THE TriCLASP STUDY

One-year outcomes of the TriCLASP post-market study

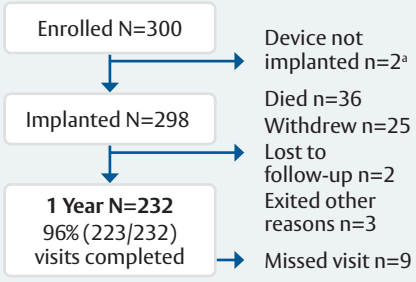
At one-year the PASCAL system demonstrated significant and sustained clinical benefits for patients with clinically significant TR:

- High Survival and low rates of HF hospitalisation
- Significant and sustained TR reduction
- Clinically meaningful improvements in functional status and quality-of-life
- Low rates of MAEs

Study design

Prospective, multicentre, single-arm, post-market clinical follow-up study to evaluate the **safety and effectiveness of the PASCAL system** in patients with **symptomatic, severe or greater TR**, in a European **post-market setting**.

Patient enrollment



Baseline characteristics

300 patients, **80±6** years old

78% NYHA III/IV

81% FTR / mixed[b]

91% Atrial fibrillation

76% TR≥ severe[c]

62% Kidney disease

[a]1 due to complex anatomy, 1 had cardiac arrest during the procedure and the device was not implanted because grasping was deemed not possible. [b]Primary 15.7%, pacer related 2.0%, indeterminate 1.3%. [c]Core laboratory: Cardialysis, Rotterdam, The Netherlands.

Low Major Adverse Events rate at 30 days[1]

1.7% Composite MAE rate

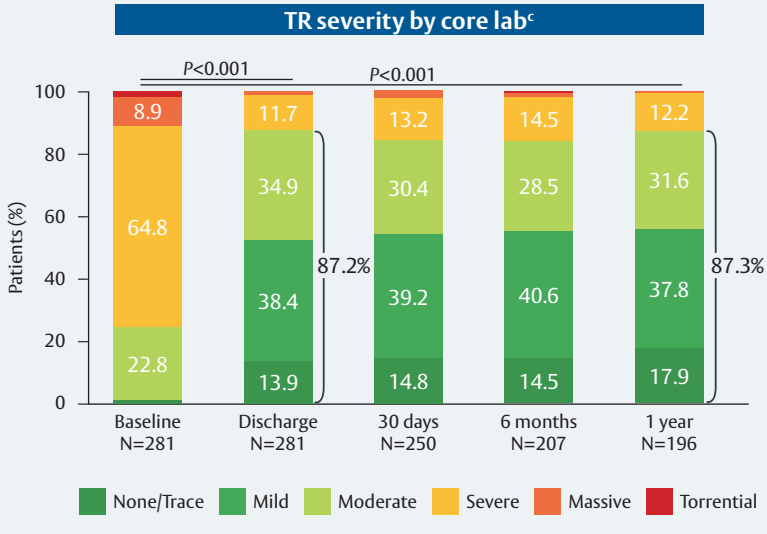
1.3% All-cause mortality

2.3% SLDA rate

[1]n=291 patients, denominator includes patients who had an event and/or were followed to at least 30 days. Patients may have had more than one event.

Significant and sustained TR reduction to 1 year

87%
of patients with TR≤2+ at 1-year with the PASCAL system

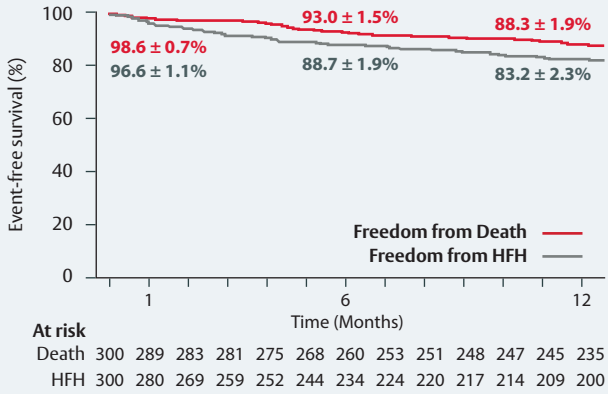


Graph shows unpaired data.

