



Laparoscopic prostatectomy for benign prostatic obstruction

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www.nice.org.uk/guidance/ipg275

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 impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laparoscopic prostatectomy for benign prostatic obstruction (BPO) is inadequate in both quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake laparoscopic prostatectomy for BPO should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety
 and efficacy, make them aware of alternative treatment options and provide
 them with clear written information. In addition, use of NICE's information for
 the public is recommended.
- 1.3 This procedure should only be carried out by surgeons with special training and experience in laparoscopic radical prostatectomy. The <u>British Association of Urological Surgeons</u> (BAUS) has produced training standards.
- 1.4 Patients should only be offered this procedure if they would otherwise be considered for open prostatectomy, rather than transurethral resection, for BPO.
- 1.5 Clinicians should submit data on all patients who receive this procedure to the BAUS Cancer Registry & Sections Audit.
- 1.6 NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Benign prostatic obstruction occurs when the prostate enlarges, pressing against the urethra and the outlet from the bladder. Symptoms include a poor urine stream, urinary frequency, urgency, leaking or dribbling, and urinary retention.
- 2.1.2 Mild symptoms can be treated by medical therapy to relax the smooth muscle of the prostate and bladder neck, reduce prostate size or prevent further enlargement. When medical therapy is inadequate, patients may be treated surgically, usually by transurethral prostatectomy. If the prostate is very large, open prostatectomy (Millin's operation) or transurethral holmium laser prostatectomy may be considered; laparoscopic prostatectomy is a possible alternative for these patients.

2.2 Outline of the procedure

2.2.1 Laparoscopic prostatectomy is performed with the patient under general anaesthesia, using either a transperitoneal or an extraperitoneal approach, with or without computer (robotic) assistance. Incisions are made in the lower abdomen to provide access for the laparoscope and surgical instruments. A transverse incision is made on the anterior wall of the prostate capsule. If a transvesical approach is used, an incision is made in the bladder neck to expose the prostate. The glandular tissue of the prostate is freed from the prostate capsule and removed through the umbilical port incision. A catheter is inserted and the prostate capsule is closed with sutures.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- A non-randomised comparative study of 20 patients treated by laparoscopic prostatectomy and 20 patients treated by open prostatectomy reported similar mean postoperative International Prostate Symptom Score (IPSS) scores in the 2 groups, of 10 and 6.7, respectively (p=0.5; preoperative scores 20.9 and 17.8, respectively; p=0.3; IPSS scores, 0 to 35 scale from mild to severe symptoms).
- The same study of 40 patients reported no significant difference between the mean postoperative maximum urine flow rates of 27.2 ml/s and 25.4 ml/s in the laparoscopic and open surgery groups, respectively (p=0.5; 8.8 ml/s and 7.7 ml/s preoperatively; p=0.4).
- 2.3.3 Four case series of 100, 60, 17 and 7 patients reported mean postoperative IPSS scores of 3.0, 5.2, 9.9 and 7.2 (24.2, 28.3, 24.5 and 22 preoperatively).
- 2.3.4 The Specialist Advisers considered key efficacy outcomes to include reduced blood loss, shorter hospital stay, improved postoperative urine flow rate and relief of urinary symptoms.

2.4 Safety

- Two non-randomised comparative studies of 60 and 40 patients reported significantly less mean blood loss with the laparoscopic approach compared with open prostatectomy 367 ml versus 643 ml (p=0.04) and 412 ml versus 688 ml (p=0.004).
- The non-randomised comparative study of 60 patients and two case series of 17 and 7 patients reported that blood transfusions were required in 3% (1 out of 30), 29% (5 out of 17) and 14% (1 out of 7) of patients. The non-randomised comparative study of 40 patients reported bleeding requiring re-operation in 5% (1 out of 20) of patients. The case series of 17 patients reported haemorrhage (not otherwise specified) in 6% (1 out of 17) of patients.
- Two case series of 100 and 60 patients reported urinary infection in 2% (2 out of 100) and 5% (3 out of 60) of patients, respectively; there was one case of septicaemia. The non-randomised comparative study of 60 patients reported port-site infection in 3% (1 out of 30) of patients.

- Three case series of 60, 18 and 17 patients each reported 1 patient with clot retention. The comparative study of 40 patients and case series of 18 patients reported urethral stricture in 5% (1 out of 20) and 6% (1 out of 18) of patients. The non-randomised comparative study of 60 patients reported bladder stenosis in 3% (1 out of 30) of patients. The case series of 60 patients reported retrograde ejaculation in 68% (41 out of 60) of patients at 6-month follow-up.
- 2.4.5 The Specialist Advisers considered theoretical adverse events to include bleeding, rectal injury, bladder neck stenosis, urinary incontinence, leakage of urine from the bladder and damage to ureteric orifices.

3 Further information

3.1 NICE has published <u>interventional procedures guidance on laparoscopic radical</u> <u>prostatectomy</u> and on <u>holmium laser prostatectomy</u>.

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 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.