

Cerebral protection in TAVR- can we do without? Impact on stroke rate, length of hospital stay and 12-month mortality

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Background

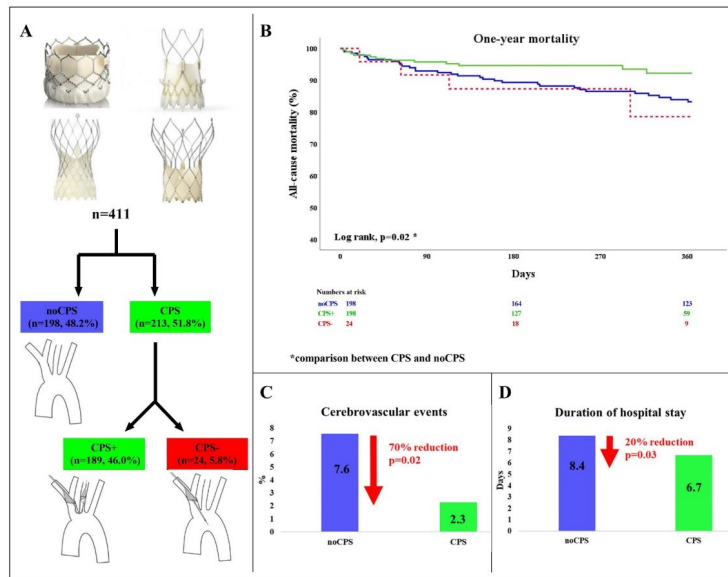
Stroke associated with transcatheter aortic valve replacement (TAVR) is a potentially devastating complication. Until recently, the Sentinel™ Cerebral Protection System (CPS; Boston Scientific) has been the only commercially available device for mechanical prevention of TAVR-related stroke. However, its effectiveness is still undetermined.

Methods

Between January 2019 and August 2020 consecutive patients were randomly assigned to TAVR with or without Sentinel™ in a 1:1 fashion. We defined as primary endpoint clinically detectable cerebrovascular events within 72 hours after TAVR, and as secondary endpoints LOS and 12-month mortality. Logistic and linear regression analyses were used to assess associations of Sentinel™ use with endpoints.

Results

Of 411 patients (80±7 y/o, 47.4% female, EuroSCORE II 6.3±5.9%), Sentinel™ was used in 213 (51.8%), with both filters correctly deployed in 189 (46.0%). 20 (4.9%) cerebrovascular events were recorded, 10 (2.4%) of which were disabling strokes.



Sentinel™ reduced cerebrovascular events in univariate analysis by 71% (OR 0.29, 95%CI 0.11-0.82; p=0.02) and after multivariate adjustment by 75% (adj. OR 0.25; 95%CI 0.08-0.80; p=0.02). Sentinel™ use was also significantly associated with shorter LOS (8.4±9.6 versus 6.7±6.1 days; p=0.03) and lower 12-month all-cause mortality (15.7% versus 7.5%, p=0.01).

Conclusion

In the present prospective all-comers TAVR cohort, Sentinel™ significantly 1) reduced cerebrovascular events, 2) shortened LOS, and 3) improved 12-month survival. These data promote the use of a CPS when implanting TAVR valves.

Figure 1. A: Patient Flow B: One-year mortality C: Cerebrovascular events D: Duration of hospital stay

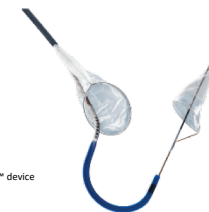


Figure 2. Sentinel™ device