

One-Year Outcome After Edge-to-Edge Valve Repair for Symptomatic Tricuspid Regurgitation: Results from the TriValve Registry

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Disclosure Statement of Financial Interest

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- Abbott Vascular and
- Edwards Lifesciences

In this presentation the **off-label / compassionate use** of the Abbott Vascular MitraClip system will be discussed.

Background

- There is an unmet need for transcatheter treatment of high-risk patients with symptomatic tricuspid regurgitation (TR).
- The transcatheter edge-to-edge repair technique has been successfully applied within off-label/compassionate use programs in selected patients with symptomatic TR.
- The impact of this approach on the clinical outcome beyond the first 30 days is not known.

Rationale

was to investigate:

- the procedural outcome
- the durability of TR reduction
- the 1-year outcome including mortality and unplanned hospitalizations for heart failure, and
- to identify predictors for:
 - procedural failure and
 - 1-year mortality

using data from the large international TriValve registry.

Methods

- TriValve registry is an international, multicenter, retrospective multi-device registry on interventional tricuspid valve repair for TR
- Subgroup analysis of patients undergoing edge-to-edge therapy in off-label/compassionate use programs at 14 study sites
- Device: “conventional” MitraClip (e.g. NT, 17mm long, Abbott Vascular)
- Site reporting for procedural, in-hospital and follow-up data as well as echocardiographic data (4-grade TR scale; 1+ to 4+)
- Main outcome measures:
all-cause mortality, unplanned repeat hospitalizations, NYHA class, presence of peripheral edema, TR grade

Patient Characteristics

(249 patients)

Age, years	77 ± 9	Hx of left heart valve intervention	
Female sex, n (%)	128 (51.4%)	surgical, n (%)	27 (10.8%)
Body-Mass-Index, kg/m ²	25.7 ± 4.9	interventional, n (%)	29 (11.6%)
EuroSCORE II, %	11.2 ± 12.3	eGFR, ml/min	44 ± 20
TR predisposing factors, n (%)		Medication, n (%)	
atrial fibrillation	183 (73.8%)	Beta blocker	214 (87.7%)
left heart valve disease	169 (67.9%)	ACE-inhibitor/AT1-blocker	176 (72.1%)
HFrEF (EF <40%)	64 (25.7%)	Furosemide (equiv. dose, mg/d)	110 ± 120
COPD	62 (24.9%)	Aldosterone antagonist	110 (45.3%)
pacing lead	74 (29.7%)		

Echocardiographic Characteristics

(249 patients)

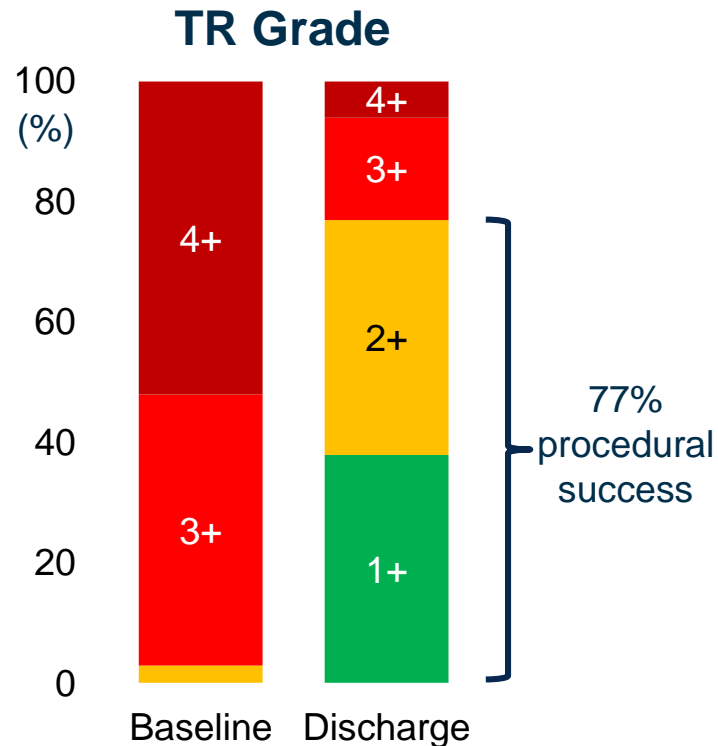
TR aetiology, n (%)	
Primary	12 (4.8%)
Secondary	222 (89.2%)
Mixed or not available	15 (6.0%)
TR jet main location, n (%)	
Central or antero-septal	221 (88.8%)
other	28 (11.2%)
Tricuspid annular diameter, mm	47.0 ±7.6
RV TAPSE, mm	15.8 ±4.3
sPAP, mmHg	43.6 ±16.0

