THE CLASP IID REGISTRY

Longest follow up from the only prospective, CEC and core-lab adjudicated registry including patients with DMR and complex mitral valve anatomy

Two-year outcomes from the CLASP IID Registry confirm the significant and sustained MR reduction and improved functional status and quality-of-life compared to baseline with the PASCAL system

Trial Overview

The CLASP IID Registry is a prospective, global, multi-center single-arm study evaluating M-TEER with the PASCAL system in patients who have significant symptomatic 3+ or 4+ **DMR**, are at **prohibitive surgical risk**, and have **complex mitral valve anatomy**.

The PASCAL system treated elderly patients with multiple comorbidities and broad range of mitral valve anatomy

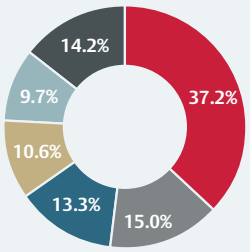
- 98 enrolled
- 81 ± 7 years old
- 69% atrial fibrillation
- 43% renal insufficiency[a]
- 57% pulmonary hypertension[b]

Enrolled PASCAL System n=98

↓

2 years
Visit completed **79.4% (54/68)**
TTE completed **70.6% (48/68)**

Death: 21
Withdrew/ exited: 9



15% of patients met two anatomical complexity criteria

Baseline anatomical complexity distribution

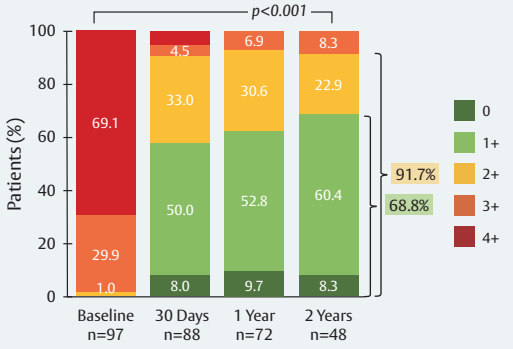
- ≥2 independent significant jets
- Bileaflet/multi scallop prolapse involvement
- Mitral valve orifice area <4.0 cm²
- Flail width >15 mm and/or flail gap >10 mm
- Significant jet in the commissural area
- Other[c]

[a] Estimated glomerular filtration rate <60 ml/min
[b] Pulmonary artery systolic pressure ≥ 30 mmHg

[c] Other includes presence of significant clefts or perforation in the grasping area (6.2%), moderate to severe calcification in the grasping area (3.5%), leaflet mobility length <8 mm (3.5%), history of endocarditis and significant tissue defects in the leaflet (0.9%)

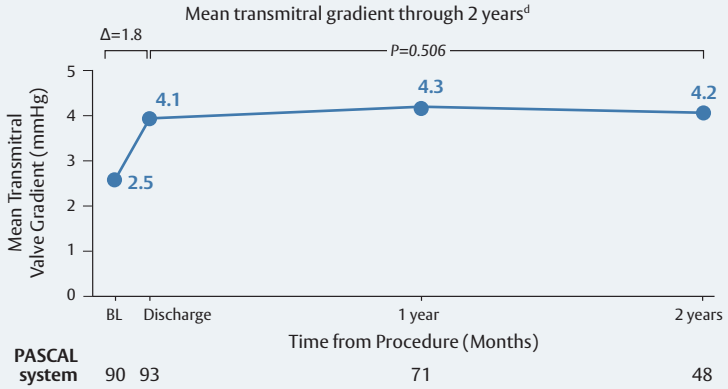
Significant and sustained MR reduction with durable transmitral valve gradient <5 mmHg at 2 years

MR reduction through 2 years[d]



Graph shows unpaired analysis.
[d] Assessed by echocardiographic core laboratory

Mean transmitral gradient through 2 years[d]



Graph shows mean and Δ represents paired change.

