News & Opinion

Efficacy of the sentinel cerebral protection system used during transcatheter aortic valve replacement

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Abbreviations

BHR PROTECT TAVI - British Heart Foundation Randomised Clinical Trial of Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation
CEPD - Cerebral embolism protection device
CPS - Cerebral protection system
Fr - French units (used to measure the size of catheters and other medical devices)
SAVR - Surgical aortic valve replacement
TAVR - Transcathether aortic valve replacement

Transcatheter aortic valve replacement (TAVR) is a treatment of choice as it is less invasive compared to surgical aortic valve replacement (SAVR). A prosthetic valve is implanted in place of the calcified valve through any of these approaches: transfemoral, transcarotid, transapical or transaortic.[1] Transfemoral is the preferred approach in most cases. Ever since its first performance in 2002, TAVR has become common in practice. Despite its popularity, its long-term durability and the complications that follow this procedure remain in question. Major complications that follow TAVR include thromboembolism, paravalvular leakage, cerebrovascular events resulting in ischemic lesions or stroke, and neurocognitive impairment.[2] The catheter may mobilise a thrombus or a clot that may travel up to the brain. Interaction between the implanted valve and the calcified valve or paravalvular leakage due to a mispositioned valve may activate the coagulation cascade and cause platelet aggregation forming a clot that might enter any cerebral artery and result in ischemia or stroke. Medications such as dual anticoagulant therapy i.e. aspirin indefinitely and any anticoagulant drug, such as clopidogrel for six months, are recommended to avoid clot and thrombus formation.[3] These concerns have led to the development of devices called cerebral embolism protection devices (CEPDs) which include filters and deflectors. These devices function mainly to filter any debris or embolus from the vessels that supply the brain and aim to collect any debris or clot traveling from the site of valve implantation towards the cerebral arteries. CEPDs are positioned at the origin of supra-aortic vessels in the aortic arch.[4]

The sentinel cerebral protection system (CPS) is the approved and most widely used CEPD in TAVR. It is a dual filter system with a proximal filter placed in the brachiocephalic trunk and a distal filter placed in the left common carotid artery. It is delivered through a 6 Fr delivery catheter through the radial artery (preferred) or the brachial artery over a 0.014" guide wire and placed before the TAVR system.[5] This placement of CPS usually takes less than 10 minutes in most individuals. It is removed through the catheter after the implantation of the prosthetic valve. This device aims to filter the blood entering the vessels that it covers and collect the debris entering the circulation. This device got approval for clinical use in 2017, and various improvements have been made to increase its safety and efficacy. The Sentinel CPS is the most studied CEPD. In a patient with normal

anatomy of vessels, this system is safe to use, with a study suggesting a procedural success rate of 85%.[6] The efficacy of the Sentinel CPS is controversial. Some old studies suggest this system is efficient in preventing ischemic lesions and stroke while also reducing the chances of dementia and neurocognitive impairment.[7] A decreased in-hospital mortality rate has also been suggested in various studies. Although, recent studies suggest that the Sentinel CPS has no major effect on reducing stroke or neurocognitive impairment.[8] At the time of publication, the BHF PROTECT TAVI trial, which began in 2020 and will conclude in 2026, is determining the impact of CEPDs on stroke rate.

The vascular anatomy also contributes to the effectiveness of the Sentinel CPS. Vascular tortuosity and variations in the anatomy of the aortic arch may contribute to the failure of Sentinel CPS administration. Complex anatomy of the aortic arch and supra-aortic vessels may make it difficult to administer the system via catheter to the designated vessels and may also increase the risk of atheroembolisation and vessel injury.

The Sentinel CPS filters three out of four arteries, the right and the left internal carotid arteries and the right vertebral artery, supplying to the brain. It fails to protect the left vertebral artery which is a major part of the posterior circulation of the brain, and the brain stem and cerebellum through the basilar artery. A left vertebral filter system called the Wirion filter can complement the Sentinel CPS to overcome this. The Wirion filter is directed towards the left vertebral artery from the radial artery over a 0.014" guidewire. The amount of debris collected in the Wirion filter is almost equal to the amount of debris collected in the Sentinel CPS, suggesting the importance of protection of the left vertebral artery for the prevention of neurocognitive impairment, ischemic lesions and stroke perioperatively.[9]

Despite the reduction in mortality, stroke continues to be a significant concern, as recent trials indicate a consistent stroke rate of 2% to 2.5% following TAVR.[10] An individualised evaluation may assist in determining its benefits for particular patients and populations. However, additional research is required to determine which patients can benefit from this device.

Contribution statement

Khadija Azeem contributed to the conception, design, and drafting of the manuscript. Ahmad Akhtar contributed to the conception and revising of the manuscript. All authors have approved the final version of the manuscript for publication.
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