

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of laparoscopic prostatectomy for benign prostatic obstruction

The prostate gland surrounds the outlet of a man's bladder. Benign prostatic obstruction occurs when the prostate gland gets bigger, squeezing the tube that carries urine from the bladder to the tip of the penis (the urethra). It can cause problems with passing urine. Laparoscopic prostatectomy involves removing the prostate gland through small cuts in the abdomen, using a fine telescope to see inside the body (also known as 'keyhole surgery').

## Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This overview was prepared in April 2008.

## Procedure name

- Laparoscopic prostatectomy for benign prostatic obstruction

## Specialty societies

- Association of Laparoscopic Surgeons of Great Britain and Ireland
- British Association of Urological Surgeons.

## Description

### *Indications and current treatment*

A non-malignant enlargement of the prostate gland becomes common in men as they age. Benign prostatic obstruction (BPO) occurs when the prostate enlarges and presses against the urethra causing it to narrow. The most

common symptoms of BPO involve changes or problems with urination. These include a hesitant, interrupted weak stream; more frequent urination, especially at night; urgency and leaking or dribbling; and urinary retention. The degree of prostate enlargement does not always correlate with the severity of symptoms.

The International Prostate Symptom Score (IPSS) is a questionnaire often used to assess symptoms of BPO (also referred to as American Urological Association [AUA] scores). It includes questions on incomplete emptying, frequency, intermittency, urgency, weak stream, straining and nocturia. In general, an IPSS symptom score of 0–7 indicates mild symptoms, 8–19 indicates moderate symptoms and 20–35 indicates severe symptoms.

If symptoms are mild, conservative management may be advised. Medical treatments for BPO include drugs that relax the smooth muscles of the prostate and bladder neck, reduce the size of the prostate or prevent progression of growth. Patients with prostate glands that are greatly enlarged are sometimes treated surgically with open prostatectomy (Millins). This procedure involves removing part of the prostate using a transcapsular retropubic approach (extraperitoneal), through a cut in the abdomen. Holmium laser prostatectomy, using a transurethral approach, is also used to treat BPO.

### ***What the procedure involves***

Laparoscopic prostatectomy for BPO is performed under general anaesthesia. It can be done using either a trans- or extra-peritoneal approach, with or without robotic assistance. In general, a number of trocars are inserted through different points of the lower abdomen to provide access for the laparoscope and surgical instruments. The prostate and bladder neck are identified and a transverse incision is made on the anterior wall of the prostate capsule below the bladder neck. If a transvesical prostatic approach is used, an incision is made in the bladder neck to expose the prostate base. Once the prostate gland is identified, it is freed from the inside of the prostate capsule, placed into a bag and extracted through the umbilical port incision. A catheter is inserted and the prostate capsule is closed with sutures.

## ***Efficacy***

### **Symptom scores**

A non-randomised comparative study including 40 patients treated with either laparoscopy or open surgery reported similar mean postoperative IPSS scores in the two groups: 10 (down from 20.9 preoperatively) in the laparoscopic group and 6.7 (down from 17.8 preoperatively) in the open group

(difference between preoperative scores in the two groups  $p = 0.3$ ; difference between postoperative scores  $p = 0.5$ )<sup>1</sup>.

In four case series of 100, 60 and 7 patients, the reported mean postoperative IPSS scores were 3.0, 5.2, and 7.2<sup>2, 3, 5</sup>. The case series of 17 patients the reported mean postoperative American Urological Score (AUA)

### **Maximum urine flow rate**

A non-randomised comparative study of 20 patients each in the laparoscopic and open surgery groups reported mean postoperative maximum flow rate of 27.2 ml/s in the laparoscopic group (8.8 ml/s preoperatively) and 25.4 ml/s in the open surgery group (7.7 ml/s preoperatively) (difference between preoperative values  $p = 0.5$ ; difference between postoperative values  $p = 0.4$ )<sup>1</sup>.

In two case series of 100 and 60 patients, the mean postoperative maximum flow rates were 26.4 and 19.9 ml/s, compared with preoperative flow rates of 6.0 and 4.8 ml/s<sup>2, 3</sup>.

### **Safety**

Two non-randomised comparative studies of 60 and 40 patients reported significantly less blood loss with the laparoscopic approach compared with open prostatectomy (367 and 412 ml versus 643 and 688 ml, respectively;  $p = 0.04$  and  $p = 0.004$ )<sup>6, 1</sup>.

