Cerebral Embolic Protection Devices during TAVI: A Meta-Analysis of 11,589 Patients with Trial Sequential Analysis

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Background:

Transcatheter aortic valve implantation (TAVI) is associated with procedure-related stroke. Cerebral embolic protection devices (CEPDs) are designed to reduce the risk of embolic debris reaching the brain; however, the evidence supporting their efficacy remains controversial.

Aim and objectives:

To evaluate the efficacy and safety of CEPDs in patients undergoing TAVI.

Methods:

Six databases were systematically searched up to April 2025. Only randomized controlled trials (RCTs) were included and critically appraised using the Cochrane Risk of Bias (ROB-2) tool. Statistical analyses were performed using R software to calculate risk ratios (RRs), and trial sequential analysis (TSA) was conducted to reduce the risk of false-positive results due to random errors.

Result:

We retrieved 1609 records. Eight RCTs (11,589 patients) were analyzed. No significant difference was observed in overall stroke incidence between CEPD and control groups (RR 0.93; 95% CI: 0.74–1.16; P=0.49), including disabling and non-disabling strokes. Device-specific analyses showed a non-significant trend toward reduced disabling stroke with the Sentinel device, while the Triguard device was associated with increased major vascular complications (RR 2.18; 95% CI: 1.04–4.59). All-cause mortality, transient ischemic attacks, bleeding, acute kidney injury, delirium, and pacemaker implantation rates were similar between groups. Notably, CEPD use was linked to a transient improvement in cognitive function (MoCA scores) at 2–5 days post-TAVI, but this effect was not sustained at later follow-ups. TSA indicated that current evidence is insufficient to definitively refute CEPD efficacy.

Conclusion:

CEPDs show no significant reduction in overall, disabling, or non-disabling stroke, nor in all-cause mortality post-TAVI.

Keywords:

Cerebral embolic protection; Transcatheter aortic valve implantation; TAVI; Stroke; Meta-analysis