

Impact of Cerebral Embolic Protection Devices on Disabling Stroke after TAVR: Results from the TVT Registry¹

Study Objectives

- To describe updated temporal trends and site-level variability in use of SENTINEL™ Cerebral Protection System among patients undergoing TAVR in the US.
- To use real-world data to investigate whether use of SENTINEL is associated with reduction in disabling stroke in patients undergoing TAVR in contemporary practice.

SENTINEL STS/ACC TVT Registry Study Design

Observational retrospective study of the relationship between use of SENTINEL and TAVR outcomes

- Data Source: STS/ACC TVT Registry (n=414,649)
- **Inclusion Criteria:** First isolated Transfemoral TAVR between 1/2018 and 6/2023; includes all TAVR devices, bicuspid valve, valve-in-valve procedures
- **Exclusion Criteria:** Emergent procedures; alternative access; sites performing <20 TAVR/yr; CEP other than SENTINEL



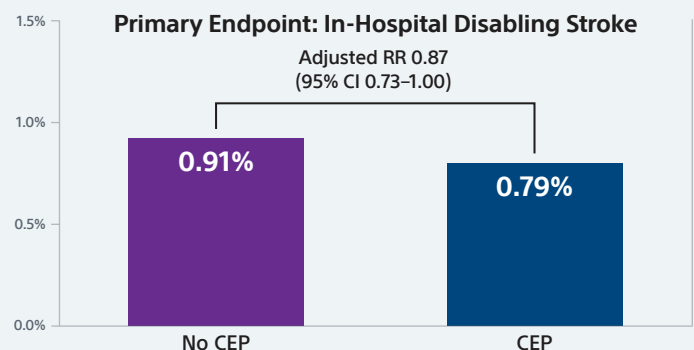
Primary Endpoint: In-hospital disabling stroke

Analytic Approaches

Primary: Instrumental Variable (IV) Analysis

- Technique originally developed in economics that takes advantage of “natural experiments” to approximate randomization
- Under appropriate assumptions, can account for both measured and unmeasured confounding and support causal inference
- Instrument = site-level preference for CEP use during the calendar quarter

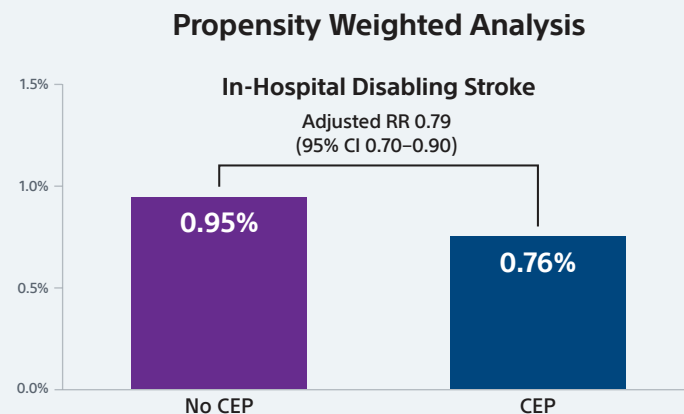
Instrumental Variable Analysis



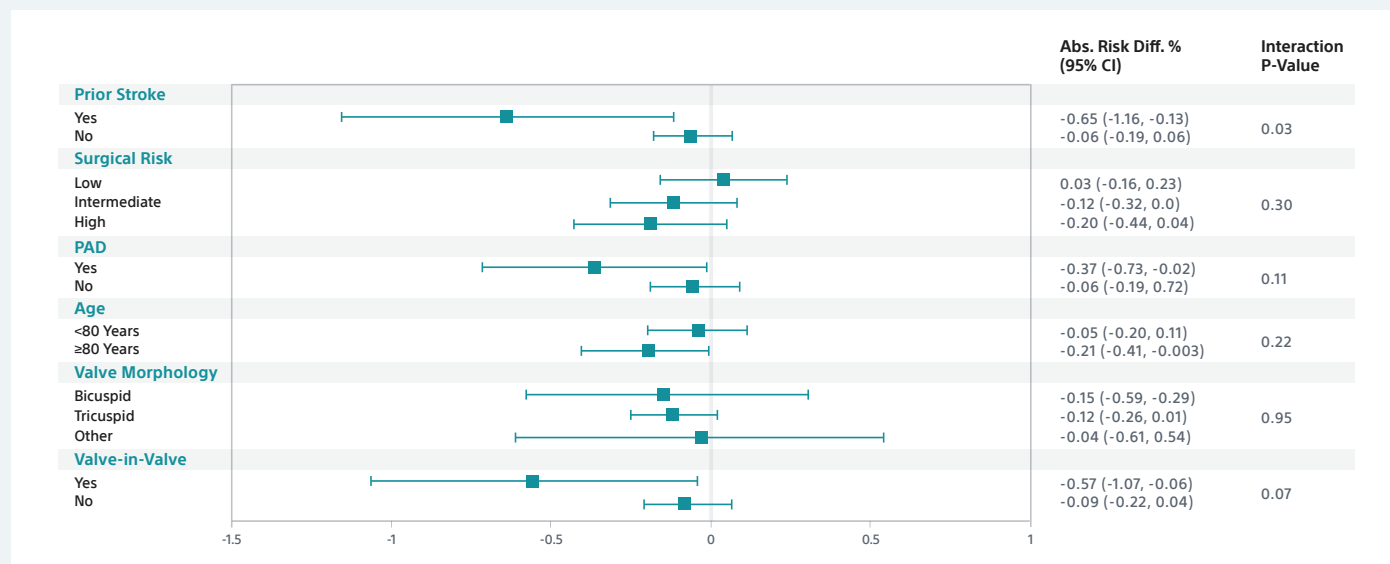
Analytic Approaches Continued

Secondary: Propensity Score Weighting

- Propensity score to predict CEP use developed based on 32 demographic, clinical, and hospital-level characteristics
- Risk-adjusted comparisons performed using overlap propensity weighting



Instrumental Variable Analysis



Main Study Findings

- SENTINEL use was associated with a small, borderline statistically significant reduction in disabling stroke in both IV analysis (**RR 0.87**; 95% CI: 0.73-1.00) and PW analysis (**OR 0.79**; 95% CI: 0.70-0.90) but was not associated with a reduction in non-disabling stroke.
- In subgroup analyses, the benefit of SENTINEL was greater among patients with prior stroke versus those without. (40% Relative Risk Reduction in disabling stroke rate compared to TAVR without SENTINEL).
- These findings provide evidence that supports a true clinical benefit of SENTINEL use for patients undergoing TAVR, limited to prevention of disabling stroke.

1. Neel Butala et al. Transcatheter Aortic Valve Replacement: Updated Results from the STS/ACC TVT Registry. Circulation Interventions. 2024.

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