NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

An intracranial aneurysm is a bulge in a blood vessel in the brain caused by a weakness in the blood vessel wall. In this procedure, a wire-mesh device is inserted through a thin tube (catheter) into the brain via a large blood vessel (endovascular) in the groin. It is guided into the aneurysm (intrasaccular) and left there to act as a plug (a blood clot forms in the device). The aim is to block the flow of blood into the aneurysm to reduce the chance of it rupturing or to stop further bleeding from an aneurysm that has already ruptured.

The National Institute for Health and Care Excellence (NICE) is looking at endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm. 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: 23 May 2019

Target date for publication of guidance: August 2019

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be done by a multidisciplinary team, except for emergency situations, when this may be replaced by a discussion between an interventional neuroradiologist and neurosurgeon.

1.3 The procedure should only be done in specialised centres with expertise in the use of this technology and access to neurosurgical facilities.

2 The condition, current treatments and procedure

The condition

2.1 An intracranial aneurysm is a bulge in a blood vessel in the brain caused by a weakness in the blood vessel wall, usually where it branches. Most brain aneurysms only cause noticeable symptoms if they rupture. However, large aneurysms may cause local compression symptoms before they rupture, such as headache. Rupture of intracranial aneurysms causes subarachnoid haemorrhage and is associated with a very poor prognosis. About 10% of people die before reaching hospital and a further 50% die within 4 weeks. About 50% of people who survive a subarachnoid haemorrhage have a persistent neurological deficit.

2.2 If an intracranial aneurysm is detected before it ruptures, treatment may be recommended to prevent it rupturing in the future. This is typically only done if the risk of a rupture is particularly high.

Current treatments

2.3 Current options for managing intracranial aneurysms include coiling, often with stent placement (stent-assisted coiling), neurosurgical clipping through a craniotomy (with or without bypass procedures), parent vessel occlusion (by open neurosurgery or by endovascular means) and conservative management. Flow diverter embolisation devices, which are placed in the parent blood vessel to divert blood flow away from the aneurysm itself, may be an option for some people with intracranial aneurysms.

The procedure

2.4 Endovascular insertion of an intrasaccular wire mesh blood-flow disruption device for intracranial aneurysm is used for the embolisation of ruptured and unruptured intracranial aneurysms. It may be particularly suitable for people with wide-necked aneurysms. The procedure is usually done under general anaesthesia. A catheter is inserted into the femoral artery and advanced into the cerebral circulation under X-ray guidance. A second, smaller catheter is put inside the first and is inserted into the aneurysm. A basket-like device made of fine wire mesh is then pushed through the second catheter and placed into the aneurysm sac. The mesh device covers the aneurysm neck and obstructs blood flow into the aneurysm sac, creating blood stasis and promoting endothelial growth across the neck of the aneurysm. The appropriate device size is selected according to the aneurysm width and height.

2.5 The aim is to prevent the aneurysm from rupturing or to stop further bleeding from an aneurysm that has already ruptured.

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 1 systematic review, 7 case series and 1 case report, 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 outcomes to be: device implantation success rate, use of adjuvant devices, angiographic aneurysm occlusion rates, Modified Rankin Scale (mRS) Score and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: intraprocedural rupture of aneurysm, other vascular damage, thromboembolic complications including device embolisation and aneurysm rebleeding.

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

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