NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic cystectomy

Laparoscopic cystectomy involves removing the bladder using small cuts (also known as 'keyhole surgery'). In women, the bladder is removed through the wall of the vagina. In men, the bladder is removed with the prostate gland, through a small cut in the wall of the abdomen. The tubes that carry urine from the kidneys to the bladder (the ureters) may then be connected to a bag worn outside the body, or parts of the bowel can be used to make an artificial bladder which is drained by a connection to the abdomen wall or to the tube that carries urine out of the body.

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 cystectomy
- Laparoscopic cystoprostatectomy

Specialty societies

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

Description

Indications and current treatment

The main indication for laparoscopic cystectomy is invasive bladder cancer. The most common grading system for bladder cancer uses three grades: grade 1 (low grade), grade 2 (moderate grade) and grade 3 (high grade). The most commonly used staging system is the TNM system (T refers to tumour size, N refers to whether lymph nodes are affected and M refers to metastasis). Stage Ta cancer is a small area of cancer just within the bladder lining. Stage T1 cancer has started to grow into the connective tissue beneath the bladder lining. Stage T2 cancer has started to grow into the muscle of the bladder wall under the connective tissue layer. Stage T3a cancer has grown through the whole layer of muscle in the bladder. Stage T3b cancer has grown through the muscle layer into the fat layer beneath. Stage T4 cancer has spread outside the bladder to the prostate, vagina or other organs in the pelvic area. Invasive bladder cancer refers to stages T2 and T3. Stage T4 is known as locally advanced bladder cancer.

The treatment for bladder cancer depends on the type of cancer, the stage and the grade. Invasive bladder cancer is usually treated with surgery or radiotherapy. Surgery involves removal of all or part of the bladder through an incision in the abdomen (open cystectomy).

Radical cystectomy requires a method of urinary diversion, unless this has been established previously as part of a simple cystectomy to defunctionalise the bladder. There are three main 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's experience.

What the procedure involves

Laparoscopic cystectomy is usually performed under general anaesthesia. The abdomen is insufflated with carbon dioxide and a number of small incisions are made to provide access for the laparoscope and surgical instruments. The ureters are isolated, ligated and divided. The vascular pedicles to the bladder are ligated, transected and stapled. In men, the bladder, prostate and seminal vesicles are dissected and removed. After

division of the prostatourethral junction, the specimen is freed and enclosed in a sac. It is retrieved intact without morcellation through an abdominal incision. A similar technique is used for women, but the specimen is extracted transvaginally. According to the tumour burden and stage, the uterus and part of the vagina may need to be taken with the bladder. Sometimes the ovaries are also removed.

Urinary diversion may be performed either intra- or extracorporeally.

Efficacy

Survival

A non-randomised comparative study reported recurrence-free survival of 77% (23/30) for laparoscopic cystectomy compared with 80% (28/35) for open cystectomy (mean follow-up periods were 38 and 46 months, respectively; $p = 0.2$)[1]. A second non-randomised comparative study reported no disease-related deaths in the 20 patients treated with laparoscopic surgery compared with 4.8% (1/21) of patients in the open cystectomy group (mean follow-up was 19 months; p = not significant)[2]. A case series of 84 patients treated with laparoscopic cystectomy reported disease-free survival of 83% (70/84) at mean follow-up of 18 months[3]. A case series of 50 patients treated by robotic assisted laparoscopic cystectomy reported disease specific survival of 94% at mean follow-up of 12 months[12]. A case series of 85 patients treated by laparoscopic cystectomy reported Local recurrence in 4% (3/85) of patients at mean follow-up of 21 months[11].

Analgesia requirement

A non-randomised comparative study of 65 patients reported that mean analgesic requirement was less in the laparoscopic group than in the open cystectomy group (32 versus 65 mg % morphine equivalent; $p = 0.001$)[1]. A second non-randomised comparative study of 42 patients reported that mean non-opioid analgesic (tramadol) requirement was 2.2 vials/day in the laparoscopic group compared with 3.9 in the open cystectomy group ($p < 0.05$)[2].

Hospital stay

Three non-randomised comparative studies of 44, 54 and 37 patients reported significantly shorter hospital stays for patients treated with laparoscopic cystectomy compared with those treated with open cystectomy (4, 5 and 8 days versus 5, 8 and 10 days, respectively; p = 0.007, 0.007 and 0.04)[5,4,6]. Two non-randomised comparative studies of 65 and 42 patients reported similar mean hospital stays for both laparoscopic and open procedures (9 versus 12 days, p = 0.22; and 18 versus 20 days, p = not significant [actual p value not given], respectively)[1,2].

Safety

Conversion to open surgery

Conversion to open surgery was reported for 0% (0/84), 2% (2/83), 3% (1/33) and 5% (1/20) of patients in five studies[3,7,4,2,10].

Intraoperative blood loss

Four non-randomised comparative studies of 65, 54, 44 and 37 patients reported significantly lower blood loss with laparoscopic cystectomy compared with open cystectomy (414, 400, 313 and 500 ml versus 825, 750, 588 and 1250 ml, respectively; p = 0.001, 0.002, <0.001 and 0.0002, respectively)[1,4-6]. A non-randomised comparative study of 42 patients reported similar blood loss in the two groups (520 ml for laparoscopic cystectomy versus 770 ml for open cystectomy; p = not significant)[2]. A non-randomised comparative study of 17 patients treated with an entirely laparoscopic approach (including urinary diversion) and 37 patients treated with an open-assisted laparoscopic approach reported significantly greater blood loss in the purely laparoscopic group of patients (788 versus 378 ml; p = 0.0002)[8]. A case series of 54 patients reported an estimated mean blood loss of 450 ml in 19 patients with two-dimensional tumours and 615 ml in 35 patients with three-dimensional (bulky) tumours[10].

