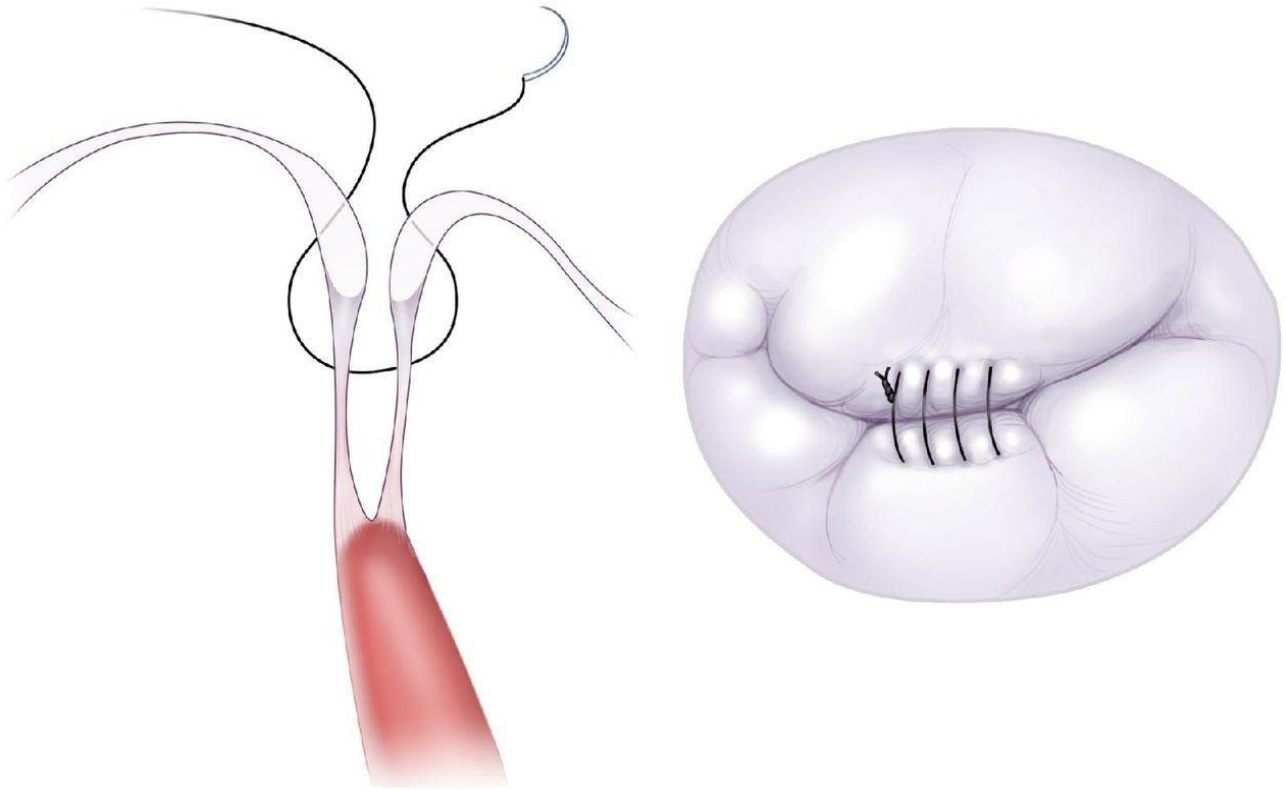
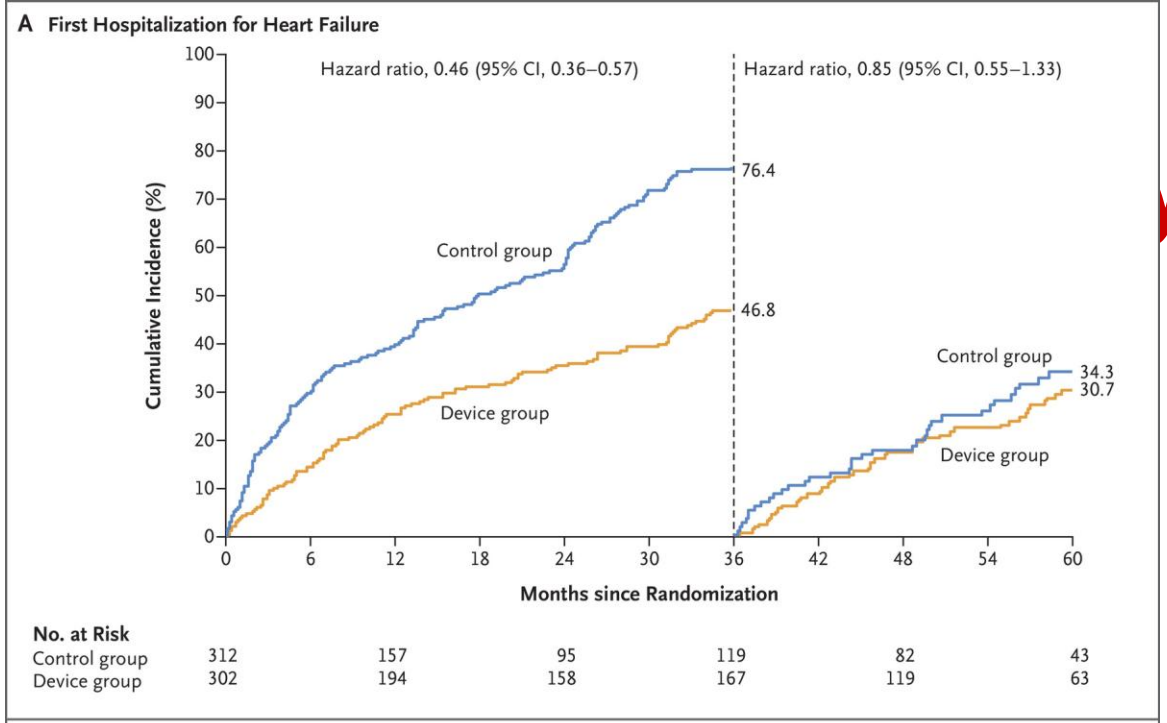
# Plastika cípů mitrální chlopně (TEER)

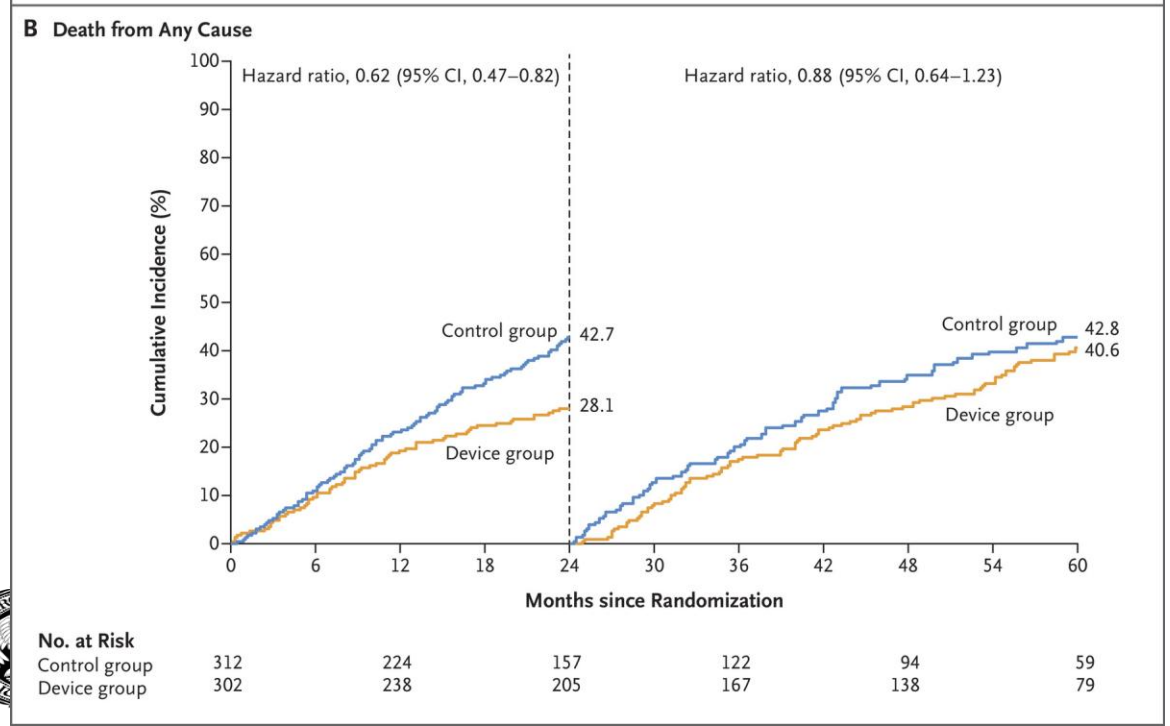
- Vychází z chirurgické techniky Alfieriho spočívající ve vytvoření dvou ústí
- Princip katetrizační intervence:
  - transeptální přístup
  - jícnové 3-D ECHO
- Největší zkušenosti MitraClip (EVEREST I, EVEREST II, COAPT, MITRA-FR, RESHAPE HF 2)
- Nověji systém Pascal



O´Gara P et al. JACC 2008

# year results




| Subgroup | Device Group | Control Group | Hazard Ratio (95% CI) |
|---|---|---|---|
| | *no. of patients with event/total no. of patients (Kaplan–Meier estimate of event rate, %)* | | |
| All patients | 213/302 (73.6) | 266/312 (91.5) | 0.53 (0.44–0.64) |
| Median age | | | |
| ≥74 yr | 118/157 (78.1) | 136/160 (93.9) | 0.57 (0.44–0.74) |
| <74 yr | 95/145 (68.6) | 130/152 (89.1) | 0.49 (0.38–0.64) |
| Sex | | | |
| Female | 64/101 (66.6) | 94/120 (83.7) | 0.60 (0.43–0.82) |
| Male | 149/201 (77.0) | 172/192 (96.2) | 0.47 (0.38–0.59) |
| Cause of cardiomyopathy | | | |
| Ischemic | 135/184 (76.1) | 159/189 (92.4) | 0.53 (0.42–0.67) |
| Nonischemic | 78/118 (69.6) | 107/123 (90.2) | 0.54 (0.40–0.72) |
| Previous cardiac resynchronization therapy | | | |
| Yes | 84/115 (74.9) | 96/109 (93.0) | 0.56 (0.41–0.75) |
| No | 129/187 (72.9) | 170/203 (90.6) | 0.52 (0.41–0.66) |
| Hospitalization for heart failure within previous yr | | | |
| Yes | 143/204 (73.7) | 175/203 (92.5) | 0.52 (0.41–0.65) |
| No | 70/98 (73.4) | 91/109 (89.0) | 0.57 (0.42–0.78) |
| Baseline NYHA class | | | |
| I or II | 92/130 (72.8) | 92/110 (88.2) | 0.55 (0.41–0.74) |
| III | 108/154 (74.5) | 143/168 (92.2) | 0.56 (0.44–0.73) |
| IV | 13/18 (72.2) | 30/33 (100) | 0.48 (0.25–0.94) |
| STS replacement score | | | |
| ≥8% | 96/126 (80.7) | 115/136 (94.8) | 0.56 (0.42–0.74) |
| <8% | 117/176 (68.7) | 151/176 (89.2) | 0.51 (0.40–0.66) |
| Surgical risk status | | | |
| High | 154/205 (79.3) | 183/218 (91.1) | 0.59 (0.47–0.73) |
| Not high | 56/94 (60.8) | 83/94 (92.0) | 0.41 (0.29–0.58) |
| Baseline grade of mitral regurgitation | | | |
| 3+ | 97/148 (69.0) | 143/172 (89.1) | 0.51 (0.39–0.66) |
| 4+ | 116/154 (78.0) | 122/139 (94.4) | 0.54 (0.42–0.70) |
| Baseline left ventricular ejection fraction | | | |
| ≥30% | 102/150 (70.8) | 125/151 (88.9) | 0.54 (0.41–0.70) |
| <30% | 94/131 (75.3) | 128/143 (95.6) | 0.45 (0.34–0.59) |
| >40% | 34/50 (72.0) | 42/53 (92.0) | 0.49 (0.31–0.79) |
| ≤40% | 162/231 (73.0) | 211/241 (92.1) | 0.50 (0.40–0.61) |
| Median baseline left ventricular end-diastolic volume | | | |
| ≥181 ml | 102/141 (75.6) | 130/147 (93.1) | 0.53 (0.40–0.69) |
| <181 ml | 94/140 (69.9) | 123/147 (91.1) | 0.47 (0.36–0.62) |