In five case series of 100, 60, 18, 17 and 7 patients, the mean blood loss ranged from 192 to 516 ml<sup>2, 3, 7, 4, 5</sup>.

One non-randomised comparative study and two case series reported blood transfusions in 3% (1/30), 29% (5/17) and 14% (1/7) of patients<sup>6, 4, 5</sup>. Bleeding requiring reoperation was reported in 5% (1/20) of patients in one study<sup>1</sup>. Another study reported haemorrhage (not otherwise specified) in 6% (1/17) of patients<sup>4</sup>.

A case series of 18 patients reported that one patient developed sepsis and persistent obstruction requiring reoperation<sup>7</sup>. A second case series of 60 patients reported septicaemia in one patient<sup>3</sup>. Two case series reported urinary infection in 2% (2/100) and 5% (3/60) of patients, respectively<sup>2, 3</sup>. A non-randomised comparative study reported a port site infection in 3% (1/30) of patients<sup>6</sup>.

Three case series, with a total of 95 patients, each reported one patient with clot retention<sup>3, 4, 7</sup>.

One non-randomised comparative study and one case series reported urethral stricture in 5% (1/20) and 6% (1/18) of patients<sup>1, 7</sup>. A non-randomised comparative study reported bladder stenosis in 3% (1/30) of patients<sup>6</sup>.

A case series of 60 patients reported retrograde ejaculation in 68% (41/60) of patients at 6 months postoperatively<sup>3</sup>.

## Literature review

### *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to laparoscopic prostatectomy for benign prostatic obstruction. Searches were conducted of the following databases, covering the period from their commencement to 30/04/2008: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy).

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with benign prostatic obstruction.
Intervention/test	Laparoscopic prostatectomy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### *List of studies included in the overview*

This overview is based on approximately 300 patients from two non-randomised comparative studies and five case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

### *Existing assessments of this procedure*

There were no published assessments from other organisations identified at the time of the literature search.

### ***Related NICE guidance***

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed below.

#### **Interventional procedures**

- Laparoscopic radical prostatectomy. NICE interventional procedures guidance 193 (2006). Available from [www.nice.org.uk/IPG193](http://www.nice.org.uk/IPG193)
- Holmium laser prostatectomy. NICE interventional procedures guidance 17 (2003). Available from [www.nice.org.uk/IPG17](http://www.nice.org.uk/IPG17)

