Tendyne systém – známe již cílovou skupinu pacientů?

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Nemocnice České Budějovice a.s.

ZSF JČÚ České Budějovice

Designed for the Mitral Anatomy to Eliminate MR

Dual-frame design provides customized anatomic fit and maintains stable hemodynamic performance

Tendyne™ TMVR System

Inner Frame
Circular, self-expanding, tri-leaflet bioprosthetic valve

Outer Frame
Contoured design respects shape of the native mitral valve

Tether
High degree of device positioning and control, including full retrievability

Apical Pad
Placed over ventricular access site

Přehled situace ČR a okolí

Počet implantací ČR – 9 center

2020	3
2021	23
2022	32
2023	31

Okolí (zavedený program)

- 1600 implantací worldwide
- Evropa + Izrael a Saudská Arábie

Tendyne™ SUMMIT Pivotal Trial Roll-In and MAC Arm Outcomes

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Piedmont Heart Institute

On behalf of the SUMMIT Investigators

Site Activation and Enrollment Status

SUMMIT TENDYNE™ TRIAL

72
SITES CURRENTLY ACTIVATED

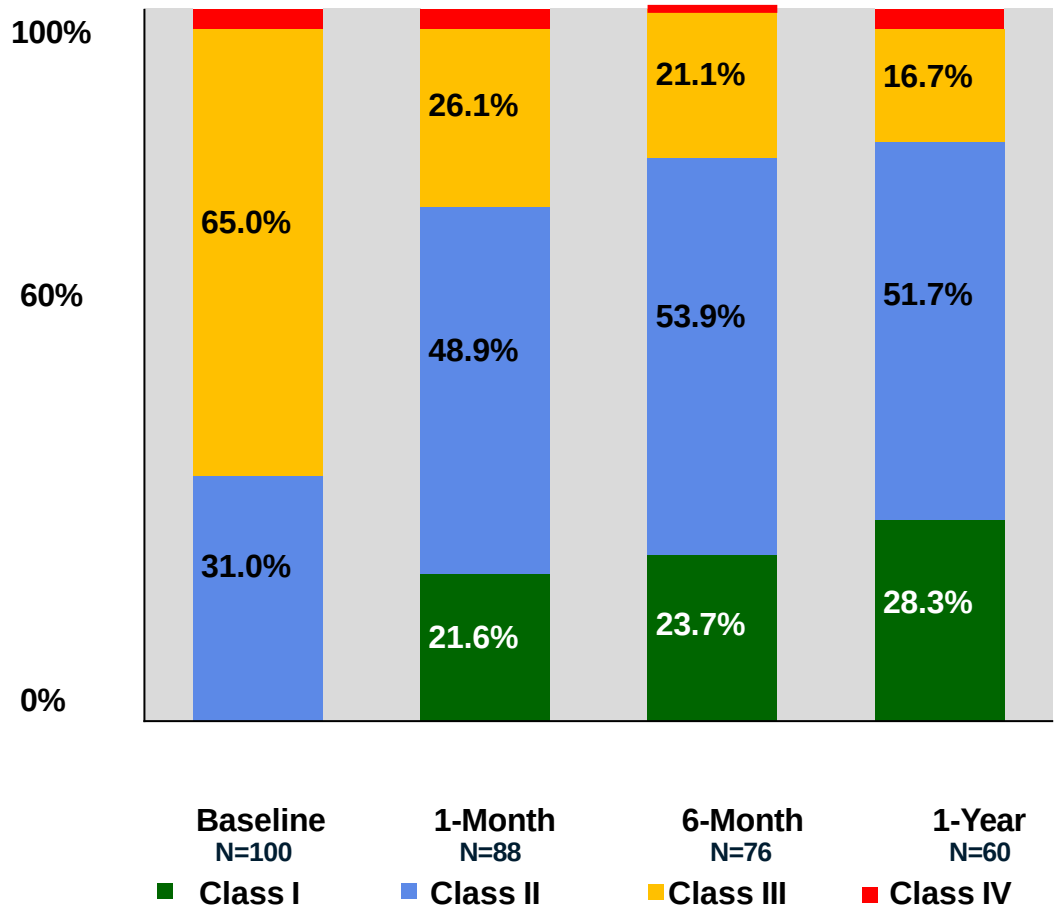
555
PATIENTS APPROVED

TOP ENROLLING SITES
(Treated Subjects)

