NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Transcatheter aortic valve implantation (TAVI) places a new valve inside a faulty valve in the heart. It is inserted through a tube (catheter), by way of a large blood vessel (artery) at the top of the leg or in the arm. This can dislodge fatty deposits that may block arteries supplying blood to the brain (a cerebral embolism), causing a stroke. In this procedure, before the new valve is inserted, a cerebral protection device is placed inside an artery near the heart. It filters the debris from the blood or deflects it away from the brain. The device is removed at the end of the TAVI procedure. The aim is to reduce the risk of stroke.

The National Institute for Health and Care Excellence (NICE) is looking at percutaneous insertion of a cerebral protection device to prevent cerebral embolism during transcatheter aortic valve implantation. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21/02/2019

Target date for publication of guidance: May 2019

1 Draft recommendations

1.1 The evidence on percutaneous insertion of a cerebral protection device to prevent cerebral embolism during 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.

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, current treatments 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 during the TAVI procedure, debris may be

dislodged which can embolise to the cerebral circulation and cause a transient ischaemic attack or 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 a transient ischaemic attack or 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 and placed into the aortic arch. It is deployed to protect the ostia of the brachiocephalic artery and the left common carotid artery, and 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 8 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 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.

Committee comments

3.4 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.

3.5 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.

3.6 Using a cerebral protection device does not eliminate the risk of embolic stroke following TAVI.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
January, 2019

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