

Edwards PASCAL Transcatheter Valve Repair System

CLASP TR Study: One-Year Outcomes



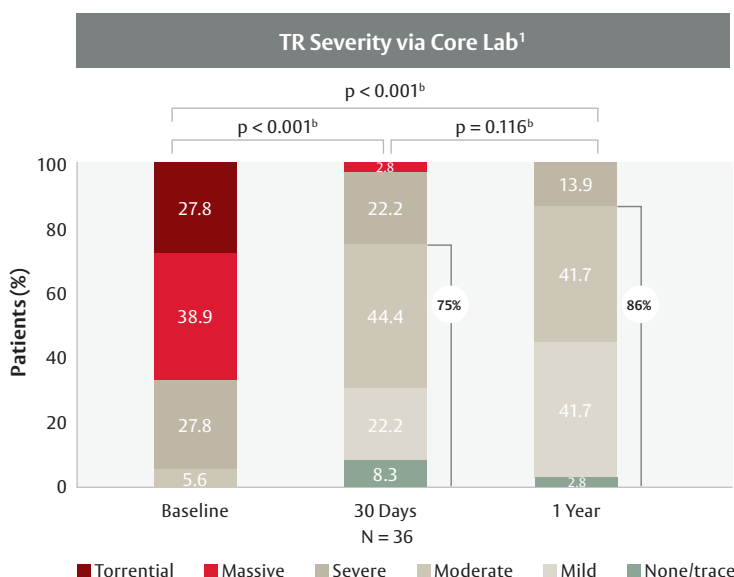
During the late-breaking trial session presented at EuroPCR2022, Prof Rebecca Hahn reported the one-year outcomes from the prospective, single-arm, multicentre CLASP TR study.

A total of 65 patients with symptomatic severe tricuspid regurgitation who were deemed appropriate for transcatheter tricuspid valve repair across 14 sites were enrolled out of which 46 had reached one-year follow-up at the time of the analysis.

Study design & baseline parameters

Study Design: Prospective, single-arm, multicentre study	
Enrolled patients: 65	Female: 55%
NYHA functional class III or IV: 71%	Tricuspid regurgitation (\geq severe) ¹ : 97% ^a
Age, years: 77 \pm 9	EuroSCORE II: 5.0 \pm 4.7 ¹

Key results



¹ Cardiovascular Research Foundation, Graph shows paired data. Two patients initially considered to have severe TR at baseline by transoesophageal echocardiography were reclassified as moderate TR by transthoracic echocardiography.

* N=64.

¹ N=62.

^a TR severity for one patient was deemed inconclusive after core laboratory adjudication.

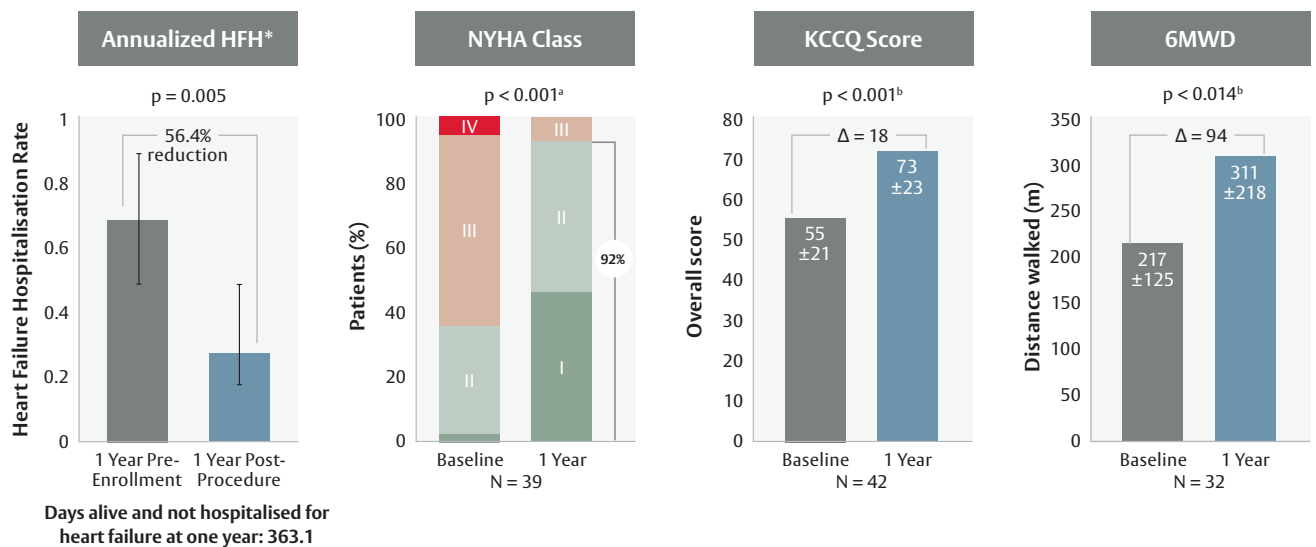
^b Wilcoxon signed-rank test.

TR: tricuspid regurgitation.



Edwards

- Sustained TR reduction at one year:
 - **86% achieving moderate or less TR**
 - **100% had ≥ 1 grade reduction and 75% had ≥ 2 grade reduction**
- A 56% reduction in the rate of annualised heart failure hospitalisation
- Significant improvements in NYHA class, KCCQ score, and 6MWD sustained at one year
- Overall mortality was 10.8% (cardiovascular mortality was 7.7%) at one year



*Pre-enrollment HFH data collected via site-reported medical history. Post-procedure HFH data was CEC adjudicated. Error bars represent 95% confidence interval. P value derived from two sample z test for incidence rate ratio on natural log scale. ^aWilcoxon signed-rank test. ^bPaired t-test. HFH, heart failure hospitalisation; NYHA, New York Heart Association; KCCQ, Kansas City Cardiomyopathy Questionnaire; 6MWD, 6-minute walk distance.

Conclusion

- At one year, transcatheter tricuspid valve repair with the PASCAL system demonstrated favourable safety and performance.
- Significant reduction in TR severity and improvements in clinical, functional, and quality of life outcomes were sustained at one year.

See what we're making possible at [Edwards.com/PASCAL](https://www.edwards.com/PASCAL)

TR: tricuspid regurgitation.

Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. EuroPCR LTB 2022

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards PASCAL, CLASP, and PASCAL are trademarks or service marks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

© 2022 Edwards Lifesciences Corporation. All rights reserved. PP--EU-4359 v1.0

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • [edwards.com](https://www.edwards.com)