

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Interventional procedures consultation document

**Endoanchoring systems in endovascular
aortic aneurysm repair**

An aortic aneurysm is a bulge in the wall of the main blood vessel (aorta) carrying blood from the heart to the body. If it bursts, it can cause severe bleeding and death. An aortic aneurysm can be treated by inserting a mesh tube (stent) inside the bulge through cuts in the groin (endovascular) using X-rays to guide it into place. The stent can sometimes leak or move out of place. In this procedure, an anchoring device (endoanchor) is inserted to help hold the stent in place. This may be done at the same time as the stent graft is put in place or during a later procedure if the stent has leaked or moved. The aim is to keep the stent in place and prevent leaks.

NICE is looking at use of endoanchoring systems in endovascular aortic aneurysm repair.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

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

Closing date for comments: 13 January 2022

Target date for publication of guidance: May 2022

1 Draft recommendations

- 1.1 For people with unfavourable aneurysm morphology needing an endovascular aortic aneurysm repair (EVAR) as a primary procedure, or for people with an existing EVAR who need a secondary procedure, evidence on the safety of using endoanchoring systems is adequate. Evidence on efficacy is limited in quantity and quality. Therefore, for these people, 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 For people with favourable aneurysm morphology needing an EVAR as a primary procedure, evidence on the safety of using endoanchoring systems is adequate. However, evidence on efficacy is inadequate in quantity and quality. Therefore, for these people, this procedure should only be used in the context of research. Find out [what only in research means on the NICE interventional procedures guidance page](#).

1.3 Clinicians wanting to use endoanchoring systems for people with unfavourable aneurysm morphology needing an EVAR as a primary procedure, or for people with an existing EVAR who need a secondary procedure should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support [shared decision making](#), including [NICE's information for the public](#).
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.4 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.5 Patient selection should be done by a multidisciplinary team.

1.6 Further research should report details of patient selection and include longer term outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Aortic aneurysms develop when the wall of the aorta weakens, causing it to bulge and form a balloon-like expansion. They can happen in the chest (thoracic aortic aneurysms) or, more commonly, below the diaphragm (abdominal aortic aneurysms).

Current treatments

- 2.2 The standard treatment for aortic aneurysm is either open surgical or endovascular repair. During open surgical repair the aneurysm is opened and a graft is sewn in above and below the weakened area to allow normal blood flow. Endovascular repair is a minimally invasive alternative to open repair. A graft is mounted on a stent, which is inserted into the aorta through catheters placed in the femoral arteries. The stent–graft is deployed under X-ray guidance and positioned across the aneurysm.
- 2.3 In endovascular aortic aneurysm repair (EVAR) procedures, the stent–graft can sometimes leak (endoleak) or move out of place (migrate), or a patient’s anatomy can make its placement difficult. Type 1 endoleaks happen around the top or bottom of grafts and are often caused by an inadequate seal.

The procedure

- 2.4 Endoanchoring systems aim to improve the fixation of the stent–graft used in EVAR. They may be used prophylactically or therapeutically at the same time as the primary procedure or during a later, secondary procedure to treat an endoleak or migration.
- 2.5 Endoanchoring implants can be inserted during a primary EVAR procedure or as a secondary procedure under general or local

anaesthesia. The implants are deployed through an applier device that consists of a catheter and a control handle. The catheter is advanced until the distal end contacts the stent-graft and vessel wall. The number of implants needed depends on the type of stent-graft and size of the native vessel. They are placed as evenly as possible around the circumference of the stent-graft. The catheter is then removed, the holes in the femoral arteries are sutured and the groin wounds closed.

3 Committee considerations

The evidence

- 3.1 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 7 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 1 non-randomised comparative study, 2 cohort studies, 1 single-arm study, which was also included in the systematic reviews, and a case series of reports on the US Food and Drug Administration Manufacturer and User Facility Device Experience Database. It is presented in [the summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: prevention of aneurysm rupture and prevention of endovascular aortic aneurysm repair graft migration.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, infection and device migration.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that the risk of migration with EVAR is related to the anatomy of the aorta and the choice of endograft.
- 3.6 The committee was informed that the use of endoanchors in a primary EVAR procedure increases the exposure to X-rays during the procedure.
- 3.7 The committee was informed that endoanchors are difficult to remove.

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Chair, interventional procedures advisory committee

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