Intraoperative and postoperative complications

Four studies reported rates of fistulae of 1% (1/83), 2% (2/84), 3% (1/33) and 8% (1/13)[7,3,4,6]. Two studies of 20 and 30 patients each reported one patient with rectal injury (5% and 3%, respectively)[5,1]. Other complications included percutaneous drainage of abscess (3% [1/33]), abdominal abscess (8% [1/13]), injury to artery (1% [1/84]), atrium rupture (not further defined) (1% [1/83]), urinary leakage (1% [1/83]), urinary tract infection (10% [8/84]) and haematoma (4% [3/84]). A case series of 85 patients treated by laparoscopic cystectomy reported trocar site seeding in 1% (1/85) of patients at a mean follow up of 21 months[11].

A case series of 50 patients treated by robotic assisted laparoscopic cystectomy reported stomal hernia in 4% (2/50) of patients at a mean follow up of 13 months[12].

A non-randomised study of 54 patients comparing a ‘pure’ laparoscopic approach (including urinary diversion) with an open-assisted laparoscopic approach reported a significantly higher rate of major complications during hospitalisation for the ‘pure’ laparoscopic group[8]. In the ‘pure’ laparoscopic group, 29% (5/17) of patients developed sepsis because of bowel and/or urine leakage. One patient died postoperatively of multisystem organ failure.

The case series of 54 patients reported unilateral or bilateral hydronephrosis in 18 patients (denominators not specified)[9].

A case report of port site metastasis 10 months after laparoscopic cystectomy was identified[9]. The patient was reported as having a high-grade high-stage transitional cell carcinoma. A second case report described injury to right external iliac artery during pelvic lymph node dissection which was repaired laparoscopically[13].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic cystectomy. Searches were conducted of the following databases, covering the period from their commencement to 14/02/2008: 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 invasive bladder carcinoma or permanent incontinence due to paraplegia, patients in whom catheterisation results in infection and unacceptable leakage or patients with refractory complications in a non-functioning bladder, when urinary diversion is already established.
Intervention/test	Laparoscopic cystectomy.
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 719 patients from six non-randomised comparative studies, five case series and two case report.

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 cystectomy. NICE interventional procedures guidance 26 (2003). Available from www.nice.org.uk/IPG026

Cancer service guidance

- Improving outcomes in urological cancers. NICE guidance on cancer services (2002). Available from www.nice.org.uk/nicemedia/pdf/Urological_Manual.pdf

Technology appraisals

- None

Clinical guidelines

- None

Public health guidance

- None

Table 2 Summary of key efficacy and safety findings on laparoscopic cystectomy

Abbreviations used: ASA, American Society of Anaesthesiologists

Study details	Key efficacy findings	Key safety findings	Comments
Hemal A (2007)[1] Study type: **non-randomised comparative study** Country: India Study period: Jun 1999–Dec 2005 Study population: patients with organ confined bladder cancer n = **65** (35 open radical cystectomy, 30 laparoscopic radical cystectomy) Mean age (years): • open = 58.9 (range 30–82) • laparoscopic = 58.2 (range 35–78) Sex (% males): • open = 94% (33/35) • laparoscopic = 93% (28/30) Inclusion criteria: organ-confined bladder cancer; tumour stage T2 or greater, or high-grade T1 cancer refractory to transurethral resection, intravesical immunotherapy and/or chemotherapy Technique: reconstructive step (ileal diversion) was performed extracorporeally. Mean follow-up (months): • **open = 46 (range 14–96)** • **laparoscopic = 38 (range 15–54)** Conflict of interest: not stated	**Surgical margins positive for bladder cancer:** • open = 2.9% (1/35) • laparoscopic = 3.3% (1/30), p = 0.20 **Mean number of lymph nodes removed (range):** • open = 14 (8–21) • laparoscopic = 12 (7–19), p = 0.41 **Recurrence-free survival at follow-up:** • open = 80% (28/35) • laparoscopic = 77% (23/30), p = 0.20 **Local recurrence:** • open = 2.9% (1/35) • laparoscopic = 0% (0/30), p = 0.20 **Metastasis:** • open = 5.7% (2/35) • laparoscopic = 10% (3/30), p = 0.32 **Deaths:** • open = 11.4% (4/35) • laparoscopic = 13.3% (4/30), p = 0.82 **Mean operative time (min):** • open = 265 • laparoscopic = 305, p = 0.02 **Mean analgesic requirement (mg % morphine equivalents):** • open = 65 • laparoscopic = 32, p = 0.001 **Mean time to oral intake (days):** • open = 5.1 • laparoscopic = 3.7, p = 0.06 **Mean hospital stay (days):** • open = 11.8 • laparoscopic = 9.2, p = 0.22 **Mean return to normal activity (days):** • open = 25 • laparoscopic = 21, p = 0.06	**Mean blood loss (ml):** • open = 825 • laparoscopic = 414, p = 0.001 **Transfusion requirement:** • open = 80.0% • laparoscopic = 46.7%, p = 0.015 ***'Major' complications*** **Rectal injury:** • open = 2.9% (1/35) • laparoscopic = 3.3% (1/30) **Bleeding:** • open = 2.9% (1/35) • laparoscopic = 3.3% (1/30) **Chest infection:** • open = 2.9% (1/35) • laparoscopic = 0% (0/30) **Wound dehiscence:** • open = 2.9% (1/35) • laparoscopic = 0% (0/30) **Total major complications:** • open = 11.4% (4/35) • laparoscopic = 6.7% (2/30), p = 0.32 ***'Minor' complications*** **Deep vein thrombosis:** • open = 5.7% (2/35) • laparoscopic = 3.3% (1/30) **Ileus:** • open = 8.6% (3/35) • laparoscopic = 3.3% (1/30) **Pyelonephritis:** • open = 2.9% (1/35) • laparoscopic = 3.3% (1/30) **Obturator nerve paresis:** • open = 0% (0/35) • laparoscopic = 3.3% (1/30) **Total minor complications:** • open = 17.1% (6/35) • laparoscopic = 13.3% (4/30), p = 0.20	The open surgery cohort included prospective and retrospective groups The choice of technique was made by the surgeon The first 10 patients treated by the laparoscopic approach were considered part of the learning curve and were not included in the study The two groups were comparable in terms of age, sex, body mass index, ASA score, number of preoperative transurethral resections and preoperative haemoglobin