0.2 0.5 1.0 1.5

Device Intervention Better — Control Therapy Better

Stone GW et al. NEJM 2023

# CLASP IID

## Inclusion Criteria

- Age ≥18 years
- Prohibitive risk for mitral valve surgery
- Candidate for M-TEER with both the PASCAL system and the MitraClip system
- Degenerative mitral regurgitation (3+ to 4+)
- Suitable valve and regurgitant jet morphology
- LVEF ≥20%, LVEDD ≤80 mm

## Exclusion Criteria

- TEE is contraindicated or screening TEE is unsuccessful
- Severe right ventricular dysfunction
- Active rheumatic heart disease or rheumatic MR etiology
- Other severe valve disorders requiring intervention or left ventricular outflow obstruction
- Clinically significant, untreated coronary artery disease
- Requiring chronic renal replacement therapy or eGFR ≤25 mL/min

## Anatomical Exclusion Criteria[a]

Presence of any of the following:

- Moderate to severe calcification in the grasping area
- Significant cleft or perforation in the grasping area
- ≥2 independent significant jets
- One significant jet in the commissural area
- Mitral valve orifice area <4.0 $cm^2$
- Leaflet mobility length <8 mm
- Severe bileaflet/multi scallop prolapse involvement

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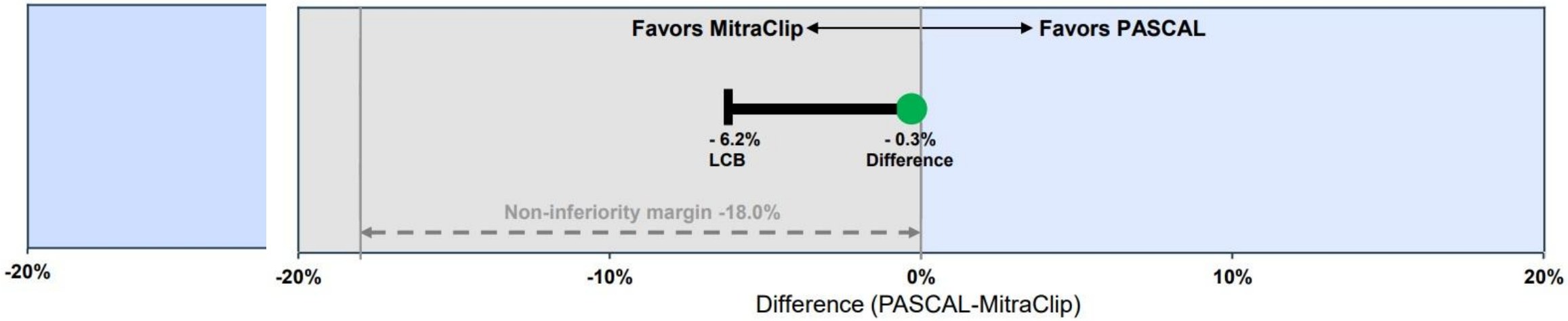
Lim DS et al. TCT 2022

# CLASP IID

## Primary Sa Primary Effectiveness Endpoint Met

*Composite MA MR ≤2+ at 6 months: 96.5% for PASCAL vs. 96.8% for MitraClip*

| PASCAL (n=1 | PASCAL (n=117) | MitraClip (n=63) | Difference | One-sided 95% LCB |
|---|---|---|---|---|
| **3.4%** (4/116 | **96.5%** (110/114) | **96.8%** (60/62) | **- 0.3%** | **- 6.2%** |

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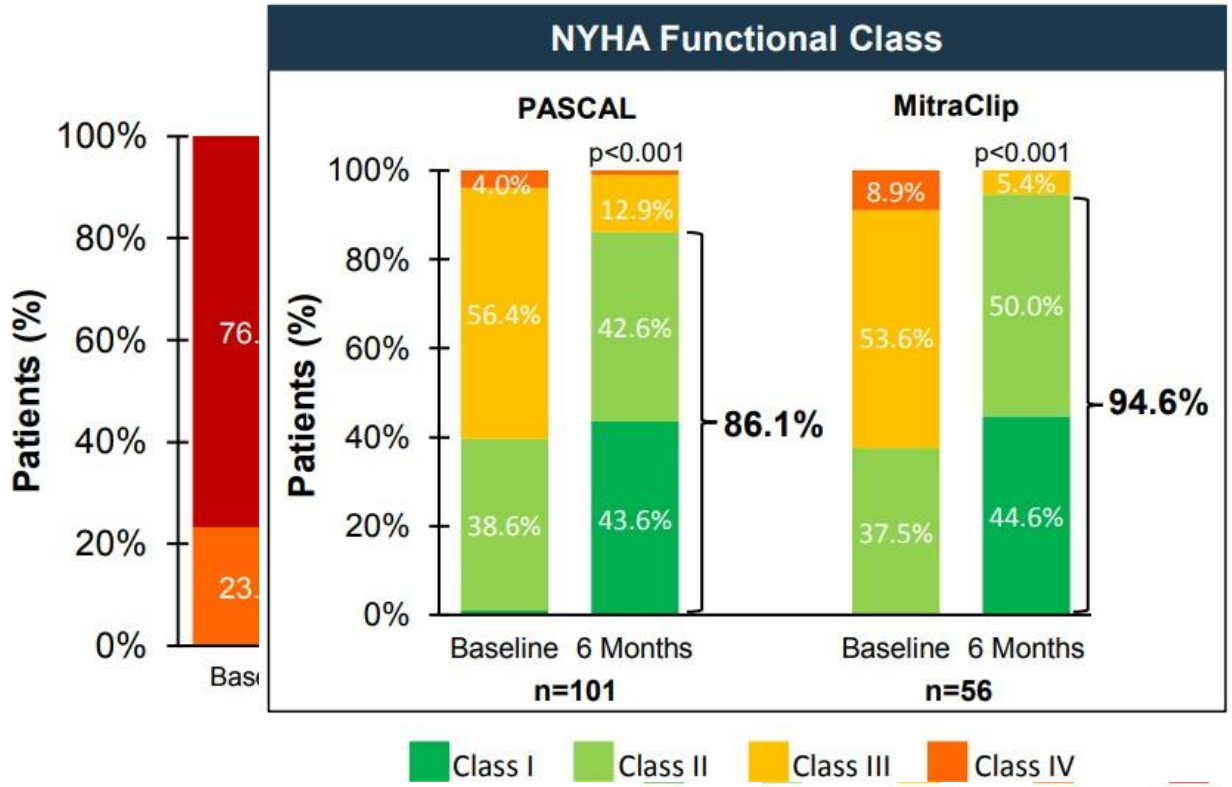
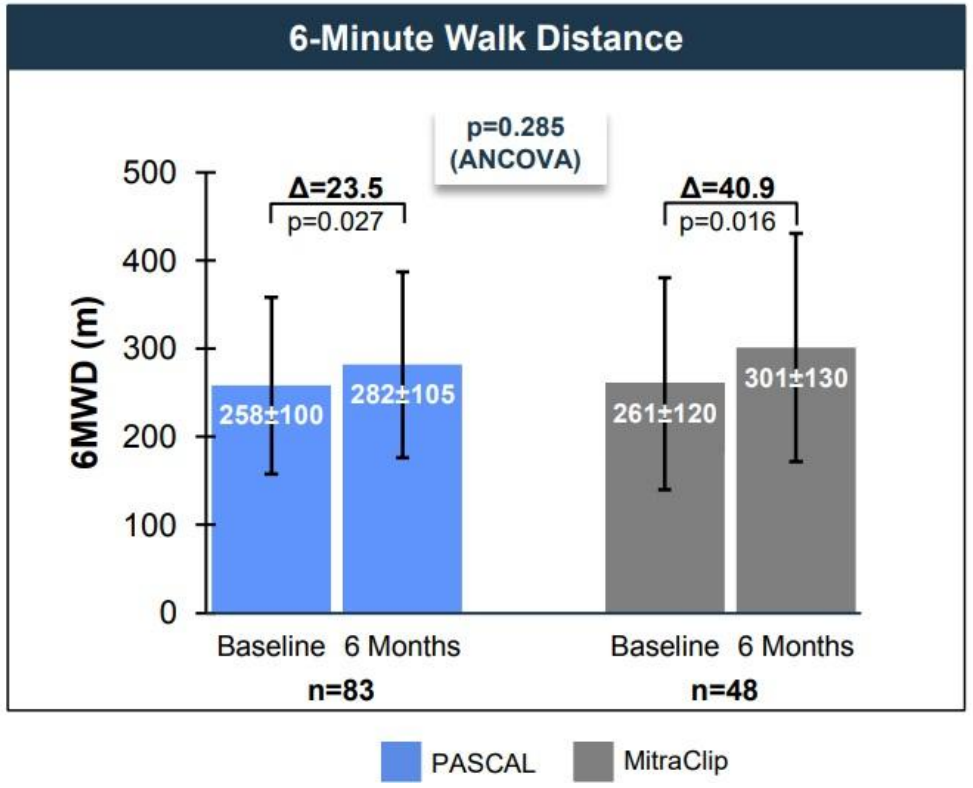
# CLASP IID

