METHODS 133 patients underwent TAVR procedures using the Claret Cerebral Protection System (CPS; Claret Medical, Inc., Santa Rosa, CA) to guard against peri-procedural strokes. Various TAVR prostheses were used (55 Sapien 3, 36 Sapien/Sapien XT, 28 CoreValve/Evolut R, 8 Portico, 4 JenaValves, 1 Centra, 1 Direct Flow) as well as different access routes (transfemoral 119, transapical 8, transaxillary 6). In 21 cases, valve-in-valve procedures were performed in degenerated surgical aortic bioprostheses; 9 patients had a left atrial appendage (LAA) thrombus. Mean patient age was 80 ± 8 years; mean logistic EuroSCORE was 27 ± 18%. Clinical follow-up was obtained at 3 days after the intervention and at discharge (mean 10 days). Histological analyses were performed in 52 patients by the CVPath Institute in Gaithersburg, MD (42 additional analyses are still in progress).

RESULTS Stroke rate after TAVR was 2.3% (3/133) at 3 days post TAVR; all were major strokes. Sapien 3 (n = 2) and Evolut R (n = 1) prostheses had been used in these patients. In 2 patients the cerebral protection device was not positioned as intended (one malpositioning, one positioning not possible due to kinking of the truncus brachiocephalicus) and in 1 patient the device dislocated during peri-procedural resuscitation and additional defibrillation in the presence of LAA thrombus. Histological investigations showed debris in the filters in 96% of cases. Debris was more common in the distal (87%) than in the proximal filter (73%). Acute thrombus was the most common type of debris found in 56% of filters. In 30% of all cases, valve and arterial wall tissue and calcification was found. Organized thrombus was found in 12%, while foreign material was found in 7% of cases. The percentage of different types of debris were similar in proximal and distal filters. Foreign material was captured in 13% and 17% (proximal/distal) of filters but was not present when using the Sapien 3 prosthesis.

CONCLUSIONS Feasibility and safety of the Claret CPS was documented in these 133 patients. Histopathological analyses showed high overall debris capture and retrieval rates with prevalence of thrombus over valve and arterial wall tissue, calcification and foreign material. Sapien 3 implantations showed no foreign material in the filters. Procedural stroke rate was low at 2.3%, occurring only when the cerebral protection device was not properly placed. Stroke rate for optimally positioned devices was 0% in this registry, which included also patients with LAA thrombus and cardiogenic shocks. Further experience and investigation is needed to ensure optimal positioning, to quantify any reduction in new cerebral lesions using protection, and to define which patients are at the higher risk for cerebral embolization.

CATEGORIES ENDOVASCULAR: Stroke and Stroke Prevention

KEYWORDS Cerebral emboli, Histological analysis, TAVR

TCT-102

SAPIEN 3 implantation in failed surgical aortic bioprostheses: Matched comparison and Insights from the Valve-in-Valve International Data (VIVID) Registry

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BACKGROUND Oral anticoagulation therapy is the gold standard strategy to avoid strokes and other thromboembolic events in patients with valvular heart disease. However, this strategy is associated with bleeding and death, and the optimal strategy is still debated. We aimed to investigate the efficacy and safety of SAPIEN 3 prosthesis implantation in patients with failed surgical aortic bioprostheses who were at the higher risk for cerebral embolization. Remaining challenges relate to residual stenosis after implantation. We report on the first comprehensive analysis of clinical outcomes of SAPIEN 3 (S3) used for IV and compare to early generation SAPIEN XT (SXT) balloon-expandable device.

METHODS A total of 404 IV VI procedures using SXT or S3 balloon expandable devices from the Valve-in-Valve International Data Registry (VIVID) registry were included. Groups were matched for baseline characteristics and surgical bioprostheses size and type. Subsequently, a group of 48 patients that underwent S3 implantation was compared to a 2:1 matched group of 96 patients that underwent SXT implantation. Procedures and clinical outcomes were defined by Valve Academic Research Consortium II (VARC-II).

RESULTS Patients included in the matched groups had an average age of 75.6±11.1yrs and 56.9% were male. Failure mode was stenosis, regurgitation and the combination of both in 35.4%, 33.3% and 29.3%, respectively. Mean STS PROM was 9±7.4%. Average bioprostheses label size was similar between the groups: 23.7±1.8 mm (S3) vs. 24.2±1.1 mm (SXT), p=0.44. Small surgical valves (label size<21mm) were apparent in 18.8% of S3 vs. 19.2% of SXT cases (p=0.88). Procedures were performed using transfemoral access in 87.5% (S3) vs. 80.2% of (SXT, p=0.28). Implantation transcatheter valve sizes were 18.1±1.8 mm (S3) vs. 17.6±1.9 mm (SXT, p=0.76), as was the rate of elevated post procedural gradients: ≥20mmHg 38.3% (S3) vs. 34.8% (SXT, p=0.69), ≥40mmHg 4.3% (S3) vs. 6.7% (SXT, p=0.56). The incidence of severe patient-prosthesis mismatch (32.4% [S3] vs. 28.1% [SXT, p=0.67] was similar but a trend towards greater effective orifice areas was observed after S3 implantation (1.4±0.4 mm [S3] vs. 1.5±0.5 mm [SXT, p=0.1]).

CONCLUSIONS In this multicenter experience, excellent clinical outcomes with low complication rates were achieved after aortic IV implantation with the S3 transcatheter heart valve. However, post-procedural gradients remained elevated with this second generation device and similar to early generation device, underlining the need for careful patient selection in order to avoid severe patient-prosthesis mismatch after IV implantation.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI, TAVR, Valve-in-valve