TR coaptation gap, mm	5.3 ±3.3
TR vena contracta width, mm	9.9 ±4.1
TR EROA, cm ²	0.70 ±0.53
TR tenting area, cm ²	2.3 ±1.5
TR coaptation depth, mm	9.4 ±4.2
Hepatic vein flow reversal, n (%)	139 (73.9%)
MR ≥3+, n (%)	108 (43.4%)
LV-EF, %	49 ±14
LVEDD, mm	51 ± 9

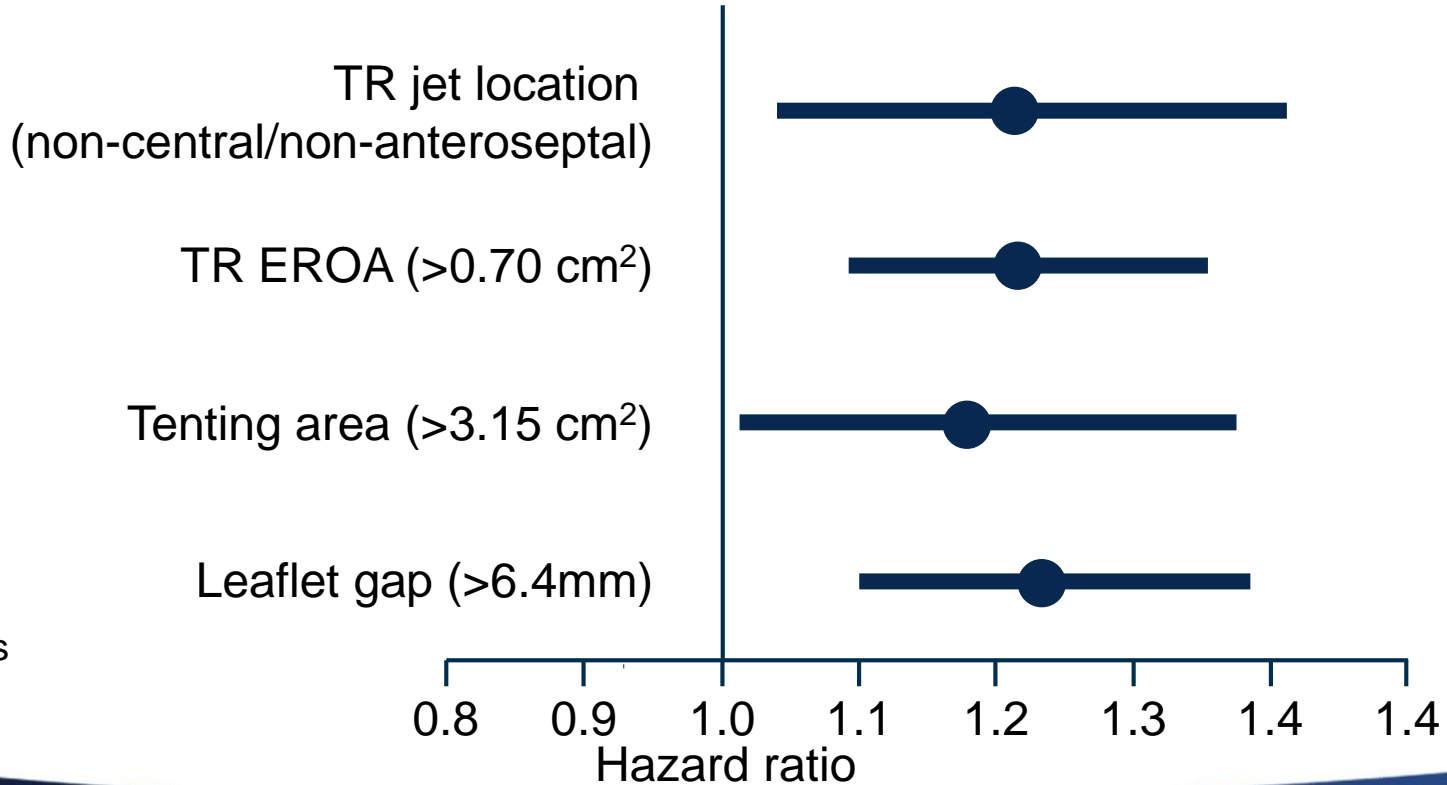
Procedural Results

(249 patients)

Number of clips	2 ± 1
	(range: 0 - 5)
Clip location, n (%)	
Antero-septal	162 (65.1%)
Antero-septal + postero-septal	52 (20.9%)
