Transcatheter Valve Repair for Tricuspid Regurgitation 1-Year Results from the PASTE Registry

Wild M. et al., *J Am Coll Cardiol.* 2024

Aim of the study

PASTE (PASCAL for Tricuspid Regurgitation – a European registry) is the largest registry on T-TEER aiming to investigate the **safety and effectiveness of the PASCAL transcatheter valve repair system** in treating severe tricuspid regurgitation **in a real-world patient population.**

Study design

Investigator-initiated, multicenter, retro- and prospective observational cohort study
Including 16 European heart valve centers & centralized analysis of all echocardiographic imaging.

Consecutive all-comer patients
PASCAL & PASCAL Precision systems.
No inclusion / exclusion criteria.

Patient baseline characteristics

n=1059 patients (53% female, 79 years old mean age, 84% in NYHA III/IV)

High surgical risk (TRI-SCORE 23%)

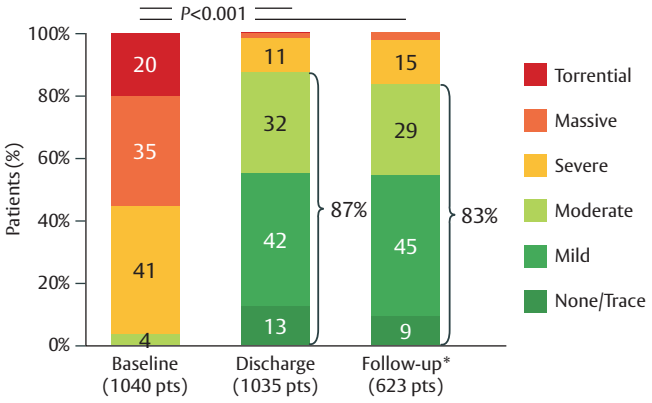
Frequent comorbidities (91% atrial fibrillation, 79% chronic kidney disease, 27% CIED lead, 66% PH, 58% previous HFH within 12 months)

TR ≥ severe in 96%
Complex anatomy: 67% lead-related, 24% coaptation gap > 8 mm; 43% >3 leaflets

Efficient and sustained TR reduction to moderate or less through 1-year follow-up

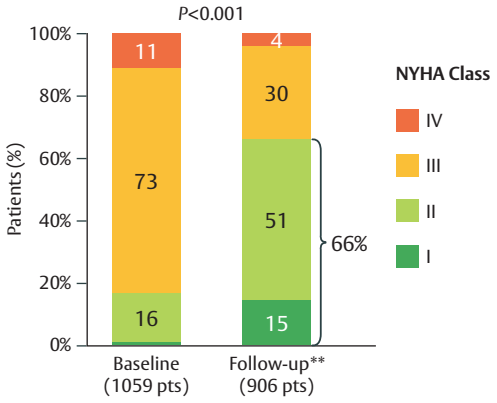
- T-TEER was associated with a **high level of success** with an implant and acute procedural success of 98% and 95%, respectively.
- **Significant and sustained clinical improvements** in terms of NYHA functional class, signs of right heart failure, 6MWD, and MLHFQ score were observed.

TR severity



83% of patients had achieved TR ≤ 2+ at 1-year follow-up

NYHA class



66% of patients had achieved NYHA I/II at 1-year follow-up

* Median follow-up duration 363 [IQR 197-412] days.
** Median follow-up duration 346 days [Q1-Q3: 189-396 days].

Graphs show unpaired data. For details on statistical analyses please see reference 1.

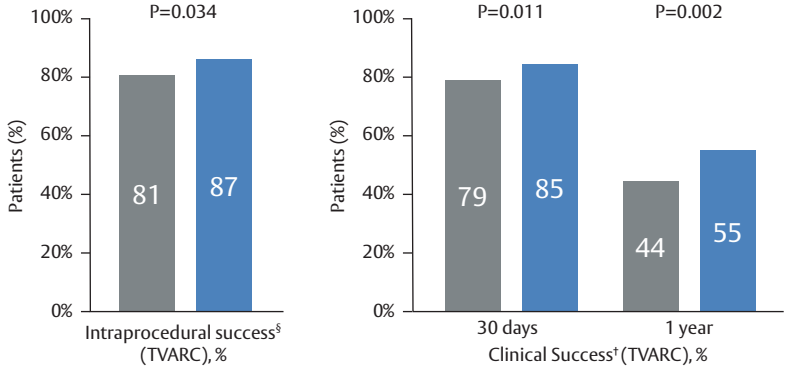
Edwards

Clinical Outcome and Events

Despite the advancement and complexity of the disease in the PASTE registry cohort, the procedure showed a **favorable safety profile**, with few clinical events, **low rates of SLDA**, and rates of all-cause mortality and HFH at 1 year comparable to reported results from other clinical trials.[2-3]

% of patients	Clinical success† (TVARC)	All-cause mortality	HFH	Combined endpoint (mortality + HFH)	TV re-intervention or surgery
30 days	84%	1.3%	1.6%	2.7%	0.5%
1 year	53%	14%	16%	24.7%	2.5%

Impact of Center Experience on Outcomes



Greater center experience (≥21 patients / year°) was linked to:

- Significantly **higher intraprocedural**§ & **clinical success**†
- Significantly **lower incidence of early SLDA**‡ (6% vs 3%, p=0.018)

Number of cases with the PASCAL system per year°

° Median number of patients/site/year: 21 [IQR 12-32] patients.

Conclusion

The PASTE registry further confirmed that the PASCAL system is **a safe and effective option for treating severe TR in a high-risk patient population:**

- High rates of acute procedural success with low rates of procedural complications.
- Efficient and sustained TR reduction to moderate or less as well as clinical improvements (NYHA, 6MWD, and MLHFQ score) through 1-year follow-up.
- Shorter procedure with improved TR reduction and higher TVARC clinical success rates in the PASCAL Precision system cohort
- Center experience (≥21PASCAL T-TEER patients/year) resulted in higher TVARC intraprocedural and clinical success.
- The severity of residual TR was significantly linked to mortality as well as the combined endpoint of mortality and HFH.

§Intraprocedural success (TVARC definition): successful delivery and deployment of the device with at least acceptable performance of the device (TR reduction ≤ moderate, TV mean gradient <5 mm Hg) in the absence of major complications during the first 24 hours. †Clinical success (TVARC definition): acceptable device performance + absence of a major device or serious adverse events including HFH, TV re-intervention + improvement in clinical status. ‡Early SLDA is defined as procedural or detected during the index hospitalization.

CIED, cardiac implantable electronic devices; *HFH*, heart failure hospitalization; *IQR*, interquartile range; *NYHA*, New York Heart Association; *MAE*, major adverse event; *MLHFQ*, Minnesota living with heart failure questionnaire; *PH*: pulmonary hypertension; *SLDA*, single leaflet device attachment; *T-TEER*, tricuspid transcatheter edge-to-edge repair; *TR*, tricuspid regurgitation; *TV*, tricuspid valve; *TVARC*, Tricuspid Valve Academic Research Consortium; *6MWD*, 6-minute walk distance.

References

1. Wild M.G. et al., Transcatheter Valve Repair for Tricuspid Regurgitation: 1-Year Results from a Large European Real World Registry. *J Am Coll Cardiol.* 2024 Oct 24:S0735-1097(24)09955-8.
2. Sorajja P. et al., Transcatheter repair for patients with tricuspid regurgitation. *N Engl J Med.* 2023;388:1833–1842.
3. Lurz P. et al., Real- world 1-year results of tricuspid edge-to-edge repair from the bRIGHT study. *J Am Coll Cardiol.* 2024;84:607–616.

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