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ONE YEAR OUTCOME IN PATIENTS UNDERGOING TRANSFEMORAL AORTIC VALVE REPLACEMENT (TAVR) WITH THE REPOSITIONABLE AND RETRIEVABLE BOSTON SCIENTIFIC LOTUS VALVE COMPARED WITH THE BALLOON-EXPANDABLE EDWARDS SAPIEN 3 DEVICE

Poster Contributions
Poster Hall, Hall C
Saturday, March 18, 2017, 3:45 p.m.-4:30 p.m.

Session Title: Interventional Cardiology: TAVR 3
Abstract Category: 17. Interventional Cardiology: Aortic Valve Disease
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Background: Residual aortic regurgitation was frequent with first generation TAVR devices. Innovations with new generation are aiming to optimize valve performance and improve clinical outcome.

Methods: We compared 30 days and 12 months outcome of the Boston Scientific Lotus Valve and the Edwards Sapien 3 valve according to VARC-2 criteria.

Results: Between 2014 and 2016 consecutive patients treated with the Boston Scientific Lotus Valve (N=202) and the Edwards Sapien 3 (N=335) were prospectively enrolled. There was no moderate or severe AR with both devices. Mild AR was lowest with the Lotus valve (5.1% vs. 3.0%, p=0.26). Early safety endpoint at 30 days was similar (7.4% for the Lotus vs. 7.4% for the Sapien 3, p=0.99) with a comparable all-cause mortality (Lotus 1.9%, Sapien 3 1.8%, p=0.87) and rate of all stroke (Lotus 2.9%, Sapien 3 2.9%, p=0.99). Major vascular complications were low with both devices (Lotus 2.9%, Sapien 3 2.4%, p=0.69). Rate of pacemaker implantation due to II° and III° atrioventricular block was significantly higher with the Lotus valve 30.2% vs. 13.4% for the Sapien 3 (p<0.01). The composite endpoint of all-cause mortality or disabling stroke at 12 months was similar for the Lotus (16.6%) and the Sapien 3 (23.2%, p=0.29). Subgroup analyses for the composite endpoint demonstrated similar results with respect to gender(p=0.44 OR 0.69, CI0.29-1.65), STS score (p=0.61, OR 0.79, CI 0.32-1.98), left ventricular ejection fraction (p=0.74, OR 0.83, CI 0.26-2.60), atrial fibrillation (p=0.17, OR 0.54, CI 0.22-1.33), diabetes mellitus (p=0.70m OR 0.80, CI 0.25-2.55), PARTNER-1 (p=0.26, OR o.43, CI 0.09-1.96) and PARTNER-2 inclusion criteria(p=0.17, odds ratio 0.53, 95%-CI 0.21-1.34).Results in patients without need for permanent pacemaker implantation were favoring the repositionable device (24.3% vs. 12.9%, p=0.04).

Conclusions: TAVR with the Sapien 3 and the Lotus valve demonstrated no postprocedural moderate or severe aortic regurgitation. Early safety endpoint and the combined endpoint of all-cause mortality and disabling stroke within 12 months were low and comparable. Need for permanent pacemaker implantation was significantly higher with the Lotus valve.