PASCAL System for the treatment of tricuspid regurgitation

Body of evidence

Clinical evidence for the use of the PASCAL system for the treatment of tricuspid regurgitation

Edwards

PASCAL System body of evidence: Tricuspid regurgitation

Consistent favourable safety and effectiveness outcomes with the PASCAL system[1–4]

2,000+ patients targeted in studies

3 studies and **1** registry*

4+ years of study†

TR severity evaluated by independent ECL

Prespecified adverse events adjudicated by CEC

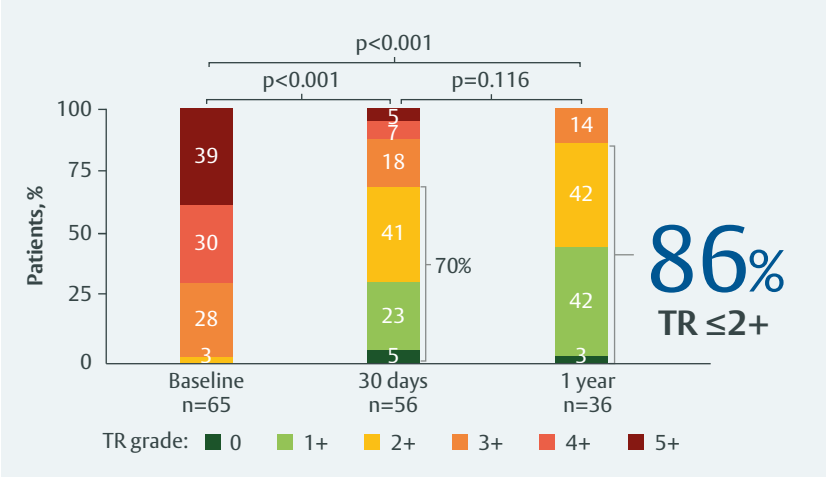
THE CLASP TR STUDY

Prospective, multicentre, single-arm early feasibility study[1]

65 patients

1 year†

Significant and sustained improvements in TR, functional status and quality of life at 1 year.[1]



88% freedom from all-cause mortality

79% freedom from HFH

92% NYHA class I/II

+18 pts KCCQ-OS

Figure shows unpaired data. Adapted from Kodali KS *et al*. 2023. For details on statistical analyses, please see reference 1.

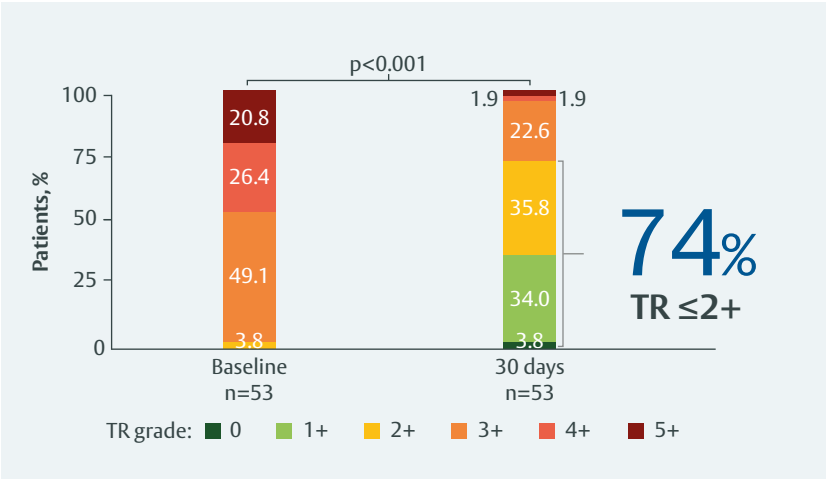
THE CLASP II TR TRIAL

Prospective, multicentre, randomised, controlled pivotal trial (roll-in cohort)[2]

73 patients†

30 days†

Significant TR reduction with no adverse safety signals, mortality or hospital readmissions in the roll-in cohort. The randomised trial is ongoing.[2]



100% freedom from all-cause mortality

100% freedom from HFH

86% NYHA class I/II

+18 pts KCCQ-OS

Figure shows paired analysis. Adapted from Young M. 2022. For details on statistical analyses, please see reference 2.

PASTE registry

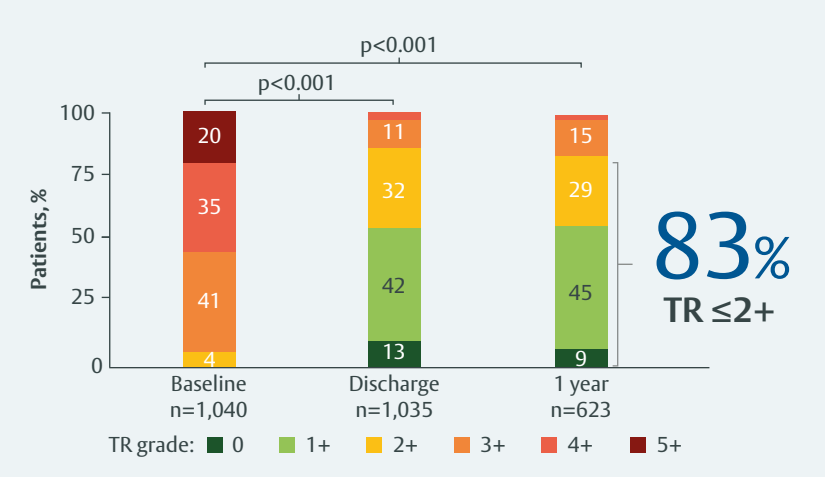
Investigator-initiated, multicentre, retrospective and prospective, observational cohort study[3]

1,059 patients

1 year

Significant and sustained TR reduction and clinical improvements at 1 year in a real-world, high-risk patient population with complex anatomy at baseline:[3]

Mean TRI-SCORE risk **23%** | Coaptation gap >8 mm **24%** | Transvalvular CIED lead **27%** | >3 leaflets **43%**



83% TR ≤2+

86% freedom from all-cause mortality

84% freedom from HFH

66% NYHA class I/II

−9 pts MLHFQ

Figure shows unpaired analysis. Adapted from Wild MG *et al*. 2025. For details on statistical analyses, please see reference 3.

