Feasibility Trial Reports Deployment of New Device for TAVI in Aortic Insufficiency

European Society of Cardiology

A new investigational device—the Helio System (TF-FA) —being developed for use with the Sapien XT Transcatheter Heart Valve was successfully deployed in all four patients in a small, first-in-human feasibility study of its use in high-risk aortic insufficiency reported at EuroPCR 2013.

The HELIO dock system acts as an anchor to help stabilise the SAPIEN XT valve for patients with aortic insufficiency. The native leaflets in the heart are captured between the transcatheter heart valve and the dock. "This is an innovative, minimally invasive approach to treat aortic insufficiency," said the lead author of the study, Sanjeevan Pasupati, specialist in coronary and structural heart disease intervention, Waikato Hospital, Hamilton, New Zealand. He explained that currently available valves anchor to calcified valves. "What makes aortic insufficiency different from aortic stenosis – for which transcatheter aortic valve implantation (TAVI) is established – is the lack of calcium in the aortic leaflets and annulus, making it challenging to anchor the transcatheter heart valve. We need a system to anchor the valve in these patients."

The prospective trial using the transfemoral or transapical approach was designed as a clinical evaluation of the safety and initial performance of the new system in high-risk aortic insufficiency. Four patients (mean age 70+10 years) were recruited at Dr Pasupati's centre between August 2011 and June 2012. Their mean logistic EuroSCORE was 8.6+1.3 and mean left ejection fraction was 57%+16%. The mean native annulus diameter was 25.4+1.1mm and the mean gradient was 20.1+8.8mmHg. They were followed-up at hospital discharge and at 30 days, six months and 12 months and will continue to be followed-up annually out to five years.

Pasupati reported that there were no in-hospital deaths. One patient had a stroke/TIA and one suffered minor vascular complication. One patient, who had pre-existing renal impairment, had an acute kidney injury. "The primary endpoint of freedom from all-cause mortality at 30 days was 100%," he told the conference, adding that all four patients were alive at one year. He added, "Successful delivery and deployment of the HELIO System and retrieval of the delivery systems resulting in improved aortic insufficiency in the earliest evaluable echocardiogram post-implant was achieved in all four patients." Aortic insufficiency improved from moderate to severe before the procedure to trivial at 30 days. Two patients followed up at 12 months had no aortic insufficiency at this time point.

Commenting on the implications of the study findings, Professor Stephan Windecker, Professor and Chief of Cardiology, Swiss Cardiovascular Center and Clinical Trials Unit Bern, Bern University Hospital, Switzerland, said, "The field of

transcutaneous aortic valve implantation is expanding in indications from its well established use in aortic stenosis to other causes of aortic regurgitation. The larger annulus size in patients with aortic insufficiency without stenosis means we need facilitating techniques to use devices previously used in aortic stenosis. In this study it is encouraging to treat patients with aortic regurgitation for which we have not previously had suitable devices."

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