Abbreviations used: ASA, American Society of Anaesthesiologists			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Porpiglia F (2007)[2] Study type: **non-randomised comparative study** Country: Italy Study period: Nov 2002–Dec 2005 Study population: patients with muscle-invasive bladder cancer n = **42** (22 open radical cystectomy, 20 laparoscopy-assisted radical cystectomy) Mean age (years): • open = 71 (range 60–82) • laparoscopic = 63.5 (range 42–78) Sex (% males): • open = 91% (20/22) • laparoscopic = 95% (19/20) Inclusion criteria: muscle-invasive bladder cancer without clinical evidence of lymph node involvement and ASA score ≤ 4 Technique: transperitoneal approach for laparoscopy; reconstructive step (neobladder or ileal diversion) was performed extracorporeally Mean follow-up (months): • **open = 19.2 (range 3–39)** • **laparoscopic = 19.5 (range 3–37)** Conflict of interest: not stated	Pathological examination showed clear surgical margins in all patients **Mean number of lymph nodes removed (range):** • open = 18.4 (13–24) • laparoscopic = 19.6 (14–25) p = not significant **Lymph node progression:** • open = 19% (4/21) • laparoscopic = 10% (2/20) p = not significant **Death linked to disease:** • open = 4.8% (1/21) • laparoscopic = 0% (0/20) p = not significant **Mean intraoperative time (min):** • open = 260 • laparoscopic = 284 p = not significant **Mean start of oral nutrition (days):** • open = 5.7 • laparoscopic = 3.3 p < 0.05 **Mean analgesic consumption (vials/day):** • open = 3.9 • laparoscopic = 2.2 p < 0.05 **Mean hospital stay (days):** • open = 19.7 • laparoscopic = 18.1 p = not significant	Conversion to open surgery = 5% (1/20) No intraoperative complications were observed in either group. **Mean blood loss (ml):** • open = 770 • laparoscopic = 520 p = not significant	Prospective data collection Each patient was offered the choice of technique The two groups were demographically comparable One patient in the open surgery group was lost to follow-up

Abbreviations used: ASA, American Society of Anaesthesiologists

Study details	Key efficacy findings	Key safety findings	Comments
Wang G (2007)[4] Study type: **non-randomised comparative study** Country: USA Study period: Feb 2006–Apr 2007 Study population: patients with bladder cancer n = **54** (21 open radical cystectomy, 33 laparoscopic robotic radical cystectomy) Median age (years): • open = 66 (range 37–88) • robotic = 70 (range 41–84) Sex (% males): • open = 62% (13/21) • robotic = 88% (29/33) p = 0.03 Muscle invasive disease (≥T2): • open = 71%(15/21) • robotic = 48% (16/33) p = 0.06 Inclusion criteria: not stated Technique: urinary diversion was performed extracorporeally (ileal conduit, Indiana pouch or orthotopic neobladder). Da Vinci robotic system used (Intuitive Surgical) Mean follow-up: not stated Conflict of interest: none stated	**Positive surgical margins:** • open = 14.3% (3/21) • robotic = 6.3% (2/32), p = 0.2 **Median number of lymph nodes removed:** • open = 20 • robotic = 17, p = 0.6 **Organ-confined disease (≤pT2):** • open = 42.9% (9/21) • robotic = 71.9% (23/32), p = 0.03 **Median operative time (min):** • open = 300 (range 165–540) • robotic = 390 (range 210–570), p = 0.03 **Median time to regular diet (days):** • open = 5 (range 4–8) • robotic = 4 (range 3–6), p = 0.002 **Median hospital stay (days):** • open = 8 (range 5–28) • robotic = 5 (range 4–18), p = 0.007	Conversion to open surgery = 3% (1/33) **Median estimated blood loss (ml):** • open = 750 • robotic = 400, p = 0.002 **Median transfusion requirement (units):** • open = 2 (range 0–7) • robotic = 0.5 (range 0–3), p = 0.007 ***'Major' complications*** **Percutaneous drainage of abscess:** • open = 4.8% (1/21) • robotic = 3.0% (1/33) **Wound dehiscence:** • open = 4.8% (1/21) • robotic = 0% (0/33) **Enterocutaneous fistula:** • open = 0% (0/21) • robotic = 3.0% (1/33) **Respiratory failure requiring reintubation on postoperative day 5:** • open = 4.8% (1/21) • robotic = 0% (0/33) **Myocardial infarction:** • open = 4.8% (1/21) • robotic = 0% (0/33) ***'Minor' complications*** **Prolonged ileus (resolved with conservative management):** • open = 4.8% (1/21) • robotic = 12.1% (4/33)	Prospective data collection The reason for choice of technique was not stated The two groups were comparable in terms of age, body mass index, ASA score, and history of previous abdominal surgery or radiation. There were more men (p = 0.03) and a trend towards more non-muscle invasive disease (p = 0.06) in the robotic cohort One conversion to open surgery was excluded from further analysis

