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EuroPCR 2025 – Meta-Analysis of Individual Patient Data from the PROTECTED TAVR and BHF PROTECT-TAVI Trials

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Paris, France, 20-23 May 2025. *The EuroPCR Course Directors have selected 3 major late-breaking trials that will be presented for the first time during the 2025 edition of EuroPCR. These trials were selected because of their design, results, and potential to impact practice, among which is the meta-analysis of data from the PROTECTED TAVR and BHF PROTECT TAVI Trials*

Background

The embolisation of debris after transaortic valve implantation (TAVI) for the treatment of aortic stenosis can lead to stroke. Cerebral embolic protection (CEP) devices, which can capture this debris and thus lower the incidence of stroke, have been deployed during TAVI, however, results from their use have been seen as inconclusive.

Recent trials, such as the PROTECTED TAVR[1] and BHF PROTECT-TAVI[2] have demonstrated no significant difference between the control arm and the CEP arm within 72 hours after TAVI or TAVR.

The current meta-analysis presented by Prof. Rajesh Kharbanda combines the results of both trials to better understand these results and allow for more definitive research for the future use of CEP in these interventions.

Results

- This meta-analysis combined individual patient data (IPD) of the 10,635 patients from both the PROTECTED TAVR (3,000 patients) and BHF PROTECT-TAVI (7,635 patients) trials – the largest randomised trials to date studying the use of a CEP during TAVI (in these trials, the SENTINEL™ device [Boston Scientific] was used).
- This analysis focused on the modified intention-to-treat population (ITT) studying results of all the randomised patients whose TAVI procedures had started and included 5,293 in the “TAVI without CEP” arm and 5,287 in the “TAVI with CEP” arm.
- The patient population of both arms were similar.
    - Mean age was 80.6 years in both groups with less than 40% women.
    - Surgical risk score, STS and EuroSCORE II were also similar in both groups, as was their medical history.
- The primary analysis looked at the difference in incidence of stroke between the interventional (CEP) and control (no CEP) arms within 72 hours after TAVI or hospital discharge.

- The combined results showed no evidence that a routine CEP strategy is effective in the modified ITT population in reducing overall stroke.
- A secondary analysis considered the per-protocol population with the Complier Average Causal Effect (CACE) adjusting the ITT estimate due to non-adherence and showed similar results.

Key learnings

- This meta-analysis confirmed that there was no reduction in periprocedural stroke after TAVI with CEP in the modified ITT population or for CEP after adjustment for non-adherence using CACE analysis.

Choice of device

SENTINEL™ device (Boston Scientific)

Conclusions and PCR recommendations

Despite a clear rationale leading to the development of CEP, this meta-analysis of individual data from 2 large RCTs (PROTECTED TAVR and BHF-PROTECT-TAVI) clearly demonstrated that there was no benefit of the routine use of CEP with the SENTINEL device during TAVI to reduce the risk of peri-procedural stroke.

The meta-analysis leads to several key points for future studies:

- The need to better understand what failure to fully deploy a CEP device clinically implies.
- Identification of any patient subgroups in which CEP may be beneficial.
- The development of a risk prediction model to identify patients at highest risk of stroke after TAVI.

References

1. Kapadia SR, et al. Cerebral Embolic Protection during Transcatheter Aortic-Valve Replacement. *N Engl J Med*. 2022;387:1253-63. doi: 10.1056/NEJMoa2204961.
2. Kharbanda RK, et al. Routine Cerebral Embolic Protection during Transcatheter Aortic-Valve Implantation. *N Engl J Med.* 2025 Mar 30. doi: 10.1056/NEJMoa2415120.

NOTES TO EDITORS

Key information

• Session: Hotline /Late-Breaking Trials: Major Late-Breaking Trials from EuroPCR 2025
• Presentation: Meta-Analysis of individual patient data from the PROTECTED TAVR and BHF PROTECT-TAVI studies
• Presenter: Rajesh Kharbanda
• Palais des Congrès Porte Maillot – Paris, France
• 21 May 2025 11:15 - 12:15 in the Theatre Bleu

NOTES TO EDITORS

About EuroPCR 2025

The World-Leading Course in interventional cardiovascular medicine and the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) will take place from 20 to 23 May 2025, onsite at the Palais des Congrès, Paris, France. A digital package is also available for those unable to join in person.

The detailed Course Programme is available on:
https://www.pcronline.com/Courses/EuroPCR/Programme

About PCR

The mission of PCR is to serve the needs of each individual patient by helping the cardiovascular community to share knowledge, experience and practice. PCR offers a large range of many other educational meetings and resources for the continuing education of the interventional cardiovascular community. These include major annual Courses across the globe, e-Learning with high-profile PCR Webinars, Courses specifically dedicated to valvular heart disease, tailor-made PCR Seminars on specific topics, online resources and medical publications such as EuroIntervention, the official journal of the EAPCI.

Gateways to all PCR activities are available on www.pcronline.com.
For further information, please contact Sally Collingridge: scollingridge@europa-group.com

About the EAPCI

The European Association of Percutaneous Cardiovascular Interventions (EAPCI) is a branch of the European Society of Cardiology. Its mission is to reduce the burden of cardiovascular disease through percutaneous cardiovascular interventions. This dynamic association represents a large community of over 8K EAPCI associates and over 1K full EAPCI members by helping them remain up to date in the constantly evolving field of PCI by publishing research and providing educational, training and certification programmes. The EAPCI also advocates for the best possible access to life saving treatments for patients through data-based advocacy at a European level.

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