was attempted and successfully accomplished in 6 of 6 patients. The primary performance endpoint of 30-day mean aortic valve pressure gradient was 11.5±5.2mmHg, as assessed by an independent core lab, and was significantly less than the performance goal of 18 mmHg (P<0.001). The primary safety endpoint of 30-day all-cause mortality was 4.2%. One-year follow-up data or death was available for 99.2% (119/120) of patients (1 patient withdrew consent at day 13). At 1 year, the rate of all-cause mortality was 10.9% (13/119), disabling stroke was 3.4% (4/119), and disabling bleeding was 5.9% (7/119). There were no repeat procedures for valve-related dysfunction, valve migration, embolization, or TAV-in-TAV. A total of 31.9% (38/119) patients had new permanent pacemaker implantation due to new or worsened conduction disturbance. By independent core lab adjudication, the 1-year mean aortic valve gradient was 12.6±5.7mmHg and mean aortic valve area was 1.7±0.5cm2. A total of 88.6% patients had no or trivial paravalvular aortic regurgitation at 1 year; no patient had moderate or severe paravalvular aortic regurgitation.

CONCLUSIONS The Lotus Valve has demonstrated negligible paravalvular regurgitation and low rates of death and stroke at 1 year. The 2-year results of the REPRISE II CE-Mark trial will provide the longest follow-up to date in the full cohort of 120 patients treated with the Lotus Valve; results will be available for the first time at TCT 2015.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI, TAVR, Transfemoral

TCT-110

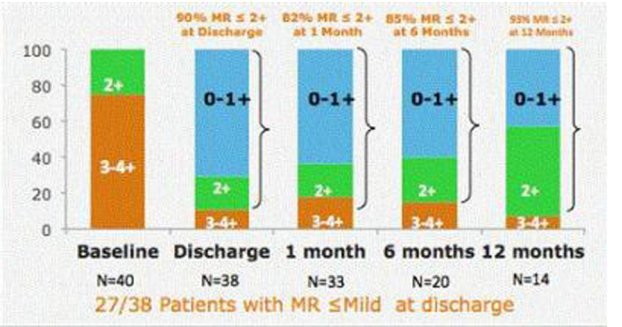
Up to One Year Follow Up Results of Transcatheter Annuloplasty Ring Multicentre Trial

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BACKGROUND The Cardioband system enables percutaneous implantation of an adjustable "surgical-like" mitral annuloplasty ring using a transseptal approach. The aim of this study was to evaluate the feasibility, safety and up to 12 month outcome of Cardioband in patients with secondary mitral regurgitation (MR) in a multicentre study.

METHODS Between February 2013 and March 2015, 40 high-risk patients with significant secondary MR were enrolled at 6 sites in Europe. After a Heart Team evaluation all patients were screened by echocardiography and cardiac CT to assess feasibility. Echocardiographic data were analyzed by an independent core-lab. Mean age was 72±7 years; thirty patients were male (75%). Mean EuroScore II 9.0%± 7.02% and median STS score 7.2 % (1.0%-34.0%). At baseline 93% of patients were in NYHA class III-IV with mean left ventricular ejection fraction of 33.3±10% (15%-57%). Device implantation was feasible in all patients (100%).

RESULTS Acute procedural success (device successfully implanted with acute reduction of MR <2+) was achieved in 92% of the patients (37/40). After cinching of the device, an average 20% reduction in the septo-lateral diameter was observed (from 37±5 mm to 29±5 mm; p<0.01). Thirty-day mortality was 5.0% (adjudicated as unrelated to the device). At 6-month follow-up (N=20) 80% of patients were in NYHA class I-II with significant improvement in quality of life (MLWHFQ from 38 to 18; p<0.05) and 85% of patients had MR≤2+. At 12 month follow-up (N=14), 70% of patients were in NYHA class I-II with significant improvement in quality of life (MLWHFQ from 35 to 17; p<0.05 and significant improvement in 6MW from 288 m to 360 m; p<0.05); 93% of patients had MR<2+).



CONCLUSIONS Transseptal direct annuloplasty with an adjustable "surgical-like" ring is feasible, with a comparable safety profile similar to other transcatheter mitral procedures. Effective reduction in MR severity is observed in most patients related to a significant septo-lateral dimension reduction. MR reduction is stable and consistent up to 12 months, with clinical benefit.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-111

Impact of Concomitant Mitral Regurgitation Following Transcatheter Aortic Valve Replacement: Insights from the US TVT National Registry

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BACKGROUND Mitral regurgitation (MR) frequently accompanies aortic stenosis (AS). Transcatheter aortic valve replacement (TAVR) is an effective treatment for severe AS, but unlike surgical treatment, cannot simultaneously address MR. The impact of concomitant MR on TAVR outcomes requires better understanding, as does the impact of TAVR on MR severity.

METHODS Patients who underwent TAVR between 1/2012 and 12/2013 in the STS-ACC TVT registry were analyzed for baseline and procedural characteristics, in-hospital and 30 day clinical outcomes as well as echo outcomes. Center for Medicare and Medicaid Services data was obtained for longer-term outcomes.

RESULTS Of 11,221 patients who underwent TAVR, 3,497 (31%) had baseline moderate (2+) MR and 602 (5%) had severe (3 to 4+) MR. As compared to patients with minimal MR (0, trace, or 1+), patients with moderate or severe MR were older, more often female, more likely NYHA class III-IV, had more atrial fibrillation/flutter, and were more likely to have a preoperative pacemaker. Patients with minimal MR had more diabetes, chronic severe lung disease, and need for home O2. Echo/cath showed patients with moderate or severe MR had lower ejection fractions, higher pulmonary artery systolic and wedge pressures. STS predicted 30-day mortality in minimal, moderate and severe MR patients were 8.1%, 9.6% and 10.7% respectively (p < 0.0001). MR improved at least 1 grade on post-procedure (pre-discharge) echocardiogram in 79% of the severe MR patients and 66% of the moderate MR patients. Unadjusted death at 30 days in the minimal, moderate and severe MR patients was 6.7%, 8.5% and 12.6%, respectively (p<0.0001). Unadjusted death at 1 year was 22.3%, 27.1% and 28.2%, respectively (p<0.0001). (Figure)

CONCLUSIONS Approximately one-third of patients presenting for TAVR in US have moderate to severe preoperative MR.

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