#### **Technology appraisals**

- None

#### **Clinical guidelines**

- None

#### **Public health guidance**

- None

**Table 2 Summary of key efficacy and safety findings on laparoscopic prostatectomy for benign prostatic hypertrophy**

Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Baumert H (2006)<sup>6</sup></p> <p><b>Non-randomised comparative study</b></p> <p>France and UK</p> <p>Study period: March 2002– March 2005</p> <p>Study population: men with symptomatic bladder outflow obstruction and estimated prostate gland volume &gt; 80 ml on transrectal ultrasound</p> <p>n = <b>60</b> (30 open simple prostatectomy, 30 laparoscopic simple prostatectomy)</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>open = 69.7 ± 7.4</li> <li>laparoscopic = 67.4 ± 6.0</li> </ul> <p>ρ = 0.21</p> <p>Preoperative prostate volume (ml):</p> <ul style="list-style-type: none"> <li>open = 106.2 ± 25</li> <li>laparoscopic = 121.8 ± 39</li> </ul> <p>ρ = 0.07</p> <p>Inclusion criteria: not stated.</p> <p>Technique: in the first 17 laparoscopic cases a Millin-type procedure was used. In the following 13 cases a 'transvesical-prostatic' approach was used. A transvesical technique was used in open group.</p> <p><b>Follow-up: not stated</b></p> <p>Conflict of interest: not stated</p>	<p>Mean intraoperative time (minutes):</p> <ul style="list-style-type: none"> <li>open = 54 ± 19</li> <li>laparoscopic = 115 ± 30</li> </ul> <p>ρ &lt; 0.01</p> <p>Mean specimen weight (g):</p> <ul style="list-style-type: none"> <li>open = 78.1 ± 42.2</li> <li>laparoscopic = 77.2 ± 32.4</li> </ul> <p>ρ = 0.93</p> <p>Mean irrigation time (days):</p> <ul style="list-style-type: none"> <li>open = 4 ± 3.5</li> <li>laparoscopic = 0.33 ± 0.7</li> </ul> <p>ρ = 0.003</p> <p>Mean post-operative catheterisation time (days):</p> <ul style="list-style-type: none"> <li>open = 6.8 ± 4.7</li> <li>laparoscopic = 4 ± 1.7</li> </ul> <p>ρ = 0.004</p> <p>Mean hospital stay (days)</p> <ul style="list-style-type: none"> <li>open = 8.0 ± 4.8</li> <li>laparoscopic = 5.1 ± 1.8</li> </ul> <p>ρ = 0.003</p> <p>Failure of 'trial without catheter' on day 2 (all catheters were successfully removed later)</p> <ul style="list-style-type: none"> <li>open = 6.7% (2/30)</li> <li>laparoscopic = 6.7% (2/30)</li> </ul>	<p>Total complications</p> <ul style="list-style-type: none"> <li>open = 30% (9/30)</li> <li>laparoscopic = 27% (8/30)</li> </ul> <p>Blood transfusion</p> <ul style="list-style-type: none"> <li>open = 16.7% (5/30)</li> <li>laparoscopic = 3.3% (1/30)</li> </ul> <p>Mean blood loss (ml)</p> <ul style="list-style-type: none"> <li>open = 643 ± 647</li> <li>laparoscopic = 367 ± 363,</li> </ul> <p>ρ = 0.045</p> <p>Self-limited stress incontinence</p> <ul style="list-style-type: none"> <li>open = 3.3% (1/30)</li> <li>laparoscopic = 3.3% (1/30)</li> </ul> <p>Reoperation to evacuate bladder clots</p> <ul style="list-style-type: none"> <li>open = 3.3% (1/30)</li> <li>laparoscopic = 0% (0/30)</li> </ul> <p>Other complications in laparoscopic group: 1 bladder stenosis (no intervention required), 1 port site infection, 1 transient fever, 1 secondary haematuria requiring repeat catheterisation and bladder irrigation.</p>	<p>Prospective data collection for laparoscopic procedures, retrospective for open procedures (last 30 consecutive open simple prostatectomies performed between January 2001 and March 2002).</p> <p>There was no significant difference in age, body mass index, or estimated preoperative prostatic size between the two groups.</p>

Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Porpiglia F (2006)<sup>1</sup></p> <p><b>Non-randomised comparative study</b></p> <p>Italy</p> <p>Study period: January 2003– April 2005</p> <p>Study population: men with indications of adenomectomy and estimated prostate volume &gt; 80 ml</p> <p>n = <b>40</b> (20 open prostatectomy, 20 Millin’s extraperitoneal laparoscopic prostatectomy)</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>open = 67.8 ± 6.84 (range 62–78)</li> <li>laparoscopic = 71 ± 6.18 (range 58–77)</li> </ul> <p>p = 0.5</p> <p>Preoperative prostate volume (ml):</p> <ul style="list-style-type: none"> <li>open = 115.6 ± 40.0 (range 80–208)</li> <li>laparoscopic = 94.2 ± 19.6 (range 80–126)</li> </ul> <p>p = 0.5</p> <p>Preoperative IPSS:</p> <ul style="list-style-type: none"> <li>open = 17.76 ± 7.7 (range 7–27)</li> <li>laparoscopic = 20.9 ± 7.0 (range 9–31)</li> </ul> <p>p = 0.3</p> <p>Preoperative maximum urine flow (ml/s):</p> <ul style="list-style-type: none"> <li>open = 7.7 ± 3.6 (range 4–14)</li> <li>laparoscopic = 8.8 ± 3.6 (range 4–16)</li> </ul> <p>p = 0.5</p> <p>Exclusion criteria: adenocarcinoma.</p> <p>Technique: extraperitoneal laparoscopic approach was used.</p> <p><b>Mean follow-up (months): 12.7 ± 6.8 (range 2–28)</b></p> <p>Conflict of interest: not stated</p>	<p>Mean operative time (minutes):</p> <ul style="list-style-type: none"> <li>open = 95.5 ± 22.5</li> <li>laparoscopic = 107.25 ± 34.9</li> </ul> <p>p = 0.6</p> <p>Mean specimen weight (g):</p> <ul style="list-style-type: none"> <li>open = 88.1 ± 43.8</li> <li>laparoscopic = 69.52 ± 21.5</li> </ul> <p>p = 0.4</p> <p>Mean postoperative catheterisation time (days):</p> <ul style="list-style-type: none"> <li>open = 5.6 ± 1.1</li> <li>laparoscopic = 6.3 ± 3.7</li> </ul> <p>p = 0.9</p> <p>Mean hospital stay (days):</p> <ul style="list-style-type: none"> <li>open = 7 ± 1.6</li> <li>laparoscopic = 7.8 ± 4.1</li> </ul> <p>p = 0.8</p> <p>Mean analgesic consumption (Tramadol) (mg):</p> <ul style="list-style-type: none"> <li>open = 430 ± 108</li> <li>laparoscopic = 385 ± 36</li> </ul> <p>p = 0.6</p> <p>Mean IPSS at 2 months postoperatively:</p> <ul style="list-style-type: none"> <li>open = 6.7 ± 3.3</li> <li>laparoscopic = 10 ± 14</li> </ul> <p>p = 0.5</p> <p>Mean maximum urine flow at 2 months: postoperatively (ml/s)</p> <ul style="list-style-type: none"> <li>open = 25.4 ± 7.3</li> <li>laparoscopic = 27.2 ± 5.5</li> </ul> <p>p = 0.4</p>	<p>Bleeding requiring reoperation:</p> <ul style="list-style-type: none"> <li>open = 0% (0/20)</li> <li>laparoscopic = 5.0% (1/20)</li> </ul> <p>Mean blood loss (ml):</p> <ul style="list-style-type: none"> <li>open = 687.5 ± 298.6</li> <li>laparoscopic = 411.6 ± 419</li> </ul> <p>p = 0.004</p> <p>Urethral stenosis</p> <ul style="list-style-type: none"> <li>open = 5.0% (1/20)</li> <li>laparoscopic = 5.0% (1/20)</li> </ul> <p>(the same patient also had mild urinary incontinence and impotence)</p>	<p>Prospective data collection.</p> <p>Patients were offered the choice of open or laparoscopic surgery.</p> <p>There was no significant difference in age, PSA level, haemoglobin levels, prostate volume, maximum flow rate or IPSS between the two groups.</p>

Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Hoepffner J-L (2006)<sup>2</sup></p> <p><b>Case series</b></p> <p>France</p> <p>Study period: January 2004– October 2005</p> <p>Study population: men with obstructive lower urinary tract symptoms with large prostates not responding to medical therapy.</p> <p><b>n = 100</b></p> <p>Mean age (years): 67.8 ± 7.6 (range 53–82)  Mean preoperative IPSS: 24.2 ± 5.1 (range 14–35)  Mean preoperative maximum urine flow (ml/s): 6.0 ± 2.4 (range 0–16.7)</p> <p>Inclusion criteria: of patients who underwent prostate biopsy, only those with benign results underwent Millin's laparoscopic prostatectomy (prostate biopsies were performed in patients with raised PSA or abnormal digital rectal examination).</p> <p>Technique: finger-assisted laparoscopic retropubic prostatectomy (Millin)</p> <p><b>Mean follow-up (months): 14.0 ± 5.2 (range 3–25)</b></p> <p>Conflict of interest: not stated</p>	<p>Mean operative time (minutes) = 66.3 ± 12.3 (range 36–91)</p> <p>Mean specimen weight (g) = 68.2 ± 15.46 (range 40.5–123.8)</p> <p>Mean postoperative catheterisation time (days) = 3.2 ± 1.0 (range 2–9)</p> <p>Mean hospital stay (days) = 4.3 ± 1.3 (range 2 – 10)</p> <p>Mean postoperative IPSS = 3.0 ± 1.6 (range 0–7)</p> <p>Mean postoperative maximum urine flow (ml/s) = 26.4 ± 5.9 (range 15.2–45.3)</p>	<p>There were no intraoperative complications and no conversions to open surgery.</p> <p>Mean blood loss (ml) = 250 ± 86.8 (range 100–503)</p> <p>Postoperative complications:</p> <ul style="list-style-type: none"> <li>• prolonged haematuria = 2% (2/100)</li> <li>• urinary infection = 2% (2/100)</li> <li>• urethral stenosis = 0% (0/100)</li> <li>• retention = 0% (0/100)</li> <li>• postoperative recatheterisation (original catheter fell out) = 1% (1/100)</li> </ul> <p>None of the patients required pads after 3 months postoperatively and erectile function was preserved in all those who were potent before surgery (65%).</p>	<p>Retrospective data collection.</p> <p>The authors state that dissection of the adenoma may be achieved more rapidly by digital assistance resulting in lower operative times.</p>



Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Mariano MB (2006)<sup>3</sup></p> <p><b>Case series</b></p> <p>Brazil</p> <p>Study period: March 1999–March 2005</p> <p>Study population: men with obstructive symptoms and enlarged prostate glands with estimated weight of at least 75 g</p> <p><b>n = 60</b></p> <p>Mean age (years): 68.5 ± 7.5 (range 49–88) Calculated prostate weight, estimated by transrectal ultrasonography (g): 144.5 ± 41.7 (range 80–422)</p> <p>Preoperative IPSS: 28.3 ± 4.75 (range 19–35)</p> <p>Preoperative maximum urine flow (ml/s): 4.8 ± 3.4 (range 5–9)</p> <p>Inclusion criteria: not stated</p> <p>31.2% (19/60) of patients had erectile dysfunction before surgery</p> <p>All patients had biopsy before surgery and BPH was diagnosed in all cases</p> <p>Technique: laparoscopic retropubic prostatectomy using a transperitoneal approach with vascular control</p> <p><b>Follow-up (months): 6</b></p> <p>Conflict of interest: not stated</p>	<p>Mean operative time (minutes) = 138.5 ± 23.4 (range 95–242)</p> <p>Mean postoperative catheterisation time (days) = 4.6 ± 1.2 (range 3–7)</p> <p>Mean hospital stay (days) = 3.5 ± 0.9 (range 2–7)</p> <p>Use of analgesics (days) = 1.5 ± 0.9 (range 1–3)</p> <p>Postoperative IPSS = 5.2 ± 2.5 (range 3–16)</p> <p>Postoperative maximum urine flow (ml/s) = 19.9 ± 3.1 (range 16–33)</p> <p>Prolonged postoperative bladder catheterisation = 1.7% (1/60)</p> <p>Approximately 80% of patients were 'delighted' with the results</p>	<p>There were no major intraoperative complications and no conversions to open surgery.</p> <p>Mean blood loss (ml) = 331.0 ± 150.0 (range 85–850)</p> <p>Postoperative complications:</p> <ul style="list-style-type: none"> <li>• retrograde ejaculation at 6 months = 68.3% (41/60)</li> <li>• prolonged ileum = 5% (3/60)</li> <li>• urinary infection = 5% (3/60)</li> <li>• clot retention = 1.7% (1/60)</li> <li>• septicaemia = 1.7% (1/60) (no further details given in paper)</li> <li>• urinary incontinence = 0% (0/60)</li> </ul> <p>The erectile function was preserved in all patients who were potent before surgery</p>	

Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>van Velthoven R (2004)<sup>7</sup></p> <p><b>Case series</b></p> <p>Belgium, the Netherlands and France</p> <p>Study period: February 2001–January 2003</p> <p>Study population: men with lower urinary tract symptoms attributable to BPH and in whom an open Millin’s operation was planned</p> <p><b>n = 18</b></p> <p>Mean age (years): 67.8                      Mean calculated prostate weight, estimated by transrectal ultrasonography (g): 95.1                      Mean preoperative maximum urine flow (ml/s): 4.3</p> <p>Four patients presented in retention</p> <p>Inclusion criteria: not stated</p> <p>Technique: laparoscopic extraperitoneal prostatectomy (Millin’s procedure)</p> <p><b>Mean follow-up (months): 8</b></p> <p>Conflict of interest: not stated</p>	<p>Mean operative time (minutes) = 145</p> <p>Mean weight of enucleated tissue (g) = 47.6</p> <p>Mean hospital stay (days) = 7</p> <p>Mean duration of postoperative stay (days) = 5.9</p>	<p>There were no conversions to open surgery</p> <p>Mean blood loss (ml) = 192</p> <p>Postoperative complications</p> <ul style="list-style-type: none"> <li>• sepsis and persistent obstruction requiring reoperation = 5.6% (1/18)</li> <li>• clot retention = 5.6% (1/18)</li> <li>• port site hernia = 5.6% (1/18)</li> <li>• minimal haematuria requiring single catheterisation = 5.6% (1/18)</li> <li>• urethral stricture = 5.6% (1/18)</li> <li>• bronchitis = 5.6% (1/18)</li> </ul>	<p>Pilot study to assess feasibility of laparoscopic approach.</p> <p>Patient selection was reportedly based on the surgeon’s preferences and not driven by the degree of expected difficulty or patient’s comorbidity.</p> <p>The authors note that these results correspond to an initial experience of the technique.</p>

Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sotelo R (2005)<sup>4</sup></p> <p><b>Case series</b></p> <p>Venezuela and USA</p> <p>Study period: August 2001 onwards</p> <p>Study population: men with symptomatic BPH due to a significantly enlarged prostate gland</p> <p><b>n = 17</b></p> <p>Mean age (years): 69.8 (range 53–82)</p> <p>Mean preoperative AUA score: 24.5 (range 15–32)</p> <p>Mean preoperative maximum urine flow (ml/min): 7 (range 5–9)</p> <p>29% (5/17) of patients had acute urinary retention</p> <p>65% (11/17) of patients were potent, 29% (5/17) were impotent</p> <p>Inclusion criteria: symptomatic BPH with a transrectal ultrasound estimated gland weight of 60 g or more, or a prostate weight of less than 60 g but with associated surgical pathology, such as multiple or large bladder calculi, or inguinal hernia</p> <p>Technique: laparoscopic simple retropubic prostatectomy</p> <p><b>Follow-up: 3 months–2 years</b></p> <p>Conflict of interest: not stated</p>	<p>Mean operative time (minutes) = 156 (range 85–380)</p> <p>Mean duration of postoperative catheterisation (days) = 6.3 (range 3–7)</p> <p>Mean hospital stay (days) = 2 (range 0.6–4.6)</p> <p>Mean postoperative AUA score = 9.9 (range 4–17)</p> <p>Mean postoperative maximum urine flow (ml/min) = 22.8 (range 15–31)</p> <p>Postoperative acute urinary retention = 0% (0/17)</p>	<p>Blood transfusion = 29% (5/17)</p> <p>Mean blood loss (ml) = 516 (range 100–2500)</p> <p>Intraoperative haemorrhage (blood loss of 2500 ml necessitating transfusion) = 5.9% (1/17)</p> <p>Postoperative complications:</p> <ul style="list-style-type: none"> <li>• clot obstruction of catheter = 5.9% (1/17)</li> <li>• upper digestive tract haemorrhage from pre-existing duodenal ulcer = 5.9% (1/17)</li> </ul> <p>41% (7/17) of patients were known to be potent postoperatively. 29% (5/17) were impotent and data were unavailable for the remaining 5 patients</p>	<p>The authors note that their technique evolved over the study period.</p>

Abbreviations used: AUA, American Urological Association; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; QOL, quality of life.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sotelo R (2008)<sup>b</sup></p> <p><b>Case series</b></p> <p>Venezuela</p> <p>Study period: January 2007 onwards</p> <p>Study population: men with symptomatic BPH</p> <p><b>n = 7</b></p> <p>Mean age (years): 64.7 (range 56–72)</p> <p>Mean preoperative IPSS: 22 (range 10–32)</p> <p>Mean preoperative maximum urine flow (ml/sec): 17.8 (range 7.5–28)</p> <p>57% (4/7) of patients had acute urinary retention</p> <p>Mean prostate weight on preoperative transrectal ultrasound = 77.7 ± 23.0 g (range 40–106)</p> <p>Inclusion criteria: not stated</p> <p>Technique: robot-assisted laparoscopic simple prostatectomy with transperitoneal approach</p> <p><b>Follow-up: not stated</b></p> <p>Conflict of interest: not stated</p>	<p>Mean operative time (minutes) = 195 (range 120–300)</p> <p>Mean duration of postoperative catheterisation (days) = 7.5 (range 6–10)</p> <p>Mean hospital stay (days) = 1.3 (range 1–2)</p> <p>Mean postoperative IPSS = 7.2 (range 2–13)</p> <p>Mean postoperative maximum urine flow (ml/sec) = 55.5 (range 36–83)</p> <p>Mean postoperative QOL score = 2.2 (range 1–4) (preoperative = 3.8, range 1–6) (QOL questionnaire was not described)</p>	<p>Blood transfusion = 14% (1/7) (secondary to epigastric artery injury)</p> <p>Mean blood loss (ml) = 381.7 (range 60–800)</p>	<p>There is a discrepancy regarding units for maximum urine flow – the abstract reports it as ml per minute whereas the table and main text state ml per second.</p>