Other	35 (14.0%)
Duration of TR procedure, min	136 ± 62
Reduction of ≥1 TR grade, n (%)	222 (89.2%)
Concomitant MR treatment, n (%)	129 (51.8%)



Independent Predictors for Procedural Failure



(cut-off values
by ROC
analyses)

Procedural results

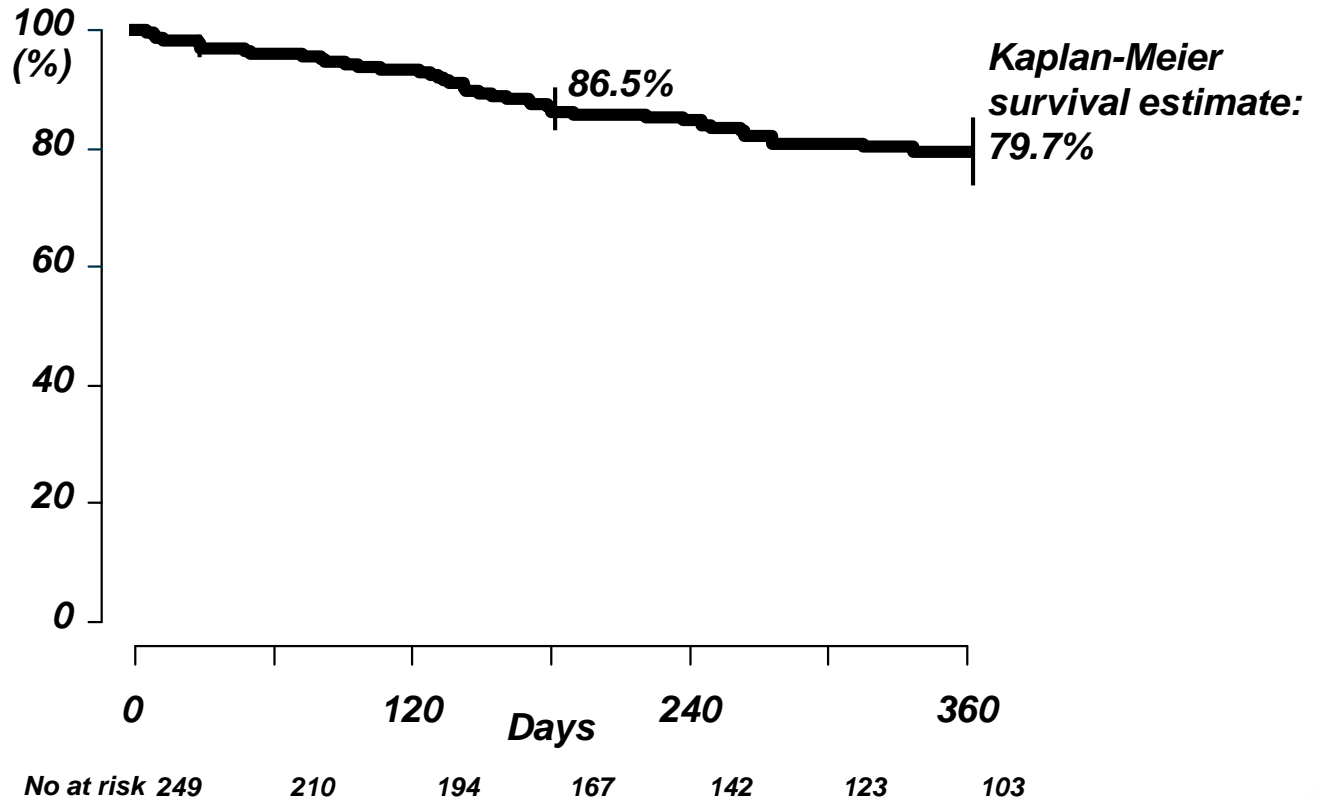
In-Hospital Events	249 patients
Mortality	7 (2.8%)
Blood transfusion / severe bleeding	15 (6.0%)
Infection	12 (4.8%)
Acute kidney injury	9 (3.6%)
Stroke	2 (0.8%)
Conversion to surgery	1 (0.4%)

