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Stent-graft placement in abdominal aortic aneurysm

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NICE interventional procedure guidance 163

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1 Guidance

This guidance replaces the previous guidance on stent-graft placement in abdominal aortic aneurysm (Interventional Procedures Guidance no. 10, September 2003). The Interventional Procedures Advisory Committee reconsidered the procedure based on the results of a systematic review commissioned by NICE, following publication of the results of the EndoVascular Aneurysm Repair (EVAR) trials.

- 1.1 Current evidence on the efficacy and short-term safety of stent-graft placement in abdominal aortic aneurysm appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Clinicians should ensure that patients fully understand the long-term uncertainties and the potential complications associated with this procedure. In particular, patients should understand: the risks of endovascular leaks; the possibility of secondary intervention; and the need for lifelong follow-up. Patients should be provided with clear written information. In addition, use of the Institute's [information for the public](#) is recommended.
- 1.3 Patient selection is important, particularly for patients who would normally be considered unfit for surgery.
- 1.4 Publication of long-term data would be useful. It is recommended that all patients who have the procedure are entered onto one of the existing registries.

2 The procedure

2.1 Indications

- 2.1.1 Stent-graft placement is used to treat aneurysms of the abdominal aorta. Weakening of the wall of the aorta can lead to widening of the vessel, or aneurysm. Aneurysms may rupture causing internal bleeding which, if untreated, is usually fatal.
- 2.1.2 The standard treatment for abdominal aortic aneurysm is open surgical repair. The aneurysm is opened and a graft is then sewn in above and below the weakened area to allow normal blood flow.

2.2 Outline of the procedure

- 2.2.1 Stent-graft placement is a minimally invasive alternative to open repair. The graft is mounted on a stent, which is inserted into the aorta via catheters in the femoral arteries. The stent-graft is deployed under X-ray guidance and positioned across the aneurysm. Additional endovascular or surgical interventions may be necessary to complete the procedure, such as insertion of stents into the iliac arteries, occlusion of selected arteries and femoro-femoral bypass grafts.

2.3 Efficacy

- 2.3.1 A systematic review of the published evidence on this procedure was commissioned by the Institute and completed in June 2005. A total of 77 studies were identified for inclusion. This comprised: four randomised controlled trials (RCTs) including the EndoVascular Aneurysm Repair (EVAR) 1 trial comparing stent-graft placement and open surgical repair, and the EVAR 2 trial comparing stent-graft placement in patients considered unfit for surgical repair with standard medical care; 17 non-randomised controlled trials; 22 comparative observational studies; 28 case series and six registry publications.

- 2.3.2 Data from the EVAR 1 trial at a median follow-up of 35 months reported an aneurysm rupture rate of 0.9% (5/543) following endovascular repair, compared with 0.2% (1/539) following open repair. Early aneurysm rupture rates of 0.2% (1/534) and 0.3% (13/3859) were reported in one non-randomised controlled trial and seven case series, respectively.
- 2.3.3 In the EVAR 1 trial, 16% (85/529) of patients required secondary intervention following stent-graft placement, compared with 7% (36/519) of patients following open repair. From the non-randomised controlled studies, secondary intervention rates were 20% following stent-graft placement and 6% following open repair.
- 2.3.4 The EVAR 2 trial reported that at 4 years, 26% of the group who had had stent-graft placement had required at least one additional intervention compared with 4% of the group who had received standard medical care. However, if crossovers are considered a secondary intervention, then the secondary intervention rate in the group that received standard medical care became comparable (approximately 30%). For more details, refer to the Sources of evidence.

2.4 Safety

- 2.4.1 From a meta-analysis of data from three RCTs, stent-graft placement was associated with a 30-day mortality rate of 2% (12/759 patients) compared with 5% (33/709 patients) for open repair. In patients considered unfit for surgery, the 30-day mortality following stent-graft placement was 9% (13/150 patients).
- 2.4.2 During more prolonged follow-up to 4 years, the EVAR 1 trial reported no significant difference between the all-cause mortality rate in the group that had had stent-graft placement and the group that had had open repair.

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- 2.4.3 The most common adverse event following stent-graft placement was endoleak originating from retrograde collateral flow into the aneurysm sac via aortic branches (type II). This occurred in 19% of patients at 1 year. Recent developments have led to a lower incidence of procedural and post-procedural complications. The incidence of pulmonary complications and haemorrhagic events was significantly lower in the stent-graft placement group than in the open repair group.
- 2.4.4 Technical complications included stent migration, which happened in 1% of patients within the first year, and stent wire fracture, which happened in 3% of patients within the first year. For more details, refer to the Sources of evidence.

2.5 Other comments

- 2.5.1 It was noted that these procedures are rapidly evolving.
- 2.5.2 The follow-up phase of the EVAR trials continues, and long-term results are expected to be published in 2010.

Andrew Dillon
Chief Executive
March 2006

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'A systematic review update of the recent evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysms', June 2005.

Information for patients

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

4 Other NICE recommendations on endovascular stent-grafts

In February 2009 NICE published guidance on [abdominal aortic aneurysm – endovascular stent-grafts](#) that complements this guidance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

It updates and replaces NICE interventional procedure guidance 10.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

20 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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