- MedStar Union Memorial (35)
- Abbott Northwestern Hospital (32)
- Cardiovascular Research Institute of Kansas (24)
- Univ of Virginia (22)
- West Virginia University (21)
- Piedmont Heart Institute (20)
- Univ of Alabama Birmingham (20)
- Northwell Health (17)
- Morton Plant (13)
- St. Thomas (13)
- Austin Heart (13)
- UC-Davis (12)
- St. Luke's (12)

Summit trial

Adverse Events (Cumulative)*	30 Days n (%)	1 Year n (%)
Any mortality	11 (11.0)	26 (27.0)
Cardiovascular mortality	10 (10.1)	20 (21.6)
Disabling stroke (all-cause)	3 (3.1)	5 (5.4)
Myocardial infarction	0 (0)	2 (2.3)
Post-op mitral reintervention	1 (1.1)	2 (2.2)
Device thrombosis		
Major	0 (0)	0 (0)
Minor**	0 (0)	2 (2.3)
Major bleeding	25 (25.1)	32 (32.4)



SUMMIT Roll-in Key Takeaways

SUMMIT TENDYNE™ TRIAL

- 100 Roll-in subjects treated at sites without prior Tendyne™ TMVR experience, including 2/3rd subjects unsuitable for TEER
- 100% Procedural survival, few procedural complications
- Most adverse events occur within first month post-procedure
  - Results reflect early experience with a new procedure in a frail, high-risk population
- MR elimination sustained through 1-year
- Increases in cardiac output and forward stroke volume
- Improved heart failure symptoms and quality of life at 1-year

TENDER

(Tendyne European Experience)

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JACC: CARDIOVASCULAR INTERVENTIONS

ORIGINAL RESEARCH

Transapical Mitral Valve Replacement

1-Year Results of the Real-World Tendyne European Experience Registry

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BACKGROUND Early studies of the Tendyne transcatheter mitral valve replacement (TMVR) showed promising results in a small selective cohort.

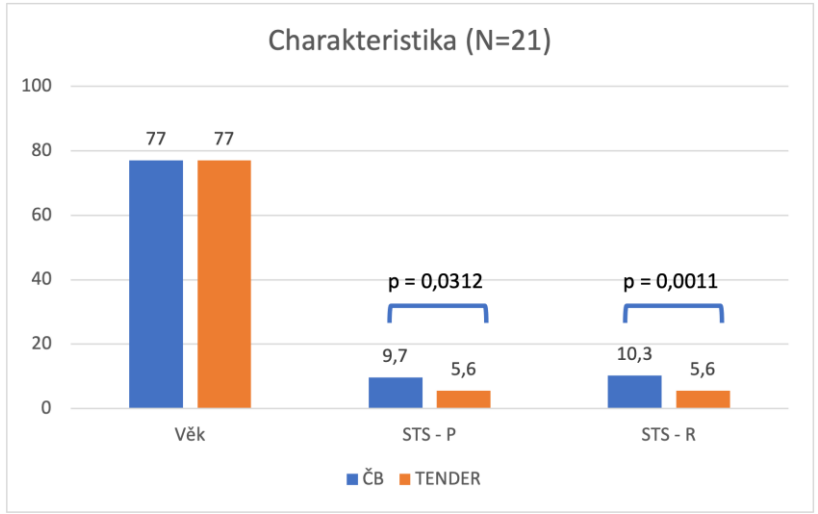
OBJECTIVES The authors present 1-year data from the currently largest commercial, real-world cohort originating from the investigator-initiated TENDER (Tendyne European Experience) registry.

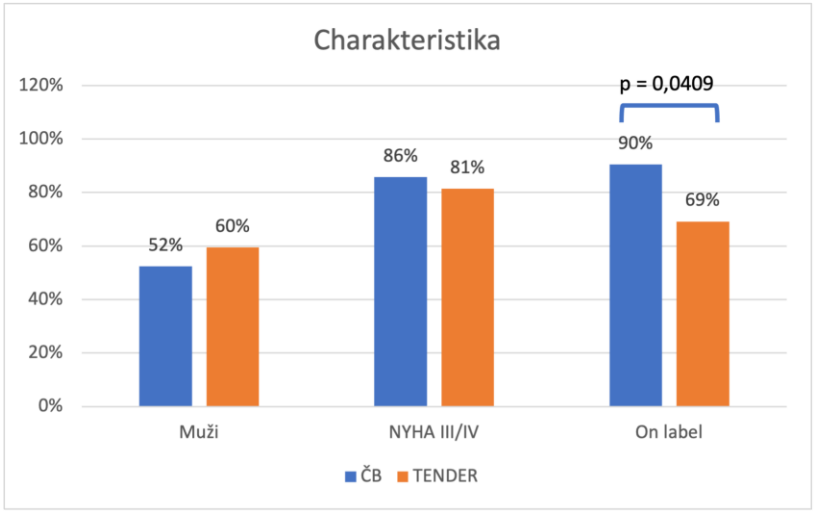
METHODS All patients from the TENDER registry eligible for 1-year follow-up were included. The primary safety endpoint was 1-year cardiovascular mortality. Primary performance endpoint was reduction of mitral regurgitation (MR) up to 1 year.

