SENTINEL™ Cerebral Protection System

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Cerebral Embolic Protection by Geographic Region[1,2]

PROTECTED TAVR Trial Background: Overall Cohort

PROTECTED TAVR (PTAVR) is a randomized control trial (RCT) including N=3,000 patients with aortic stenosis enrolled at 51 sites globally and randomized 1:1 to TAVR with SENTINEL (n=1,501) or TAVR without SENTINEL (control group, n=1,499) (Feb 2020-Jan 2022).

Primary Endpoint:
All-stroke through 72 hours post-TAVR procedure or hospital discharge (whichever comes first).

Main PTAVR Overall Cohort Findings:

- Primary endpoint was not met but there was a numerical trend towards lower rate of **all-stroke** in patients treated with SENTINEL, with a 21% relative risk reduction in **all-stroke** at discharge or 72 hrs (p=0.3).
- Secondary analyses of **disabling stroke** showed a 60% relative risk reduction in **disabling stroke** at discharge or 72 hrs (p=0.02) in patients treated with SENTINEL.

Post-hoc US Cohort Study:

- Objective: To explore regional differences in the association of CEP utilization with stroke outcomes in patients undergoing TAVR.
- The post-hoc analysis evaluated outcomes in patients enrolled in the US (N=1,833; TAVR with SENTINEL n=914 or TAVR without SENTINEL n=919) and OUS (Outside of the US: Europe and Australia) (N=1167; TAVR with SENTINEL n=587 or TAVR without SENTINEL n=580).
  - Primary endpoint and secondary analyses were similar to the PTAVR overall cohort.

Patient Characteristics:

- Patients in US cohort were younger, more predominantly male, had a lower prevalence of atrial fibrillation, and a higher prevalence of bicuspid aortic valves, diabetes, and peripheral vascular disease compared to OUS cohort.
- As for the procedural practices, there was a higher usage of balloon expandable valves for TAVR in the US (77.7% US vs 42.4% OUS; p<0.001) and a lower rate of pre-dilation (27.5% US vs 60.1% OUS; p<0.001) versus OUS, reflective of the current clinical practice trends in both regions.

Stroke Outcomes - Baseline Characteristics:

Primary Endpoint:

In the US cohort, the primary endpoint showed a significant reduction in **all-stroke** for TAVR with SENTINEL (1.3.%) vs TAVR without SENTINEL (2.6%), representing a 50% relative risk reduction in **all-stroke** at discharge or 72-hours (p=0.045).

No significant difference was observed in the OUS cohort (TAVR with SENTINEL 3.7% vs TAVR without SENTINEL 3.3%; p=0.662).

Secondary Analysis:

Secondary analyses of **disabling stroke** in the US cohort showed a statistically significant 73% relative risk reduction at discharge or 72-hours in TAVR with SENTINEL (0.4%) vs TAVR without SENTINEL (1.5%) (p=0.018).

No significant difference was observed in the OUS cohort (TAVR with SENTINEL 0.7% vs TAVR without SENTINEL 1.0%; p=0.545).