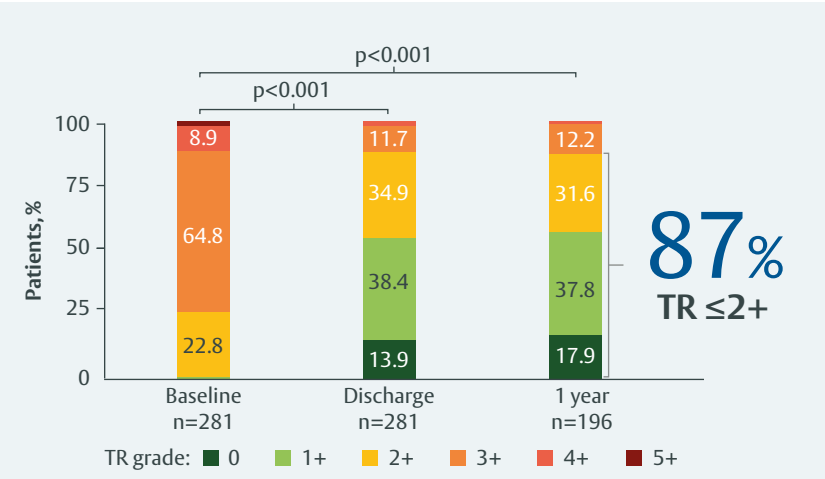
THE TriCLASP STUDY

Prospective, multicentre, single-arm, post-market clinical follow-up[4]

300 patients

1 year†

Significant and sustained improvements in TR reduction, functional status and quality of life at 1 year in patients with clinically significant TR in a post-market setting.[4]



87% TR ≤2+

88% freedom from all-cause mortality

83% freedom from HFH

75% NYHA class I/II

+8 pts KCCQ-OS

Figure shows unpaired analysis. Adapted from Hausleiter J. 2024. For details on statistical analyses, please see reference 4.

*CLASP TR, TriCLASP, CLASP II TR and PASTE registry.

†Based on reported follow-up.

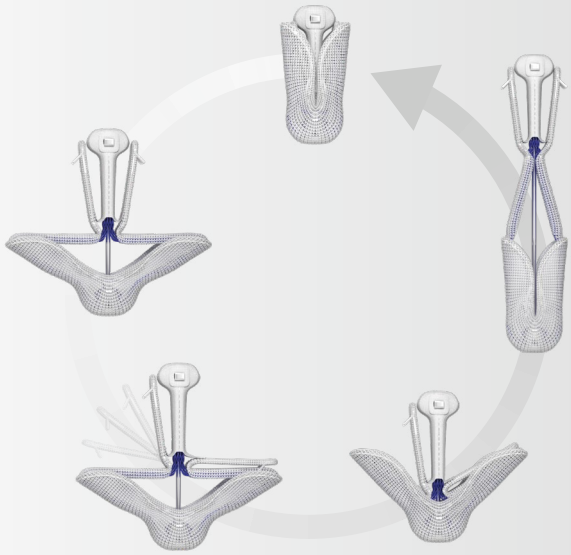
Edwards PASCAL Precision System

Accurate, intuitive control
Advanced catheter and handle design facilitates smooth navigation and implant deployment*

Versatile implant configuration
Adapt to specific procedural and anatomical needs

Atraumatic clasp and closure
Enhance leaflet capture with atraumatic reclasp capabilities

Predictable release
Deploy the implant with procedural confidence†



*Design data on file and marketing evaluation.
†Performance and design data on file.

Learn more about the PASCAL system at Edwards.com/gb/PASCAL

For details on statistical analyses, please see references 1–4.

Abbreviations

CEC:	clinical events committee
CIED:	cardiac implantable electronic device
ECL:	echocardiography core lab
HFH:	heart failure hospitalisation
KCCQ-OS:	Kansas City Cardiomyopathy Questionnaire overall summary score
MLHFQ:	Minnesota Living with Heart Failure Questionnaire
NYHA:	New York Heart Association
TR:	tricuspid regurgitation

References

1. Kodali SK, Hahn RT, Davidson CJ *et al*. 1-Year outcomes of transcatheter tricuspid valve repair. *J Am Coll Cardiol*. 2023; **81:** 1766–76.
2. Young MN. Transcatheter tricuspid valve repair: The CLASP II TR trial roll-in cohort. PCR London Valves, 2022, London, UK.
3. Wild MG, Stolz L, Rosch S *et al*. Transcatheter valve repair for tricuspid regurgitation: 1-year results from a large European real-world registry. *J Am Coll Cardiol*. 2024; 2025; **85:** 220–31.
4. Hausleiter J. Transcatheter tricuspid valve repair: TriCLASP study 1-year results. PCR London Valves, 24–26 November 2024, London, UK.

Medical device 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).

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