### ***Validity and generalisability of the studies***

- The exact technique used varied between and within studies.
- One study used a robot-assisted approach for all patients<sup>5</sup>.
- Two studies did not specify that the inclusion criteria included significantly enlarged prostate glands<sup>5, 7</sup>.
- Most of the studies represent early experience of the technique.

### **Specialist Advisers' opinions**

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr C Eden, Mr F Keeley (British Association of Urological Surgeons).

- Both Specialist Advisers considered the procedure to be a minor variation of an existing procedure.
- Theoretical adverse events include bleeding, rectal injury, bladder neck stenosis, incontinence, leakage of urine from the bladder and damage to ureteric orifices.
- Other options exist for managing bladder outlet obstruction caused by enlarged prostates.
- Key efficacy outcomes include blood loss, hospital stay, postoperative flow rate and relief of urinary symptoms.
- The procedure should only be done by surgeons who have training and extensive experience of laparoscopic radical prostatectomy.
- The potential impact on the NHS is minor.

### **Issues for consideration by IPAC**

None other than those listed above.

## References

1. Porpiglia F, Terrone C, Renard J et al. (2006) Transcapsular adenomectomy (Millin): a comparative study, extraperitoneal laparoscopy versus open surgery. *European Urology* 49: 120–6.
2. Hoepffner J-L, Gaston R, Piechaud T et al. (2006) Finger Assisted Laparoscopic Retropubic Prostatectomy (Millin). *European Urology Supplements* 5: 962–7.
3. Mariano MB, Tefilli MV, Graziottin TM et al. (2006) Laparoscopic prostatectomy for benign prostatic hyperplasia: a six-year experience. *European Urology* 49: 127–31.
4. Sotelo R, Spaliviero M, Garcia-Segui A et al. (2005) Laparoscopic retropubic simple prostatectomy. *Journal of Urology* 173: 757–60.
5. Sotelo R, Clavijo R, Carmona O et al. (2008) Robotic simple prostatectomy. *Journal of Urology* 179: 513–5.
6. Baumert H, Ballaro A, Dugardin F et al. (2006) Laparoscopic versus open simple prostatectomy: a comparative study. *Journal of Urology* 175: 1691–4.
7. van Velthoven R, Peltier A, Laguna MP et al. (2004).Laparoscopic extraperitoneal adenomectomy (Millin): pilot study on feasibility. *European Urology* 45: 103–9.

## Appendix A: Additional papers on laparoscopic prostatectomy for benign prostatic obstruction

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Blew B, Fazio L, Pace K et al. (2005) Laparoscopic simple prostatectomy. Canadian Journal of Urology 12: 2891–4.	n = 1	Extraperitoneal approach used Estimated blood loss = 600 ml Postoperative maximum flow rate = 12 ml/s	Case report
Mariano MB, Graziottin TM, Tefilli MV (2002) Laparoscopic prostatectomy with vascular control for benign prostatic hyperplasia. Journal of Urology 167: 2528–9.	n = 1 Follow-up = 5 months	Estimated blood loss = 800 ml Normal continence and potency at follow-up	Case report
Nadler R, Blunt L, User H, et al. (2004) Preperitoneal laparoscopic simple prostatectomy. Urology 63: 778–9.	n = 1	Estimated blood loss = 300 ml At 6 weeks, patient reported normal continence and complete relief of voiding symptoms	Case report
Ray D, Ducarme G, Hoepffner J et al. (2005) Laparoscopic adenectomy: a novel technique for managing benign prostatic hyperplasia. BJU International 95: 676–8.	n = 5	No blood transfusion or infection reported  All patients had normal continence postoperatively	Larger case series are included
Rehman J, Khan SA, Sukkarieh T et al. (2005) Extraperitoneal laparoscopic prostatectomy (adenomectomy) for obstructing benign prostatic hyperplasia: transvesical and transcapsular (Millin) techniques. Journal of Endourology 19: 491–6.	n = 2  Follow-up = 12 months	Estimated blood loss < 50 ml and < 200 ml. At follow-up, flow rate > 20 ml  Normal continence and sexual potency in both men	Larger case series are included
Yuh B, Laundgani R, Perlmutter A, Eun D, Peabody JO, Mohler JL, Strickler H, Guru KA (2008) Robot-assisted Millin's retropubic prostatectomy: case series. Canadian Journal of Urology 15: 3	n = 3	Estimated blood loss from 150 – 1125 ml (1125 ml in adedmona of 640 gm)  One case of bladder neck contracture requiring transurethral incision of bladder neck.	Larger case series are included; safety event has been reported