Abbreviations used: ASA, American Society of Anaesthesiologists			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Pruthi R (2007)[5] Study type: **non-randomised comparative study** Country: USA Study period: Jan 2006–Oct 2006 Study population: men with clinically localized urothelial carcinoma of the bladder n = **44** (24 open radical cystoprostatectomy, 20 robotic-assisted laparoscopic radical cystoprostatectomy) Mean age (years): • open = 68.2 (range 51–58) • robotic = 62.3 (range 54–76), p = 0.028 Nerve sparing procedure: • open = 29% (7/24) • robotic = 85% (17/20) Inclusion criteria: not stated Technique: urinary diversion was performed extracorporeally (ileal conduit or neobladder). Da Vinci robotic system used for cystoprostatectomy and bilateral pelvic lymph node dissection portions of the procedure and for pre-placing urethral anastomotic stitches in orthotopic neobladder cases Mean follow-up: not stated Conflict of interest: not stated	**Positive surgical margins:** • open = 4.2% (1/24) • robotic = 0% (0/20) **Mean number of lymph nodes removed (range):** • open = 16 (7–25) • robotic = 19 (6–29) **Pathological stage T2N0 or less:** • open = 50.0% (12/24) • robotic = 70.0% (14/20) **Mean operative time (hours) overall:** • open = 3.7 (range 2.6–5.0) • robotic = 6.1 (range 4.3–7.2), p < 0.001 **Mean operative time (hours) in most recent 10 cases:** • open = 3.8 • robotic = 5.2, p = 0.003 **Mean time to bowel movement (days):** • open = 3.8 • robotic = 2.8, p < 0.001 **Mean hospital stay (days):** • open = 5.3 • robotic = 4.4, p = 0.007	**Mean estimated blood loss (ml):** • open = 588 (range 200–1100) • robotic = 313 (range 100–700) p < 0.001 **Bladder perforation:** • open = 4.2% (1/24) • robotic = 0% (0/20) **Complication rate for laparoscopic robotic procedure = 30% (6/20):** • postoperative bleeding • rehospitalisation for nausea/vomiting • deep venous thrombosis • peristomal omental herniation • rectal injury • delirium tremens (the paper did not discuss the complication rate in the open surgery group)	Retrospective data collection The reason for choice of technique was not stated. The authors note that patients selected to undergo the robotic procedure tended to have better performance status and lower comorbidities than those in the open group (reflected by the lower mean age of the robotic group). Both groups of patients underwent the procedure during the same study period The authors state that the robotic cystectomy series reported represents the initial experience with the procedure No long-term follow-up

Abbreviations used: ASA, American Society of Anaesthesiologists

Study details	Key efficacy findings	Key safety findings	Comments
Galich A (2006)[6] Study type: **non-randomised comparative study** Country: USA Study period: not stated Study population: patients undergoing radical cystectomy for malignancy (33 transitional cell carcinoma, 2 rectal adenocarcinoma, 1 prostate adenocarcinoma, 1 leiomyosarcoma) n = **37** (24 open radical cystectomy, 13 robotic laparoscopic radical cystectomy) Median age (years): • open = 70.5 (range 27–86) • robotic = 70 (range 38–88) Sex (% males): • open = 75% (18/24) • robotic = 77% (10/13) Organ-confined disease (≤pT2): • open = 37.5% (9/24) • robotic = 53.8% (7/13) p = 0.49 Exclusion criteria for robotic group: morbid obesity, prior pelvic radiation or significant medical comorbidities, including pulmonary obstructive airway disease Technique: all urinary diversions were performed extracorporeally in the robotic group (ileal conduit, ileal neobladders, Indiana pouch). Da Vinci Surgical Robotic System was used. Mean follow-up: not stated Conflict of interest: none	**Positive surgical margins:** • open = 12.5% (3/24) • robotic = 0% (0/13) p = 0.54 **Median operative time (minutes):** • open = 395 (range 300–664) • robotic = 697 (range 240–828) p = 0.0002 **Median hospital stay (days):** • open = 10 (range 6–35) • laparoscopic = 8 (range 4–23) p = 0.044	**Median estimated blood loss (ml):** • open = 1250 (range 300–10,200) • robotic = 500 (range 100–1000) p = 0.0002 **Blood transfusion rate:** • open = 75% (18/24) • robotic = 53.8% (7/13) p = 0.27 **Perioperative complication rate:** • open = 16.7% (4/24) • robotic = 15.4% (2/13) p = 1.00 **Wound dehiscence:** • open = 4.2% (1/24) • robotic = 0% (0/13) **Myocardial infarction:** • open = 8.3% (2/24) • robotic = 0% (0/13) **Pneumonia:** • open = 4.2% (1/24) • robotic = 0% (0/13) **Enterovesical fistula, small bowel obstruction:** • open = 0% (0/24) • robotic = 7.7% (1/13) **Abdominal abscess:** • open = 0% (0/24) • robotic = 7.7% (1/13) One perioperative death caused by central venous line sepsis occurred in the open group	Consecutive patients undergoing radical cystectomy over the same time period by a single surgeon There may be some selection bias in that morbidly obese patients were not offered robotic cystectomy as a treatment option No long-term follow-up

