

Edwards PASCAL Transcatheter Valve Repair System

MiCLASP Post-Market Study: 1-Year Outcomes

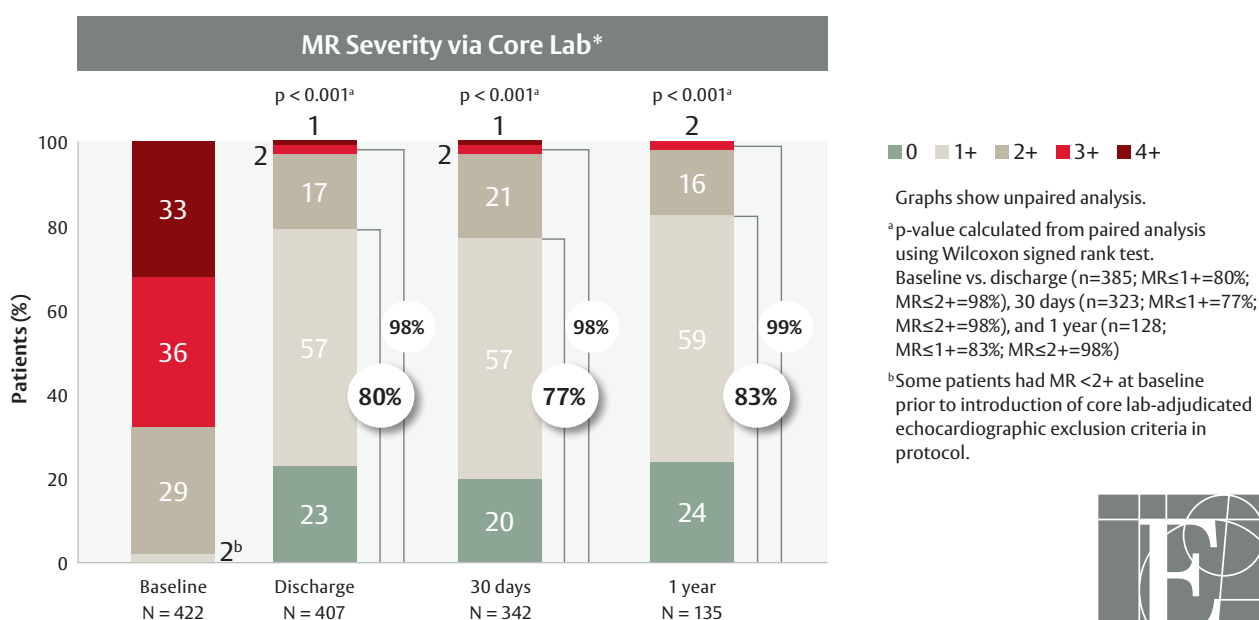


Professor Lurz reported the 1-year outcomes of the single-arm, multi-centre MiCLASP post-market clinical follow-up (PMCF) study.

Study design & baseline parameters¹

Study design: prospective, single arm, multi-centre study		
Enrolled patients: 500	Male: 59%	Age, years (mean): 77 ± 10
NYHA functional class III or IV: 77%	STS score (MV repair): 5.1 ± 4.3	Euroscore II: 7.6 ± 7.5
MR etiology: Functional 64%, degenerative 32%, mixed 4% and 1% other/unavailable		

Key results

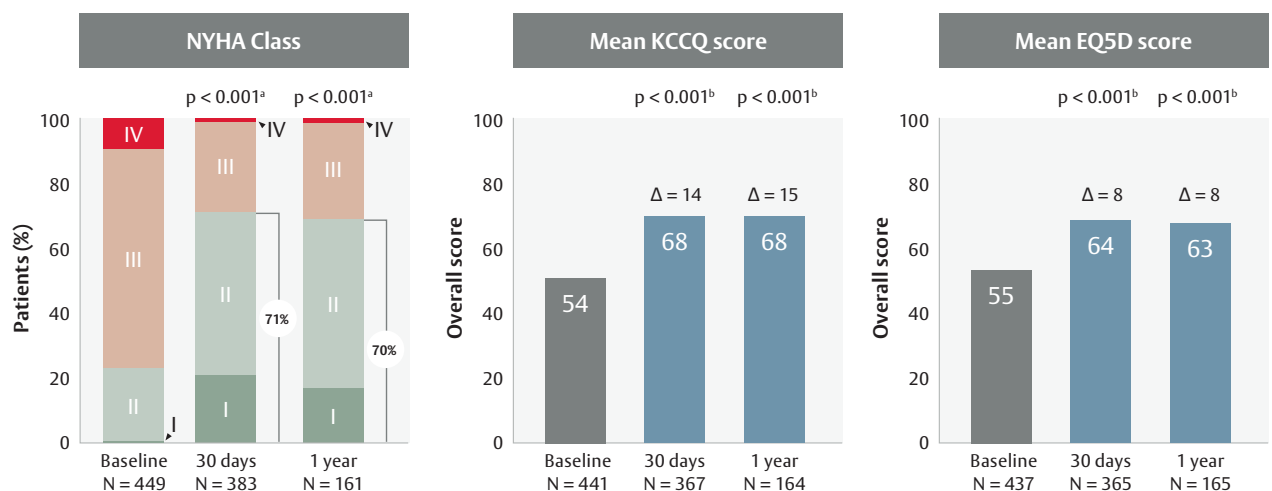


*Cardiovascular Core Lab at Morristown Medical Center
 NYHA: New York Heart Association; STS: Society for Thoracic Surgeons; MR: mitral regurgitation; MV: mitral valve



Outcomes at 1 year:

- High survival and low event rates
- Low rate of heart failure hospitalisation
- Core lab-adjudicated sustained MR $\leq 1+$ durability with 83% patients at MR $\leq 1+$
- Significant and sustained clinical, functional and quality-of-life improvements
- Positive outcomes in both FMR and DMR patients



Graphs show unpaired data. Δ and p-values calculated from paired analysis. ^aWilcoxon signed rank test. ^bStudent's t-test

NYHA: New York Heart Association; KCCQ: Kansas City Cardiomyopathy Questionnaire; EQ5D: EuroQol 5 Dimensions Health Questionnaire

Conclusion

- In the ongoing MiCLASP post-market study at 1 year, the PASCAL system demonstrated favourable safety and sustained MR reduction accompanied by significant symptomatic and quality-of-life improvements.

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

MR: mitral regurgitation; FMR: functional mitral regurgitation; DMR: degenerative mitral regurgitation

¹Lurz P. One-year outcomes for transcatheter mitral repair from the MiCLASP study. PCR London Valves 2022

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