

Edwards PASCAL Transcatheter Valve Repair System

CLASP 2-Year Multicenter Study Results¹



CLASP study shows sustained MR reduction and positive left ventricular remodeling accompanied by high survival and low HF Hospitalization rate



Study design & baseline parameters¹

Study Design: Multicenter, multinational, prospective, single-arm study

Total patients: 124

FMR: 69% | DMR: 31%

Baseline NYHA Class III/IV: 60.2%

MR severity $\geq 3+$: 100%

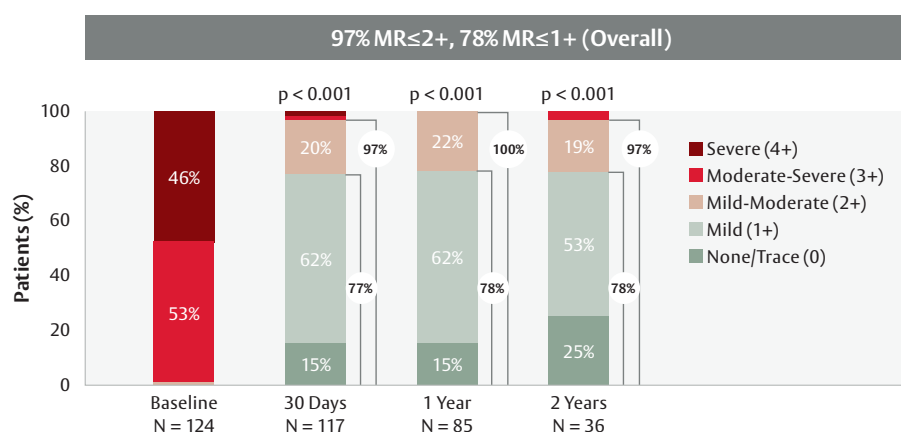
Mean age: 74.9 years

PISA EROA: $0.38 \pm 0.15 \text{ cm}^2$

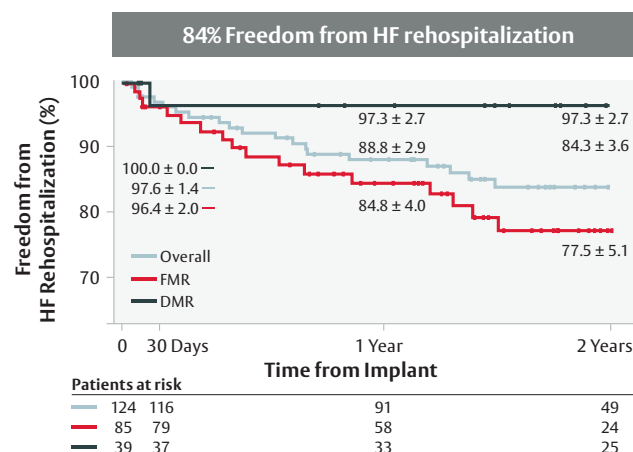
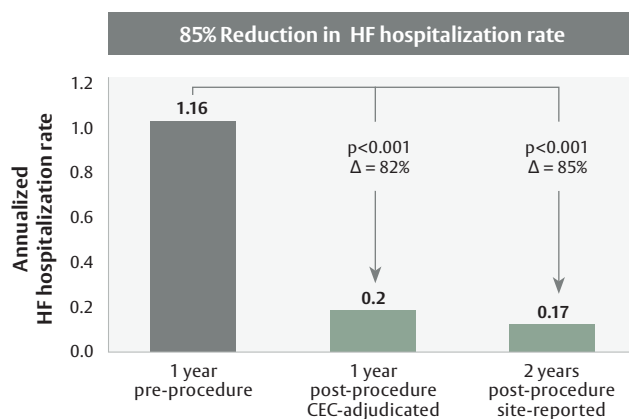
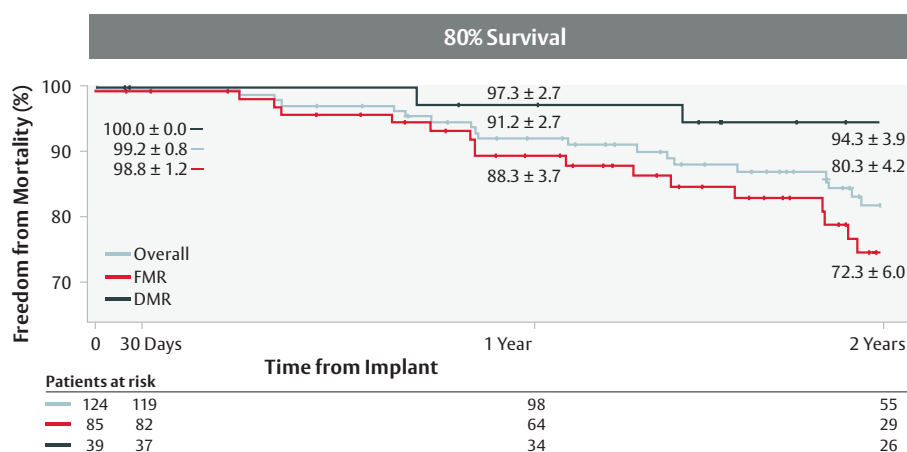
Regurgitant volume: $57.3 \pm 19.7 \text{ ml}$

