Edwards PASCAL Transcatheter Valve Repair System

TriCLASP Post-Market Study: 30-Day Outcomes

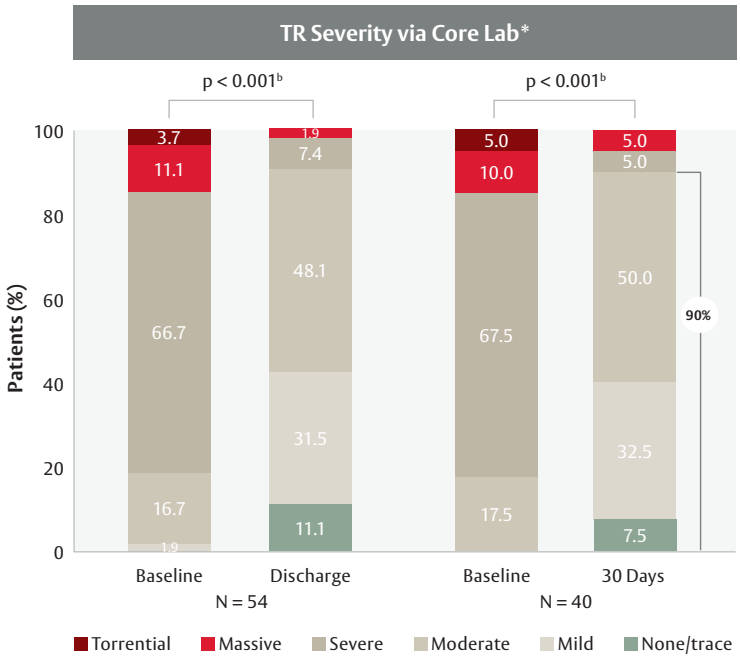
THE TriCLASP STUDY

During the late-breaking trial session, Professor Stephan Baldus reported the 30-day outcomes from the prospective, single-arm, multi-centre TriCLASP post-market clinical follow-up (PMCF) study.

Study design & baseline parameters[1]

Study Design: Prospective, single-arm, multicentre study	
Enrolled patients: 74	Female: 58%
NYHA functional class III or IV: 77%	Tricuspid regurgitation (≥ severe)*: 83%[a]
Age, years: 80 ± 6	STS score, MV Repair: 9.0 ± 6.9

Key results



Graphs show paired data.

* Core laboratory: Cardialysis.

[a] TR severity for 10 patients was reclassified to moderate or less after core lab adjudication.

[b] Wilcoxon signed-rank test.

NYHA, New York Heart Association.

STS, Society for Thoracic Surgeons.

TR: tricuspid regurgitation.

MV: mitral valve.

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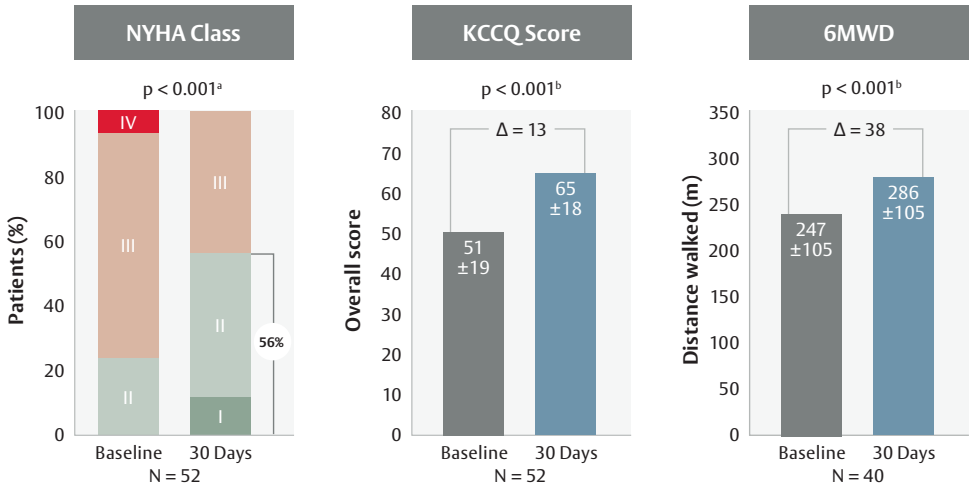
THE TriCLASP STUDY

- TR reduction at 30 days:
  - **88% of patients achieving ≥1 TR grade reduction**
  - **90% had moderate or less TR**
- 97% freedom from major adverse events
- NYHA class I/II was achieved in 56%, 6MWD improved by 38 m, and KCCQ scores improved by 13 points (all p<0.001 from baseline)



Graphs show paired data. [a]Wilcoxon signed-rank test. [b]Paired t-test for mean ± SD.
NYHA, New York Heart Association; KCCQ, Kansas City Cardiomyopathy Questionnaire; 6MWD, 6-minute walk distance

Conclusion

- The transcatheter PASCAL repair system in a European post-market setting confirms both favourable safety and effectiveness at 30 days in symptomatic patients with severe TR.

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TR: tricuspid regurgitation.

[1]Baldus S. 30-Day outcomes for transcatheter tricuspid repair: TriCLASP post-market study. LBT EuroPCR2022

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