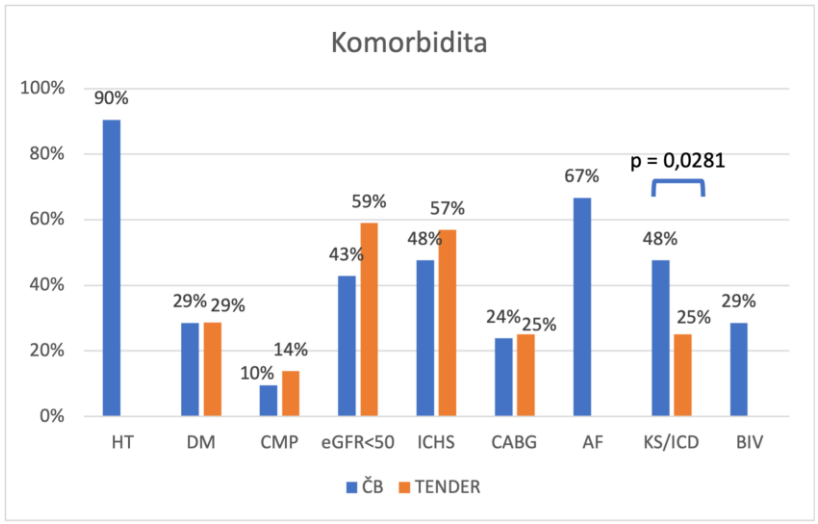
RESULTS Among 195 eligible patients undergoing TMVR (median age 77 years [Q1-Q3: 71-81 years], 60% men, median Society of Thoracic Surgeons Predicted Risk of Mortality 5.6% [Q1-Q3: 3.6%-8.9%], 81% in NYHA functional class III or IV, 94% with MR 3þ/4þ), 31% had "real-world" indications for TMVR (severe mitral annular calcification, prior mitral valve treatment, or others) outside of the instructions for use. The technical success rate was 95%. The cardiovascular mortality rate was 7% at 30 day and 17% at 1 year (all-cause mortality rates were 9% and 29%, respectively). Rein- tervention or surgery following discharge was 4%, while rates of heart failure hospitalization reduced from 68% in the preceding year to 25% during 1-year follow-up. Durable MR reduction to #1þ was achieved in 98% of patients, and at 1 year, 83% were in NYHA functional class I or II. There was no difference in survival and major adverse events between on-label use and "real-world" indications up to 1 year.

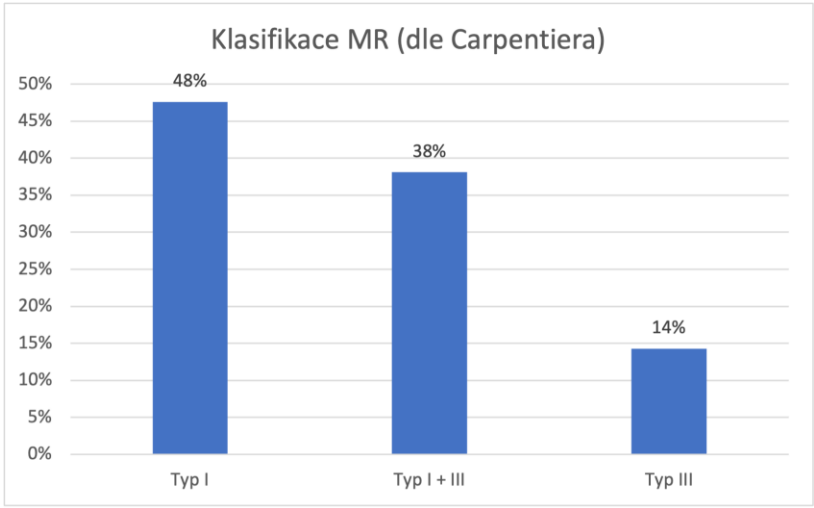
CONCLUSIONS This large, real-world, observational registry reports high technical success, durable and complete MR elimination, significant clinical benefits, and a 1-year cardiovascular mortality rate of 17% after Tendyne TMVR. Outcomes were comparable between on-label use and "real-world" indications, offering a safe and efficacious treatment option for patients without alternative treatments. (Tendyne European Experience Registry [TENDER]; NCT04898335)

