VARC was significantly higher in the ES3 population with 93% vs. 76% in the CV group (p<0.01). There was no annulus rupture, coronary obstruction or periprocedural death. The rate of postprocedural non-disabling or disabling stroke was similar. There was a statistical significance in the rate of paravalvular aortic regurgitation by postprocedural echocardiography with moderate or severe aortic regurgitation of 20% in the CV population versus 1% in the ES3 population (p<0.01). Numbers for mild regurgitation were 43 % vs. 31 % (p=0.22), none or trace 37% vs. 68% (p<0.01), respectively. Life threatening bleeding according to VARC was similar (CV 1% vs. ES3 0%, p=0.37). There was a statistical significant lower rate of post-procedural new pacemaker implantation for the ES3 with 15% versus 31% for the CV (p<0.01).

CONCLUSIONS Transfemoral TAVI with the new ES3 compared with the CoreValve was associated with a statistical significant lower rate of moderate or severe aortic regurgitation, significant lower need for pacemaker implantation and a significant higher rate of device success according to VARC.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, TAVI

TCT-631

Comparison of the second generation Edwards Sapien 3 valve with the Edwards Sapien XT for transfemoral aortic valve implantation (TAVI)

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BACKGROUND Moderate and severe aortic regurgitation after TAVI with the Edwards Sapien XT (EXT) valve were associated with a higher acute and long-term mortality in the Partner trial. The second generation Edwards Sapien S3 (ES3) valve has an outer skirt at the distal part of the valve, designed to reduce paravalvular aortic regurgitation. We compared outcome of patients after TAVI with the EXT and ES3 in 200 patients.

METHODS The first 100 consecutive patients treated with the ES3 were compared with the last 100 consecutive patients treated with the EXT valve (Clinical Trial Registration: NCT02162069). Mean STS-Score was 11±8%. Postprocedural paravalvular regurgitation, rate of pacemaker implantation and device success were analyzed according to VARC criteria. Sizing was based on multislice computer tomography performed with a 256 Philips Brilliance iCT scanner. Measurements of aortic annulus, left ventricular outflow tract (LVOT) and distance from annulus to coronary ostia were measured with a dedicated software (3mensio Structural Heart,version 7.0).

RESULTS Baseline characteristics were similar between the EXT and ES3 population Also the following computer tomography acquired parameters did not differ significantly between the EXT and ES3 population: aortic annulus area derived diameter 24.4±2.3 vs. 24.7±2.4 mm (p=0.37), aortic annulus perimeter derived diameter 25.7±2.4 vs. 25.4±2.5 mm (p=0.45), aortic annulus area 467±99 vs. 483±96 mm2 (p=0.25), LVOT area derived diameter 24.3±2.8 vs. 24.6±2.6 mm (p=0.48), LVOT perimeter derived diameter 25.5±2.9 vs. 25.6±2.6 mm (p=0.94), LVOT area 471±108 vs. 480±101 mm2 (p=0.52), heavy calcification of the aortic annulus (Rosenhek Grade IV) 94% vs. 100% (p=0.67) or heavy calcification of the LVOT 32% vs. 33% (p=0.88). Size of the EXT was 23mm in 31%, 26mm in 44%, 29mm in 25%. Numbers for ES3 were 29%, 50% and 21%, respectively. Post dilation was done in 1% after EXT implantation and none after ES3 implantation. Rate of device success according to VARC was high in both groups (p=0.77). There was one intraprocedural death in the EXT group, none in the ES3 population. There was no annulus rupture or coronary obstruction. The rate of postprocedural stroke was similar (p=0.52). There was a higher rate of mild to severe aortic regurgitation in postprocedural echocardiography of 42% in the EXT population versus 32% in the ES3 group (p=0.12). No severe aortic regurgitation was found in neither group. Life threatening bleeding according to VARC was significantly lower with ES3 versus EXT (0% vs. 9%, p<0.01). The need for permanent pacemaker implantation was higher for EXT with 22% versus 15% for ES3 (p=0.20).

CONCLUSIONS Transfemoral TAVI with the second generation ES3 compared with the EXT resulted in a lower rate of aortic regurgitation (mild-severe), lower need for pacemaker implantation and a significantly lower bleeding risk.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic valve stenosis, TAVI

TCT-632

Implementation of a Moderate Sedation Protocol for Transfemoral Transcatheter Aortic Valve Replacement: A Review at 6 Months

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BACKGROUND Transfemoral transcatheter aortic valve replacement (TF TAVR) can be performed under general anesthesia (GA) or moderate sedation (MS). Despite observational studies suggesting a shorter length of stay (LOS), shorter procedural time and a similar mortality rate with MS, only 5% of patients undergoing TF TAVR in the United States are done with this type of anesthesia. We reviewed the implementation of a MS for TF TAVR protocol at a single institution with no previous experience with this technique.

METHODS Patients with severe obstructive sleep apnea (OSA), likely difficult intubation, inability to tolerate supine position due to musculoskeletal disease, or barriers to communication including altered mental status were performed under GA with intraoperative transesophageal echocardiography. All others received MS with an ilioinguinal nerve block and intraoperative transthoracic echocardiography. The MS for TF TAVR protocol was implemented on October 9th, 2014. The records of patients undergoing TF TAVR 6 months before and after protocol implementation were retrospectively reviewed.

RESULTS In the pre protocol group 33 patients underwent TF TAVR under GA and no patients received MS. In the post protocol group, 97 underwent TF TAVR, 81 (83.5%) of which received MS. OSA was the most common reason for GA (N=10, 62.5%). Conversion from MS to GA occurred in 2 cases (2.5%) due to procedural complications, of which 1 resulted in death. All other cases involving MS were tolerated well and there were no anesthesia related complications. Post procedural LOS (3.2 days vs. 5.0 days, p=0.002) and procedure time (144.0 minutes vs. 96.1 minutes, p<0.001) were both significantly shorter in post protocol group. The post protocol group was also significantly less likely to require a skilled nursing facility upon discharge (24.2% vs. 8.2%, p=0.027). In hospital mortality was similar between groups (N=2 6.1% vs. N=3, 3.1%, p=0.601).

	Pre-Protocol	Post-Protocol	p-Value
N	33	97	
Moderate Sedation: N (%)	0 (0)	81 (83.5)	
Post Procedure Length of Stay: Days	5.0 ± 3.2 (4)	3.2± 2.8 (3)	0.002
Procedure Time: Minutes	144.0 ± 54.9 (129)	96.1 ± 31.3 (88)	<0.001
Skilled Nursing Facility on Discharge: N (%)	8 (24.2)	8 (8.2)	0.027
In Hospital Mortality: N (%)	2 (6.1)	3 (3.1)	0.601

NOTE: Values are in numbers, means ± SD (medians), or numbers (percentages).

CONCLUSIONS The MS for TF TAVR protocol appears safe and can be rapidly implemented at institutions with no previous MS experience. This technique is feasible in the majority of patient undergoing TF TAVR. Post procedural LOS and procedural time are multifactorial, but this data further suggests MS may be beneficial in select patients.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Anesthesia, Sedation, TAVR