

# Stent-graft placement in abdominal aortic aneurysm

Interventional procedures guidance

Published: 22 March 2006

[www.nice.org.uk/guidance/ipg163](http://www.nice.org.uk/guidance/ipg163)

## 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.

This guidance replaces IPG10.

# 1 Guidance

This guidance replaces the previous interventional procedures guidance on stent-graft placement in abdominal aortic aneurysm (IPG10). 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 information for the public for this guidance 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 6 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 of 543) following endovascular repair, compared with 0.2% (1 of 539) following open repair. Early aneurysm rupture rates of 0.2% (1 of 534) and 0.3% (13 of 3,859) were reported in 1 non-randomised controlled trial and 7 case series, respectively.
- 2.3.3 In the EVAR 1 trial, 16% (85 of 529) of patients required secondary intervention following stent-graft placement, compared with 7% (36 of 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 1 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 3 RCTs, stent-graft placement was associated with a 30-day mortality rate of 2% (12 of 759 patients) compared with 5% (33 of 709 patients) for open repair. In patients considered unfit for surgery, the 30-day mortality following stent-graft placement was 9% (13 of 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.
- 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.

## 3 Further information

### Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the [systematic review update of the recent evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysms](#).

### 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.

### Other NICE recommendations on endovascular stent-grafts

In March 2020, NICE published [guidance on abdominal aortic aneurysm](#) that complements

this guidance.

## Update information

### Minor changes since publication

**January 2012:** minor maintenance.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).