Předoperační charakteristika ČB

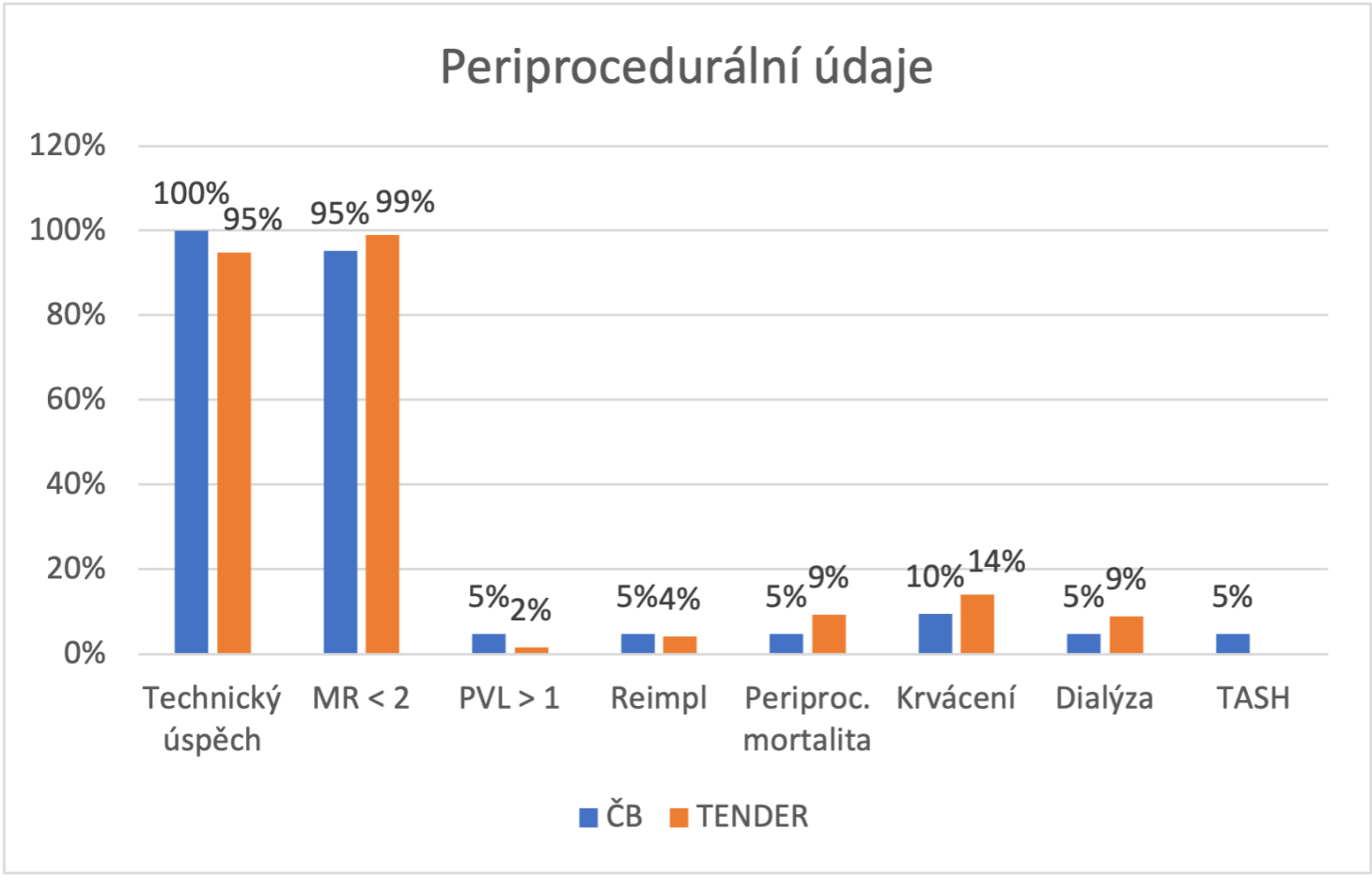




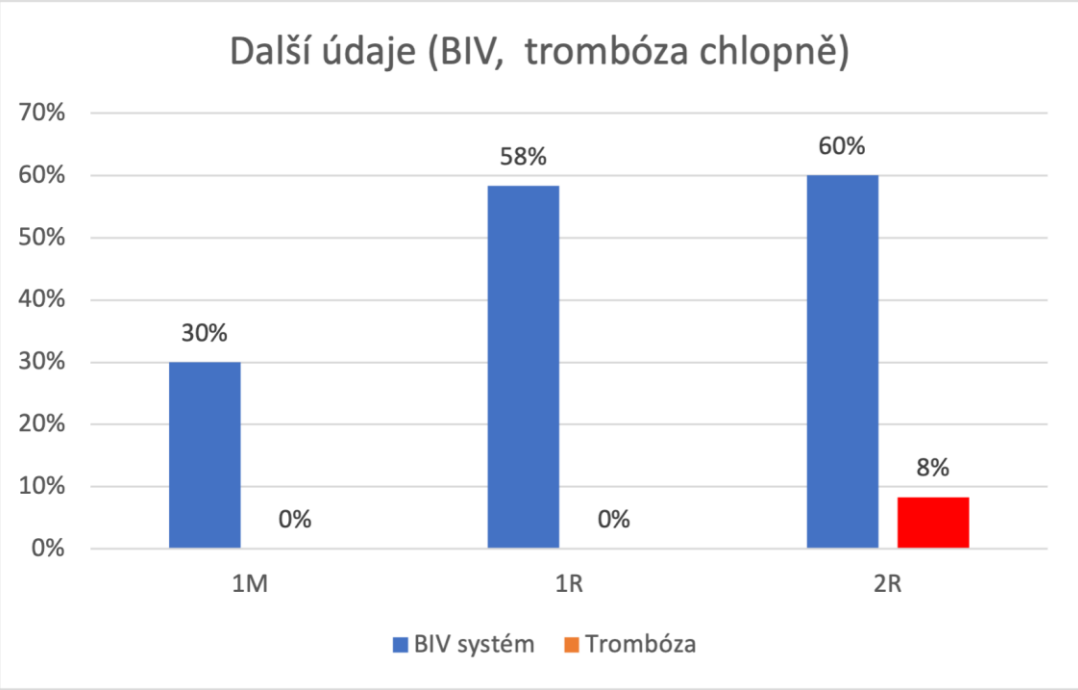


