



**NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**  
**INTERVENTIONAL PROCEDURES PROGRAMME**

**Interventional procedure overview of  
Laparoscopic Cystectomy**

**Introduction**

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

**Procedure name**

(Transperitoneal or transvaginal) laparoscopic (radical) cystectomy  
Laparoscopic removal of the bladder  
Cystoprostatectomy

**Specialty society**

*British Association of Urological Surgeons*

**Executive summary**

Laparoscopic cystectomy is a procedure used to remove the bladder, usually as a consequence of bladder cancer. It is not possible to assess the procedure on its own, as some method of urinary diversion is usually required. A search of the literature located 20 studies (all case series or case studies), of which 5 were selected for this review. A list of annexed studies is provided. The selected studies were chosen based on recency and numbers of patients. However, while the papers are recent, the number of patients on whom the procedure has been reported remains small. Only 2 of the papers report any follow-up, and that is scant.

A brief appraisal of all the available literature suggests that the procedure, (including the urinary diversion) is long (7-11 hours) and difficult. One patient died apparently as a consequence of the procedure (haemorrhage). Most complications involve the bowel or subsequent urine leakage.

It is not possible to comment on efficacy, as the relevant outcome measures such as cancer recurrence and incontinence have generally not been reported. Furthermore, the efficacy of the open procedure is not established.

**Indication(s)**

- Invasive bladder carcinoma
- Ongoing incontinence due to paraplegia, where catheterisation results in infection and ongoing leakage

- Refractory complications in a defunctionalized bladder, where urinary diversion is already established (simple cystectomy)

### Summary of procedure

Laparoscopic cystectomy involves removal of the bladder through a small incision in the peritoneum, or through the vaginal wall in female patients. In male patients the prostate is also removed (cystoprostatectomy).

Radical cystectomy requires a method of urinary diversion, unless this has been established previously where the bladder was defunctionalized (simple cystectomy). There are three methods of urinary diversion:

- Ileal conduit (a segment of ileum is used to redirect urine away from the bladder, to a stoma in the abdomen where it is collected in a bag)
- Continent urinary diversion (an internal reservoir is created for the storage of urine using parts of the bowel. It is emptied by passing a catheter typically through an umbilical stoma)
- Neobladder (similar to continent urinary diversion except that the neobladder is connected to the urethra and patients can learn to maintain continence by muscle training).

The options for each patient are limited by their clinical status and the presence of a viable urethra, patient preference and surgeon experience. In the literature for laparoscopic cystectomy various methods of urinary diversion are described. The literature includes examples of procedures being performed both intra- and extracorporeally.

According to Carvalho *et al.*<sup>2</sup>, the advantages of the laparoscopic cystectomy include: decreased surgical morbidity, good visualization of the pelvic structures, decreased blood loss, reduced postoperative ileus, shorter hospital stay, and improved cosmesis. Limitations include a significant learning curve, increased operative time with financial costs, and unknown risk of port-site metastases.

Open cystectomy is the surgical alternative to the laparoscopic procedure.

### Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on laparoscopic cystectomy (removal of the bladder) in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports.

Studies were selected where the bladder was fully removed, and, where necessary, urinary diversion was established. Studies using cadavers were excluded. Tabulated studies are given in the reference list with reasons for

inclusion stated. Studies for which data were not tabulated are listed in the annex following the reference list.

### **List of studies found**

Total number of studies found: 20

- Case series (English) 8
- Case series (German) 1
- Case reports (English) 10
- Case reports (Spanish) 1

### **Summary of key efficacy and safety findings**

See following tables.

### **Abbreviations**

LRC	Laparoscopic radical cystectomy
MI	Myocardial infarction
UTI	Urinary tract infection

