

Laparoscopic radical prostatectomy

Interventional procedures guidance

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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, 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.

This guidance replaces IPG16.

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 NICE's information for the public 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 1,439 men treated with laparoscopic radical prostatectomy (any approach) and 24% of 22,164 men treated with open radical prostatectomy. For more details, see the [overview](#).
- 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% to 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, see the [overview](#).
- 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 NICE has issued [interventional procedures 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 NICE has also issued a [guideline on prostate cancer: diagnosis and management](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).