Follow-up data:

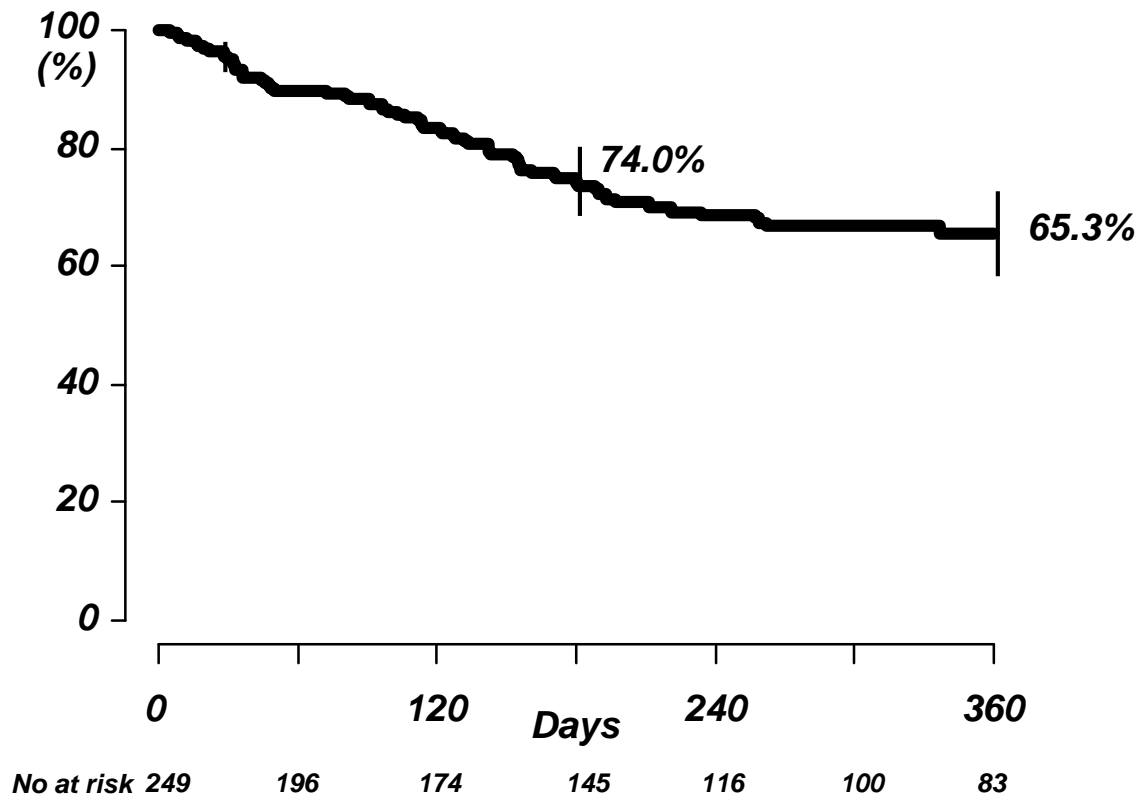
Mean FU: 292 ±195 days

FU on mortality: 100%