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Case series</i>			
<p><b>Abdel-Hakim et al.<sup>1</sup> 2002, EGYPT</b></p> <p>9 patients LRC and orthotopic neobladder (minilaparotomy n=3 and extracorporeally n=6). Date not stated.</p> <p><i>Follow-up:</i> none</p> <p><i>Selection criteria:</i> muscle-invasive, stage T<sub>2</sub> grade 2 or 3 transitional-cell carcinoma (n=8) and verrucous squamous-cell carcinoma (n=1).</p>	<p>Median operative time (hours) 8.3 (6.5-12)</p> <p>Cystectomy time – 1<sup>st</sup> 8h; 9<sup>th</sup> 3.5h</p> <p>Stents removed 8<sup>th</sup> day post-op.</p> <p>Lymph nodes and surgical margins tumour free</p>	<p>1/9 deep femoral thrombosis</p> <p>1/9 wound infection</p> <p>Blood loss (ml): 150 – 500</p> <p>No blood transfusions</p>	<p><i>Comments:</i> Procedure described as difficult and technically demanding. Evidence of steep learning curve in LRC times.</p> <p>No details given as to whether patients were consecutive. Efficacy difficult to judge, with no follow-up period and limited range of outcome measures reported.</p> <p>Editorial comment suggests that procedure would be best for thin patients with minimally invasive tumours. Also suggests wide excision of vascular pedicles may be difficult laparoscopically</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Case series</i>			
<p><b>Carvalho and Gill<sup>2</sup> 2002, USA</b></p> <p>11 patients. 10 LRC and urinary diversion performed intracorporeally, 1 LRC and “Indiana Pouch” (urinary diversion) construction performed extracorporeally. 8 males had radical cystoprostatectomy, 3 females had anterior pelvic exenteration.</p> <p>Date not stated.</p> <p><i>Follow-up:</i> none</p> <p><i>Selection criteria:</i> organ-confined muscle-invasive bladder cancer, recurrent multifocal carcinoma in situ that has failed intra-vesical chemotherapy.</p> <p><i>Exclusions:</i> prior pelvic radiotherapy, multiple previous abdominal operations, active bladder or upper tract infection, coagulopathy and extra-vesicle involvement by the bladder cancer.</p>	<p>Mean operative time (hrs) 7.3 (6.5 – 11.5*)</p> <p>Conversion to open 0</p> <p>Mean<sup>§</sup> hospital stay (days) 7 (4 – 30)</p> <p>Operative time for first patient: 11.5 hours, and 7 hours in the last patient.</p> <p>Surgical margins –ve for cancer in 100% patients</p> <p>* States 11.5 in text, 11.0 in table</p> <p>§ States mean in text, median in table</p>	<p><u>Major</u> (n=2; 18%)</p> <p>Bowel obstruction (1/11)</p> <p>Bowel perforation/delayed mortality due to aspiration pneumonia complications (1/11)</p> <p><u>Minor</u> (n=3; 27%)</p> <p>Sub-acute bowel obstruction (1/11)</p> <p>Abductor spasm (2/11)</p> <p>Mean blood loss (cc) 330</p> <p>Blood transfusion required - 2 patients</p>	<p><i>Comments:</i> procedure described as requiring considerable dexterity. Steep learning curve.</p> <p>No details given as to whether patients were consecutive. Efficacy difficult to judge, with no follow-up period and limited range of outcome measures reported.</p> <p>Currently not able to perform nerve-sparing procedure.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Case series</i>			
<p><b>Denewer <i>et al.</i><sup>3</sup> 1999, EGYPT</b></p> <p>10 patients, LRC with continent pouch constructed via open procedure. Date not stated.</p> <p><i>Follow up:</i> none</p> <p><i>Selection criteria:</i> bladder carcinoma, No regional lymph node metastasis and no evidence of distant metastasis (N0-M0): Group 1 (n=2), primary presentation in transitional or squamous cell lesion; Group 2 (n=8) presentation bilharizial bladder carcinoma T3 or T4 stage, usually following unsuccessful radiation therapy (1 to 4 months prior to surgery).</p>	<p>Mean duration of laparoscopic cystectomy (minutes): 160 (140 – 190)</p> <p>Duration of non-laparoscopic pouch formation about 55 minutes.</p> <p>Hospital stay (days) 10-13</p>	<p><i>Mortality:</i> 1/10 operative death from haemorrhage (group 2 patient)</p> <p><i>Morbidity:</i> Intraoperative – 1/10 clipping of an external iliac artery (group 1). Postoperative: 1/10 self-limiting fistula (group 2), 1/10 deep venous thrombosis (group 1), 1/10 pelvic collection (group 1), same patient later developed upper UTI.</p> <p>Mean intraoperative blood transfusion (units) 2.2 (2 – 3)</p>	<p><i>Comments:</i> authors state procedure allows precise radical lymphadenectomy, earlier postoperative mobility, fewer wound complications and shorter hospital stay than found with their open patients.</p> <p>No details given as to whether patients were consecutive. Efficacy difficult to judge, with no follow-up period and limited range of outcome measures reported.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Case series</i>			
<p><b>Gupta et al.<sup>4</sup> 2002, INDIA</b></p> <p>5 patients, LRC with intracorporeal ileal conduit urinary diversion. 1 female had LRC transvaginally. Feb. 2000.</p> <p><i>Follow up:</i> 2-years</p> <p><i>Selection criteria:</i> locally invasive but organ-confined carcinoma of urinary bladder. Negative radiological tests before surgery, informed consent.</p>	<p>Mean duration of surgery (h) 7.5 (7-8)</p> <p>Mean days to ambulation 2.6 (2-5)</p> <p>Mean days to oral intake 3</p> <p>Mean hospital stay (days) 12.2 (8-22)</p> <p>Mean return to light work (days) 19.8 (13-35)</p> <p>*Calculated from raw data presented in paper; note in text mean hospital stay is stated as 7(6-22)</p> <p>Surgical margins of bladder specimen -ve for cancer 100%</p> <p>At 2 years: 2/5 patients died (1 septicaemia following unrelated pulmonary infection and multi-organ failure at 9m; 1 from MI at 12m). 3/5 normal upper tracts on intravenous urogram and no evidence of local recurrence or metastatic disease.</p>	<p>1/5 twisted bowel mesentery proximal to ileo-ileal anastomosis (5d postop). Bowel continuity restored at 12w.</p> <p>1/5 abdominal distension with low-grade fever (3w postop). Lasted 10d.</p> <p>1/5 transient left adductor spasm postop., resolved in 1w.</p> <p>Mean blood loss (ml) 360 (300-400)</p> <p>Blood transfusions 0</p>	<p><i>Comments:</i> discrepancy in figures given for length of hospital stay. Describes intracorporeal laparoscopic urinary diversion as most challenging part of procedure.</p> <p>Not clear if patients were consecutive.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Case series</i>			
<p><b>Türk <i>et al.</i><sup>5</sup> 2002, GERMANY</b></p> <p>11 patients, LRC and intracorporeal construction of continent urinary diversion using Mainz pouch II. March 2000 - December 2001.</p> <p><i>Follow-up:</i> 13.4 months (1-21 months)</p> <p><i>Selection criteria:</i> Muscle-invasive bladder tumour (9 patients) T1-G3 tumour (2 patients)</p>	<p>No conversion to open procedure</p> <p>Mean* surgery time (hours) - 6.7 (5.5-7.9)</p> <p>Mean<sup>§</sup> length of hospital stay (days): 12 (10-13)</p> <p>Surgical margins –ve for cancer 100%; 1/11 had metastases in lymph nodes and received adjuvant chemotherapy</p> <p>At follow-up - no nerve function complications or obstruction to upper urinary passages.</p> <p>100% patients had full continence day and night.</p> <p>Follow-up without local or systemic progression</p> <p>*Described as mean in English &amp; German abstract (mittlere), but as “mediane” in results section.</p> <p><sup>§</sup> “Mittlere” and Mittel used (translated as mean)</p>	<p>1/11 pouch leak (6w post op); 1/11 pouch-vaginal fistula (4w post op)</p> <p>Mean blood loss (ml): 220 (150-300)</p> <p>No blood transfusion required</p>	<p><i>Comments:</i> German article, translated.</p> <p>Not clear if patients were consecutive</p> <p>Authors state that procedure has less morbidity and faster recovery and that low levels of blood loss, fluid shifts, and electrolyte loss considerably reduce cardiovascular stress.</p> <p>Also state that radical cystectomy and construction of continent urinary diversion represent the limit of technically feasible laparoscopy and should be done exclusively in specialised centres.</p>