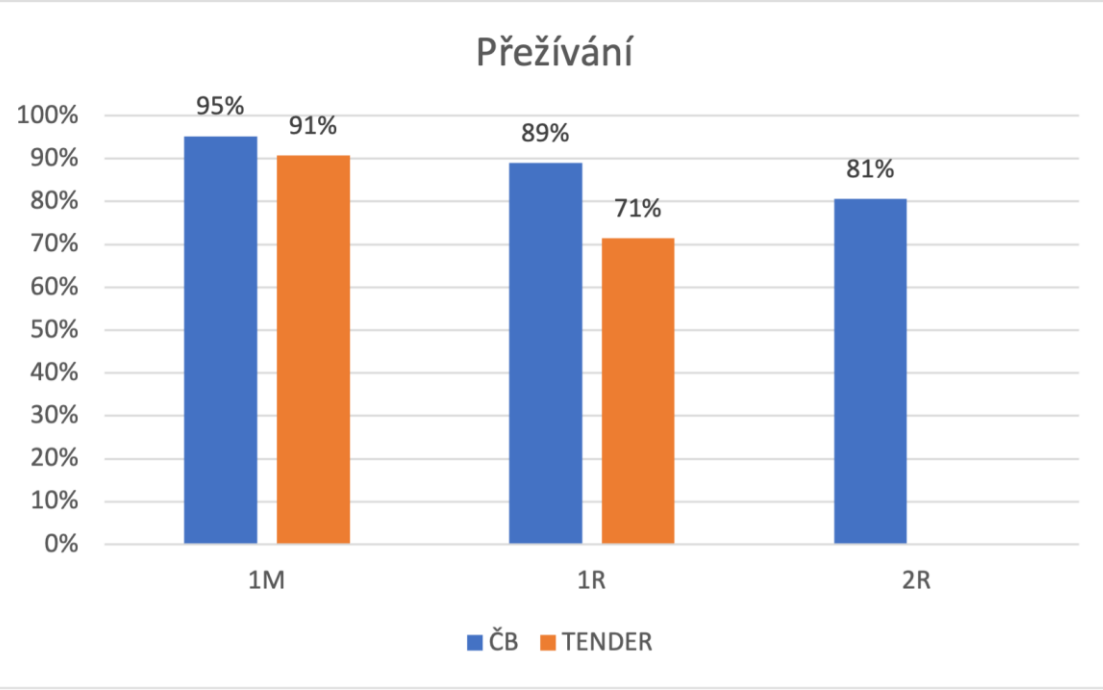


Periproceduralní data

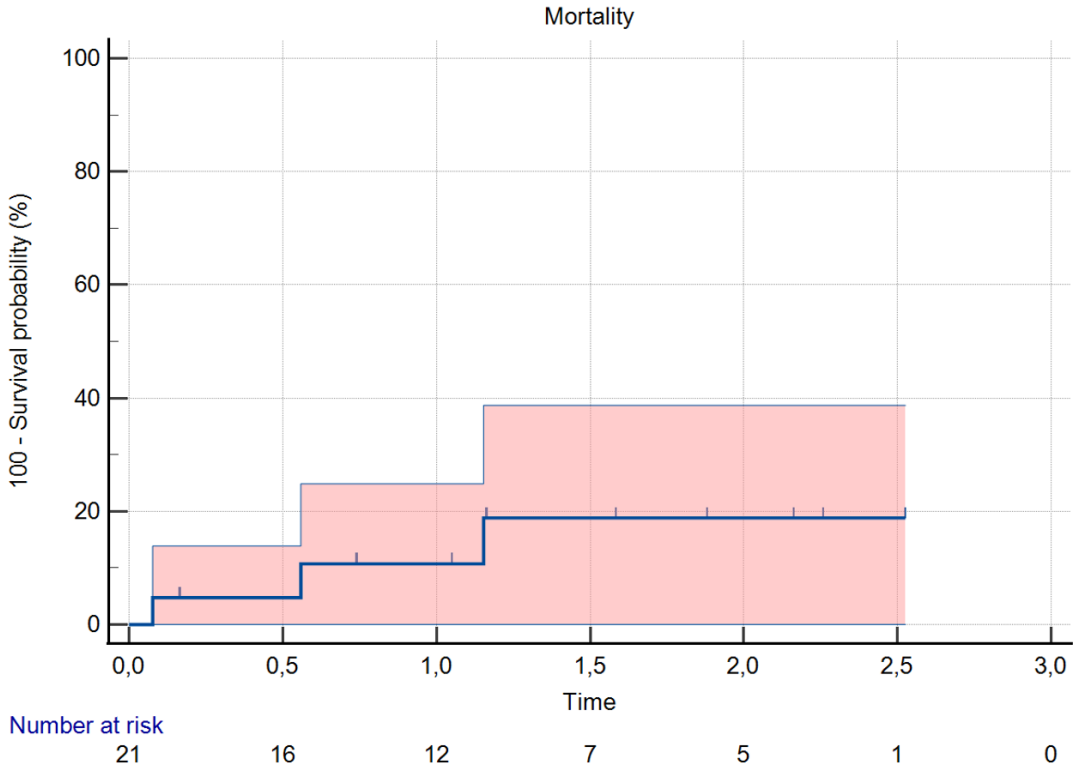


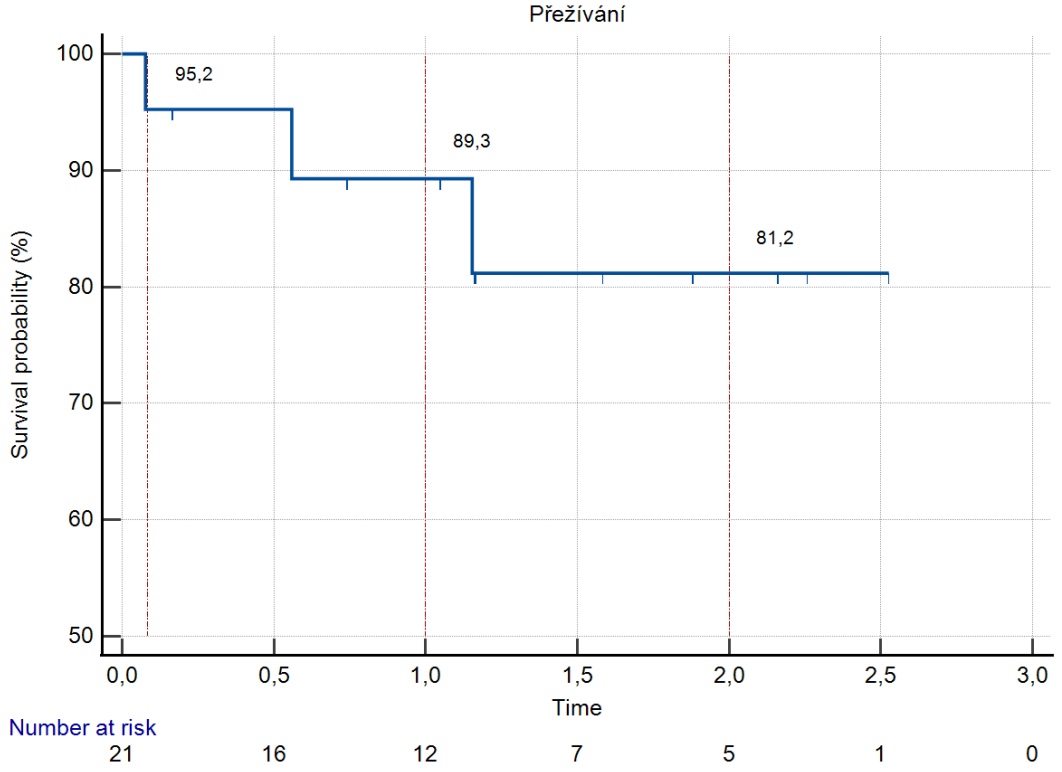
