

Laparoscopic radical prostatectomy

This guidance replaces 'Interventional procedure guidance 016' issued in October 2003.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laparoscopic radical prostatectomy appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Clinicians should ensure that men understand the benefits and risks of all the alternative treatment options. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG193publicinfo).
- 1.3 Clinicians undertaking laparoscopic radical prostatectomy require special training. The British Association of Urological Surgeons has produced training standards.

2 The procedure

2.1 Indications

- 2.1.1 Laparoscopic radical prostatectomy is indicated for localised prostate cancer with no evidence of spread beyond the prostate or of distant metastases.
- 2.1.2 Alternative treatment options include active monitoring (sometimes called watchful waiting), open radical prostatectomy, external beam radiotherapy, low-dose brachytherapy, combined external beam radiotherapy with high-dose brachytherapy, high-intensity focused ultrasound therapy, and cryotherapy.

2.2 Outline of the procedure

- 2.2.1 A laparoscope and trocars are inserted through small incisions in the abdominal wall. The approach can be either transperitoneal or extraperitoneal. The prostate, adjacent tissue and lymph nodes are dissected and removed, and the urethra, which is cut during the procedure, is reconnected. Lymph nodes can be removed during the procedure for histological examination before removing the prostate. Robotically assisted laparoscopic prostatectomy is a development of this procedure but it is not yet clear whether there is any advantage over conventional laparoscopy.

2.3 Efficacy

- 2.3.1 In a systematic review of non-randomised controlled studies, biochemically assessed recurrence-free survival ranged between 84% (36 months' follow-up) and 99% (30 months) following transperitoneal laparoscopic radical prostatectomy, between 81% (10 months) and 91% (12 months) following extraperitoneal laparoscopic radical prostatectomy, and between 92% (8 months) and 95% (3 months) following robotically assisted laparoscopic radical prostatectomy. None of these outcomes was significantly different from those observed in men undergoing open radical prostatectomy.
- 2.3.2 In a systematic review of non-randomised controlled trials, 8 of 11 studies comparing either the transperitoneal or extraperitoneal laparoscopic approach with open radical prostatectomy reported no significant difference in rates of tumour-positive resection margins between the two procedures. The other three studies in the

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This guidance is written in the following context

This guidance represents the view of the Institute, which 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

review reported significant differences: 50% (transperitoneal) versus 29% (open) ($p = 0.03$), 14% (transperitoneal) versus 26% (open) ($p = 0.02$) and 26% (extraperitoneal) versus 40% (open) ($p = 0.0001$). Pooled data from six case series and two databases indicated a tumour-positive resection margin in 20% of 1439 men treated with laparoscopic radical prostatectomy (any approach) and 24% of 22,164 men treated with open radical prostatectomy. For more details, refer to the 'Sources of evidence' section.

2.3.3 The Specialist Advisers stated that the benefits of laparoscopic radical prostatectomy may include low positive surgical margin rates, and good biochemically assessed recurrence-free survival.

2.4 Safety

- 2.4.1 In a systematic review of ten non-randomised controlled studies, five studies reported no significant differences between the different methods of radical prostatectomy in rates of post-operative urinary continence. One study reported a significant difference that favoured laparoscopic surgery, and four did not report whether differences in continence rates were statistically significant.
- 2.4.2 In a review of pooled data, the mean blood loss was less with laparoscopic radical prostatectomy (505 ml) or robotically assisted laparoscopic prostatectomy (231 ml) than with open surgery (727 ml) (p value not reported).
- 2.4.3 In the studies that reported on erectile dysfunction as a complication, potency was retained in 53–62% of men who were potent at baseline. Preserved potency rates of 82% were reported in men treated with robotically assisted laparoscopic radical prostatectomy. In a systematic review of non-randomised controlled studies, three studies reported that there was no significant difference in potency rates following laparoscopic or open radical prostatectomy. For more details, refer to the 'Sources of evidence' section.
- 2.4.4 The Specialist Advisers stated that adverse events reported with laparoscopic radical prostatectomy were similar to those for open procedures. Additional theoretical complications include gas embolus, bowel damage and haemorrhage.

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1136. 'Understanding NICE guidance' can be obtained by quoting reference number N1137.

The distribution list for this guidance is available at www.nice.org.uk/IPG193distributionlist

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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3 Further information

3.1 The Institute has issued interventional procedure guidance on: high-intensity focused ultrasound for prostate cancer (www.nice.org.uk/IPG118guidance), cryotherapy for recurrent prostate cancer (www.nice.org.uk/IPG119guidance), cryotherapy as a primary treatment for prostate cancer (www.nice.org.uk/IPG145guidance) and low-dose-rate brachytherapy for localised prostate cancer (www.nice.org.uk/IPG132guidance) and high-dose-rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer (www.nice.org.uk/IPG174guidance).

3.2 The Institute is also developing a clinical guideline on the diagnosis and treatment of prostate cancer (see www.nice.org.uk for more information).

Andrew Dillon
Chief Executive
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Information for patients

The Institute has produced information describing its guidance on this procedure for patients ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG193publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document. 'Interventional procedure overview of laparoscopic radical prostatectomy', April 2006.

Available from: www.nice.org.uk/IP39aoverview