Abbreviations used: ASA, American Society of Anaesthesiologists			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Haber G-P (2007)[8] Study type: **non-randomised comparative study** Country: USA Study period: December 1999–March 2006 Study population: patients with bladder cancer n = **54** (17 'pure laparoscopic' radical cystectomy, 37 open-assisted laparoscopic radical cystectomy) Mean age (years): 65 (range 26–87) Sex (% males): 68.5% (37/54) (paper does not state percentage for each group) 35 patients had muscle-invasive bladder cancer, 19 had recurrent high-risk, non-muscle-invasive bladder cancer 85% of patients had an ASA score of 2 or more Inclusion criteria: not stated Technique: urinary diversions were performed extracorporeally in the open-assisted laparoscopic group (ileal conduit or orthotopic neobladder). An intracorporeal approach was used in the pure laparoscopic group Mean follow-up (months): • **pure laparoscopic = 28** • **open-assisted laparoscopic = 23** Conflict of interest: not stated	**Operative time (hours):** • pure laparoscopic = 9.4 • open-assisted laparoscopic = 6.3 p < 0.0001 **Time to oral intake (days):** • pure laparoscopic = 6 • open-assisted laparoscopic = 3 p = 0.005 **Time to ambulation (days):** • pure laparoscopic = 7.8 • open-assisted laparoscopic = 2.4 p < 0.0001	**Blood loss (ml):** • pure laparoscopic = 788 • open-assisted laparoscopic = 378 p = 0.0002 **Blood transfusion rate:** • pure laparoscopic = 23% • open-assisted laparoscopic = 3% p = 0.01 **'Major' complications during hospitalization (defined as the need for open repeat surgery):** • pure laparoscopic = 29% (5/17) (all patients had sepsis because of bowel and/or urine leakage; one patient died postoperatively of multisystem organ failure) • open-assisted laparoscopic = 11% (4/37) (one patient developed urinary extravasation and the other three patients had partial small bowel obstruction) p = 0.08 **'Major' complications after discharge:** • pure laparoscopic = 6% (1/17) (vaginal fistula treated with neobladder repair and interposition grafting) • open-assisted laparoscopic = 11% (4/37) (two small bowel obstructions, one ureteral stenosis and one vaginal fistula treated with conversion to ileal conduit) p = 0.56	There were no significant differences between the two groups in terms of age, comorbidities or pathological stage of malignancy The authors note that all the major complications were related to the urinary diversion. They have abandoned the pure laparoscopic approach because of the high major morbidity rate The pure laparoscopic procedures in the series were the initial such procedures performed

Cathelineau X (2005)[3] Study type: **case series** Country: France Study period: May 2001–Feb 2005 Study population: patients with transitional cell carcinoma of the bladder n = **84** Median age (years): 61 (range 36–79) Sex (% males): 84.5% (71/84) TNM stage: • pTa-1 = 16% (13/84) • pT2 = 70% (59/84) • pT3 = 13% (11/84) • pT4 = 1% (1/84) ASA classification: • class 1 = 25% (21/84) • class 2 = 58% (49/84) • class 3 = 14% (10/84) • class 4 = 3% (2/84) 38% (32/84) of patients had significant history of open or laparoscopic abdominal/pelvic surgery Inclusion criteria: not stated Technique: creation of ileal conduit or neo-bladder was done extracorporeally Mean follow-up (months): **18 (range 1–44)** Conflict of interest: none stated	Positive surgical margins = 0% (0/84) At mean follow-up of 18 months, there were no cases of trocar site or abdominal incision seeding Disease-free survival = 83% (70/84) Overall survival = 100% (84/84) Pelvic recurrence = 2.4% (2/84) Metastatic disease = 9.5% (8/84) Local recurrence and metastatic disease = 3.6% (3/84) Median operative time (minutes) = 280 (range 215–330) Median hospital stay (days) = 12 (range 8–31)	Conversion to open surgery = 0% (0/84) Median blood loss (ml) = 550 (range 150–2000) Blood transfusion rate = 5% **Intraoperative complications:** • injury to right epigastric artery = 1.2% (1/84) **Postoperative complications:** • urinary tract infection = 9.5% (8/84) • haematoma = 3.6% (3/84) • urinary fistulae = 2.4% (2/84) • pulmonary embolism = 1.2% (1/84) • pyelonephritis = 1.2% (1/84) • wound dehiscence = 0% (0/84) • wound abscess = 0% (0/84) • death = 0% (0/84)	The authors note that laparoscopic enteroplasty and laparoscopic cutaneous urinary diversion have been abandoned by the centre after two complications of leakage at the site of the intestinal re-anastomosis in an irradiated or tuberculous bladder. They note that the major role of laparoscopy in radical cystectomy is bladder removal without a significant incision or overstretching tissues with a retractor

Sighinolfi MC (2007)[7] Study type: **case series** Country: Italy Study period: November 2004 Study population: patients with muscle-invasive bladder cancer n = **83** Median age (years): not stated Sex (% males): not stated Inclusion criteria: not stated Technique: urinary diversion was done extracorporeally. Mean follow-up (months): **9 (range 1–36)** Conflict of interest: none stated	No tumour seeding was identified in any patient Disease progression = 8.4% (7/83) Deaths = 19.3% (16/83) Mean operative time (minutes) = 520 (range 264–760) Mean hospital stay (days) = 13.2 (range 8–19)	Conversion to open surgery = 2.4% (2/83) Mean blood loss (ml) = 376 (range 200–600) Blood transfusion rate = 6.0% (5/83) **Postoperative complications:** • urinary leakage = 1.2% (1/83) • fistula = 1.2% (1/83) • atrium rupture = 1.2% (1/83) (no description given in paper)	Questionnaire survey of 10 centres with experts in laparoscopic surgery. Of the 10 centres contacted, five chose to participate Follow-up period varied between study centres

