Cerebral Embolic Protection Devices in Transcatheter Aortic Valve Replacement: A Meta-Analysis of Randomized Controlled Trials

Transcatheter Cardiovascular Therapeutics (TCT) 2025

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Disclosure of Relevant Financial Relationships

- I, Mostafa Ali, DO NOT have any financial relationships to disclose.
- Faculty disclosure information can be found on the TCT App.

Background

- Stroke remains a serious complication of TAVR (2–6%).
- Cerebral Embolic Protection Devices (CEPDs) capture or deflect debris.
- Previous trials show mixed results.
- This meta-analysis evaluates clinical efficacy and safety outcomes.

Objective

- To evaluate the impact of CEPDs on:

– Stroke (overall, disabling, and non-disabling)
– Mortality, bleeding, and vascular complications

- Using data from randomized controlled trials only.

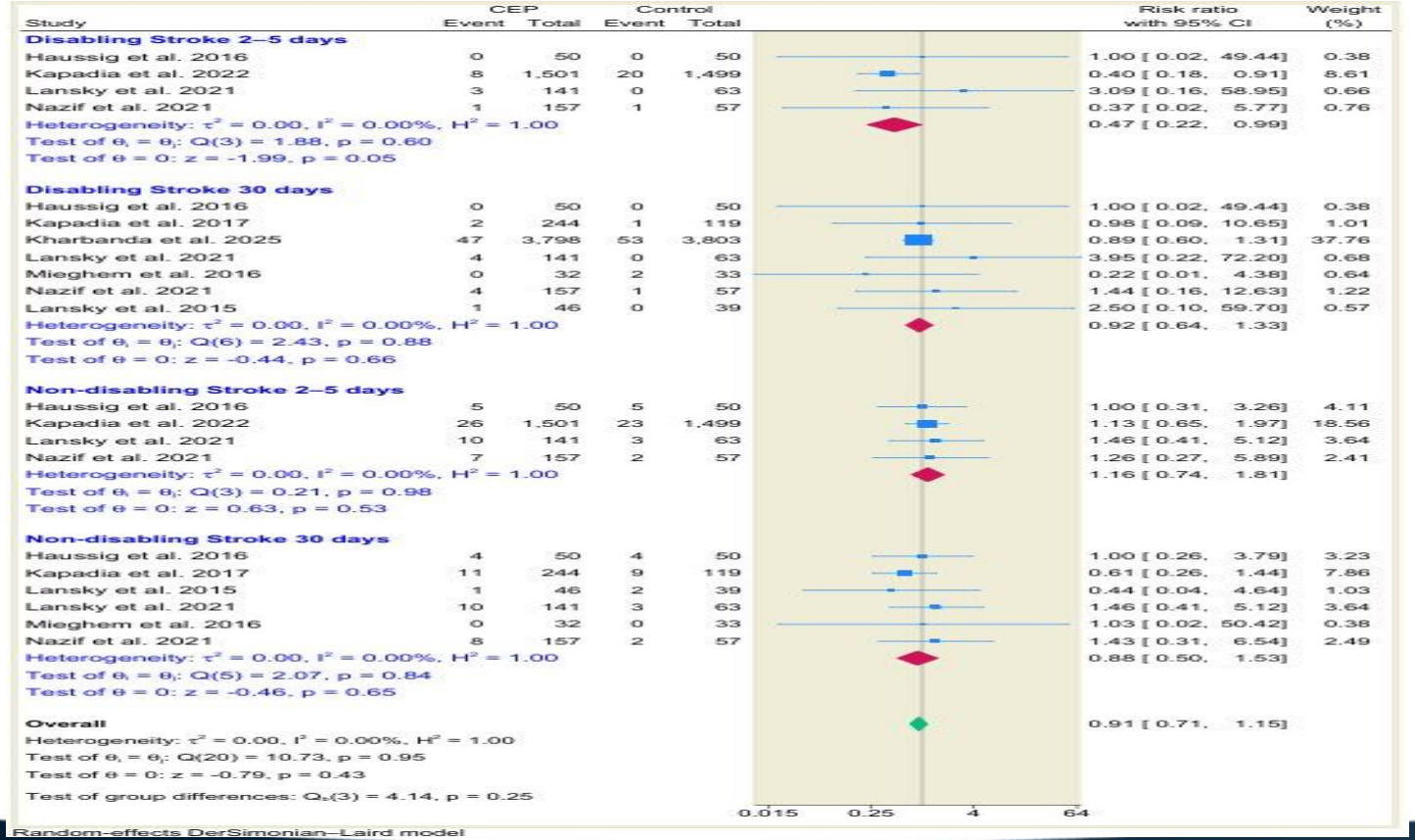
Methods

- Systematic search: PubMed, Scopus, Cochrane, Web of Science (June 2025).
- Inclusion: RCTs comparing CEPD vs Control during TAVR.
- Random-effects model; Risk Ratio (RR) [95% CI].
- Primary outcome: overall stroke at 2–5 and 30 days.