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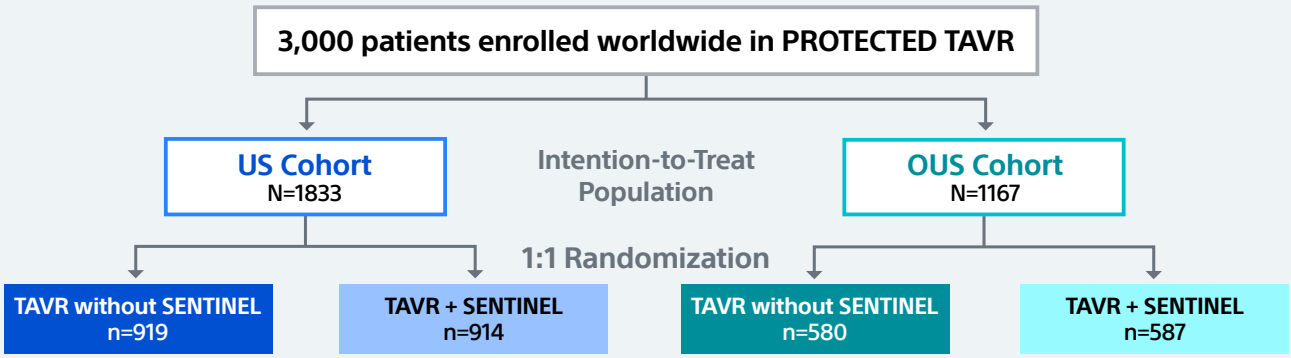
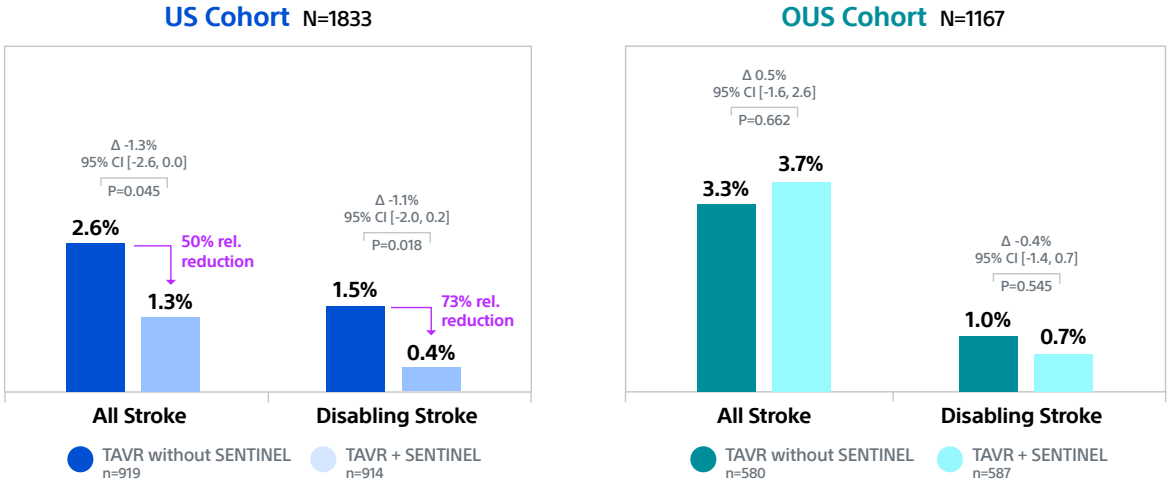
Study Design



Follow-up at Discharge/72 hrs post TAVR

Stroke Outcomes by Geographic Region

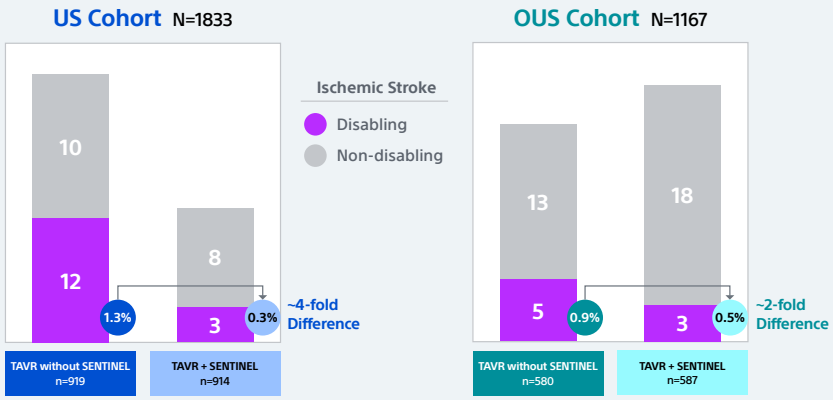


All-stroke and disabling stroke at discharge or 72 hrs after TAVR by geographic region

Ischemic Stroke Outcomes by Geographic Region

In the US cohort, ischemic stroke rate was ~4-fold lower in TAVR with SENTINEL patients (0.3%) vs TAVR without SENTINEL (1.3%).

In OUS cohort, ischemic stroke showed a ~2-fold lower rate in TAVR with SENTINEL patients (0.5%) vs TAVR without SENTINEL (0.9%).



Ischemic Stroke at discharge or 72 hrs after TAVR by geographic region

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Conclusions

- In US patients, TAVR with SENTINEL was associated with a 50% relative risk reduction for overall stroke and a 73% relative risk reduction for disabling stroke compared to TAVR without SENTINEL at discharge or 72 hrs.
- A treatment effect on stroke risk reduction was not observed in OUS cohort.
- Patients treated with SENTINEL and discharged within 72 hrs were more likely to be discharged home compared to patients who did not have SENTINEL used during TAVR.
- For patients who did require a longer hospital stay (>72 hrs), those who did not have SENTINEL used were more likely to need higher-intensity care.
- Lastly, there was no statistically significant difference between the two cohorts when looking at safety rates of all-cause mortality and stroke, acute kidney injury, or CEP access site-related vascular complications.
- Regional differences in patient practices and procedural characteristics may impact the effectiveness of SENTINEL in reducing TAVR-related stroke.

1. Makkar RR. et al. Cerebral Embolic Protection by Geographic Region. A Post Hoc Analysis of the PROTECTED TAVR Randomized Clinical Trial. *JAMA Cardiology*. 2024.

2. Kapadia SR. et al. Cerebral Embolic Protection during Transcatheter Aortic-Valve Replacement. *NEJM*. 2022.

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