



Laparoscopic prostatectomy for benign prostatic obstruction

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www.nice.org.uk/guidance/ipg275

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 <u>information for
 patients</u> ('Understanding NICE guidance') 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.

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.

2.3 Efficacy

- 2.3.1 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 two groups, of 10 and 6.7, respectively (p = 0.5) (preoperative scores 20.9 and 17.8, respectively; p = 0.3) (IPSS scores, 0–35 scale from mild to severe symptoms).
- 2.3.2 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

2.4.1 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).

- 2.4.2 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% (1/30), 29% (5/17) and 14% (1/7) of patients. The non-randomised comparative study of 40 patients reported bleeding requiring re-operation in 5% (1/20) of patients. The case series of 17 patients reported haemorrhage (not otherwise specified) in 6% (1/17) of patients.
- 2.4.3 Two case series of 100 and 60 patients reported urinary infection in 2% (2/100) and 5% (3/60) of patients, respectively; there was one case of septicaemia. The non-randomised comparative study of 60 patients reported port-site infection in 3% (1/30) of patients.
- 2.4.4 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% (1/20) and 6% (1/18) of patients. The non-randomised comparative study of 60 patients reported bladder stenosis in 3% (1/30) of patients. The case series of 60 patients reported retrograde ejaculation in 68% (41/60) 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 The Institute has published interventional procedures guidance on laparoscopic radical prostatectomy and on holmium laser prostatectomy.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding

NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 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.

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

Changes since publication

9 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and 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.

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 <u>Healthcare Improvement Scotland</u>.