2-year outcomes for transcatheter repair in patients with functional mitral regurgitation from the CLASP study

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On behalf: The CLASP Study Investigators

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Background: Transcatheter mitral valve repair has emerged as a favourable option in patient care for treating functional mitral regurgitation (FMR) with a need for longer term data. We herein report two-year outcomes from the FMR group of the multicentre, prospective, single arm CLASP study with the PASCAL transcatheter valve repair system.

Methods: Patients with symptomatic, clinically significant FMR ≥3+ as evaluated by the core laboratory and deemed candidates for transcatheter repair by the local heart team were eligible for the study. Follow-up was conducted at 30 days, one year, and two years with echocardiographic outcomes evaluated by the core laboratory at all timepoints and major adverse events (MAEs) evaluated by an independent clinical events committee to one year (site-reported thereafter).

Results: Eighty-five FMR patients were treated with mean age 72 years, 55% male, 65% in NYHA Class III-IVa, 37% LVEF, and 100% MR grade ≥3+. Successful implantation was achieved in 96% of patients. MAEs included one cardiovascular mortality (1.2%) and one conversion to mitral valve replacement surgery (1.2%) at 30 days, and two reinterventions between 30 days and two years. Kaplan-Meier (KM) estimates for survival were 88% at one year and 72% at two years. Freedom from heart failure (HF) rehospitalization KM estimates were 81% at one year and 78% for two years. The reduction in annualized HF hospitalization rate was 81% at two years (p<0.001). MR ≤1+ was achieved in 73% of patients at 30 days, 75% at one year, and 84% at two years; MR ≤2+ was achieved in 96% of patients at 30 days, 100% at one year, and 95% two years (all p<0.001). Mean LVEDV of 199 mL at baseline decreased by 9 mL at 30 days (p=0.039), 29 mL at one year (p<0.001), and 31 mL at two years (p<0.001). NYHA class I/II was achieved in 87% of patients at 30 days, 86% at one year, and 88% at two years (all p<0.001). Six-minute walk distance (6MWD) improved by 22 m at 30 days (p=0.004) and 40 m at one year (p=0.003). Kansas City Cardiomyopathy Questionnaire (KCCQ) score improved by 16 points at 30 days and one year (all p<0.001).

Conclusions: In the CLASP study, the PASCAL transcatheter valve repair system demonstrated sustained favourable outcomes at two years in patients with FMR. Results showed a high survival rate of 72% and freedom from HF rehospitalization of 78% at two years. An 81% reduction in annualized HF hospitalization rate was observed. At two years, sustained MR reduction of MR ≤2+ was achieved in 95% and MR ≤1+ in 84% of patients, with evidence of left ventricular reverse remodelling. Improvements in functional status were significant and sustained at two years. The CLASP IIF randomized pivotal trial is ongoing.