National Institute for Health and Clinical Excellence

Endovascular stentâ "graft placement in thoracic aortic aneurysms and dissections

Issued: June 2005

NICE interventional procedure guidance 127 www.nice.org.uk/ipg127

Contents

1 Guidance	3
2 The procedure	4
2.1 Indications	4
2.2 Outline of the procedure	4
2.3 Efficacy	4
2.4 Safety	5
2.5 Other comments	6
3 Further information	7
Sources of evidence	7
Information for patients	7
4 About this guidance	8

1 Guidance

- 1.1 Current evidence on the safety and efficacy of endovascular stentâ "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 stentâ "graft placement in thoracic aortic aneurysms and dissections into the thoracic stentâ "graft registry supported by the Vascular Society of Great Britain and Ireland and the <u>British Society of Interventional Radiology</u>.
- 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 stentâ "graft placement involves inserting a metallic stent covered with graft material inside the aorta. This is usually achieved by catheterising the femoral arteries. The stentâ "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 stentâ "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 stentâ "grafts.

Andrew Dillon Chief Executive June 2005

3 Further information

Sources of evidence

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

<u>'A systematic review of the recent evidence for the efficacy and safety relating to the use of endovascular stentâ</u> <u>"graft (ESG) placement in the treatment of thoracic aortic disease</u>, April 2005.

Information for patients

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

4 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.

We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also <u>available</u>.

Changes since publication

24 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.

Copyright

© National Institute for Health and Clinical Excellence 2005. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for

educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

Contact NICE

National Institute for Health and Clinical Excellence Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk nice@nice.org.uk 0845 033 7780