Yuh (2008)[10] Study type: **case series** Country: USA Study period: Nov 2007– July 2007 Study population: patients with muscle-invasive bladder cancer or high-grade T1 bladder cancer n = **54** Median age (years): 67 Sex (% males): 76% (41/54) 19 tumours were classified as two dimensional (2D or flat) and 35 as three dimensional (3D or bulky) TNM stage (2D): • pT0-T2 = 63% (12/16) • p T3-T4 = 37% (7/16) TNM stage (3D): • pT0-T2 = 34% (12/25) • p T3-T4 = 66% (23/25) Mean ASA score: • 2D = 2.2 • 3D = 2.4 Inclusion criteria: consecutive patients recruited to Roswell Park Cancer Institute (Buffalo, NY) Technique: robot-assisted radical cystectomy Mean follow-up (months): **not stated** Conflict of interest: none	**Positive surgical margins:** 2D group: 19 (0%) 3D group: 7 (30%) (p = 0.154) (denominators not explicitly stated) **Mean lymph nodes removed:** 2D: 20 3D: 15 (p = 0.298) **Mean operative duration from incision to completion of cystectomy:** 2D: 161 min 3D: 187 min (p = 0.077) **Median hospital stay** = 9.1 days	**Conversion to open surgery:** This was required in 2 (6%) in the 3D group (denominator not specified). One patient was unable to tolerate the Trendelenburg position; the second patient had a tumour that invaded the rectum. **Estimated mean blood loss:** 2D: 450 ml 3D: 615 ml (p = 0.263) Transfusion was required in 20% (7/25) patients in the 3D group and no patients in the 2D group. **Detected hydronephrosis upon assessment**: 2D: 16% (3/16) 3D: 43% (15/25)	The study reported differences between those classified by two dimensional and three dimensional tumours. The authors evaluated hydronephrosis and staging by CT urogram.

<table>
<tr>
<td>Huang J (2008)[11]

Study type: case series

Country: China

Study period: Dec 2002 to May 2006

Study population: bladder cancer. T1 n=5, T2a n=40, T2b n=13, T3b n=26, T4a n=1, Tis associated n=3.

n = 85

Median age 62 (years):
Sex 91% males:

Inclusion criteria: not reported

Technique: laparoscopic radical cystectomy

Mean follow-up: 21 months

Conflict of interest: none</td>
<td>Surgical parameters
There was no conversion to open surgery.
Median operative time 320 mins (range 210 to 605 mins).
Median blood loss 280ml (range 50 to 1000ml). 23.5% of patients required blood transfusion (absolute numbers not repored).

Urinary function
Day time and night time urinary continence was achieved in 91% (62/68) and 82% (56/68) of patients at 6 months follow up.

Survival.
Local recurrence occurred in 4% (3/85) of patients.
Distance metastases occurred in 6% (5/85) of patients.

Of the 40 patients with 2 years follow up overall survival was 90% (36/40) and recurrence free survival was 85% (34/40)</td>
<td>Complications
There was no perioperative mortality.

<table>
<tr><th>Outcome</th><th>Rate</th></tr>
<tr><td>Trocar site seeding</td><td>1% (1/85)</td></tr>
<tr><td>Uretero-pouch anastomotic stricture</td><td>4% (3/85)</td></tr>
<tr><td>Vesicourethral anastomotic stricture</td><td>1% (1/85)</td></tr>
<tr><td>Pouch-vaginal fistula</td><td>1% (1/85)</td></tr>
<tr><td>Colonic-pouch fistula</td><td>1% (1/85)</td></tr>
<tr><td>Ioleo-pouch fistula</td><td>1% (1/85)</td></tr>
<tr><td>Pneumonia</td><td>1% (1/85)</td></tr>
<tr><td>Plelonephiritis</td><td>1% (1/85)</td></tr>
</table>
</td>
<td>Initial experience with laparoscopic cystectomy at the institution

Method of patient selection for laparoscopic surgery not described</td>
</tr>
</table>

Pruthi (2008)[12] Study type: **case series** Country: USA Study period: Jan 2006 to Dec 2007 Study population: bladder cancer. cT1 or less n=12, cT2 n=37, cT4 n=1. n = **50** Median age 64 (years): Sex: 80% males Inclusion criteria: not reported Technique: robot-assisted radical cystectomy Mean follow-up (months): **13.2 months** Conflict of interest: not reported	**Surgical parameters** No positive surgical margins. **Survival.** Mean lymph nodes removed: 19 (range 8-37) Recurrence in 14% (7/50) of patients – 6% (3/50) of patients died from urothelial carcinoma and 4% (2/50) died of other causes. Disease specific survival 94%.	**Complications** Stomal hernia in 4% (2/50) of patients, partial ureteral obstruction in 2% (1/50) of patient.	Retrospecitve database review Initial experience with robot assisted laparoscopic cystectomy at the institution Patient selection for open or robotic surgery made at surgeons' discretion determined by overall health status Timing of adjuvant chemotherapy determined by patient performance status.

