

Emboliner Non-Inferior to Sentinel for TAVR Cerebral Protection

Written by The Life Science Feed Editorial Team · Published 19 May 2026 · Edited by William Lopes

Transcatheter aortic valve replacement (TAVR) is associated with a risk of periprocedural stroke and subclinical cerebral embolic lesions. Cerebral protection devices aim to mitigate this risk, but comparative effectiveness data between different systems are limited. The PROTECT trial, presented at ACC.26, provides a head-to-head comparison, indicating that the Emboliner embolic protection catheter is non-inferior to the Sentinel cerebral protection system for reducing new cerebral lesions.

KEY TAKEAWAYS

- The Pivot: Direct comparison data now exist for two commonly used cerebral protection devices in TAVR.
- The Data: Emboliner demonstrated non-inferiority to Sentinel for the primary endpoint of new cerebral lesion volume.
- The Action: Clinicians have further evidence to guide device selection for cerebral protection during TAVR, with Emboliner offering a comparable safety and efficacy profile.

Transcatheter aortic valve replacement (TAVR) has become a standard treatment for severe aortic stenosis, but concerns persist regarding neurological complications, particularly periprocedural stroke and subclinical cerebral emboli. These events are often attributed to debris dislodged during valve manipulation and deployment. Cerebral protection devices are designed to capture such embolic material, thereby reducing the incidence of neurological injury. While several devices are available, direct comparative trials assessing their efficacy and safety profiles have been scarce, leaving clinicians to rely largely on single-arm studies or indirect comparisons.¹

The Emboliner embolic protection catheter (Emboliner, Inc.) is a single-filter device designed to cover all three major cerebral arteries originating from the aortic arch. The Sentinel cerebral protection system (Boston Scientific) is a dual-filter device, typically deployed in the brachiocephalic and left common carotid arteries. Both systems aim to prevent embolic debris from reaching the cerebral circulation during TAVR. The PROTECT trial was designed to provide a direct, randomized comparison of these two systems.²

The PROTECT Trial: Design and Findings

The PROTECT trial was a prospective, multicenter, randomized, controlled, non-inferiority study. It enrolled 600 patients undergoing TAVR at 25 sites. Patients were randomized in a 1:1 fashion to receive either the Emboliner embolic protection catheter or the Sentinel cerebral protection system. The primary endpoint was the total volume of new cerebral lesions, as assessed by diffusion-weighted magnetic resonance imaging (DW-MRI) performed between 2 and 7 days post-procedure. Secondary endpoints included the number of new lesions, lesion volume per territory, and clinical

neurological events, including stroke and transient ischemic attack (TIA), at 30 days.³

Baseline characteristics were well-balanced between the two groups. The mean age of participants was 79.2 ± 6.1 years, and 52% were male. The mean Society of Thoracic Surgeons (STS) score was $4.8 \pm 2.1\%$. All patients underwent successful TAVR procedures.⁴

For the primary endpoint, the mean total volume of new cerebral lesions was 145.3 mm³ in the Emboliner group and 152.7 mm³ in the Sentinel group. The difference in mean lesion volume was -7.4 mm³ (95% CI: -35.1 to 20.3 mm³). The upper bound of the 95% confidence interval for the difference was below the prespecified non-inferiority margin of 40 mm³, thereby demonstrating non-inferiority of the Emboliner system compared to the Sentinel system.⁵

Regarding secondary endpoints, the mean number of new cerebral lesions was 4.1 ± 2.5 in the Emboliner group and 4.3 ± 2.7 in the Sentinel group ($P=0.67$). The incidence of clinical stroke at 30 days was 2.0% in the Emboliner group and 2.3% in the Sentinel group ($P=0.81$). There were no significant differences in the rates of TIA or other neurological adverse events between the two groups. Device-related complications, such as vascular access site complications or device embolization, were rare and comparable between both arms.⁶

The PROTECT trial provides important evidence for the use of cerebral protection during TAVR. The non-inferiority finding for Emboliner against Sentinel suggests that both devices offer comparable protection against new cerebral embolic lesions. This trial addresses a critical gap in the literature by offering a direct comparison, which is essential for informing clinical decision-making.⁷

Limitations of the study include the reliance on DW-MRI as a surrogate endpoint for clinical neurological events. While DW-MRI lesions are associated with an increased risk of future neurological events, their direct clinical significance in the immediate post-TAVR period is still an area of ongoing research. Furthermore, the trial did not assess long-term cognitive outcomes, which could be influenced by subclinical embolic events. Future studies should focus on longer-term follow-up and the correlation between DW-MRI findings and sustained cognitive function.⁸

Readers seeking further information on transcatheter valve interventions and associated cerebral protection strategies can find extensive detail in the acclaimed Oxford Handbook of Cardiology.

CLINICAL IMPLICATIONS

The PROTECT trial offers a rare and valuable head-to-head comparison in the medical device space, a domain often dominated by single-arm studies and marketing claims. For clinicians, the demonstration of non-inferiority for Emboliner against Sentinel means that choice can now be informed by more than just familiarity or anecdotal experience. Both devices appear to offer similar levels of cerebral protection, at least as measured by new lesion volume on DW-MRI. This allows for greater flexibility in device selection, potentially driven by factors such as ease of use, specific patient anatomy, or cost, rather than perceived differences in efficacy.

From an industry perspective, this trial levels the playing field somewhat. Boston Scientific's Sentinel has been a prominent player, but Emboliner now has direct comparative data to support its use. This competition is healthy, as it may drive innovation and potentially reduce costs, ultimately benefiting healthcare systems and patients. However, the reliance on DW-MRI as a primary endpoint, while standard for these trials, still leaves a gap in understanding the direct impact on long-term patient-reported cognitive outcomes. The medical community, and indeed regulatory bodies, should continue to push for studies that link these surrogate markers

to more clinically meaningful endpoints.

For patients undergoing TAVR, the availability of multiple, demonstrably effective cerebral protection options is a positive development. While the absolute reduction in stroke rates remains modest with these devices, the effort to mitigate any potential neurological injury is important. Patients can be reassured that their clinicians have evidence-based choices for devices aimed at protecting their brain during a complex procedure. The ongoing challenge remains to translate these imaging findings into tangible improvements in quality of life and cognitive function over the long term, which is where future research must focus to truly protect the patient, not just the head.

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