## Specialist advisor's opinion / advisors' opinions

*Specialist Advice was sought from the British Association of Urological Surgeons*

**Efficacy:** The Specialist Advisors expressed some concern regarding the efficacy of this procedure. Two of the Advisors considered that it was too early to comment and that the lack of available evidence made it impossible to judge. One Advisor commented that there were still concerns about the efficacy of open cystectomy, and that published case series have reported similar cancer control data for laparoscopic and open cystectomy.

**Safety:** The majority of Specialist Advisors did not report specific complications. However, one Advisor listed bleeding, port site recurrence and bowel injury as potential risks. They agreed that training was crucial and that the procedure should be performed only by surgeons who have been trained in the technique and have extensive experience in laparoscopic surgery.

### Issues for consideration by IPAC

Many papers on this procedure regard laparoscopic cystectomy with urinary diversion as a difficult procedure. There have been no substantial long-term assessments of the procedure, and no comparative studies or trials. Information is scant even though the procedure was first reported in 1992.

### References

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  - *Recent case series, 9 patients*
2. Carvalho EF, Gill IS. Laparoscopic cystectomy: indications and limitations. *Archivos Espanoles de Urologia* 55(6):721-9, 2002;-Aug.
  - *Recent case series, 11 patients*
3. Denewer A, Kotb S, Hussein O, El-Maadawy M. Laparoscopic assisted cystectomy and lymphadenectomy for bladder cancer: initial experience. *World Journal of Surgery* 1999;23 (6):608-611.
  - *Fairly recent case series, 10 patients*
4. Gupta NP, Gill IS, Fergany A, Nabi G. Laparoscopic radical cystectomy with intracorporeal ileal conduit diversion: five cases with a 2-year follow-up. *BJU International* 2002;90(4):391-396.
  - *Recent case series, some follow-up; 5 patients*
5. Turk I, Davis JW, Deger S, Winkelmann B, Schonberger B, Schellhammer PF, Loening SA. [Laparoscopic radical cystectomy with intracorporeal creation of a continent urinary diversion. Future or present?]. [German]. *Urologe* 2002;41(2):107-112.
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**ANNEX: Studies that met the inclusion criteria but which were not tabulated.**

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