## Appendix B: Related NICE guidance for laparoscopic prostatectomy for benign prostatic obstruction

Guidance	Recommendations
Interventional procedures	<p><b>Laparoscopic radical prostatectomy. NICE interventional procedures guidance 193 (2006)</b></p> <p>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.</p> <p>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 <a href="http://www.nice.org.uk/IPG193publicinfo">www.nice.org.uk/IPG193publicinfo</a>).</p> <p>1.3 Clinicians undertaking laparoscopic radical prostatectomy require special training. The British Association of Urological Surgeons has produced training standards.</p> <p><b>Holmium laser prostatectomy. NICE interventional procedures guidance 17 (2003)</b></p> <p>1.1 Current evidence on the safety and efficacy of holmium laser prostatectomy appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.</p> <p>1.2 Clinicians undertaking this procedure require specialist training. The British Association of Urological Surgeons has agreed to produce training standards.</p>



## Appendix C: Literature search for laparoscopic prostatectomy for benign prostatic obstruction

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/4/2008	Issue 2, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	30/4/2008	N/A
HTA database (CRD website)	30/4/2008	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/4/2008	Issue 2, 2008
MEDLINE (Ovid)	30/4/2008	1950 to April Week 3 2008
MEDLINE In-Process (Ovid)	30/4/2008	April 29, 2008
EMBASE (Ovid)	30/4/2008	1980 to 2008 Week 17
CINAHL (Search 2.0, NLH)	30/4/2008	1982 to date (via Dialog)
BLIC (Dialog DataStar)	1/5/2008	N/A
National Research Register (NRR) Archive	29/4/2008	N/A
UK Clinical Research Network (UKCRN) Portfolio Database	1/5/2008	N/A
Current Controlled Trials <i>meta</i> Register of Controlled Trials - <i>m</i> RCT	29/4/2008	N/A
Clinicaltrials.gov	24/4/2008	N/A

Websites searched on 29/04/2008:

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites (N/A)
- General internet search

### MEDLINE search strategy

IP overview: Laparoscopic prostatectomy for benign prostatic obstruction

The MEDLINE search strategy was adapted for use in the other sources.

1	Laparoscopy/
2	Laparotomy/
3	Robotics/
4	Laparoscop\$.tw.
5	Laparotom\$.tw.
6	Robotic\$.tw.
7	Millin\$.tw.
8	or/1-7
9	Prostatectomy/
10	Prostatectom\$.tw.
11	Adenomectom\$.tw.
12	or/9-11 (19658)
13	8 and 12
14	Prostatic Diseases/
15	Prostatic Hyperplasia/
16	(Prostat\$ adj3 Disease\$.tw.
17	(Prostat\$ adj3 Adenoma\$.tw.
18	(Benign\$ adj3 prostat\$ adj3 enlargement\$.tw.
19	(Benign\$ adj3 prostat\$ adj3 hyperplas\$.tw.
20	(Benign\$ adj3 prostat\$ adj3 hypertroph\$.tw.
21	(Benign\$ adj3 prostat\$ adj3 obstruction\$.tw.
22	(Bladder\$ adj3 Outflow\$ adj3 Obstruction\$.tw.
23	BPH.tw.
24	BPO.tw.
25	BOO.tw.
26	or/14-25
27	13 and 26
28	Animals/
29	Humans/
30	28 not (28 and 29)
31	27 not 30