Echocardiographic FU: 79%

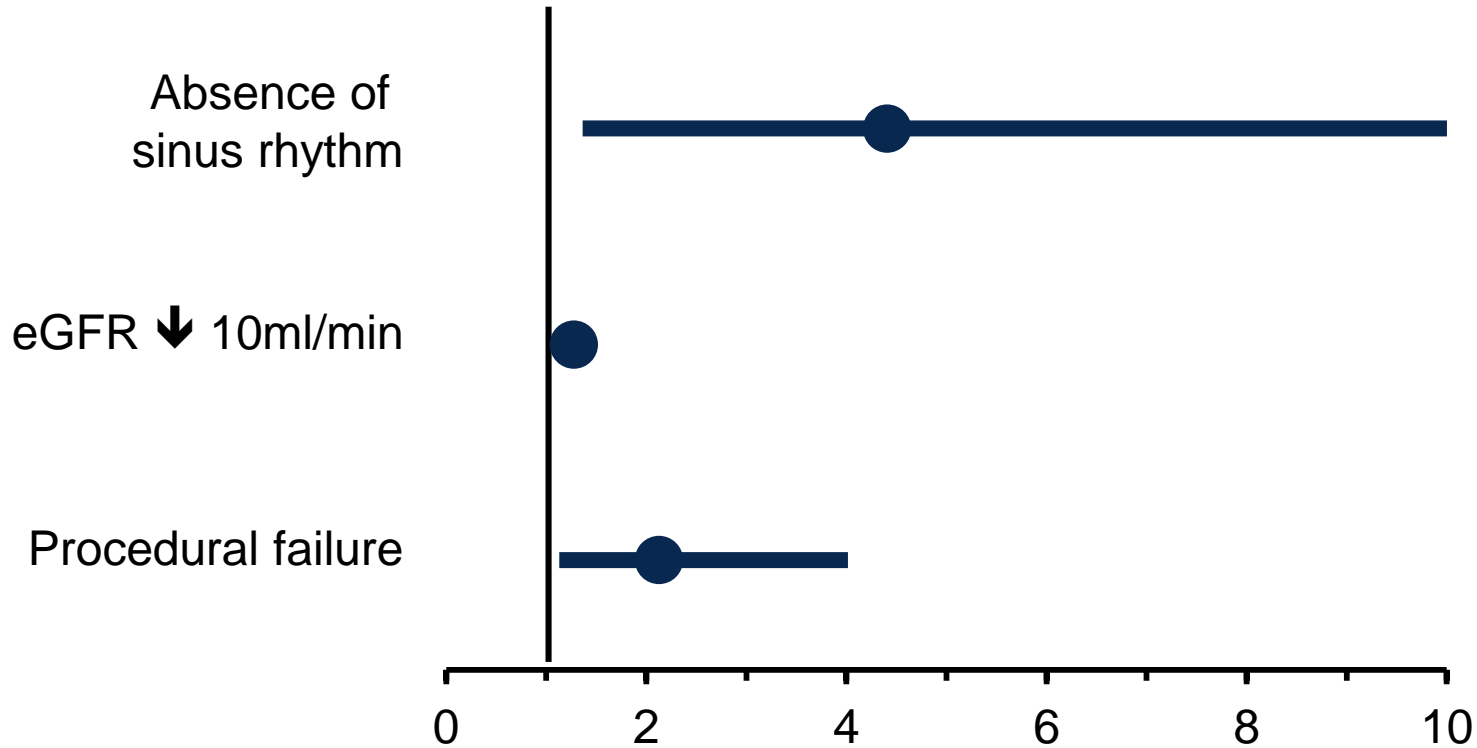
Mortality



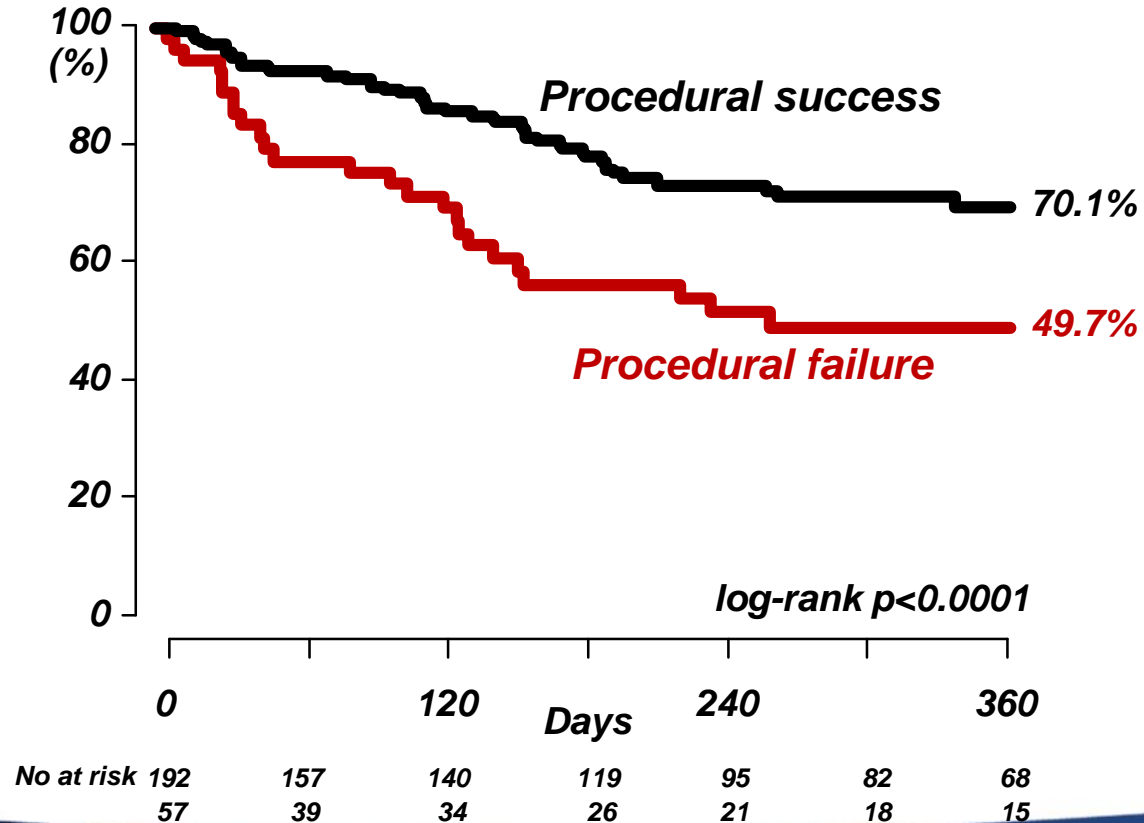
Mortality and Unplanned Hospitalization for Heart Failure



