Six-month and one-year outcomes with the PASCAL transcatheter valve repair system for patients with mitral regurgitation from the multicentre, prospective CLASP study

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Background: Transcatheter mitral valve repair has emerged as a viable option for treating mitral regurgitation (MR). We report results from the multicentre, prospective, single arm CLASP study with the PASCAL transcatheter valve repair system.

Methods: 109 patients with clinically significant MR deemed candidates for transcatheter repair by the local heart team were treated in the CLASP study. The study evaluated safety, performance, clinical and echocardiographic outcomes and included an independent clinical events committee and echocardiographic core lab. The primary safety endpoint was a composite MAE rate at 30 days of cardiovascular mortality, stroke, MI, new need for renal replacement therapy, severe bleeding, and re-intervention for study device-related complications.

Results: Mean age was 76 years, 54% male, 57% NYHA Class III/IV, 100% MR grade $\geq$3+ with 62% functional, 31% degenerative, 7% mixed etiology. Successful implantation was achieved in 95% of patients. At 30 days, the MAE rate was 8.3% including one cardiovascular mortality due to cardiogenic shock as a result of severe bleeding at the contralateral arterial access site for hemodynamic monitoring further complicated by disseminated intravascular coagulation, one stroke, and one conversion to mitral valve replacement surgery. In paired analysis, 88% of patients were in NYHA Class I/II ($p<0.001$), MR grade was $\leq$1+ in 79% of patients and $\leq$2+ in 96% of patients. Significant improvements in 6MWD (+27 m, $p<0.001$) and KCCQ (+16 points, $p<0.001$) were observed. The six-month data will be available for presentation. In addition, we report one-year follow up of the first 62 patients (ITT): 93% one-year survival rate (Kaplan-Meier estimate), no stroke, no late reintervention, one late MI. In paired analysis, MR grade was $\leq$1+ in 82% of patients and $\leq$2+ in 100% of patients. 88% of patients were in NYHA Class I/II ($p<0.001$), 6MWD improved by 21 m ($p=0.124$) and KCCQ improved by 13 points ($p<0.001$).

Conclusions: This study demonstrates the PASCAL transcatheter valve repair system is safe and resulted in robust MR reduction with 100% of patients achieving MR $\leq$2+, and $\sim$ 80% MR $\leq$1+, sustained at one year. Results show high survival and low complication rates, and sustained improvements in functional status, exercise capacity, and quality of life at one year in patients with clinically significant, symptomatic MR. The CLASP IID/IIF pivotal trial is underway.