Mean vena contracta width, A-P: $6.3 \pm 1.4 \text{ mm}$

Robust and significant MR Reduction



High Survival Rate and Low Heart Failure Hospitalization rates



Procedural characteristics

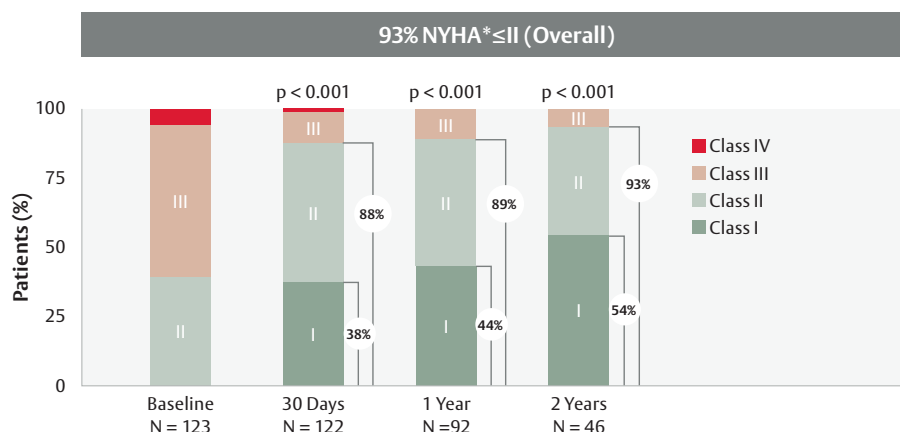
Successful implant rate: 96%

Procedure time (mean, skin to skin): 109 (82, 158)

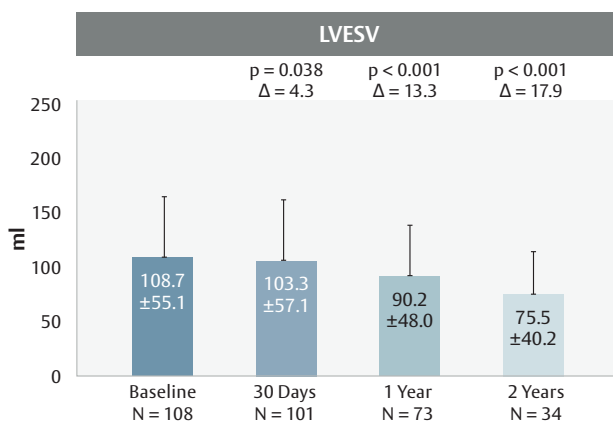
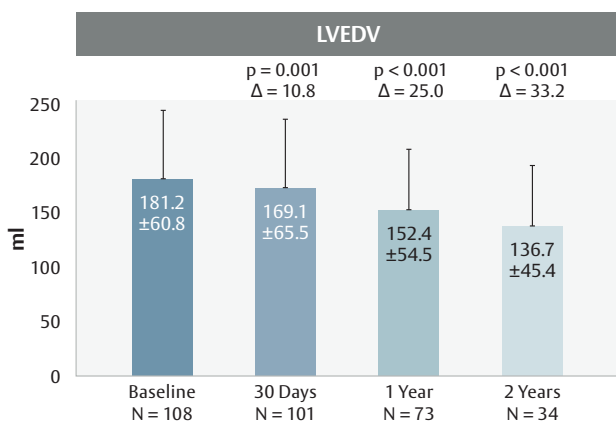
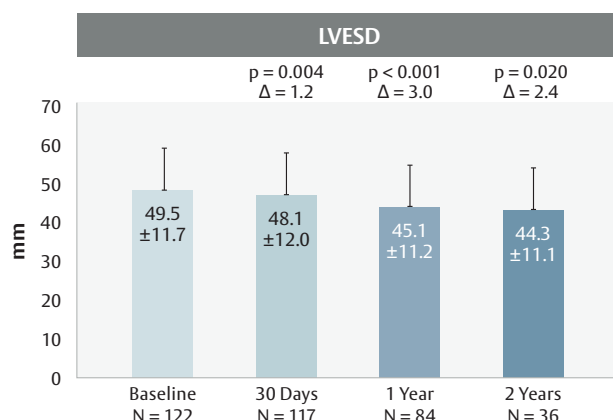
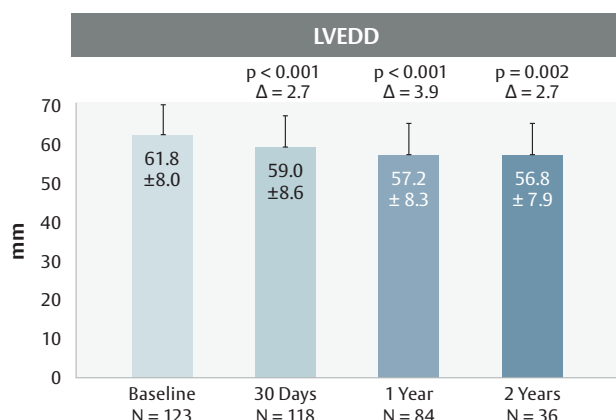
Mean number of devices implanted: 1.0 (1.0-2.0)

Length of hospital stay: 2.0 (1.0, 3.0)

Sustained Functional improvement




Positive left ventricular remodeling in the overall population over time



Conclusions:

The PASCAL transcatheter valve repair system achieved high rates of 2-year survival with significant reduction in annualized HF hospitalization, thanks to durable and sustained MR reduction with evidence of LV reverse remodeling and significant improvement in functional status.¹



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* New York Heart Association, Functional Classification (NYHA)

¹ Szerlip M, et al. 2-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study. *JACC Cardiovasc Interv*. 2021 May 7;S1936-8798(21)00675-0. doi: 10.1016/j.jcin.2021.04.001

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