NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Endovascular aneurysm sealing for abdominal aortic aneurysm

The aorta is the largest artery (blood vessel) in the body. An abdominal aortic aneurysm is a swelling of part of the aorta, inside the abdomen. The swelling happens because there is a weakness in the wall of the aorta. In endovascular aneurysm sealing, 2 stents (tiny tubes) are inserted through a small cut in the skin and then through the arteries to the aneurysm. The aneurysm is sealed off around the stents with a polymer.

The National Institute for Health and Care Excellence (NICE) is examining endovascular aneurysm sealing for abdominal aortic aneurysm and will publish guidance on its safety and efficacy to the NHS. NICE’s Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about endovascular aneurysm sealing for abdominal aortic aneurysm.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE’s formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
The Advisory Committee will then prepare draft guidance which will be the basis for NICE’s guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is 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 the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would 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 NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 6th August 2015

Target date for publication of guidance: October 2015

1 Provisional recommendations

1.1 Current evidence on the safety and efficacy of endovascular aneurysm sealing for abdominal aortic aneurysm is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 NICE encourages further research on this procedure in the form of controlled clinical trials and observational studies, which may include registry data collection. Long-term outcomes, comparisons with endovascular aneurysm repair and all complications should be
reported. 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. In some cases 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 which is now commonly used. This is done by inserting a stent graft via 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 via each
femoral artery and advanced through 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 using a syringe, which prepares the endobags. 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 grafts 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 2 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 [add URL].

4.1 A case series of 34 patients with abdominal aortic aneurysm (AAA) treated by endovascular aneurysm sealing reported technical success (defined as the successful delivery and deployment of the device) in 100% (34/34) of patients.

4.2 The case series of 34 patients reported no conversion to open surgical repair.
4.3 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 1 endoleak (also described in section 5).

4.4 A non-randomised prospective cohort study of patients with AAA treated by endovascular aneurysm sealing (n=20) or open surgery (n=20) reported mean SF-36 scores (± standard deviation) for the physical component summary, 1 month after the procedure, of 47 (±3) for endovascular aneurysm sealing and 38 (±3) for open surgery (p<0.001; there was no difference between groups at baseline). One year after the procedure, the scores were 48 (±4) for endovascular aneurysm sealing and 42 (±3) for open surgery (p<0.001). For the mental component summary of the SF-36 questionnaire, 1 month after the procedure, the scores were 44 (±4) for endovascular aneurysm sealing and 37 (±3) for open surgery (p<0.001; there was no difference between groups at baseline). One year after the procedure, the scores were 40 (±4) for endovascular aneurysm sealing and 39 (±4) for open surgery (p value not significant).

4.5 The specialist advisers listed key efficacy outcomes as complete exclusion of the aneurysm, mortality during the procedure, 30-day mortality, AAA-related mortality, aortic rupture mid- and long-term, endoleak, adjunctive procedures, re-intervention 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 information, see IPCD: Endovascular aneurysm sealing for abdominal aortic aneurysm.
detailed information on the evidence, see the [interventional procedure overview](#).

5.1 Death was reported in 6% (2/34) of patients in a case series of 34 patients with abdominal aortic aneurysm (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 computerised tomography (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.

5.2 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 1 endoleak seen on 30-day CT scan; it resolved spontaneously by 60 days. The other patient had a distal type 1 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. Endoleak was reported in 4% (2/48) of patients in a case series of 48 patients with AAA treated by endovascular aneurysm sealing (results only reported in a conference abstract); 1 patient had a proximal type 1 endoleak and the other patient had a type 2 endoleak from the internal iliac artery. The proximal type 1 endoleak was embolised with a liquid embolic agent but this was complicated by reflux of the liquid into the proximal left stent of the device. A covered stent was positioned within the proximal left stent of the device to isolate the displaced embolic agent. The type 2
endoleak was treated by extension iliac endografts (timing not reported and no further details provided).

5.3 Stenosis and kinking of the distal limb of the device were reported in 4% (2/48) of patients in the case series of 48 patients. These were treated by extension iliac endografts (no further details provided).

5.4 Complete occlusion of the left stent of the device with preserved perfusion of the left leg was reported in 1 patient in the case series of 48 patients. This was treated conservatively (no further details provided).

5.5 Partial renal infarcts with preserved renal function were reported in 6% (3/48) of patients in the case series of 48 patients (no further details provided).

5.6 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 patients with AAA (no further details provided).

5.7 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, rupture of the aneurysm sac during
the procedure, failure to exclude the sac from the arterial blood flow, occlusion of the stent producing ischaemia of lower limbs, migration of the aneurysm, 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 will oppose to the thrombus rather than to the vessel wall.

6 Committee comments

6.1 The Committee noted that there is a lack of studies comparing endovascular aneurysm sealing with standard endovascular aneurysm repair (EVAR).

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

7 Further information

7.1 For related NICE guidance, see the NICE website.

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