THE CLASP IID TRIAL

## MR Reduct
*Significant MR*

## Functional Outcomes
*Significant improvement in functional capacity at 6 months*

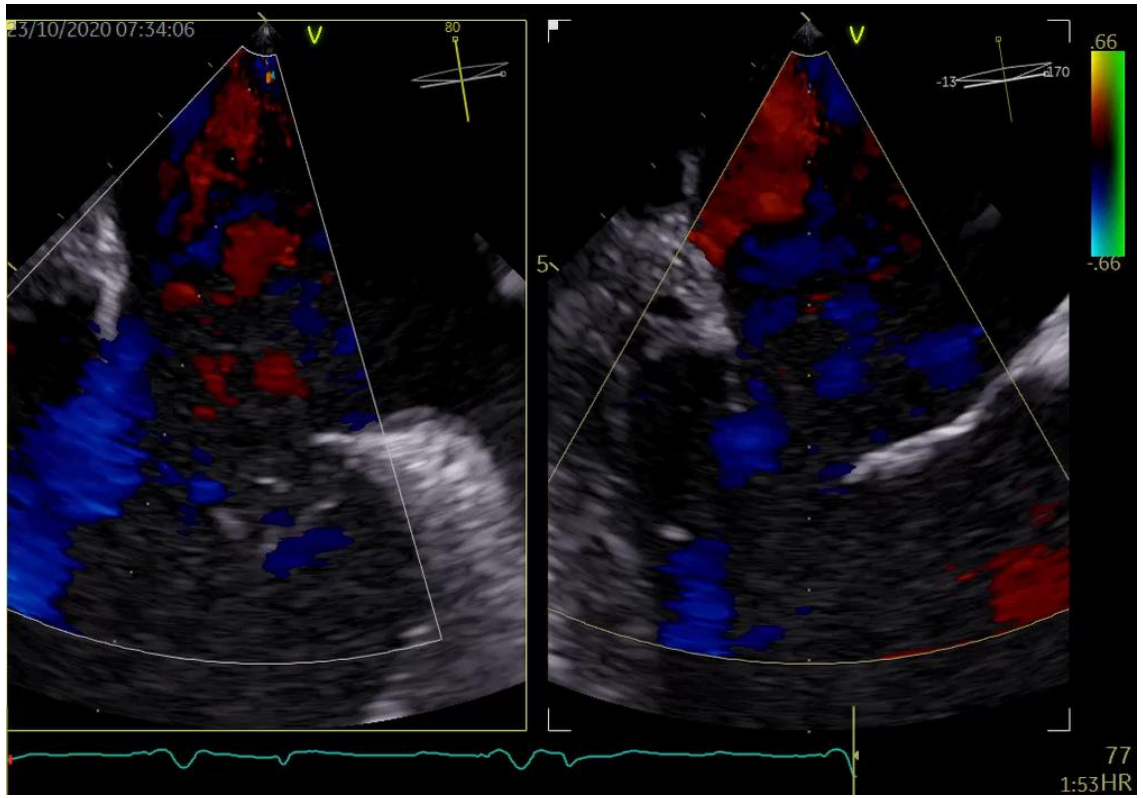


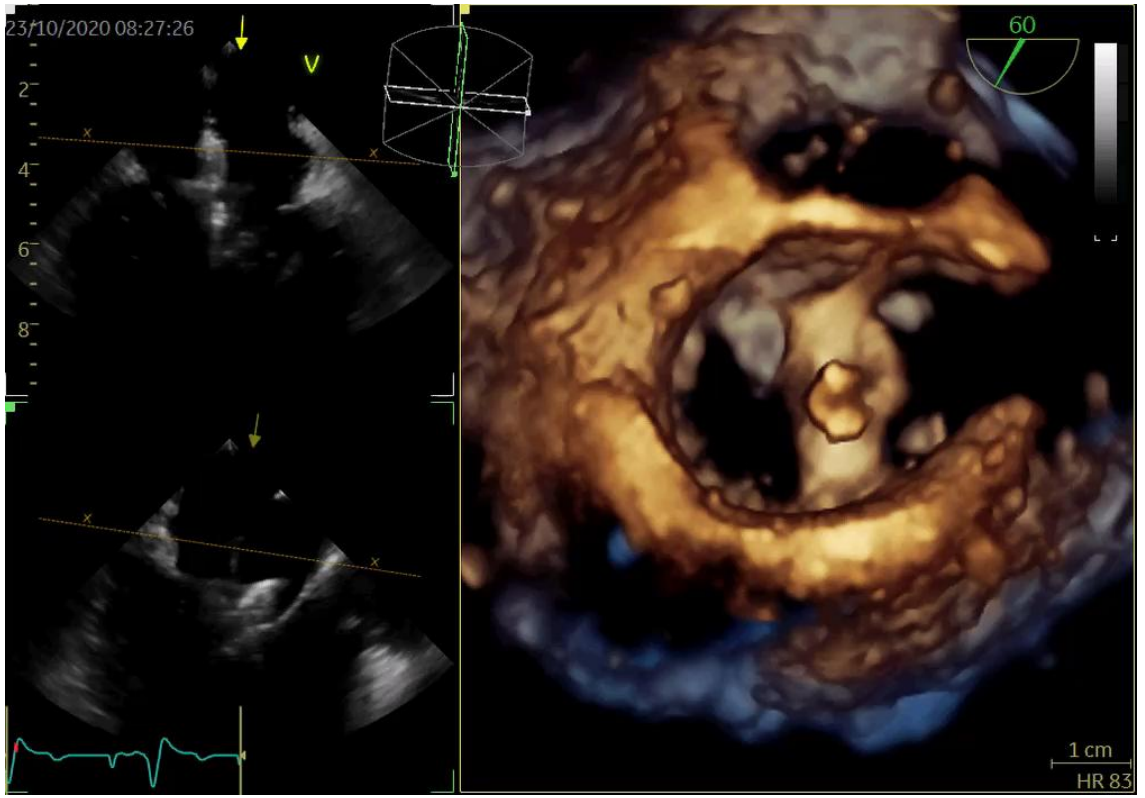

Lim DS et al. TCT 2022

# Plastika mitrální chlopně systémem Pascal

## TEE – X-plane barevný Doppler




## TEE – 3-D orientace klipu

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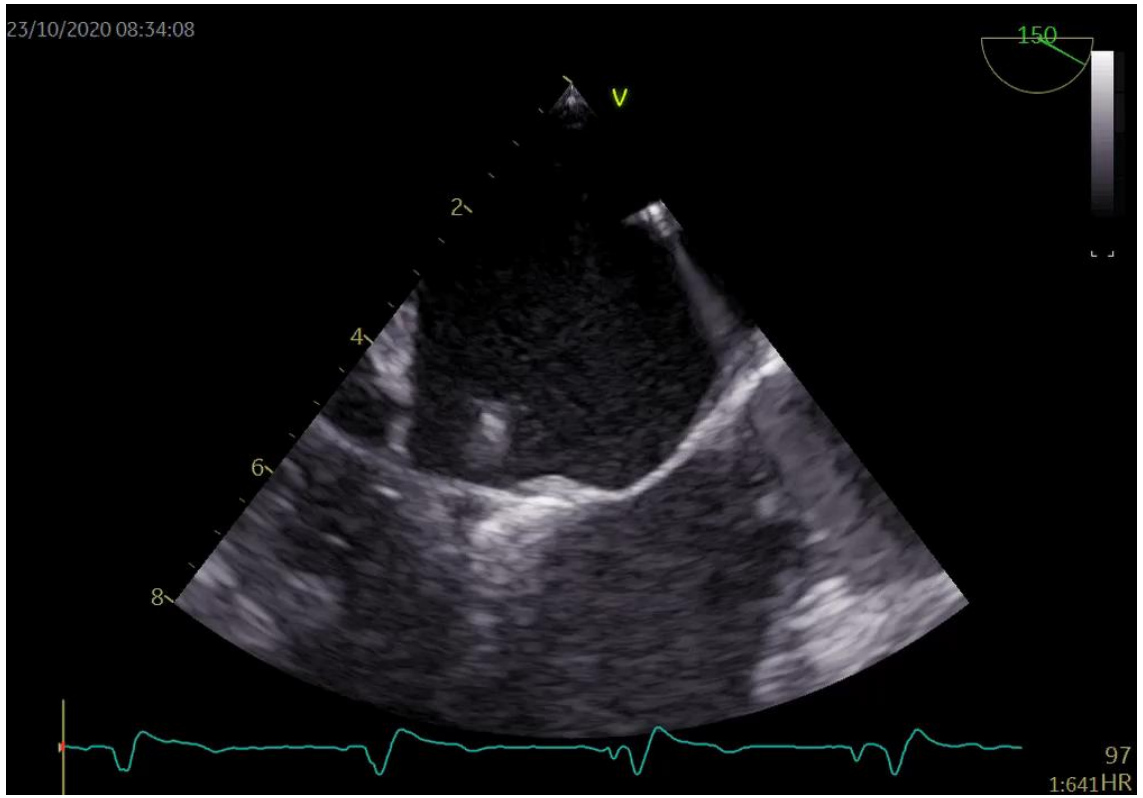
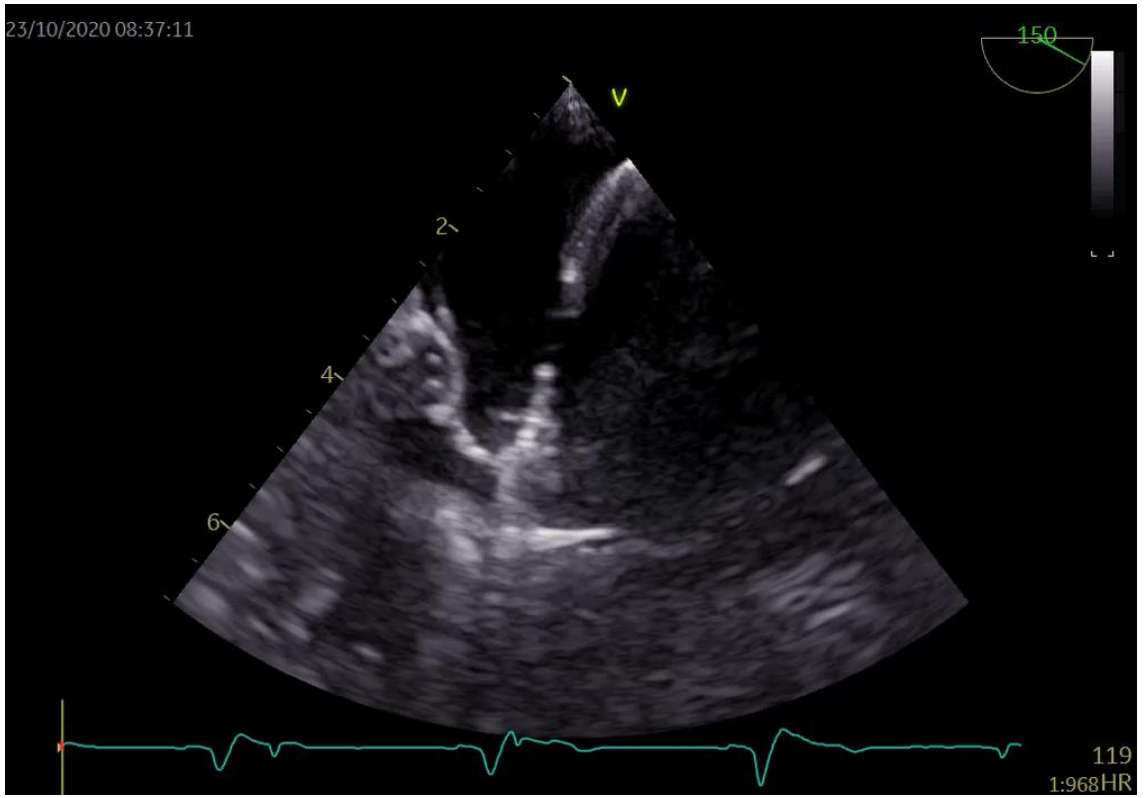
# Plastika mitrální chlopně systémem Pascal

