



Laparoscopic repair of abdominal aortic aneurysm

Interventional procedures guidance Published: 22 August 2007

www.nice.org.uk/guidance/ipg229

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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 There is adequate evidence of the safety and efficacy of laparoscopic repair of abdominal aortic aneurysm, but the technical demands are such that this procedure should not be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake laparoscopic repair of abdominal aortic aneurysm should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the procedure and its place in the elective treatment of abdominal aortic aneurysm. They should provide patients with clear, written information. In addition, the patient should be informed of other available techniques, and told that conversion to open surgery may be necessary. Use of NICE's information for the public is recommended.
- 1.3 Clinicians undertaking this procedure should submit data on all patients to the National Vascular Database held by the Vascular Society.
- 1.4 Selection of patients should be performed by a multidisciplinary team experienced in the management of aortic aneurysms and able to offer alternative treatment options.
- 1.5 This procedure should be performed by vascular surgeons who have had training in advanced laparoscopic surgery, and are mentored in these techniques.

2 The procedure

2.1 Indications

- Dilatation of the aorta forming an aneurysm occurs in about 2% of men over the age of 65 (it is less common in women). Small aneurysms may present no problems, but some continue to grow, and larger aneurysms can leak or rupture. This carries a high risk of mortality, even when it is possible to offer emergency surgery. Preventive treatment is often advised for patients with aneurysms that represent an appreciable rupture risk.
- The traditional 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. A less invasive approach is now commonly used, involving endovascular stent graft placement via the femoral arteries, but not all aneurysms are suitable for endovascular treatment.

2.2 Outline of the procedure

Laparoscopic repair of abdominal aortic aneurysm can be done by hand-assisted laparoscopic surgery (HALS) or by the technically more demanding totally laparoscopic surgery (TLS). In HALS, a midline minilaparotomy incision is made for insertion of one of the surgeon's hands to aid the procedure. In both techniques, small skin incisions are made for insertion of a laparoscope and instruments to guide and/or perform the repair. Lumbar arteries and the inferior mesenteric artery are dissected and clipped. Clamps are applied above and below the aneurysm, the sac is opened and thrombus removed. A prosthetic vascular graft is anastomosed to the proximal and distal ends of the aorta. The aneurysm wall and the posterior parietal peritoneum may be closed to cover the graft.

2.3 Efficacy

- In three non-randomised controlled trials, mean hospital length of stay (LOS) was 5.9 (HALS), 6.2 and 6.3 (TLS) days, compared with 9.4, 10.0 and 10.2 days following open repair. One non-randomised controlled study reported that mean LOS was broadly similar following HALS (7.4 days) and endovascular stenting (6.4 days).
- In one case series, mean LOS was 5 days for TLS (n=131) and 7 days for HALS (n=215). In a second case series, mean LOS for HALS was reported as 4.4 days. There was a statistically significant difference in mean LOS between the first 30 patients (5.3 days) and the last 92 patients (4.1 days) treated at one institution (p=0.001). For more details, see the overview.
- 2.3.3 All Specialist Advisers considered this procedure to be novel and of uncertain efficacy. They considered key efficacy outcomes for this procedure to be successful complete repair, open conversion rates, operative time, intensive care unit and overall hospital LOS, patient quality of life, renal function and need for return to theatre. Some Specialist Advisers suggested that there would be longer operating times, particularly early in the learning curve.

2.4 Safety

- 2.4.1 Postoperative death rates following laparoscopic aneurysm repair have been reported as 3% (1 out of 29) and 4% (1 out of 24; HALS), and 5% (3 out of 60) and 10% (2 out of 20; TLS).
- One non-randomised controlled trial reported that the rate of renal insufficiency was 2% (1 out of 60) following laparoscopic repair compared with 11% (11 out of 100) following open repair. Other complications reported following laparoscopic aneurysm repair include bleeding from the hypogastric artery in <1% (1 out of 122; HALS) and bleeding requiring reoperation in 2% (1 out of 60; TLS).
- In three non-randomised controlled trials that compared laparoscopic aneurysm repair with open surgery, the mean operative time was longer in the laparoscopic (181 [HALS], 462 and 468 minutes [TLS]) than in the open surgery groups (136,

300 and 301 minutes, respectively; significance not reported). A fourth non-randomised controlled study comparing HALS with endovascular stenting reported that mean operative time was longer in the HALS group (198 and 149 minutes, respectively; not statistically significant).

- In one case series mean operative time was 257 minutes with HALS; in another it was 175 minutes with HALS and 265 minutes with TLS. For more details, see the overview.
- 2.4.5 Safety outcomes highlighted by the Specialist Advisers were death within 30 days and late mortality, and major complications such as blood loss, infection, and multiple organ failure. They all agreed that the safety of this novel procedure is uncertain and that advanced training in laparoscopic surgical techniques is important.

2.5 Other comments

2.5.1 It was noted that the different laparoscopic techniques have differing technical demands and training requirements. The Committee considered that total cross-clamp time and long-term graft performance are important outcome measures.

3 Further information

3.1 NICE has issued <u>interventional procedures guidance on stent-graft placement in abdominal aortic aneurysm</u> and <u>endovascular stent-graft placement in thoracic</u> aortic aneurysms and dissections.

Sources of evidence

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

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

ISBN: 978-1-4731-6256-3

Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.