El-Tabey N (2005)[9] Study type: **case report** Country: Egypt Study period: not stated Study population: 52-year-old male patient with transitional cell carcinoma of the bladder n = **1** Pathological grade: pT3bN0 Inclusion criteria: not stated Technique: robot-assisted laparoscopic technique was used. Specimen was entrapped in a sac and retrieved intact without morcellation. The extraction incision was used for exteriorisation of part of the bowel and an ileal-W orthotopic neobladder was created. Da Vinci surgical system used (Intuitive Surgical) Follow-up: **10 months** Conflict of interest: none stated		**Port site metastasis** 10 months after cystectomy, the patient presented with a small, well-circumscribed, hard, 4 × 4 cm mass at the anterior abdominal wall at the site of the port at the left midclavicular line Needle biopsy from the mass showed evidence of high-grade (grade 3) transitional cell carcinoma. The patient was given only palliative analgesics because he refused the options of local excision with adjuvant radiotherapy and/or chemotherapy	The authors state that to the best of their knowledge, this is the first report of port site metastasis Case 12 in a series of 17 (study listed in appendix A: Menon et al. 2003) The authors note that this was a high-stage, high-grade transitional cell carcinoma, which is a pathology well known for its seeding potential

Castillo (2008)[13] Study type: **case report** Country: Chile Study period: not reported Study population: bladder carcinoma with previous endoscopic resection and radiotherapy. Male 100%, Age 29 years. n = **1** Inclusion criteria: not reported Technique: laparoscopic radical cystoprostatectomy with complete bilateral lymphadenectomy. Follow-up: **every 6 months (total not stated)** Conflict of interest: Not reported		**Complications** injury to right external iliac artery during pelvic lymph node dissection before laparoscopic radical cystoprostatectomy. A 1cm tear inadvertently produced caused by heat from the ligasure device. Bleeding controlled by a grasper. Laparoscopic repair using regular open surgery bulldog clamps placed proximal and distal to the tear. Prolene patch repair with two figure of 8 sutures. Cystoprostatectomy carries out without incident.	The denominator number of cases undertaken at the institution is not reported.

Validity and generalisability of the studies

- None of the comparative studies randomised patients to each study group and there may be some selection bias.
- A range of techniques was used for urinary diversion. Only one study used an intracorporeal approach. The operative time is likely to depend on the type of urinary diversion used.
- Two studies state that they have abandoned the total laparoscopic approach because of the high complication rates; they now perform all urinary diversions extracorporeally.
- Two studies noted that the patients in the laparoscopic group were the initial patients to be treated with such a procedure. A third study specifically excluded the first 10 patients to be treated as they were considered to be part of the learning curve.
- Some of the studies used robotic assistance for the laparoscopic procedures.
- One non-randomised comparative study stated that patients had tumour stage T2 or greater or high-grade T1 cancer refractory to transurethral resection, intravesical immunotherapy and/or chemotherapy[1].
- Some studies included patients with non-muscle-invasive bladder cancer, who are likely to have a more favourable outcome with regard to survival than patients with more advanced disease.

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 J Hammonds, Mr F Keeley, Professor T McNicholas, Mr A Timoney (British Association of Urological Surgeons, BAUS).

- One Specialist Adviser considered the procedure to be definitely novel and of uncertain safety and efficacy, and two considered it to be a minor variation of an existing procedure.
- Theoretical adverse events include difficulty controlling haemorrhage, bowel injury, bowel obstruction, laparoscopic technique may not allow as radical an excision as

open surgery, particularly for lymph nodes, inadequate cancer clearance, port site metastasis, loss of tactile sensation to assess disease intraoperatively and prolonged operative time.

- Anecdotal adverse events include long operating times, conversion to open surgery, bowel fistula, peritonitis.
- Key efficacy outcomes include positive margin rates, mortality, blood loss, blood transfusion rates, time to discharge, analgesic requirements, extent of lymph node dissection, time to return to full activity, 5-year survival (cancer specific).
- High-level laparoscopic training is required. There are BAUS guidelines on training required for laparoscopic procedures.
- The procedure has not been performed for long enough or in sufficient numbers to be able to evaluate the incidence of metastasis or local recurrence of cancer.
- BAUS has a register for both open and laparoscopic cystectomies.
- The procedure should only be performed in major cancer centres and with the involvement of a multidisciplinary team.

Issues for consideration by IPAC

- None other than those listed above.

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1. Hemal AK, Kolla SB (2007) Comparison of laparoscopic and open radical cystoprostatectomy for localized bladder cancer with 3-year oncological followup: a single surgeon experience. Journal of Urology 178:2340–3.

2. Porpiglia F, Renard J, Billia M et al. (2007) Open versus laparoscopy-assisted radical cystectomy: results of a prospective study. Journal of Endourology 21;325–9.

3. Cathelineau X, Arroyo C, Rozet F et al. (2005) Laparoscopic assisted radical cystectomy: the Montsouris experience after 84 cases. European Urology 47:780–4.

4. Wang GJ, Barocas DA, Raman JD et al. (2007) Robotic vs open radical cystectomy: prospective comparison of perioperative outcomes and pathological measures of early oncological efficacy. BJU International 101:89–93.

5. Pruthi RS, Wallen EM (2007) Robotic assisted laparoscopic radical cystoprostatectomy: operative and pathological outcomes. Journal of Urology 178:814–8.

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7. Sighinolfi MC, Micali S, Celia A et al. (2007) Laparoscopic radical cystectomy: an Italian survey. Surgical Endoscopy 21:1308–11.

