Six-month outcomes from the multicenter, prospective study with the novel Pascal transcatheter valve repair system for patients with mitral regurgitation in the CLASP study

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Background: Severe mitral regurgitation may lead to an impaired prognosis if left untreated. Transcatheter treatment options have emerged as an alternative to surgery and an adjunct to medical therapy. We report the six-month results of the PASCAL transcatheter valve repair system in treating patients with mitral regurgitation enrolled in the multicenter, prospective, single arm CLASP study.

Methods: The PASCAL implant is comprised of two broad and curved paddles, two clasps capable of independent leaflet capture, and a Nitinol woven spacer which enable optimized leaflet capture, intended to reduce mitral regurgitation while minimizing concentrated stress on the leaflets. Eligible patients had clinically significant MR despite optimal medical therapy and were deemed candidates for transcatheter mitral repair by the local Heart Team. Safety, performance, and clinical outcomes were prospectively assessed at baseline, discharge, 30 days, and 6 months post-procedure. All major adverse events (MAE) were adjudicated by an independent clinical events committee and echocardiographic images were assessed by a core lab. The MAE rate was the primary safety endpoint, defined as the composite of cardiovascular mortality, stroke, MI, new need for renal replacement therapy, severe bleeding, and re-intervention for study device-related complications.

Results: Between June 2017 and September 2018, 62 patients were enrolled at 14 sites worldwide for transcatheter mitral valve reconstruction using the PASCAL system. The mean age was 76.5 years (62.9% male). All patients had MR grade =3+, with 59% functional, 34% degenerative, and 7% mixed etiology. The average STS Score for MV repair was 4.4%, EuroSCORE II was 5.2%, and 51.6% of patients were in NYHA Class III/IV. Successful implantation of the PASCAL device was achieved in 95% of patients. At discharge, 95% of patients had MR grade =2+ with 81% grade =1+. The MAE rate was 4.8%. At 30-day follow-up, paired analyses shows that 98% of patients had MR grade =2+ with 81% grade =1+ and 88% were in NYHA Class I/II (p<0.0001). The 6MWD improved by 38.9 m (p=0.0015) and was accompanied by average improvements in KCCQ and EQ5D scores by 14.1 points (p<0.0001) and 8.3 points (p=0.0028), respectively. The six-month data will be available for presentation.

Conclusions: In this early device experience, the Edwards PASCAL transcatheter valve repair system showed
an acceptable safety profile and performed as intended in treating patients with mitral regurgitation. The PASCAL device resulted in significant MR grade reduction, which was associated with clinically and statistically significant improvements in functional status, exercise capacity, and quality of life. Continued follow-up is warranted to validate these initial promising results.