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Interventional procedures

Patient Organisation Submission

NICE Interventional Procedures: Percutaneous insertion of a cerebral protection device to prevent cerebral embolic events during transcatheter aortic valve implantation IP1237

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	
2. Name of organisation	King's College Hospital NHS Foundation Trust
3. Job title or position	1. Consultant Cardiologist, King's College Hospital 2. Consultant Cardiologist, King's College Hospital
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	NHS Foundation Trust

5. How did you gather the information about the experiences of patients and carers to help your submission?

(For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)

1. Both contributors have extensive experience as TAVI operators in a centre which carries out 150 cases per year. Embolic protection has been used in our centre in approximately 5% of these cases, and includes experience with a number of devices.
2. Two patients treated with cerebral protection were approached for their views on the perceived risk of stroke before the procedure.

Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

   1) From the patient perspective, a risk of a cerebrovascular event weighs more heavily than almost any other complication, with the risk of long-term disability and loss of independence. A CVA has significant implications in patients' long term recovery, increasing the need for social support and rehabilitation.

   2) Apart for the patients, an uneventful recovery is important to carers since the burden for ongoing support after the procedure falls to them. Permanent neurological damage or decline both in cognitive and functional status has repercussions for carers and their support network.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are?

   TransCatheter Aortic Valve Intervention (TAVI) is used to treat patient with severe aortic stensosis. Cerebrovascular events remain a recognised complication of TAVI, ranging from 2-5 % at 30 days[1,2]. Cerebral Protection Devices (CPD) have been developed to reduce the risk of peri-procedural stroke by deflecting or capturing embolic material produced during device manipulation/implantation.

   The rate of cerebrovascular events post TAVI has been usually assessed at 30days, and can be classified to overt injury, symptoms without injury (TIA, delirium) and covert injury. A more refined clinical approach using neurocognitive assessment and diffusion weighted brain MRI scan can detect subclinical brain injury[3,4]. The embolisation risk is high during the TAVI procedure, with the use of large bore devices in a degenerative aortic valve. A variety of cerebral protection devices have been developed aiming to capture or deflect particles that account for brain injury. Studies have reported a high success rate of delivery and placement of these devices, low complication rate and short procedural time with the caveat of increased cost[3]

   Embolic protection devices are not used in the UK in the general population undergoing TAVI, but those in whom the risk of a peri-procedural embolic event is high. This particularly applies to patients with mobile structures or atherothrombotic material on or around the aortic valve or in the ascending aorta. They have also been used to treat patients with left ventricular thrombus who are undergoing TAVI. In many of these cases the TAVI procedure could not be safely carried out without the use of cerebral protection.

   From the patient perspective the use of CPD is seen in a very positive light. In this group of patients the perceived risk of a stroke is significantly higher than the general population undergoing TAVI.

Disadvantages of the procedure or operation

8. What do patients (or carers) think the disadvantages of the procedure or operation are?

Potential disadvantages of the procedure are difficulty in patient selection and the cost of the device. It has been proved that after a short learning curve, CPD can be deployed safely with a very short procedural time.

There is strong interest and debate in interventional community regarding selected vs wide spread use of such devices. There have been both randomised[3,4] and non-randomised trials[6]. Meta-analysis of randomised trials failed to demonstrate statistical significance of stroke reduction or neuro-cognition preservation despite a strong trend to a reduction in peri-procedural stroke and a reduced volume of ischaemic lesions in subjects treated with CPD[7]. It has been contemplated that the use of non-validated neurocognitive tools, large numbers of patients with brain volume loss/abnormal MRI findings pre TAVI and pre-existing cognitive decline may have masked the clinical benefit in these studies.

Use of the device requires an additional (usually radial 6Fr) access site puncture. The devices used have an excellent safety profile and from the patient perspective there are few disadvantages to the use of these devices.

Patient population
9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why. As outlined above patients with high risk valve morphological features may qualify for CPD placement. The use in unselected patients has been tested in clinical trials and despite encouraging results showing a reduction in ischaemic lesions on MRI, there has been little effect on the incidence of clinical stroke. As it stands there is an open debate for wide spread use that needs to be validated in larger studies. Despite the above uncertainties there are an increasing number of centres across Europe and USA that use CPD as standard of care.
Equality
10. Are there any potential equality issues that should be taken into account when considering this topic?
Other issues
11. Are there any other issues that you would like the Committee to consider?
Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. Transcatheter Aortic Valve Implantation (TAVI) carries a stroke risk of >2-5 % at 30 days[1,2].
2. The use of CPD is both safe and efficacious in terms of debris capture and a reduction in embolic events during TAVI, although has not been shown to reduce clinical stroke rates in an unselected population.
3. The use of CPD is currently limited to those with high risk anatomical features, who may be denied a TAVI procedure without access to this technology.
4. The perceived risk of stroke is a major concern for patients (and their carers).
5. In the context of the above we advocate the use of CPD use in selected patients. A widespread use of CPD, despite being an attractive concept, is not fully supported by current evidence.

References.

- 1. Makkar RR et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. (2012) 366:1696–704.
- 2. Leon MB et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med. (2016) 374:1609–20.
- 3. Haussig S et al . Effect of a Cerebral Protection Device on Brain Lesions Following Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Stenosis: The CLEAN-TAVI Randomized Clinical Trial. JAMA. 2016 Aug 9;316(6):592-601
- 4. Kapadia SR et al. Protection Against Cerebral Embolism During Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2017 Jan 31;69(4):367-377
- 5. Kroon HG et al. Need for Embolic Protection During Transcatheter Aortic Valve Implantation: An Interventionalist's Perspective on Histopathology Findings. Interv Cardiol. 2017 May;12(1):36-39
- 6. Seeger J et al . Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement Significantly Reduces Death and Stroke Compared With Unprotected Procedures. JACC Cardiovasc Interv. 2017 Nov 27;10(22):2297-2303

7. Lam HT et al. Evidence for Cerebral Embolic Prevention in Transcatheter Aortic Valve Implantation (TAVI) and Thoracic. Endovascular Aortic Repair (TEVAR). Ann Vasc Surg. 2018 Sep 12. pii:S0890-5096(18)30754-4

Thank you for your time.

Please return your completed submission to ip@nice.org.uk