NICE guidance

Endoanchoring systems in endovascular aortic aneurysm repair

Interventional procedures guidance
Published: 25 May 2022

www.nice.org.uk/guidance/ipg725

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 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.
- Enter details about everyone having endoanchoring systems in endovascular aortic aneurysm repair into the National Vascular Registry and review local clinical outcomes.
- 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 person'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 are inserted under general or local anaesthesia. The implants are deployed through an applier device consisting 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 the 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 are 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 8 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 that was also included in the systematic reviews, a case report, and a case series of reports from 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 endovascular aortic aneurysm repair (EVAR) is related to the anatomy of the aorta and the choice of endograft.
- Using endoanchors in a primary EVAR procedure increases the exposure to X-rays during the procedure.
- Endoanchors are difficult to remove.
- This procedure is primarily intended to be used for people with unfavourable aneurysm morphology and this is where most of the evidence comes from.
- This procedure is also used for people with favourable aneurysm morphology who develop an intraoperative complication such as an endoleak during a primary EVAR. Data collection in this group of people would be helpful.

ISBN: 978-1-4731-4595-5

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation