Endovascular aneurysm sealing for abdominal aortic aneurysm

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. However, 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.

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.

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 aneurysm sealing for abdominal aortic aneurysm is adequate in the short term but there are uncertainties about safety and efficacy in the longer term. Therefore, this
procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do endovascular aneurysm sealing for abdominal aortic aneurysm should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainties about the procedure's long-term safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Clinicians should enter details about all patients having endovascular aneurysm sealing for abdominal aortic aneurysm onto the National Vascular Registry.

1.4 NICE encourages further research on this procedure in the form of controlled clinical trials, observational studies and analysis of registry data. Details about patient selection, including anatomical details, should be clearly documented. Research should compare the procedure with conventional stent graft endovascular aneurysm repair. All complications should be reported. Long-term outcomes should be described as data become available. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 An abdominal aortic aneurysm is a dilatation of part of the aorta. Aneurysms may leak or rupture, causing internal bleeding and death. Some patients with a ruptured aneurysm will survive long enough to have surgical repair, but the mortality is high. If a large aneurysm is detected, then treatment is often advised to prevent rupture.

2.2 The traditional treatment for abdominal aortic aneurysm is open surgical repair. Endovascular aneurysm repair (EVAR) is a less invasive alternative method that is now commonly used. This is done by inserting a stent graft through catheters in the femoral arteries. The stent graft is held in place by self-expanding radial force, supplemented by balloon expansion and by integral hooks, which attach it to the wall of the aorta. A snug fit is important to prevent blood from flowing between the stent graft and the aorta (an endoleak) and to prevent the stent graft from migrating.
3 The procedure

3.1 Endovascular aneurysm sealing is a new approach to standard endovascular aneurysm repair (EVAR). It uses a polymer filling to form a rubbery cast within the aneurysm sac, which excludes it from the circulation. The aim is to stabilise the stent graft position and reduce the rate of endoleaks and repeat interventions.

3.2 With the patient under general, regional or local anaesthesia, and using fluoroscopic guidance, guidewires are introduced through each femoral artery and advanced into the aneurysm. A device (consisting of integral catheters with a balloon expandable stent and attached endobags) is advanced over each guidewire and carefully positioned within the aneurysm. The catheters are connected to an external console and a vacuum is created within the endobags using a syringe. The balloons are inflated to expand the stents. A biostable polyethylene glycol polymer is injected through the catheters into the endobags under pressure monitoring. As the polymer is injected, the endobags expand to fill the aneurysm sac, sealing it off from the circulation and holding the stent graft in place.

3.3 Possible advantages of using endovascular aneurysm sealing over standard EVAR alone include its use for aneurysms with shorter necks, and the reduced risk of type II endoleaks (persistent filling of the aneurysm sac by retrograde flow in the lumbar and inferior mesenteric arteries).

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 A retrospective case series of 171 patients with abdominal aortic aneurysm (AAA) treated by endovascular aneurysm sealing reported technical success (defined as the successful deployment of the device without endoleak of any type) in 99% (169/171) of patients. A prospective case series of 150 patients with AAA treated by endovascular aneurysm sealing reported technical success (defined as the deployment of the device in the planned location and without unintentional coverage of both internal iliac arteries or any visceral aortic
branches and with the removal of the delivery system) in 100% (150/150) of patients.

4.2 The retrospective case series of 171 patients and the case series of 34 patients reported no conversion to open surgical repair. The prospective case series of 150 patients reported conversion to angioplasty and stenting in 1 patient. This was an attempt to rescue the procedure that failed because of coverage of a renal artery during the procedure (also described in section 5.13).

4.3 The retrospective case series of 171 patients reported 16 secondary procedures performed for complications related to the aneurysm or its repair, exclusive of diagnostic procedures, in 9% (15/171) of patients within 14 months after the procedure; 11 were performed within 30 days of the index procedure and 5 after 30 days. Five of the reinterventions were for endoleaks, 5 for device occlusions, 2 for access-related external iliac lesions, 2 for femoral false aneurysm, 1 for distal embolism and 1 for infected groin haematoma. At 12-month follow-up, 90% (95% confidence interval [CI] 85% to 96%) of patients had not had an aneurysm-related reintervention. The case series of 34 patients reported secondary interventions in 6% (2/34) of patients; 1 was done within 30 days after the procedure (no further details provided) and the other was 15 months after the procedure to treat a distal type I endoleak (also described in section 5.2).

4.4 The retrospective case series of 171 patients reported no aneurysm rupture within 14 months after the procedure.

4.5 The retrospective case series of 171 patients reported device patency (defined as freedom from occlusion) of 98% (95% CI 96% to 100%) at 1 month and 94% (95% CI 89% to 98%) at 12 months.

4.6 The specialist advisers listed key efficacy outcomes as complete exclusion of the aneurysm, AAA-related mortality, aortic rupture mid- and long-term, endoleak, adjunctive procedures, reintervention rate, and length of stay in hospital.
5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Death caused by multisystem organ failure was reported in 1 patient on day 4 in a prospective case series of 150 patients with abdominal aortic aneurysm (AAA) treated by endovascular aneurysm sealing. Death was reported in 1 patient on day 18 in a case series of 105 patients with non-ruptured infrarenal AAA; the cause of death was not determined. The postoperative CT scan demonstrated good graft position in a pararenal aneurysm and no endoleak. Death was reported in 1% (2/171) of patients in a retrospective case series of 171 patients with AAA treated by endovascular aneurysm sealing. One patient died of sepsis on day 101 after the procedure; it was reported that the source of sepsis was not identified but that graft infection could not be entirely excluded. Death was reported in 6% (2/34) of patients in a case series of 34 patients with AAA treated by endovascular aneurysm sealing. One patient died within 30 days after the procedure of multisystem organ failure. The authors state that this death was not device-related "as evidenced by post-procedure CT scan and post-mortem examination of the aneurysm and device". The other patient died 10 months after the procedure of congestive heart failure; this patient had a normal CT scan at 6-month follow-up. Death was reported in 1 patient at 10 weeks after the procedure in a case series of 30 patients with primary infrarenal AAA; it was reported that the death was from unrelated causes. All-cause death was reported in 1% (3/277) of patients within 30 days after the procedure and in 4% (11/272) of patients from 31 days up to 1 year after the procedure in a symposium presentation reporting on the 1-year outcomes of the EVAS FORWARD global registry. The causes of the deaths that occurred within 30 days of the procedure were: 1 hospital-acquired pneumonia at day 5, 1 gastrointestinal haemorrhage at day 15 and 1 aspiration pneumonia at day 19. One late AAA-related death was caused by an aorto-duodenal fistula at day 148 (also described in section 5.18).

5.2 Endoleak during the procedure was reported in 1% (2/171) of patients in the case series of 171 patients; 1 type Ib endoleak was treated successfully by deployment of a covered stent during the procedure, and 1 type II endoleak was diagnosed at completion angiography and confirmed on duplex ultrasound at
follow-up of 2 and 6 months. After the procedure, endoleaks were detected in 8% (13/171) of patients in follow-up imaging studies. Type Ia endoleaks were reported in 3% (5/171) of patients; 3 at 1-month and 2 at 6-month follow-up. Spontaneous resolution of 1 type Ia endoleak was reported in 1 patient; 2 patients were successfully treated (1 by deployment of covered stents followed by embolisation and the other by embolisation alone) and 2 patients were observed without intervention. Type Ib endoleaks were reported in 2% (3/171) of patients; 3 at 1-month and 1 at 6-month follow-up (1 patient had bilateral Ib endoleaks). All 4 endoleaks were successfully treated by deployment of a covered stent extension. Type II endoleaks were reported in 4% (4/171) of patients; 1 was reported at 1 month, 1 at 6 months, 1 at 12 months and the timing of the last 1 was unknown. One endoleak was of uncertain origin and was present on CT scan at 1-month follow-up but had spontaneously resolved at 1-year CT scan.

5.3 Endoleak within 30 days of the procedure was reported in 4% (4/105) of patients in the case series of 105 patients; all were type Ia endoleaks, in patients classified as having hostile proximal aortic neck morphology. It was reported that all were caused by technical issues during the procedure. All were successfully treated by transcatheter embolisation.

5.4 Endoleak was reported in 6% (2/34) of patients over a mean follow-up of 15 months in the case series of 34 patients. One patient had a proximal type I endoleak seen on 30-day CT scan; it resolved spontaneously by 60 days. The other patient had a distal type I endoleak, because the device endobag was too short to fully fill the aneurysm sac. This endoleak persisted with no change in aneurysm size for 12 months. The patient was treated by a secondary endovascular procedure at 15 months, with placement of coils and an iliac extender, resulting in complete resolution of the endoleak. No endoleaks were reported within 30 days after the procedure in the case series of 30 patients.

Endoleak was reported in 1% (4/277) of patients within 30 days after the procedure and in 2 patients out of 269 between 31 days and 1 year after the procedure in the symposium presentation on the 1-year clinical data of the EVAS FORWARD registry. Of the 4 endoleaks reported within 30 days, 3 were type Ia and 1 was type II. Of the 2 endoleaks reported between 31 days and 1 year after the procedure, 1 was type Ia and 1 was type II.
Iatrogenic arterial injuries were reported in 2% (2/105) of patients in the case series of 105 patients. Both resulted from iliac injury during stent deployment and both were treated successfully by deployment of covered stents.

Blood loss of more than 1 litre was reported in 1% (2/277) of patients within 30 days after the procedure in the symposium presentation on the 1-year clinical outcomes of the EVAS FORWARD registry.

Sustained intraoperative iatrogenic disruption of the AAA during the prefill step was reported in 1 patient in the prospective case series of 150 patients. On evacuating the prefill from the endobags, the patient’s blood pressure dropped because of presumed disruption of the aneurysm after pressurisation of the sac during the prefill. The procedure was completed successfully by injecting polymer into the endobags as planned.

Myocardial infarction was reported in 1% (2/277) of patients within 30 days after the procedure and in 1 out of 272 patients between 31 days and 1 year after the procedure in the symposium presentation on the 1-year clinical outcomes of the EVAS FORWARD registry.

Stroke was reported in 1 out of 277 patients within 30 days after the procedure and in 1% (3/272) of patients between 31 days and 1 year after the procedure in the symposium presentation on the 1-year clinical outcomes of the EVAS FORWARD registry.

Renal failure was reported in 1% (2/272) of patients between 31 days and 1 year after the procedure in the symposium presentation on the 1-year clinical outcomes of the EVAS FORWARD registry.

Respiratory failure was reported in 1 patient in the prospective case series of 150 patients (no further details provided). Respiratory failure was reported in 1% (2/277) of patients within 30 days after the procedure and in 1% (2/272) of patients between 31 days and 1 year after the procedure in the symposium presentation on the 1-year clinical outcomes of the EVAS FORWARD registry.

Acute thrombosis of the stent was reported in 1 patient in the case series of 20 patients. It was successfully treated by thrombolytic therapy.
Stenoses within the endovascular aneurysm sealing device were observed in 3% (5/171) of patients in the case series of 171 patients; 3 were reported at 1-month and 2 at 6-month follow-up. Stent-graft limb stenosis within 30 days of the procedure was reported in 3% (3/105) of patients in the case series of 105 patients. All 3 patients had unilateral limb stenoses of 50% or more based on ultrasound duplex imaging and were treated by angioplasty and adjunctive stenting. The cause was reported to be inadequate stent dilatation during the original procedure and placement of the distal limb at a site of potential kink. Device occlusion was reported in 5% (8/171) of patients in the case series of 171 patients; 7 were reported at 1-month and 1 at 3-month follow-up. Five of the patients with occlusion were treated by a second intervention (no further details provided).

Stent migration was reported in 2% (2/105) of patients in the case series of 105 patients; the patients had angulated aneurysm necks and large aneurysms, and the stents deviated from their original deployment position during inflation of the endobags. The stents were observed to separate during endobag inflation, to move laterally towards the wall of a large aneurysm, and pulled down in the aneurysm neck leading to a more distal deployment than anticipated (no further details provided).

Renal artery inadvertently covered by the endovascular aneurysm sealing system because of malpositioning of the endograft was reported in 1 patient in the prospective case series of 150 patients. The patient had a procedure for renal stenting that failed because it was not possible to access the artery.

Procedural damage to 1 of the endobags was reported in 1 patient in the prospective case series of 150 patients. This was secondary to catheter manipulation in calcified anatomy after initial prefill. It manifested as blood in the aspirated saline. Polymer filling and the implant procedure were completed; angiographic appearance of the implant showed aneurysm exclusion with a single endobag.

Gastrointestinal disorders associated with surgery were reported in 10% (2/20) of patients in the endovascular aneurysm sealing group and in 60% (12/20) of patients in the open surgery group in a non-randomised prospective cohort study of 40 patients with AAA (no further details provided).
5.18 A case report of 2 patients with AAA reported successful surgical explantation of the endovascular aneurysm sealing device following secondary aneurysm infection. In 1 patient, the cause of the aneurysm infection was not identified, in the other patient the infection was caused by an aortoduodenal fistula (also described in section 5.1).

5.19 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: procedural or late aortic rupture, and 'toothpasting' of the aneurysm thrombus into renal arteries. They considered that the following were theoretical adverse events: device failure, failure to exclude the sac from the arterial blood flow, long-term integrity of the polymer in the endobags, long-term interaction of the surface of the endobag with the adjacent aneurysm wall, and the effect of a large volume thrombus on graft migration because the endobags may oppose to the thrombus rather than to the vessel wall.

6 Committee comments

6.1 The Committee noted a lack of studies comparing endovascular aneurysm sealing with conventional endovascular aneurysm repair (EVAR). This and the lack of long-term outcome data underpinned the recommendation for further research. The Committee noted that the evidence base was rapidly accumulating.

6.2 The Committee noted that the technology for this procedure is evolving.

6.3 The Committee was advised of the potential for further endoleaks to develop after the procedure in the long-term.

7 Further information

7.1 For related NICE guidance, see the NICE website.
Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

www.nice.org.uk/accreditation