Follow up


Další údaje (BIV, trombóza chlopně)
70%
60%
50%
40%
30%
20%
10%
0%
30%
0%
58%
0%
60%
8%
1M
1R
2R
BIV systém
Trombóza

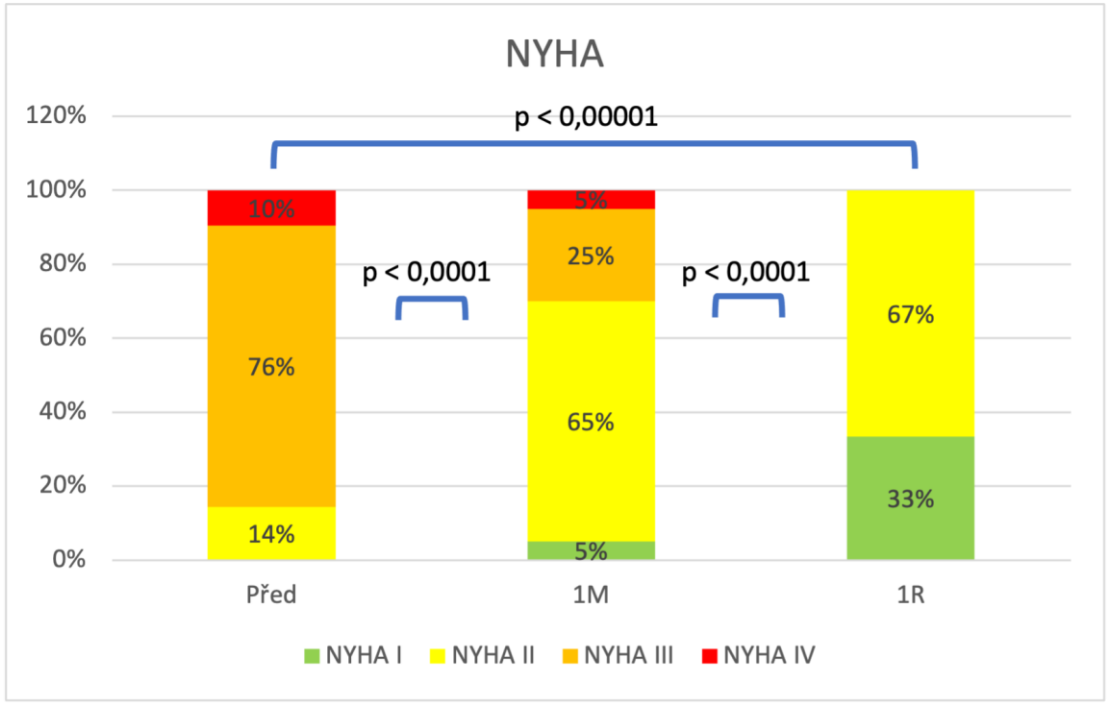

Přežívání
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
95%
91%
89%
71%
81%
1M
1R
2R
ČB
TENDER

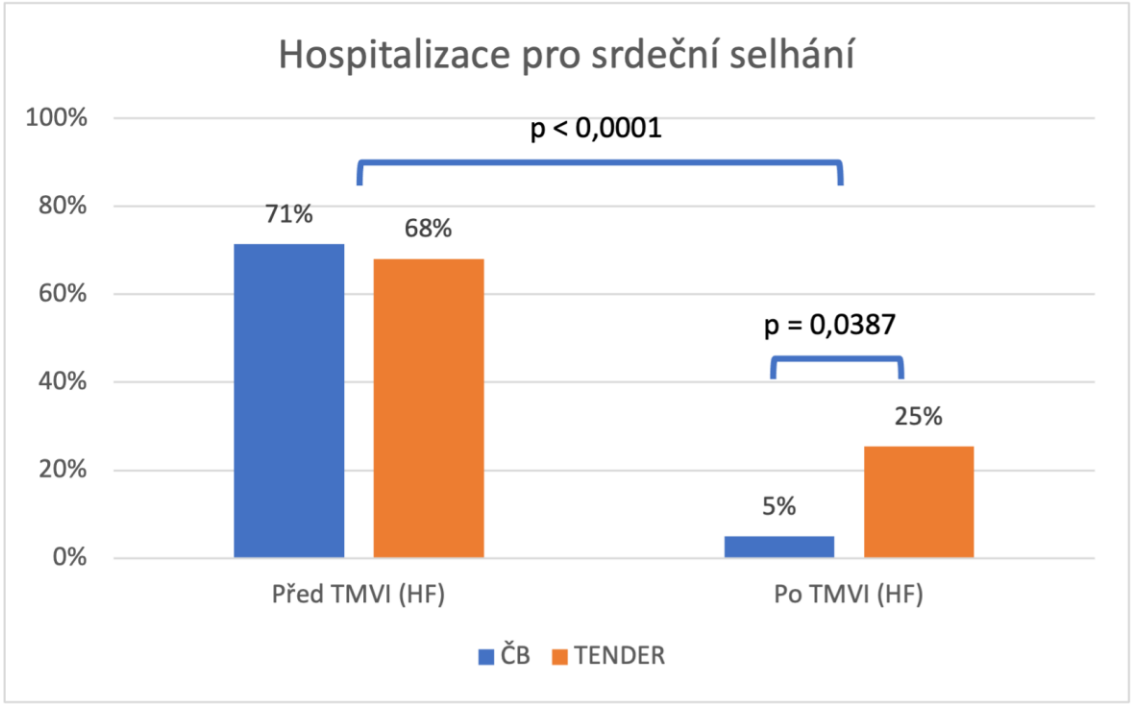
Follow up


Mortality
100 - Survival probability (%)
100
80
60
40
20
0
0,0
0,5
1,0
1,5
2,0
2,5
3,0
Time
Number at risk
21
16
12
7
5
1
0


Přežívání
Survival probability (%)
100
90
80
70
60
50
95,2
89,3
81,2
0,0
0,5
1,0
1,5
2,0
2,5
3,0
Time
Number at risk
21
16
12
7
5
1
0

Follow up


NYHA
120%
100%
80%
60%
40%
20%
0%
p < 0,00001
p < 0,0001
p < 0,0001
10%
76%
14%
5%
25%
65%
5%
67%
33%
Před
1M
1R
NYHA I
NYHA II
NYHA III
NYHA IV


Hospitalizace pro srdeční selhání
100%
80%
60%
40%
20%
0%
p < 0,0001
71%
68%
p = 0,0387
5%
25%
Před TMVI (HF)
Po TMVI (HF)
ČB
TENDER

Známe cílovou skupinu pacientů?

- <u>Ještě ne, ale posouváme se</u>
- **Velmi vysoká efektivita v redukci MI napříč etiologií**
- Středně (a vysoce) rizikový nemocný pro klasickou operaci – vč. reoperací a polyvalvárních procedur
- Věk (> 70 ev. 75 let)?
- Carpentier I a III?
- Neo LVOT >500 a <300 mm^2 vyšší riziko?

KI – jen relativní (nezhoršují výsledky?)

- LVEDD > 70 mm
- LVEF < 30%
- Primary MR + LVESD ≤ 30mm
- MS + MR< III/IV
- Předchozí mitrální (ale i některé aortální nebo trikuspidální) intervence
- Těžká/významná kalcifikace mitrálního anulu