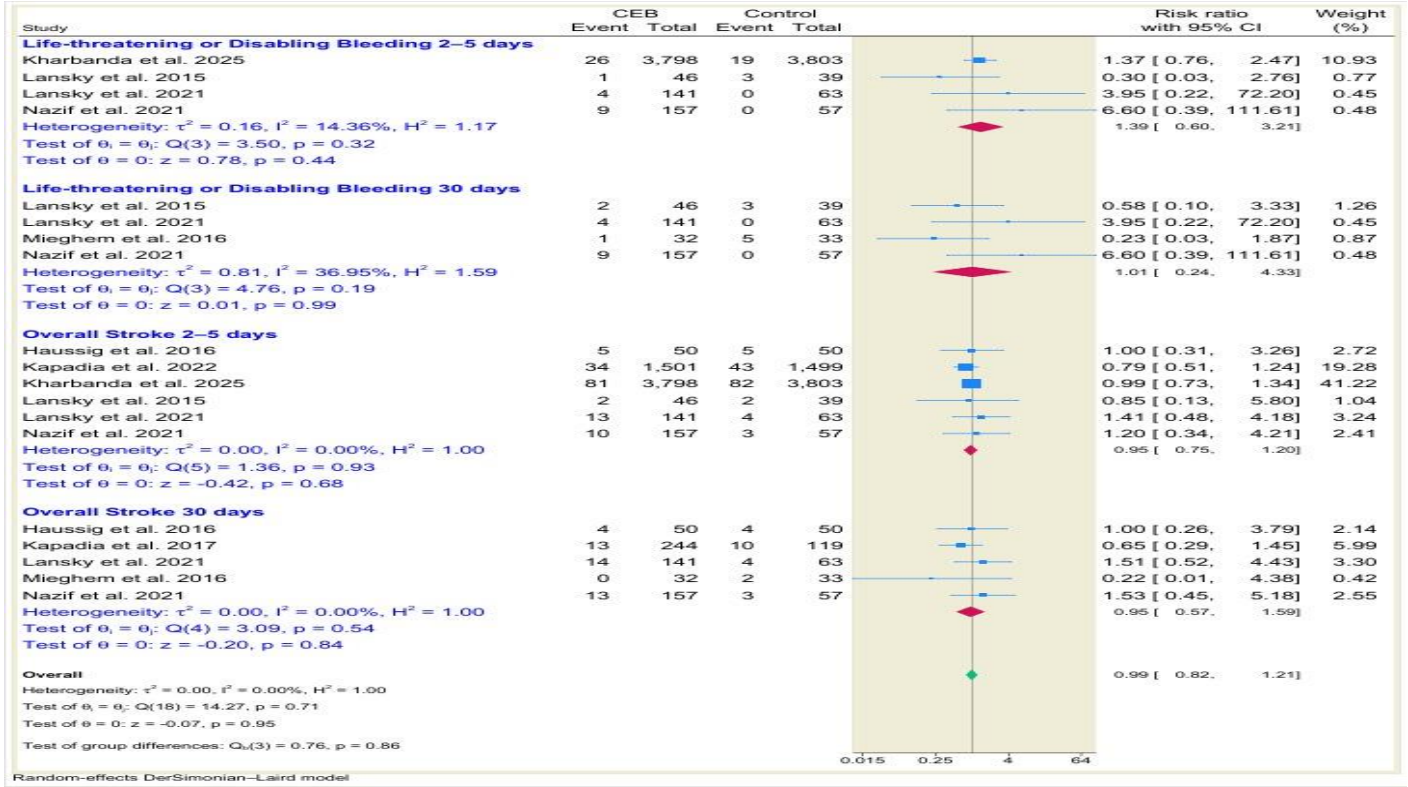
Included Studies

- 8 RCTs (n = 11,623):
- CLEAN-TAVI, MISTRAL-C, DEFLECT III, REFLECT I/II,
- SENTINEL, PROTECTED TAVR, BHF PROTECT-TAVR.
- Devices: Sentinel, TriGuard, EMBOL-X.

