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Adoption of a Strategy of Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement is Associated with Fewer Neurologic Events in a Large Volume Center

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Background

- Sentinel device is approved for cerebral embolic protection (CEP) during transcatheter aortic valve replacement (TAVR)
- Randomized clinical trails evaluating the impact of CEP on peri-procedural neurologic events are largely inconclusive and underpowered[1,2]

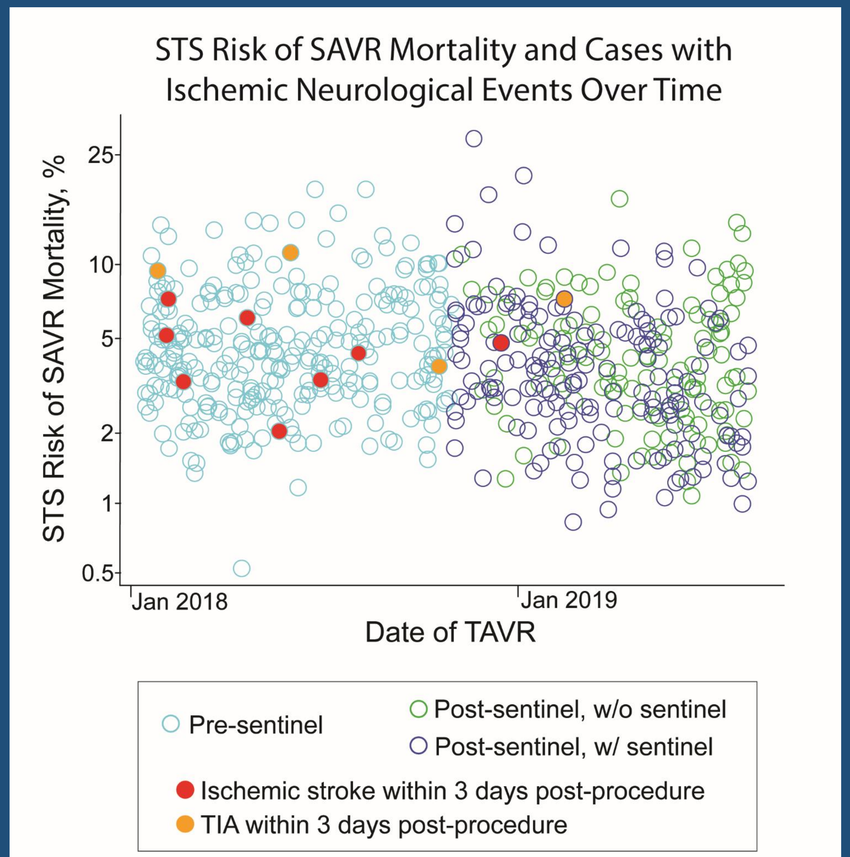
Objective

Objective: Evaluate the real-world impact of our high-volume TAVR program's decision to use CEP in all transfemoral patients without an anatomic or clinical contraindication.

Methods

- Retrospective analysis of all patients who underwent transfemoral TAVR for one year after CEP implementation on 10/15/2018, compared to one year prior
- Primary outcome was peri-procedural (within 3 days) ischemic stroke and transient ischemic attack (TIA)
- Secondary outcomes included procedural outcomes and peri-procedural (within 3 days) hemorrhagic stroke, mortality, life threatening or major bleeding, major vascular complications, and new dialysis
- Chi-square test or Fisher exact test was used to compare events pre- and post-CEP implementation

In a single-center, high-volume TAVR program, **fewer ischemic neurological events** occurred after **adoption of Sentinel** for all anatomically- and clinically-appropriate patients.



