

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

Interventional procedures guidance
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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.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysms is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Patient selection should be done by a multidisciplinary team, except for in 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 aneurysms 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 13 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 non-randomised comparative studies, 9 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.
- 3.4 Eight commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).