## TEE – chytání cípů




## TEE – posterior leaflet recapture

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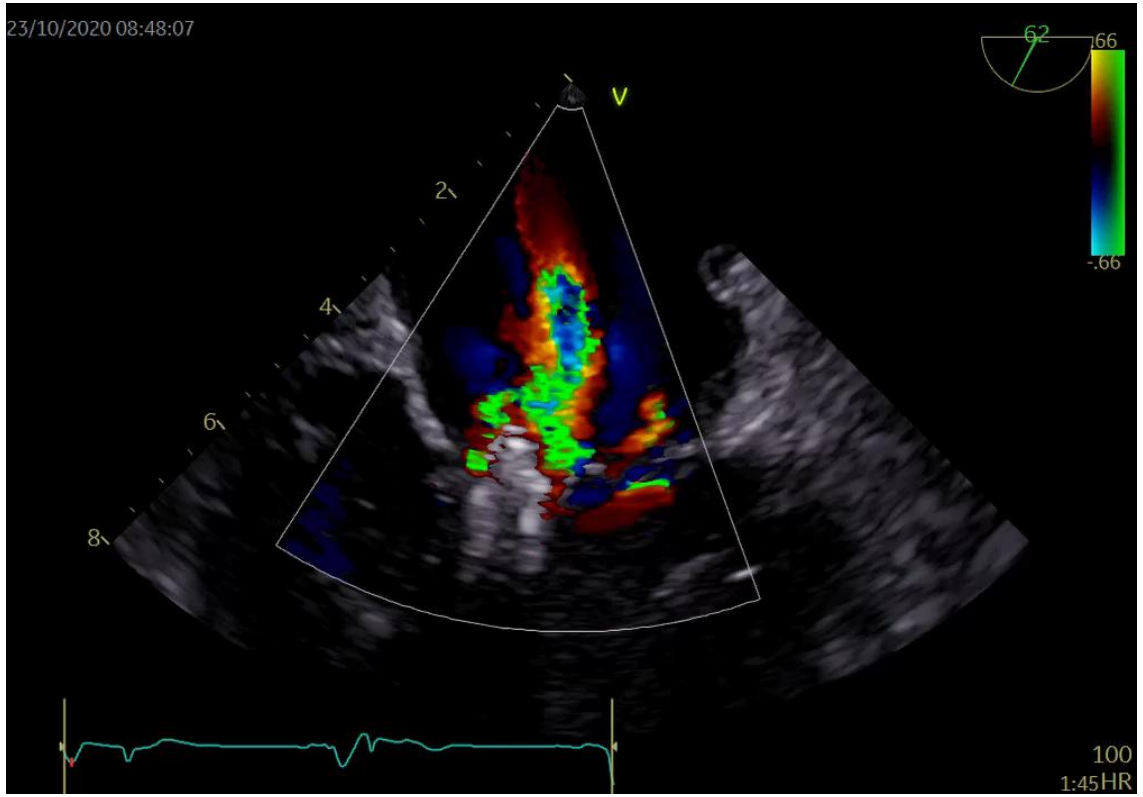
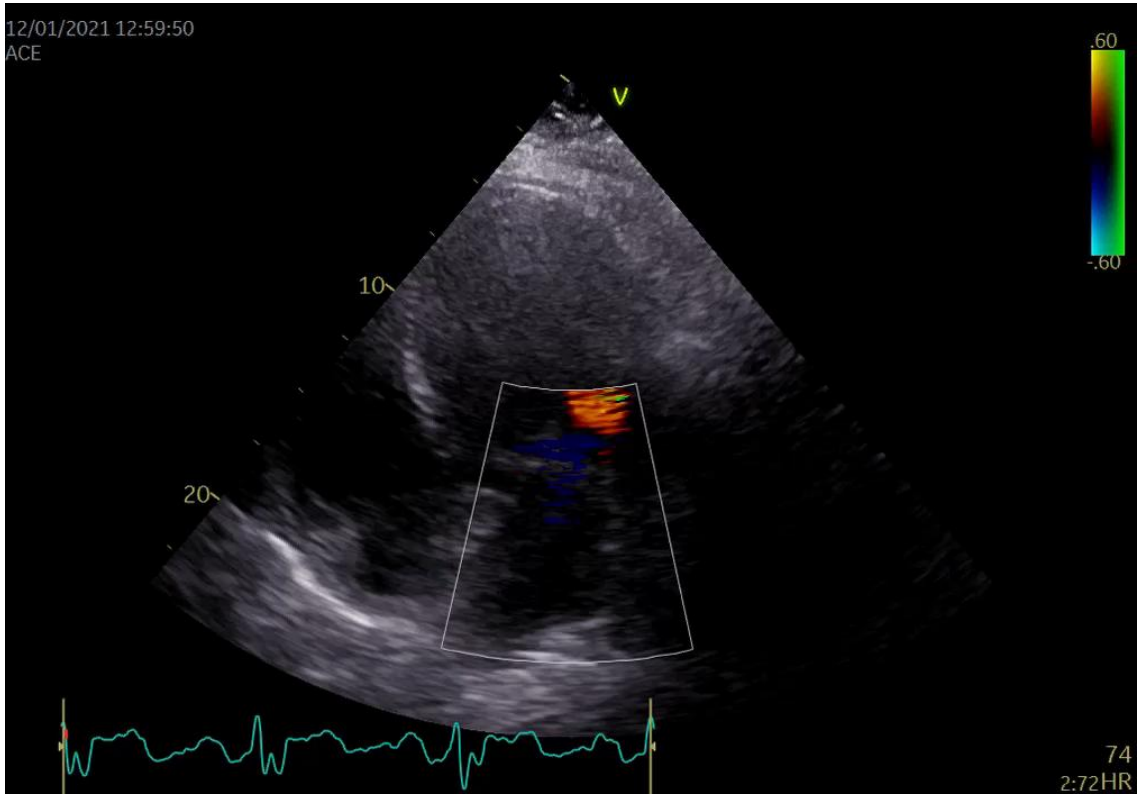
# Plastika mitrální chlopně systémem Pascal

## TEE – finální výsledek




## TTE – kontrola po 3 měsících

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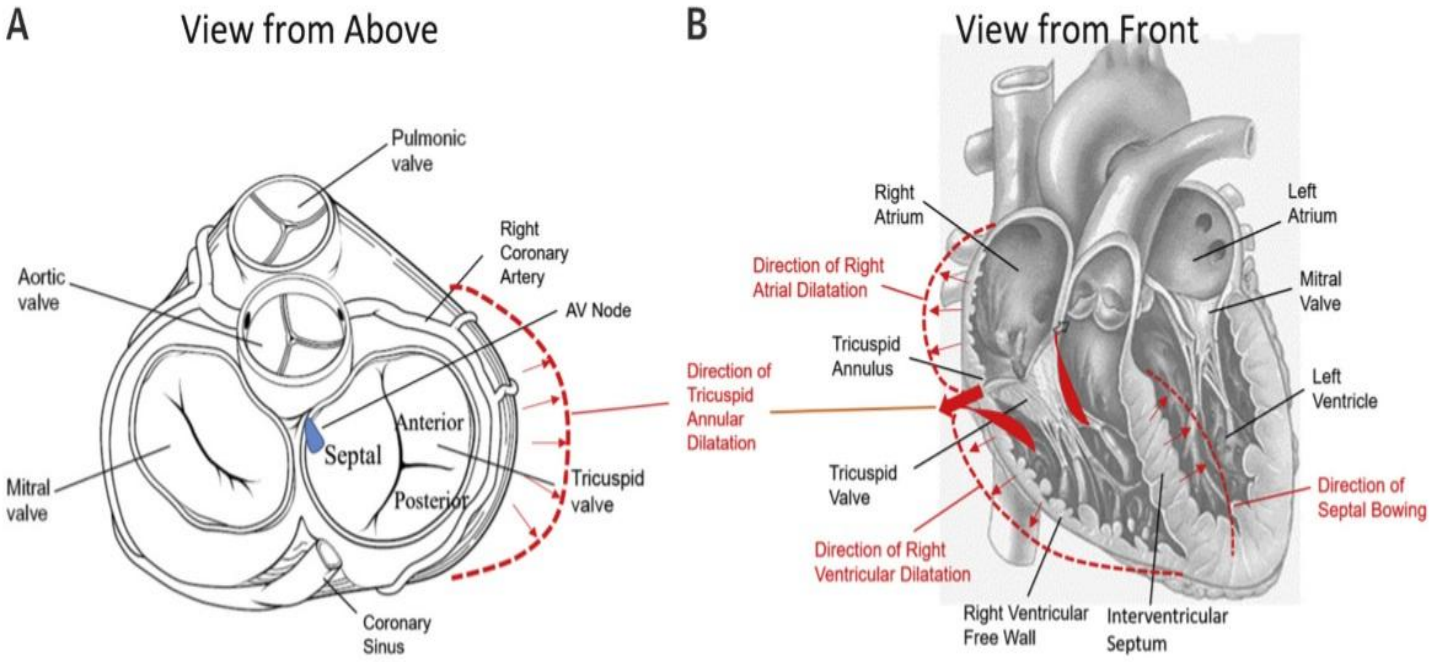
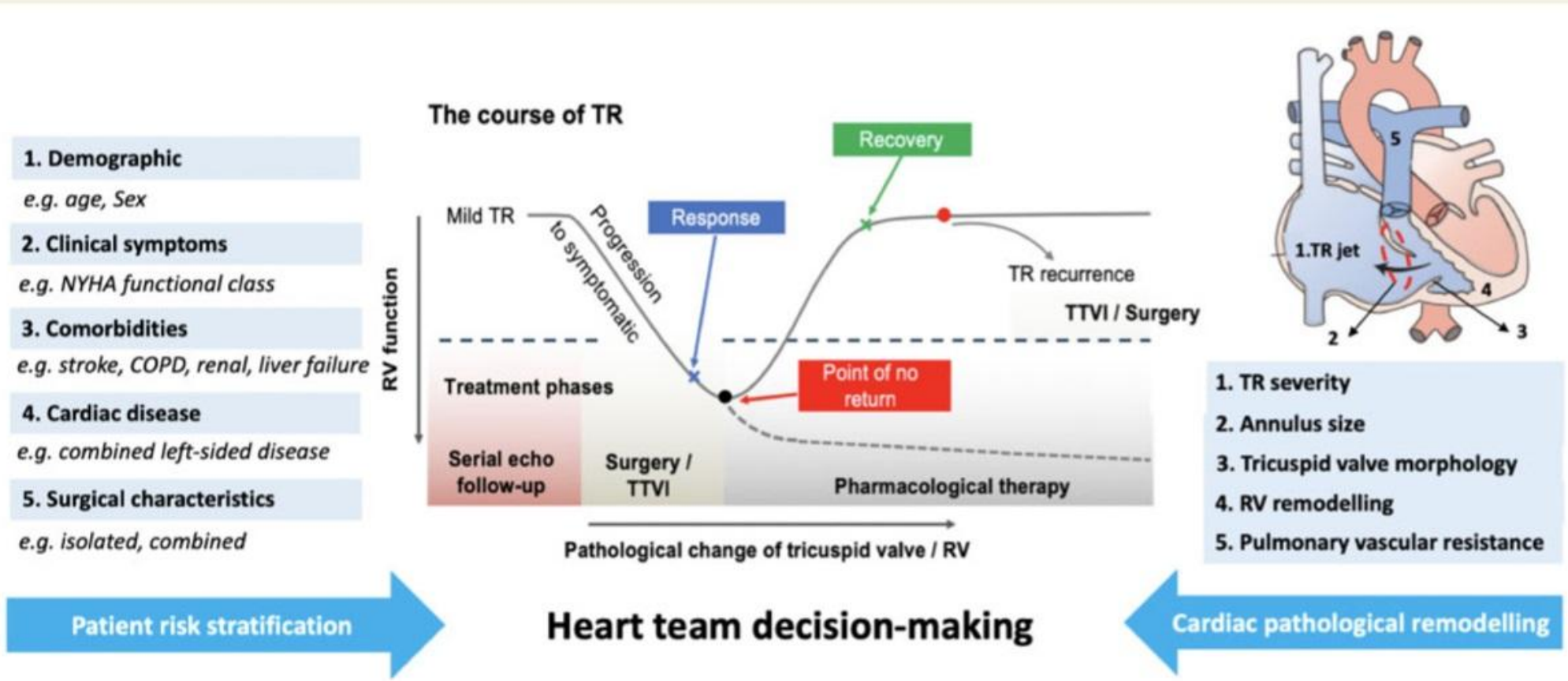
# Trikuspidální chlopeň

