THE REPOSITIONABLE LOTUS AORTIC VALVE REPLACEMENT SYSTEM: SIX-MONTH OUTCOMES IN THE REPRISE I FEASIBILITY STUDY

Oral Contributions
West, Room 2009
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Session Title: Transcatheter Aortic Valve Replacement (TAVR) I: Evolving Data
Abstract Category: 49. TCT@ACC-i2: Aortic Valve Disease
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Background: Transcatheter aortic valve replacement (TAVR) demonstrates promising outcomes in inoperable and high-risk patients (pts) with severe, symptomatic aortic stenosis (AS). However the use of current generation TAVR devices is associated with a higher risk of stroke, vascular complications and aortic regurgitation (AR) when compared with surgical AVR. The repositionable and fully retrievable Lotus Valve is designed to facilitate precise positioning and minimize paravalvular AR. Results beyond 3 months have not yet been reported.

Methods: The REPRISE I prospective, single-arm, 3-center feasibility study assesses safety and performance of the 23mm Lotus Valve in symptomatic pts with severe calcified AS and high surgical risk.

Results: The Lotus Valve was implanted in 11 pts (mean STS score 4.9±2.5%, mean logistic euroSCORE 9.5±4.4%). At baseline 6 pts were NYHA Class II, 5 were Class III. Clinical procedural success was achieved in 9/11 (due to a major ischemic stroke in 1 pt and a mean post-procedure gradient of 22mmHg, above the 20mmHg VARC threshold, in 1 pt). Partial resheathing and repositioning was performed in 4/4; none required full retrieval. There were no deaths, MIs, or repeat procedures for valve-related dysfunction through 3 months. The 3-month VARC safety composite was 3/11 (2 pts with non-valve-related disabling bleeding, 1 with major ischemic stroke and vascular complication). Conduction disturbance requiring a new pacemaker occurred in 4 pts (2 with complete AV block). Only 2 were pacemaker dependent at 3 months. At 3 months, 7 pts were NYHA Class I, 3 were Class II, and 1 was Class III. Mean aortic gradient was 53.9±20.9mmHg at baseline, 13.7±3.7mmHg at discharge, and 12.0±2.2mHg at 3 months (P<0.001). Mean AVA was 0.7±0.2cm2 at baseline, 1.5±0.2cm2 at discharge, and 1.6±0.2cm2 at 3 months (P<0.001). At 3 months, core laboratory adjudicated paravalvular AR was mild in 2 pts and absent in 9.

Conclusions: Three-month feasibility results suggest that the Lotus Valve can be positioned accurately and successfully with virtually no AR and low clinical event rates, supporting further study in a larger, more rigorous trial. Six-month data will be presented for the first time at ACC 2013.