NICE guidance

Laparoscopic radical prostatectomy

Interventional procedures guidance
Published: 22 November 2006
www.nice.org.uk/guidance/ipg193

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. However, 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.

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.

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 IPG16.

1 Guidance

This guidance replaces 'Interventional procedure guidance 16' issued in October 2003.

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 is recommended.

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 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.

3 Further information

3.1 The Institute has issued interventional procedure guidance on: high-intensity focused ultrasound for prostate cancer, cryotherapy for recurrent prostate cancer, cryotherapy as a primary treatment for prostate cancer, low dose rate brachytherapy for localised prostate cancer and high dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer.

3.2 The Institute is also developing a clinical guideline on the diagnosis and treatment of prostate cancer (Now published as 'Prostate cancer: diagnosis and treatment').

Andrew Dillon
Chief Executive
November 2006

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.

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.

4 Other NICE recommendations on prostate cancer

NICE has also published a clinical guideline on prostate cancer in February 2008.

5 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.

It updates and replaces NICE interventional procedure guidance 16.

This guidance has been incorporated into the NICE pathway on prostate cancer, along with other related guidance and products.

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

Changes since publication

19 January 2012: minor maintenance.

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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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.