- Obtížné klinické hodnocení symptomů
- Obtížná kvantifikace (výrazně volum dependentní)
- Obtížně zobrazení z TEE
- Obtížné hodnocení funkce pravé komory




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

# 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

# Možnosti léčby trikuspidální regurgitace

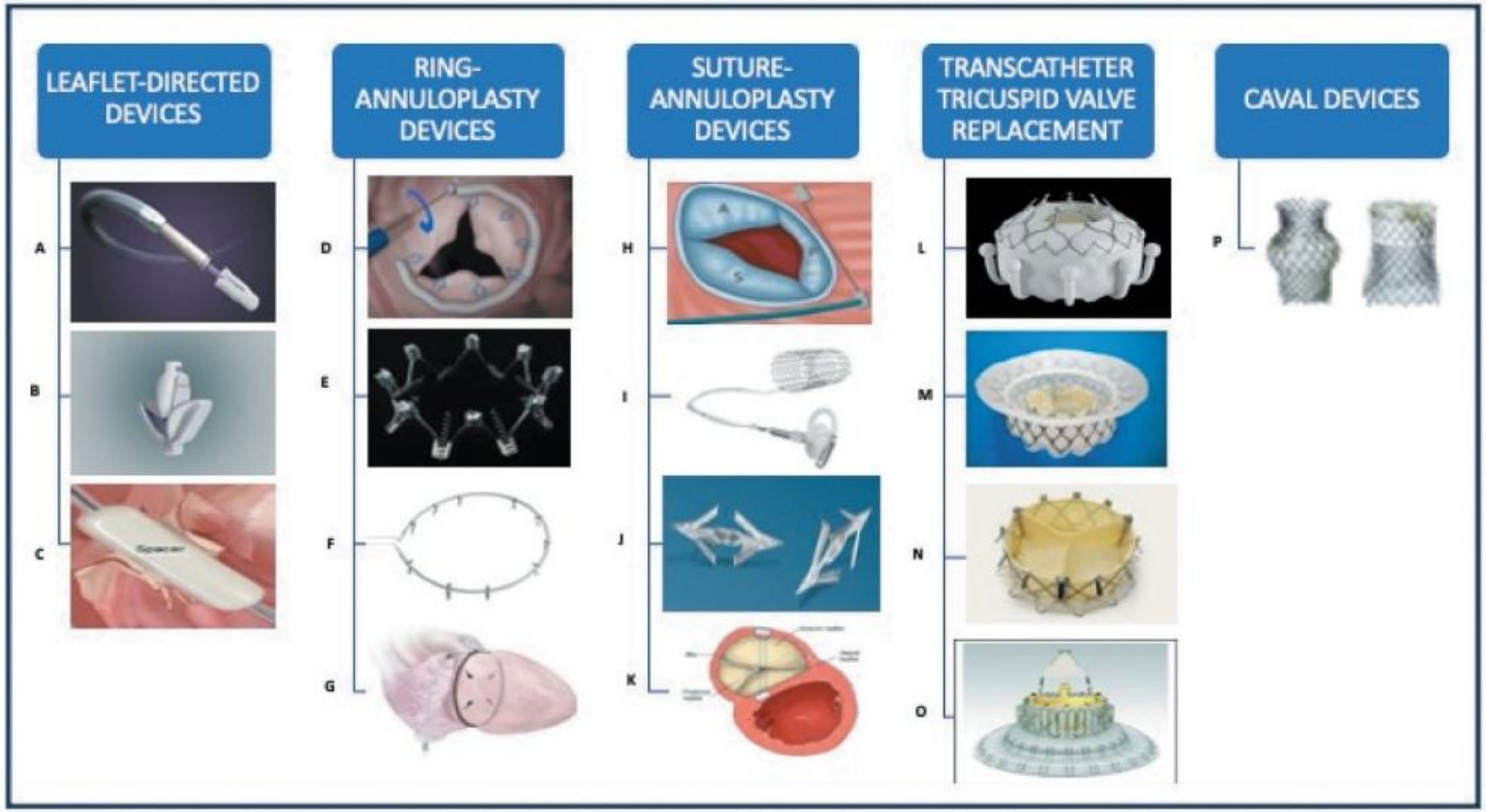



**Figure 3.** Transcatheter treatment options for severe tricuspid regurgitation.

A. MitraClip/TriClip, B. PASCAL, C. FORMA Spacer (no longer available), D. Cardioband, E. Millipede IRIS, F. DaVingi TR System, G. TRAIPTA technique, H. TriAlign (no longer available), I. TriCinch (no longer available), J. MIA device, K. PASTA technique, L. EVOQUE valve, M. Intrepid valve, N. NaviGate, O. LUX-valve, P. TricValve

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Rahgozar K et al. Expert Rev Cardiovasc Ther 2021

# „Nová klasifikace trikuspidální regurgitace“

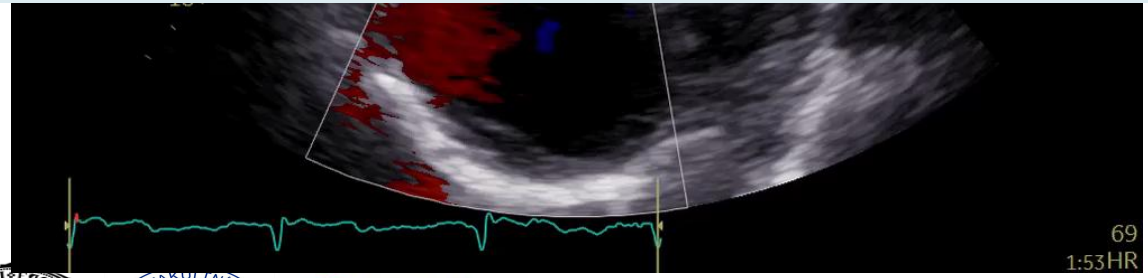
**Masivní trikuspidální regurgitace před E2E katetrizační plastikou**

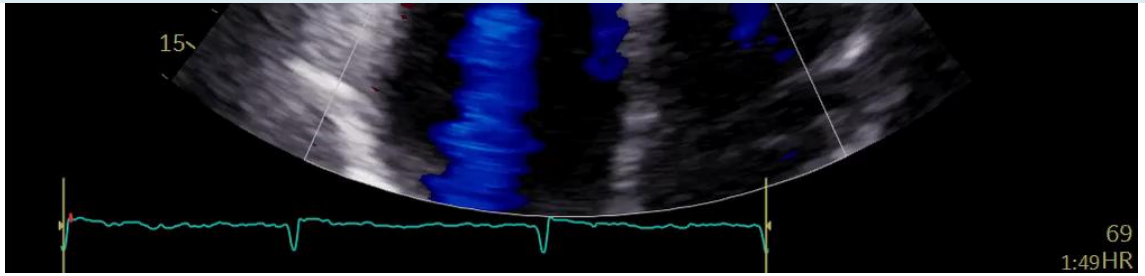
**Středně těžká až těžká trikuspidální regurgitace po E2E plastice**

**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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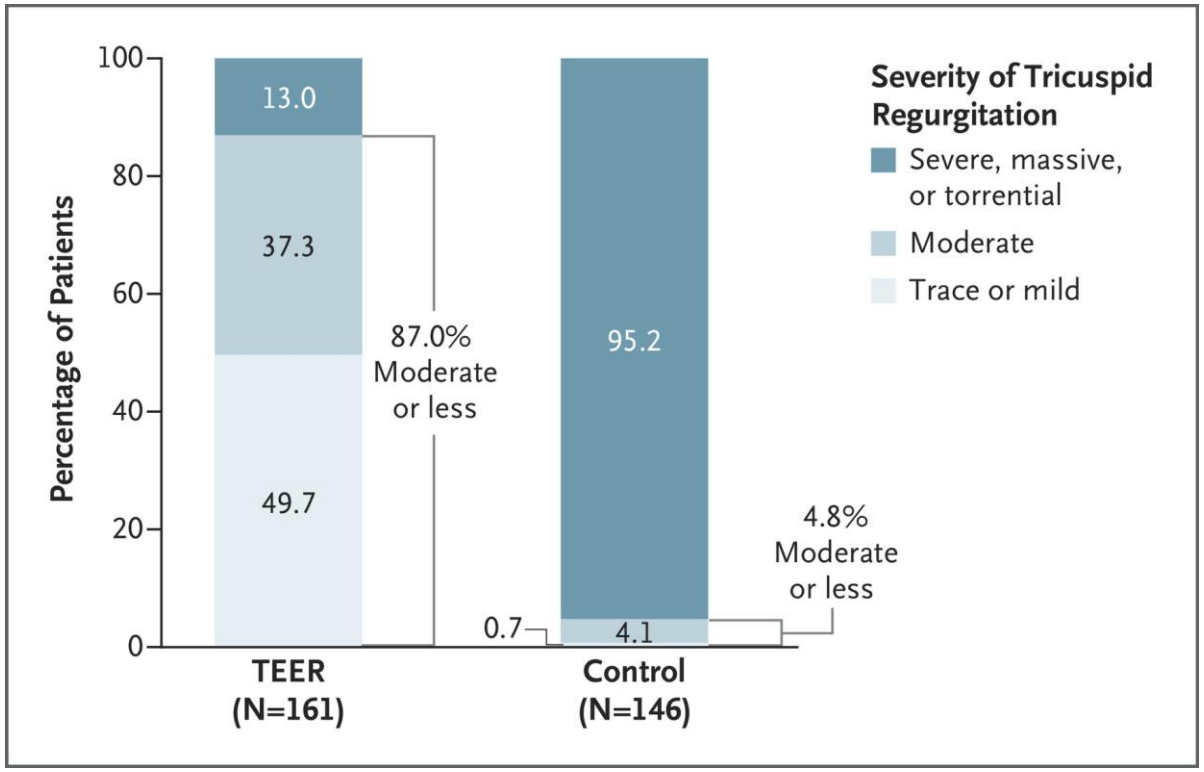
# TRILUMINATE study

