Endovascular stent–graft placement in thoracic aortic aneurysms and dissections

Interventional procedures guidance
Published: 22 June 2005

www.nice.org.uk/guidance/ipg127

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 Guidance

1.1 Current evidence on the safety and efficacy of endovascular stent–graft placement in thoracic aortic aneurysms and dissections indicates that it is a suitable alternative to surgery in appropriately selected patients, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 Clinicians should enter all patients having endovascular stent–graft placement in thoracic aortic aneurysms and dissections into the thoracic stent–graft registry supported by the Vascular Society of Great Britain and Ireland and the British Society of Interventional Radiology.

1.3 The procedure should be performed by a multidisciplinary team with access to facilities for cardiothoracic surgery and cardiopulmonary bypass.

2 The procedure

2.1 Indications

2.1.1 A thoracic aortic aneurysm is a condition in which weakening of the wall of the aorta leads to a localised dilatation of the vessel. In an aortic dissection, there is leakage of blood between the layers of the vessel wall. Aneurysms and dissections may rupture, causing massive internal bleeding. Rupture of the thoracic aorta has high mortality, even with treatment.
2.1.2 Conventional surgery for aneurysms of the thoracic aorta involves replacing the affected part of the aorta with a synthetic graft. Aortic dissections may be managed medically or surgically, depending on the site involved and whether there are complicating features.

2.2 Outline of the procedure

2.2.1 Endovascular stent–graft placement involves inserting a metallic stent covered with graft material inside the aorta. This is usually achieved by catheterising the femoral arteries. The stent–graft is positioned and deployed using X-ray guidance.

2.3 Efficacy

2.3.1 A systematic review of the published evidence on this procedure was commissioned by the Institute. A total of 29 studies were identified for inclusion (27 case series and two comparative observational studies).

2.3.2 In one comparative study, the technical success rate was 100% (67/67 patients). The overall technical success rate was 93% across 18 studies (16 case series and two comparative studies).

2.3.3 The rate of conversion to open repair varied from 0% (0/26 patients) to 7% (1/14 patients). The proportion of patients who experienced an increase in aneurysm size varied from 0% (0/18) to 7% (2/29) of patients. In the study with the largest number of patients, the aneurysm increased in size (by 5 mm) in 5% (4/84) of patients. The proportion of patients who experienced a decrease in aneurysm size varied from 100% (18/18) to 17% (5/29) of patients. For more details, refer to the Sources of evidence.

2.4 Safety

2.4.1 The 30-day mortality rate varied from 0% (in several studies with a combined population of 94 patients) to 14% (2/14 patients). The overall mortality ranged from 3% (1/37 patients) to 24% (11/46 patients) across 17 studies with a mean follow-up of 14 months.
2.4.2 The most commonly reported complication following endovascular stent–graft placement was endoleak (incomplete sealing of the aneurysm). Nineteen studies reported at least one patient with an endoleak, with a mean incidence of 13% over 12 months (the total number of patients in these studies was 752; follow-up ranged from 3 to 25 months). Five studies with a total of 83 patients reported that there were no cases of endoleak during a mean follow-up period of 12 months.

2.4.3 Injuries to the access artery were reported in nine case series, and included iliac artery dissection in 4% (1/26) of patients, perforation of the iliac artery in 4% (1/27) and dissection/rupture of the femoral artery in 6% (2/34) of patients. One case series reported stent fracture in 13% (11/84) of patients, and six cases of stent migration were reported across 15 case series.

2.4.4 Other reported complications included wound complications in 25% (8/32) of patients, stroke in 19% (8/43), renal failure requiring dialysis in 11% (2/19) and paraplegia in 7% (3/43) of patients. For more details, refer to the Sources of evidence.

2.5 Other comments

2.5.1 It was noted that there was a lack of long-term data on the durability of stent–grafts.

3 Further information

Sources of evidence

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

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.

Update information

Minor changes since publication

January 2012: minor maintenance.

ISBN: 978-1-4731-4547-4

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.