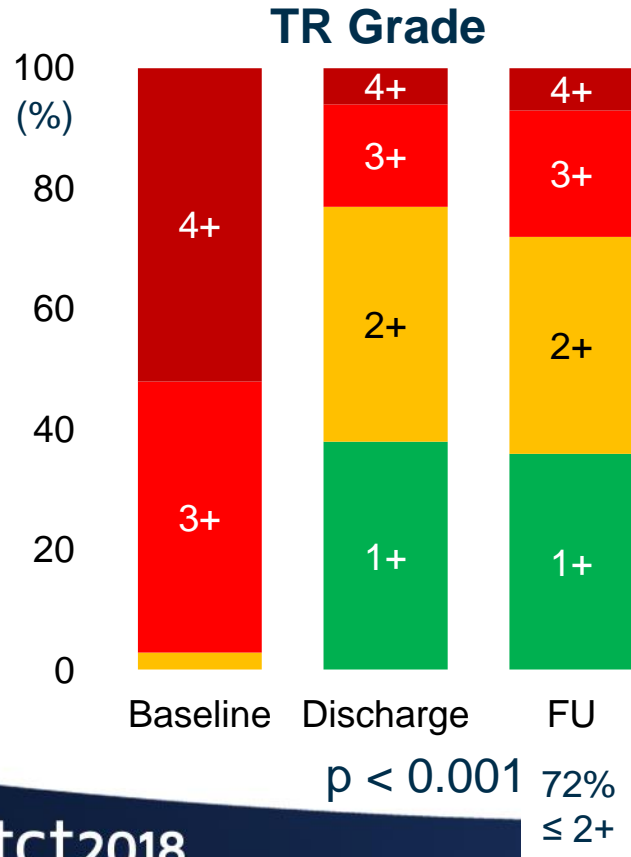
Independent Predictors for Mortality



Procedural Success and Mortality & Re-Hospitalization

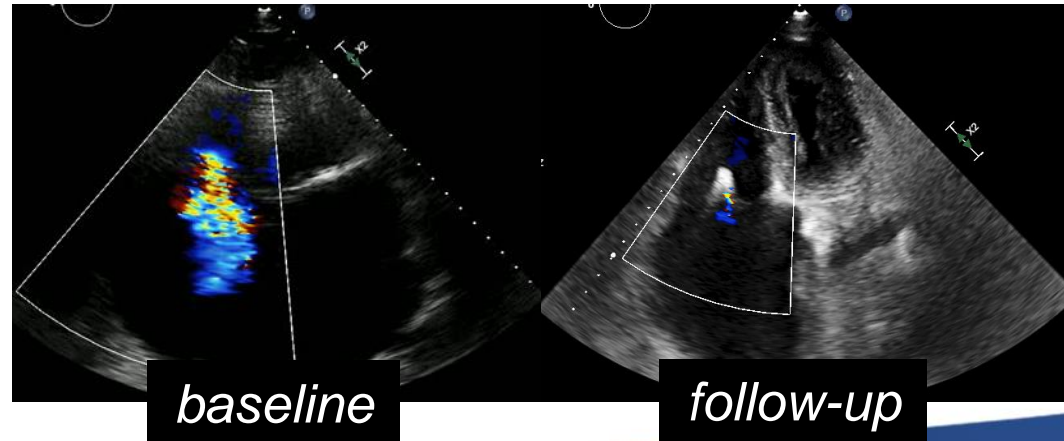


Echocardiographic Durability

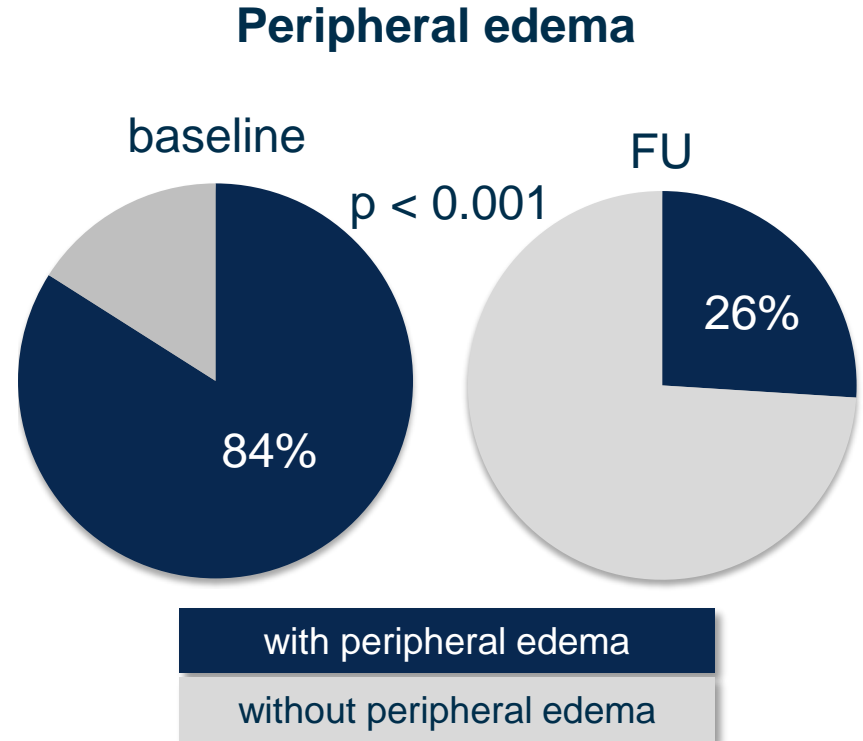
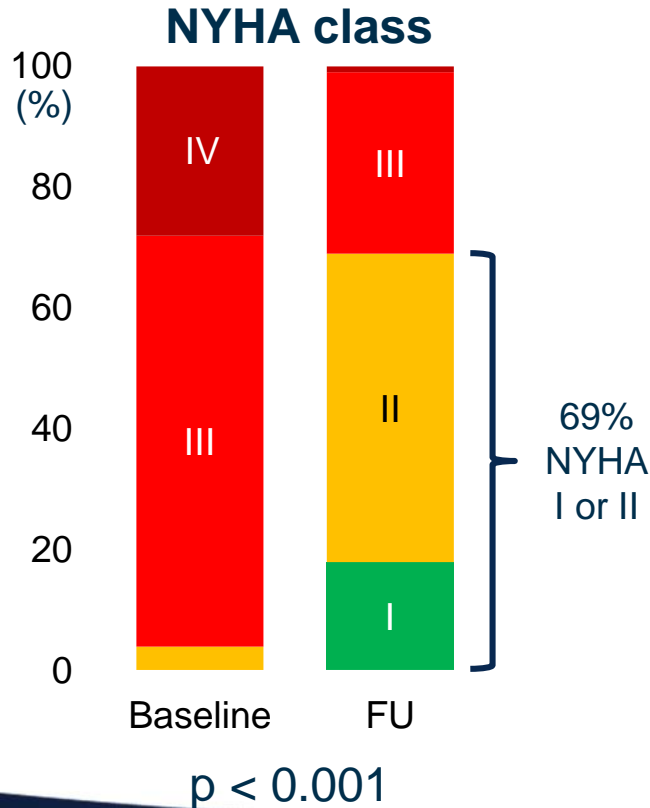


84 y old male patient

- NYHA III – IVa with recent cardiac decompensation
- Stroke 2016, atrial fibrillation, reduced kidney function, obstructive lung disease



Clinical Improvement



Limitations

- No procedural recommendations
- No independent event adjudication
- No central echocardiographic core lab assessment

Conclusions

- Interventional tricuspid edge-to-edge valve repair in this large patient cohort was safe.
- The procedure resulted in a high procedural success rate (77% of patients with TR $\leq 2+$).
- The morphologic criteria: larger coaptation gaps, larger tenting area, larger EROA, and TR jet location were associated with procedural failure.

Conclusions

- The valve repair resulted in a durable TR reduction at 1-year follow-up, which was associated with a significant symptomatic improvement.
- Considering the sick and frail patient cohort, the absolute 1-year mortality rate of 17.7% is remarkably low.
(TRAMI 20.3%, TVT registry 25.8%, Everest HR 22.8%, and Mitra-Fr 24.3%)
- Procedural failure was identified as independent predictor for mortality, which may suggest that edge-to-edge tricuspid valve repair might impact survival in this high-risk patient population.

Isolated TR vs. Combined MR+TR Treatment