## Závažnost trikuspidální regurgitace po 30 dnech




Sorajja P et al. NEJM 2023


**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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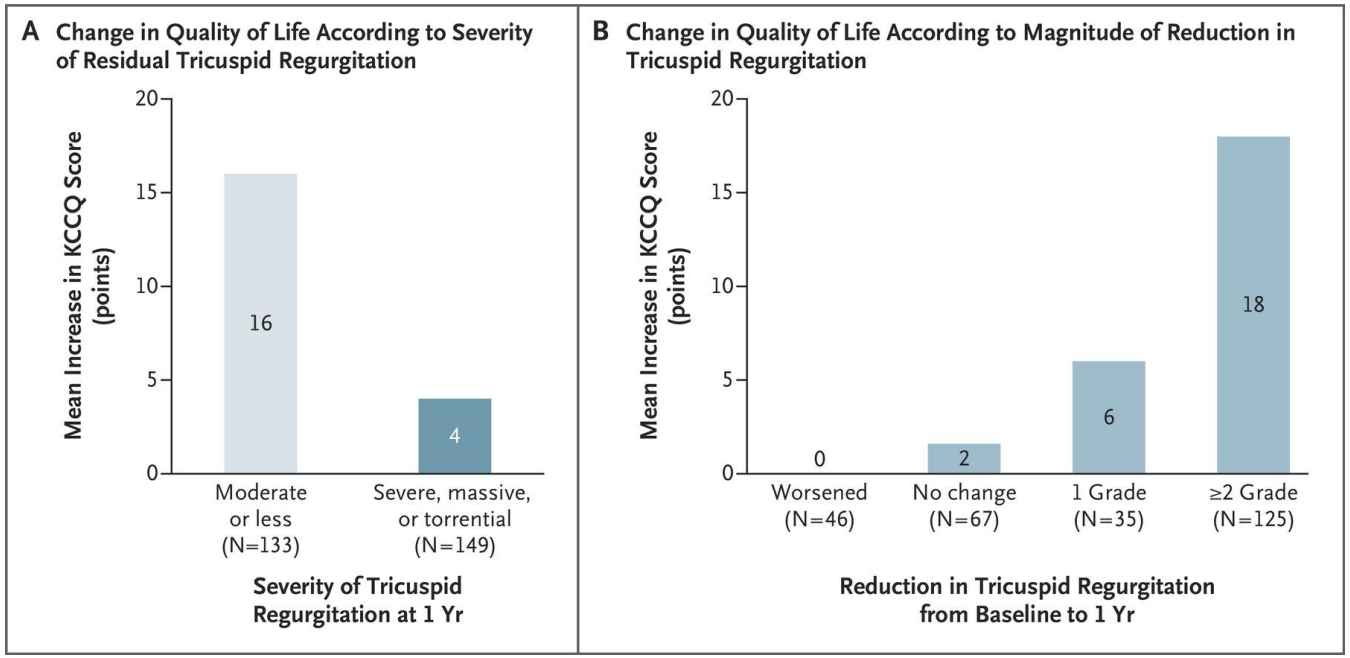
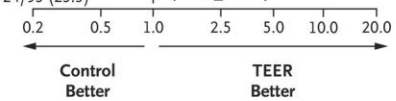
# TRILUMINATE study



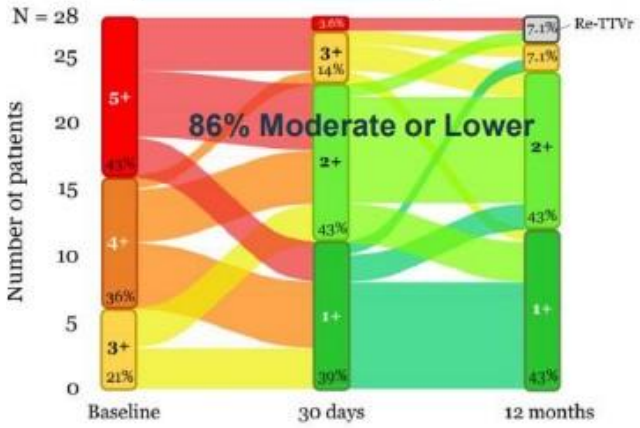

Sorajja P et al. NEJM 2023

| 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) |

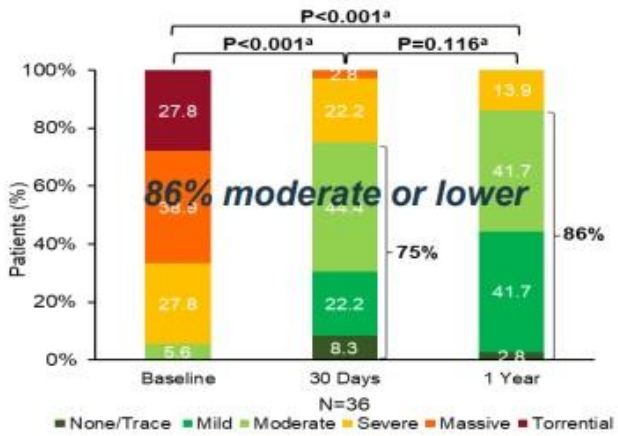


# Efekt T-TEER je konzistentní

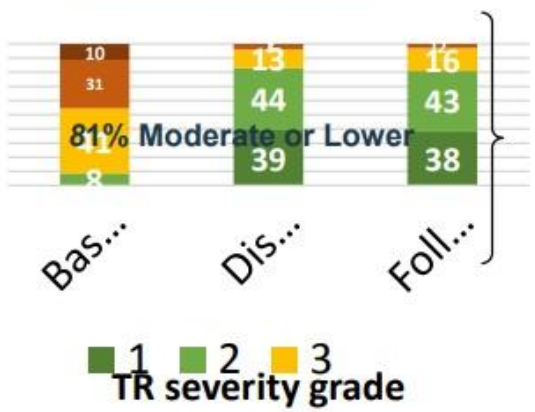
**CLASP CU**



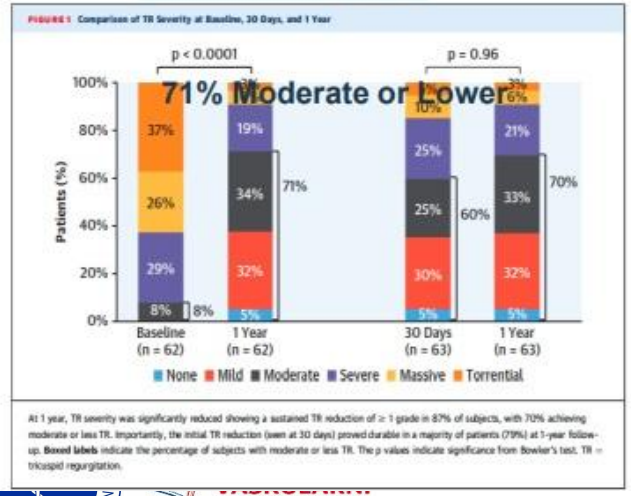

**CLASP TR EFS**



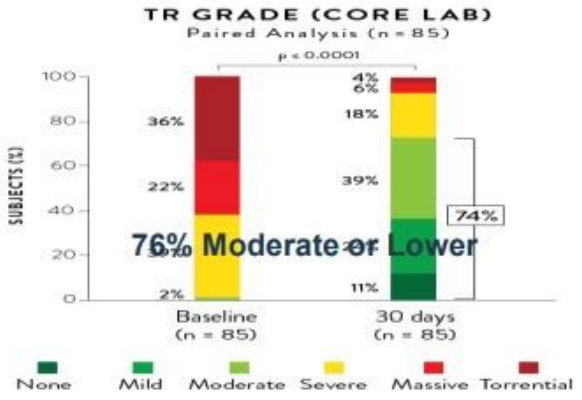

**PASTE Registry**



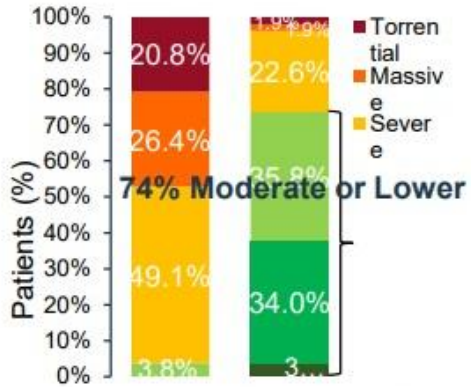

**Triluminate Registry**




**Triluminate Pivotal Roll In**




**CLASP II TR Roll In**

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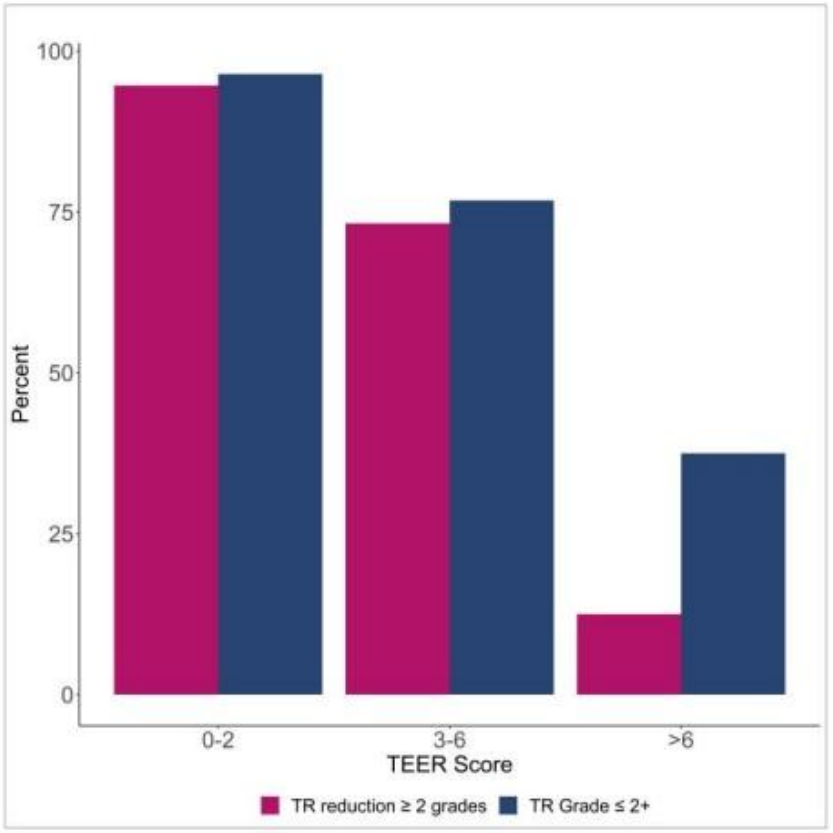
# T-TEER prognostické skóre