Edwards

Low rate of all-cause mortality and HF hospitalisation with significant reduction in annualised rate of HF hospitalisation to 1 year

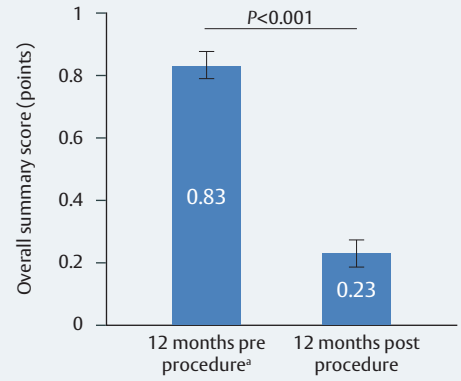
Freedom from all-cause mortality and HF hospitalisation



Graph shows Kaplan-Meier analysis time to first event (KM estimate ± SE). Error bars represent 95% confidence interval.

88% **Freedom from all cause mortality at 1-year**

Annualised rate of HF hospitalisation

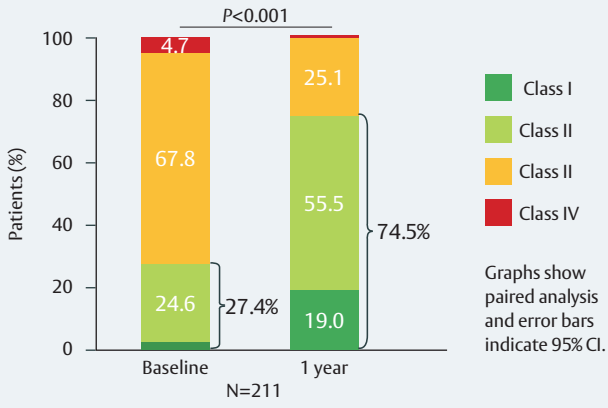


[a]Pre-procedure hospitalisation is site reported; post-procedure hospitalisation is adjudicated by CEC.

72% **Relative reduction in annualised HF hospitalisation rate**

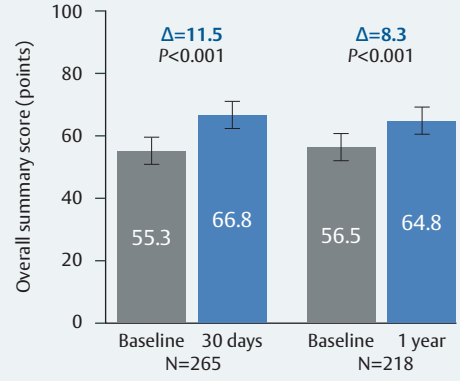
Significant improvements in functional and quality of life outcomes at 1 year

NYHA Class



75% **of patients had achieved NYHA Class I/II at 1-year with the PASCAL system**

KCCQ Score



+8.3 **Point improvement on KCCQ from baseline to 1 year**

Conclusion

One-year outcomes from the TriCLASP study confirm sustained safety and effectiveness of the PASCAL system in patients with clinically significant TR in a post-market setting.

TR: tricuspid regurgitation; FTR: functional tricuspid regurgitation; MAE: major adverse events; HF: Heart faulire; CEC: clinical events committee; SLDA: single leaflet device attachment; KCCQ: Kansas City Cardiomyopathy Questionnaire; NYHA: New York Heart Association

For details on statistical analyses please see reference 1

Reference

1. J. Hausleiter. Transcatheter Tricuspid Valve Repair: TriCLASP Study 1-Year Results. PCRLV 2024, Tricuspid Hotline. 25th Nov. 2024.

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