92%
Of patients with MR≤2+ at 2 years[1]

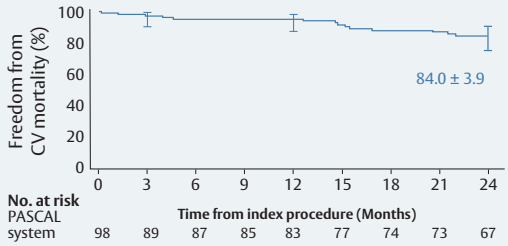
69%
Of patients with MR≤1+ at 2 years[1]

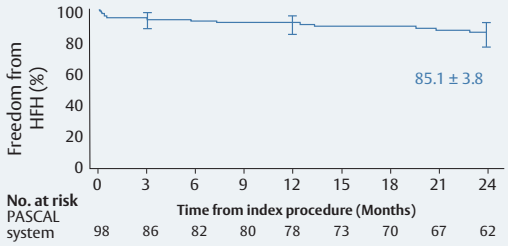
4.2 mmHg
Mean transmitral valve gradient at 2 years[1]

M-TEER: mitral transcatheter edge-to-edge repair, CEC: Clinical Events Committee, DMR: degenerative mitral regurgitation, MR: mitral regurgitation, TTE: transthoracic echocardiogram, BL: baseline

Edwards

High freedom from cardiovascular mortality and heart failure hospitalization at 2 years



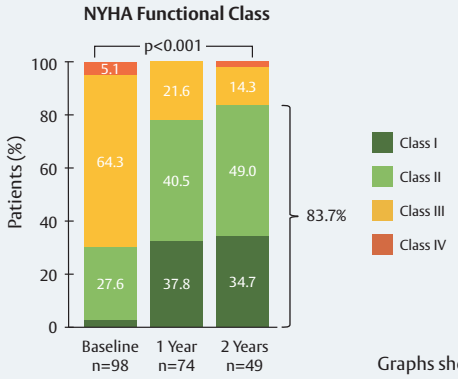


Graphs show Kaplan-Meier analysis time to first event (KM estimate±SE) and error bars represent 95% CI.

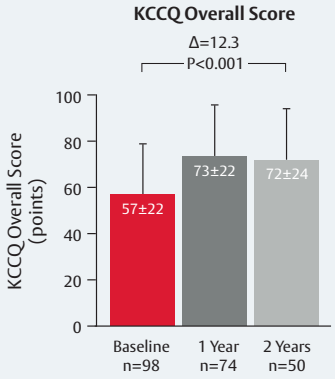
84% **Freedom from CV mortality with the PASCAL system[1]**

85% **Freedom from HFH with the PASCAL system[1]**

Meaningful and sustained improvements in functional and quality-of-life outcomes at 2 years



Graphs show unpaired analysis.



84% **of patients in NYHA class I/II at 2 years[1]**

12 POINT **improvement in KCCQ from baseline to 2 years[1]**

Conclusion

- Two year outcomes confirm the sustained safety and effectiveness of the PASCAL system in prohibitive surgical risk DMR patients with complex mitral valve anatomy.
- These results emphasize the value of the PASCAL system in successfully treating a wide range of DMR patients, including those with complex valve anatomy historically considered unsuitable for M-TEER.
- Based on the CLASP IID trial data[2,3] the IFU were updated by removing some anatomical considerations[a] from the warnings for patients with mitral regurgitation (consult eifu.edwards.com when applicable).

[a] Evidence of moderate-to-severe calcification in the grasping area; Presence of two or more significant jets; Presence of one significant jet in the commissural area; Mitral valve area < 4.0 cm²; Flail width > 15 mm and/or flail gap > 10 mm

CV: Cardiovascular, HFH: Heart Failure Hospitalization, NYHA: New York Heart Association, KCCQ: Kansas City Cardiomyopathy Questionnaire, IFU: Instructions for Use

For details on statistical analyses please see reference 1

Reference

1. Zahr F, et al. CLASP IID Randomized Trial and Registry: Two-Year Outcomes of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation. Presented at: TCT Annual Congress; 2024 Oct 30; Washington, DC
2. Zahr F, et al. One-year Outcomes from the CLASP IID Randomized Trial for Degenerative Mitral Regurgitation. *JACC Cardiovasc Interv.* 2023;16(23):2803-2816.
3. Smith RL, et al. One-year Outcomes of Transcatheter Edge-to-Edge Repair in Anatomically Complex Degenerative Mitral Regurgitation Patients. *JACC Cardiovasc Interv.* 2023;16(23):2820-2832

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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