**The Tricuspid TEER Scoring system**

| Parameters | Straightforward (0 points) | Moderate (1 point) | Complex (2 points) |
|---|---|---|---|
| Septolateral Gap | 0 - 2 mm | 3 - 6 mm | > 6 mm |
| 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) |

[1]to the coaptation-line

**Procedural success in each T-TEER-Score group**

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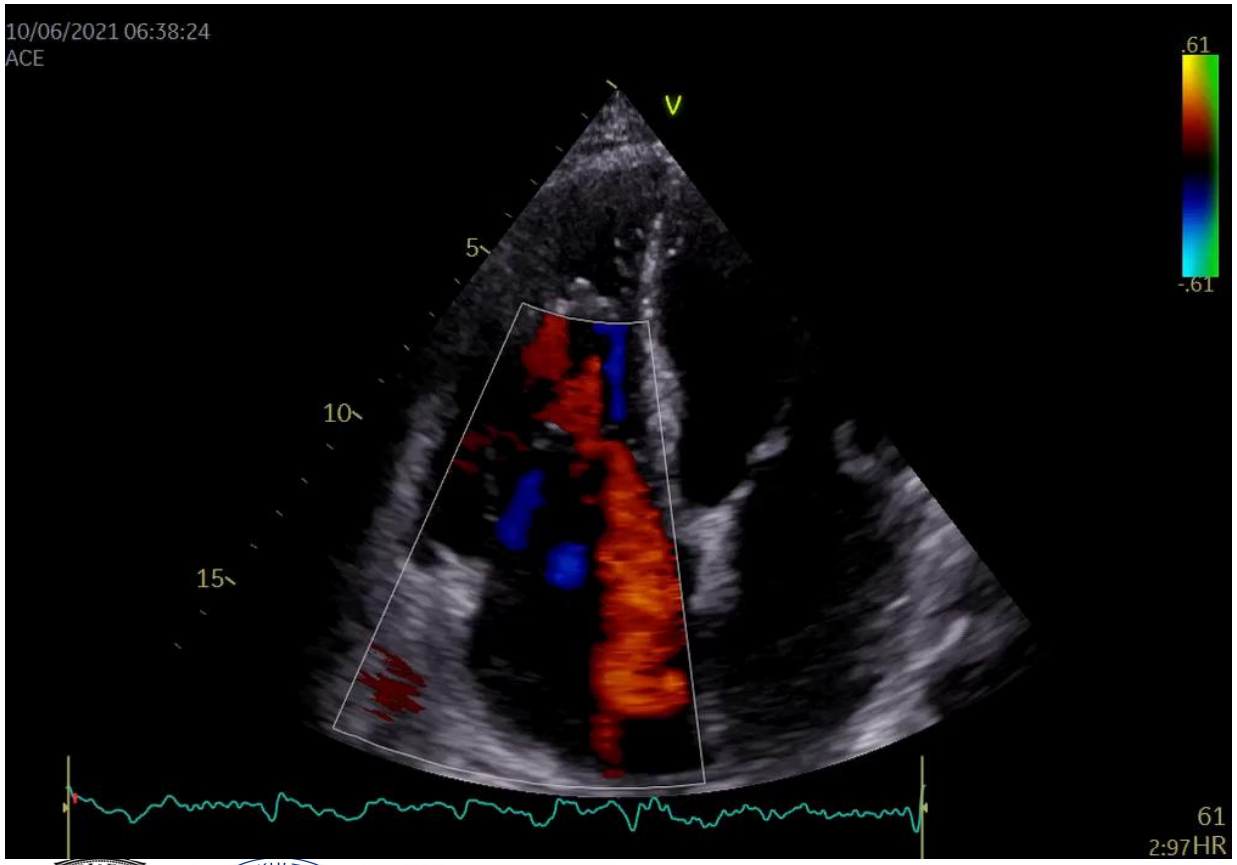
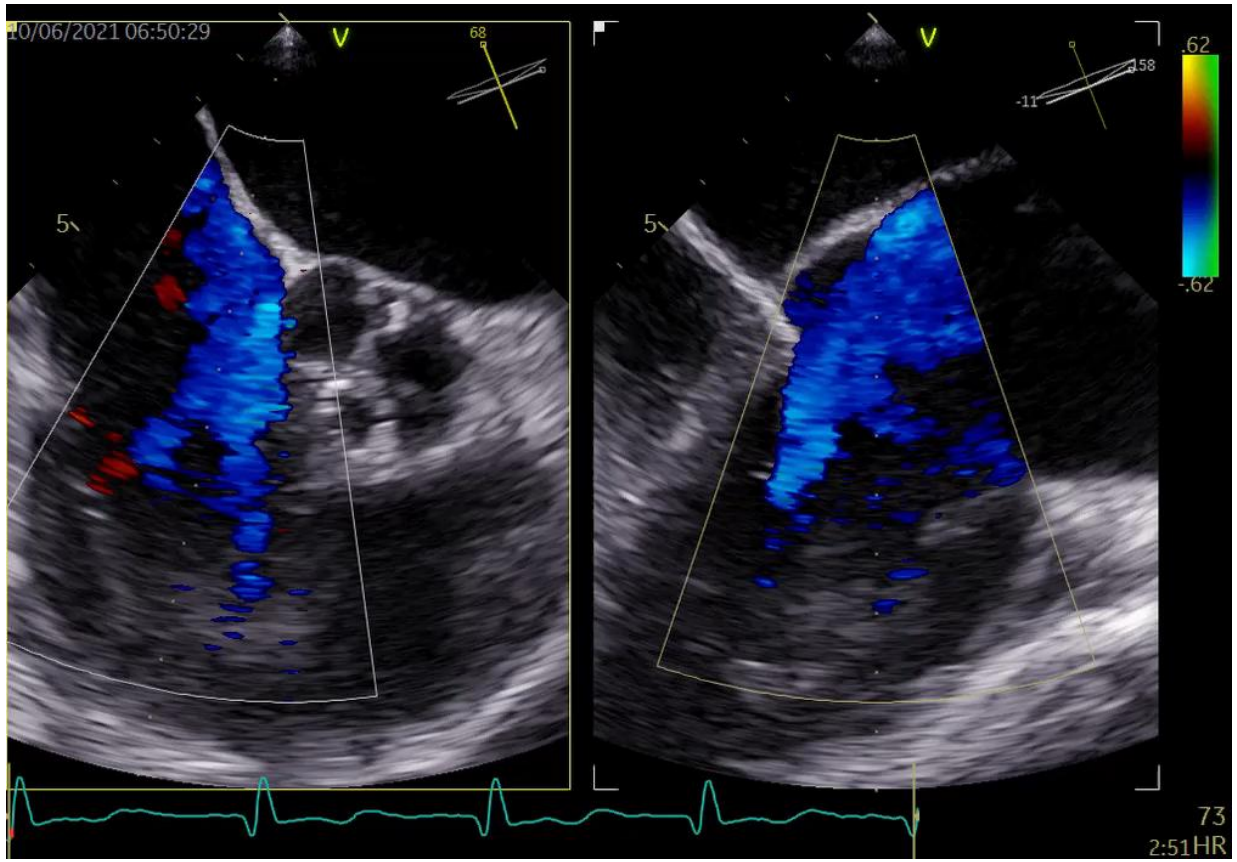
# Plastika trikuspidální chlopně pomocí Pascal

