NICE National Institute for Health and Care Excellence

NICE guidance

Percutaneous insertion of a cerebral protection device to prevent cerebral embolism during TAVI

HealthTech guidance

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www.nice.org.uk/guidance/htg515

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG650.

1 Recommendations

1.1 The evidence on percutaneous insertion of a cerebral protection device to prevent cerebral embolism during transcatheter aortic valve implantation (TAVI) raises no major safety concerns other than those associated with the TAVI procedure. However, the evidence on efficacy for preventing TAVI-related stroke is inconclusive. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do percutaneous insertion of a cerebral protection device to prevent cerebral embolism during TAVI should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients and their carers understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public is recommended.
- Details of all patients should be entered into the UK TAVI registry.

1.3 Patient selection for this procedure should be done by the multidisciplinary team that is considering the suitability of TAVI.

1.4 This procedure should only be done in specialised centres, and only by clinicians and teams with specific training and experience in complex endovascular interventions. Centres doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

1.5 NICE encourages further research on percutaneous insertion of a cerebral protection device to prevent cerebral embolism during TAVI. This should include

details of patient selection and risk stratification for TAVI-related stroke. NICE may update the guidance on publication of further evidence.

2 The condition and procedure

The condition

2.1 Transcatheter aortic valve implantation (TAVI) aims to provide a less invasive alternative to open cardiac surgery for treating aortic stenosis, avoiding the need for sternotomy and cardiopulmonary bypass. However, debris may be dislodged during the TAVI procedure. This can enter the cerebral circulation and embolise, causing cerebral ischaemic events including a stroke.

The procedure

2.2 Percutaneous insertion of a cerebral protection device aims to prevent debris dislodged during TAVI from passing into the cerebral circulation. The aim is to reduce the risk of cerebral ischaemic events including a stroke.

2.3 During the TAVI procedure, before the valve is inserted, a cerebral protection device is inserted percutaneously through the radial or femoral artery. Depending on the type of device used, it is placed into the aortic arch or into the brachiocephalic (innominate) and left common carotid arteries. It is deployed to protect the ostia of the brachiocephalic (innominate) artery and the left common carotid artery. It may also protect the left subclavian artery, depending on the type of device used. It works either by filtering dislodged debris from the blood, or by deflecting dislodged debris away from the cerebral circulation to the systemic circulation. The device is removed at the end of the TAVI procedure.

2.4 The evidence review identified 3 types of cerebral protection devices. One is a deflector system that covers all 3 main branches of the aortic arch. The 2 other types cover the brachiocephalic trunk and the left common carotid artery; 1 is a filter system, the other is a deflector system.

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 4 randomised controlled trials, 1 non-randomised comparative study, 1 patient-level pooled analysis and 1 case series, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcome to be: reduction in TAVI-related embolic strokes.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: vascular damage and bleeding.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 There are different types of devices available to prevent cerebral embolism during TAVI, and they work in different ways. The committee noted that most of the evidence it reviewed came from 1 type of device, and that the technology is evolving.

3.6 Embolic stroke following TAVI is rare, but when it happens it can be devastating. The studies reviewed by the committee had limited statistical power to evaluate rare outcomes.

3.7 Using a cerebral protection device does not eliminate the risk of embolic stroke

following TAVI.

3.8 Detecting cerebral lesions resulting from incomplete protection is challenging and the methods for doing it may have differed between the studies.

3.9 The valves used for the TAVI procedure differ, but cerebral protection benefit during TAVI has been demonstrated across all valve types.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 650 has been migrated to HealthTech guidance 515. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.