Results

Table 1: Patient and Procedural Characteristics

Variable	Pre-sentinel	Post-sentinel	P-value	Post-sentinel		
				No CEP device	CEP device	P-value
# patients	294	294		126	168	
Age, yrs	81.0 (75.7-86.6)	80.9 (75.1-86.4)	0.747	81.0 (76.7-86.4)	80.9 (74.1-86.5)	0.405
Female	148 (50.3)	131 (44.6)	0.16	55 (43.7)	76 (45.2)	0.786
Caucasian	286 (97.3)	286 (97.3)	>0.999	120 (95.2)	166 (98.8)	0.078
BMI	27.9 (24.8-33.8)	28.1 (24.8-32.4)	0.865	28.5 (25.0-32.1)	27.4 (24.7-32.9)	0.394
Prior PAD	55 (18.7)	85 (28.9)	0.004	51 (40.5)	34 (20.2)	<0.001
Prior stroke	32 (10.9)	34 (11.6)	0.794	10 (7.9)	24 (14.3)	0.092
Prior TIA	21 (7.1)	31 (10.5)	0.146	16 (12.7)	15 (8.9)	0.298
Prior CABG	41 (13.9)	49 (16.7)	0.36	26 (20.6)	23 (13.7)	0.114
Prior AV surgery	32 (10.9)	43 (14.7)	0.169	18 (14.3)	25 (15.0)	0.870
NYHA class 3/4	163 (55.4)	165 (56.1)	0.868	71 (56.3)	94 (56.0)	0.946
STS score, %	4.3 (3.0-6.7)	3.6 (2.4-5.8)	0.001	4.1 (2.5-6.3)	3.3 (2.3-5.4)	0.059
TAVR device success	279 (94.9)	287 (97.6)	0.082	123 (97.6)	164 (97.6)	>0.999
Fluoroscopy time	8.1 (6.1-11.0)	10.5 (8.0-14.7)	<0.001	8.7 (6.2-10.7)	12.1 (9.8-16.4)	<0.001
Procedure time	56.0 (48.0-67.0)	63.0 (55.0-74.0)	<0.001	57.0 (49.0-70.0)	66.0 (59.0-77.2)	<0.001

Table 2: Peri-procedural Outcomes

Variable	Pre-sentinel	Post-sentinel	P-value	Post-sentinel		
				No CEP device	CEP device	P-value
No ICU stay	252 (85.7)	263 (89.5)	0.169	110 (87.3)	153 (91.1)	0.298
Post-op LOS	1.0 (1.0-2.0)	1.0 (1.0-2.0)	0.592	2.0 (1.0-3.0)	1.0 (1.0-2.0)	0.012
Ischemic stroke or TIA	10 (3.4%)	2 (0.7%)	0.037	0 (0.0%)	2 (1.2%)	0.509
Ischemic stroke	7 (2.4)	1 (0.3)	0.068	0 (0.0)	1 (0.6)	>0.999
TIA	3 (1.0)	1 (0.3)	0.624	0 (0.0)	1 (0.6)	>0.999
Hemorrhagic stroke	0 (0.0)	0 (0.0)	N/A	0 (0.0)	0 (0.0)	N/A
Major/life-threatening bleed	0 (0.0)	2 (0.7)	0.499	1 (0.8)	1 (0.6)	>0.999
Major VC	10 (3.4)	9 (3.1)	0.816	6 (4.8)	3 (1.8)	0.179
New dialysis	1 (0.4)	1 (0.4)	>0.999	1 (0.8)	0 (0.0)	0.419
Mortality	0 (0.0)	1 (0.3)	>0.999	1 (0.8)	0 (0.0)	0.429

Data presented as median (IQR) or n (%)
BMI = body mass index, CABG = coronary artery bypass graft, CEP = cerebral embolic protection, ICU = intensive care unit, LOS = length of stay, NYHA = New York Heart Association, PAD = peripheral artery disease, STS =Society of Thoracic Surgeons, TIA = transient ischemic attack, TAVR = transcatheter aortic valve replacement, VC = vascular complication

- Among the 168 patients with CEP device, there were 4 (2.4%) partial deployments
- One ischemic stroke occurred in the left-sided circulation in a CEP patient in whom only the innominate filter could be deployed

Conclusions

- In our program, adoption of a strategy utilizing cerebral embolic protection in all anatomically and clinically suitable TAVR patients was associated with fewer ischemic neurological events.
- The Sentinel device was used in 57% of all patients undergoing transfemoral TAVR, and was associated with an increase in procedure time and fluoroscopy time of 9.0 and 3.4 minutes, respectively.

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References: Kapadia SR, et al., J Am Coll Cardiol. 2017 Jan 31;69(4):367-377; Seeger J, et al., Eur Heart J. 2019 May 1;40(17):1334-1340; Seeger J., Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, University of Ulm, presented at TVT 2018.

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