## Těžká trikuspidální regurgitace (4D)



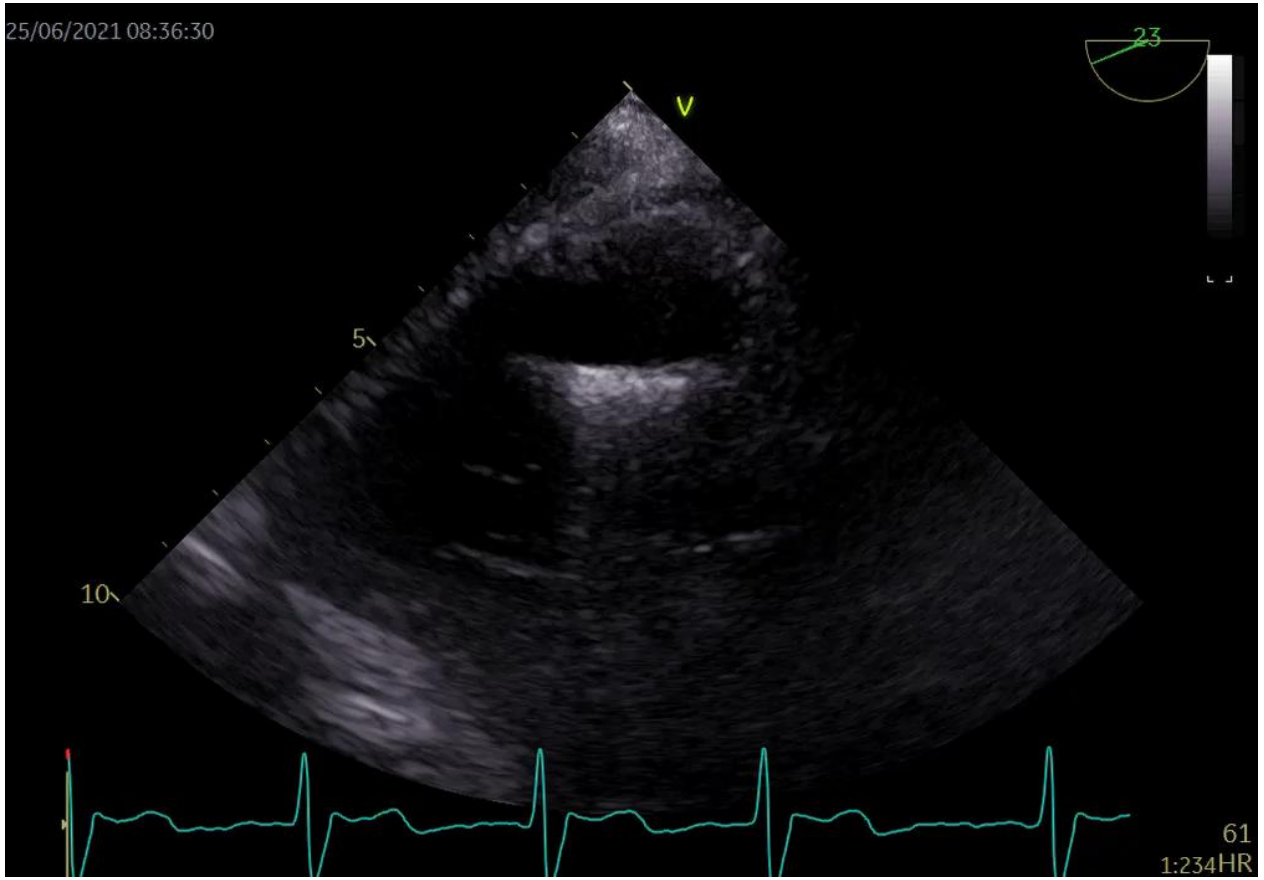

## TEE před výkonem



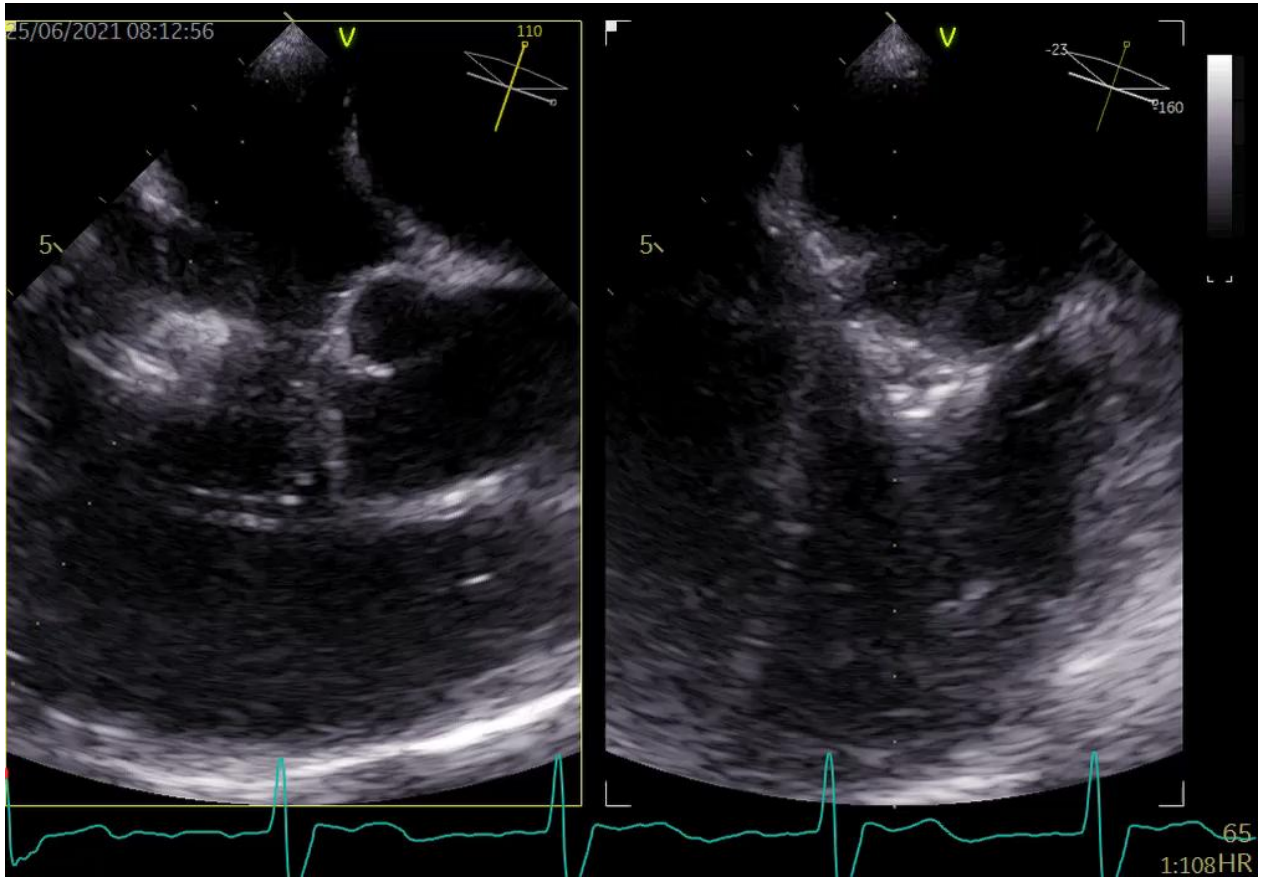

z obrazového archivu VFN

# Plastika trikuspidální chlopně pomocí Pascal

## TEE – transgastrická projekce




## TEE – chytání cípů chlopně

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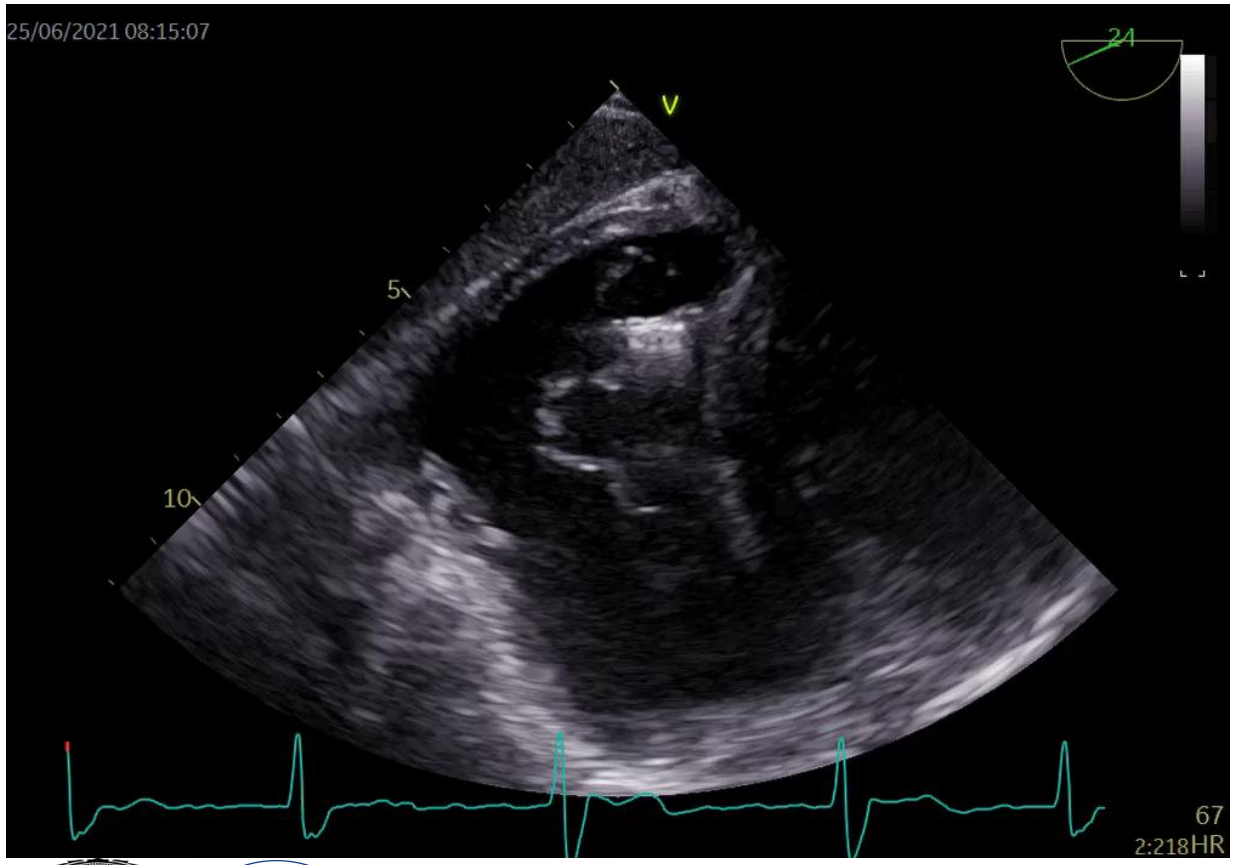
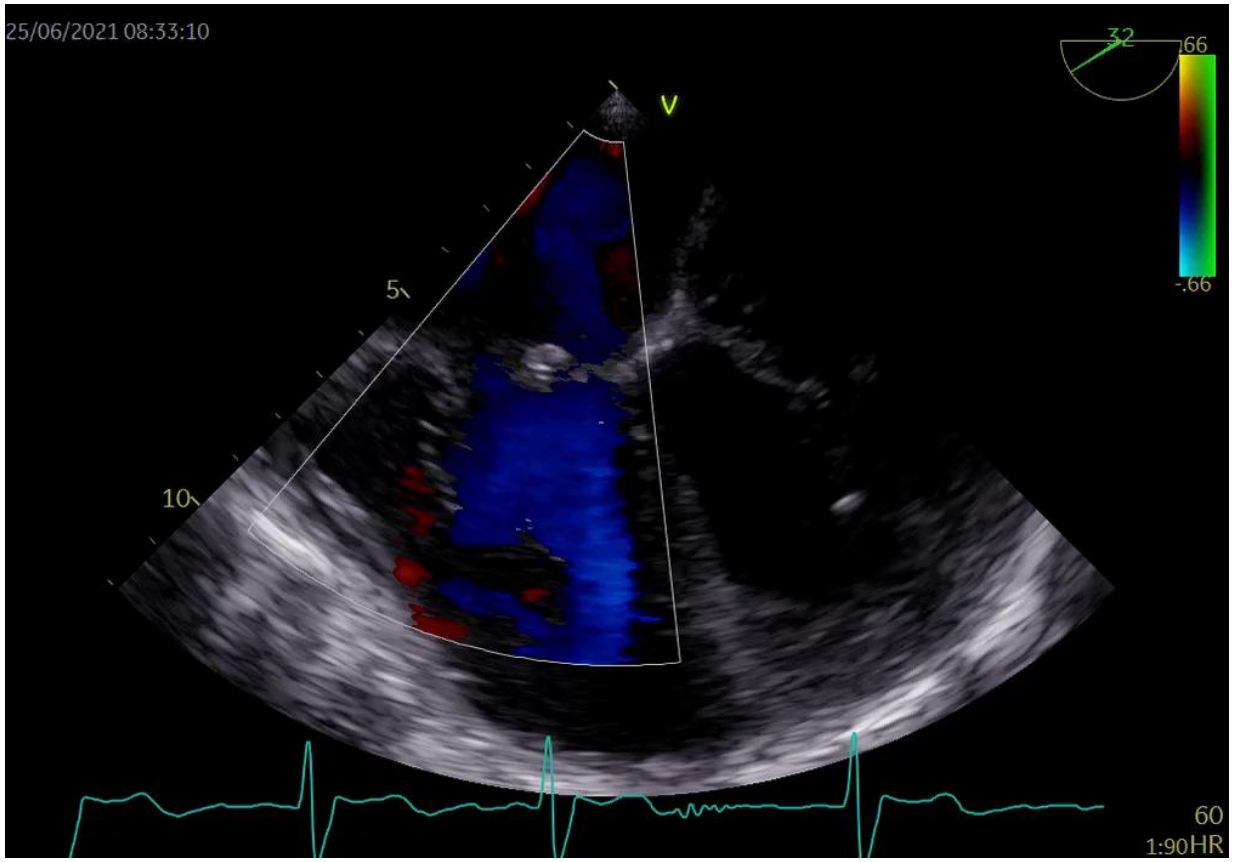
# Plastika trikuspidální chlopně pomocí Pascal

## Transgastrická projekce s finální pozicí klipu




## Regurgitace na konci výkonu

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# Závěr

- Katetrizační plastika (TEER) mitrální chlopně je dnes zavedenou klinickou metodou s prokázaným efektem na morbiditu a mortalitu
- Přestože její korekce je stále primárně doménou kardiochirurgie existují dnes všeobecně akceptované indikace k jejímu použití
- Katetrizační plastika trikuspidální chlopně (T-TEER) je efektivní možností léčbě u vybrané skupiny pacientů
- V budoucnosti očekáváme upřesnění indikace kdy TEER provádět

# DĚKUJI ZA POZORNOST!

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