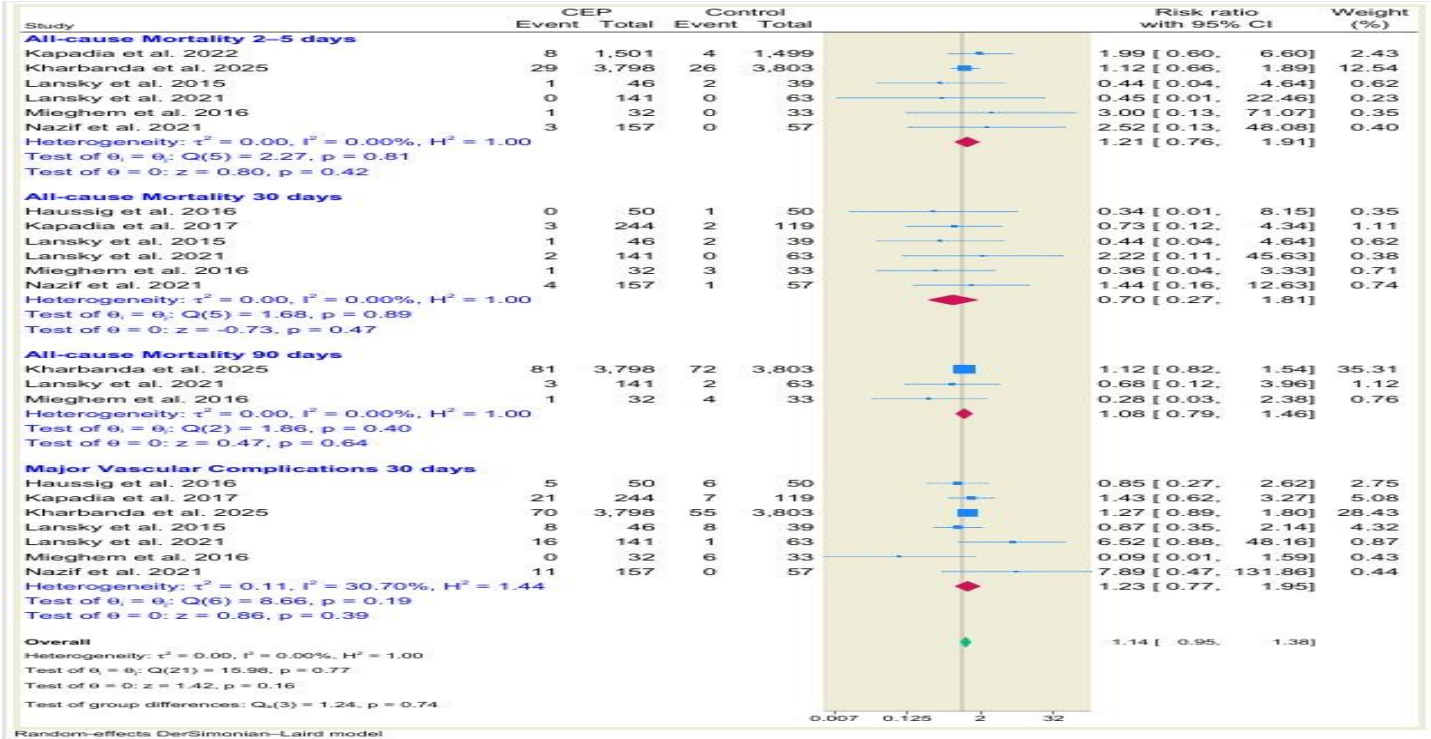
Results – Early Disabling Stroke



Results – Other Outcomes



Results – Other Outcomes



Discussion

- Findings align with Balata et al 2025 and Warraich et al 2025 meta-analyses.
- CEPDs reduce early disabling stroke but not overall stroke or mortality.
- Small absolute benefit may still be clinically meaningful.
- Routine use not justified; selective use may be appropriate.

Limitations

- Low event rates.
- Device heterogeneity (Sentinel vs TriGuard vs EMBOL-X).
- Limited follow-up and MRI standardization.

Conclusion

- CEPDs reduce early disabling stroke after TAVR.
- No significant difference in overall stroke or mortality.
- Supports selective, not routine, use in high-risk patients.
- Future: cost-effectiveness and long-term outcomes.

Clinical Implications

- Consider in prior stroke, heavy calcification, or high-risk anatomy.
- Tailored approach improves neuroprotection.
- Encourages ongoing innovation in device design.

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