8. Haber G-P, Campbell SC, Colombo JR et al. (2007) Perioperative outcomes with laparoscopic radical cystectomy: 'pure laparoscopic' and 'open-assisted laparoscopic' approaches. Urology 70:910–5.

9. El-Tabey NA, Shoma AM (2005) Port site metastasis after robot-assisted laparoscopic radical cystectomy. Urology 66:1110.e1–e3.

10. Yuh B, Padalino J., Butt Z.M. et al. (2008) Impact of tumour volume on surgical and pathological outcomes after robot-assisted radical cystectomy. BJU International 102 (7): 840-843.

11. Huang J, Lin T., Xu K. et al. (2008) Laparoscopic radical cystectomy with orthotopic ileal neobladder: a report of 85 cases. Journal of Endourology 22 (5): 939-946.

12. Pruthi RS,Wallen E.M. (2008) Is Robotic Radical Cystectomy an Appropriate Treatment for Bladder Cancer? Short-Term Oncologic and Clinical Follow-Up in 50 Consecutive Patients. Urology 72 (3): 617-620.

13. Castillo OA, Peacock L., Vitagliano G. et al. (2008) Laparoscopic repair of an iliac artery injury during radical cystoprostatectomy. Surgical Laparoscopy, Endoscopy & Percutaneous Techniques 18 (3): 315-318.

Appendix A: Additional papers on laparoscopic cystectomy

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
Abraham JB, Young JL, Box GN et al. (2007) Comparative analysis of laparoscopic and robot-assisted radical cystectomy with ileal conduit urinary diversion. Journal of Endourology 21:1473–80	Non-randomised comparative study n = 34	Robot-assisted approach appeared to have shorter learning curve, with less blood loss, fewer postoperative complications and earlier return of bowel function than laparoscopic approach	Larger comparative studies are included
Arroyo C, Andrews H, Rozet F et al. (2005) Laparoscopic prostate-sparing radical cystectomy: the Montsouris technique and preliminary results. Journal of Endourology 19:424–8	Case series n = 25 Follow-up = 9 months	Prostate-sparing radical cystectomy Complications: 1 urinary leak, 1 lymphocele, 1 port-site hernia Two metastases and one local recurrence (at 6 months)	Larger case series with longer follow-up are included
Basillote JB, Abdelshehid C, Ahlering TE (2004) Laparoscopic assisted radical cystectomy with ileal neobladder: a comparison with the open approach. Journal of Urology 172:489–93	Non-randomised comparative study n = 24	No significant differences between laparoscopic and open approach with regard to operative time, blood loss and complication rates Postoperative analgesic use was significantly less and length of hospital stay was shorter for laparoscopic group	Larger comparative studies are included
Butt ZM, Perlmutter A.E., Piacente P.M. et al. (2008) Impact of body mass index on robot-assisted radical cystectomy. Journal of the Society of Laparoendoscopic Surgeons 12 (3): 241-245.	Case series N = 51 Follow-up not stated	Positive margins in 12% (6/49) Mean operative time: 180 min Mean blood loss: 546.4 ml Postoperative complications in 27% (13/49) of patients including death (1), myocardial infarction (1), dysrhythmia (1), pulmonary embolism/DVT (2), renal failure (1), hemorrhage (2), sepsis (2). (results presented for patients categorised by their BMI)	Appendix A Complications have been reported in table 2 [This study may include patients in the Guru study of 67 patients and Yuh study of 54 patients (recruited during a similar time period at the same centre).]
Cansino JR (2006) Laparoscopic radical cystectomy: initial series and analysis of results. European Urology, Supplements 5:956–61	Case series n = 35	Because of high rate of ureterointestinal stenosis in the first 26 cases, urinary diversion was changed from open to laparoscopic	Larger case series are included

Castillo OA, Abreu SC, Mariano MB et al. (2006) Complications in laparoscopic radical cystectomy. The South American experience with 59 cases. International Brazilian Journal of Urology 32:300–5	Case series n = 59	Mortality = 3% (2/59) (1 upper gastrointestinal bleed, 1 pulmonary embolism) Conversion to open surgery = 2% (1/59) Blood transfusion = 20% (12/59) Surgical reintervention = 5% (3/59) (2 hernias, 1 bowel obstruction)	Larger case series are included

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
DeGer S, Peters R, Roigas J et al. (2004) Laparoscopic radical cystectomy with continent urinary diversion (rectosigmoid pouch) performed completely intracorporeally: an intermediate functional and oncologic analysis. Urology 64:935–9	Case series n = 20 Median follow-up = 33 months	Two patients required reoperation (1 persistent leakage of the pouch, 1 rectovaginal fistula) One patient developed obstruction, resulting in loss of function of right kidney (asymptomatic) No patient developed local recurrence. Three patients developed systemic disease and two of these died of the disease 15 and 24 months after surgery	Larger case series are included
Gao ZL, Fan J, Zhao JJ et al. (2007) Laparoscopic radical cystectomy with extracorporeal ileal conduit urinary diversion for treatment of Chinese bladder cancer patients. Urologia Internationalis 79:204–9	Case series n = 46 Mean follow-up = 6 months	Disease-free survival = 96% Blood transfusion = 4% (2/46) No intraoperative complications Urine leakage = 2% (1/46) Partial small bowel obstruction = 4% (2/46)	Larger case series are included
Guru KA, Kim HL, Piacente PM et al. (2007) Robot-assisted radical cystectomy and pelvic lymph node dissection: initial experience at Roswell Park Cancer Institute. Urology 69:469–74	Case series n = 20	One conversion to open surgery Two ‘major’ complications – small bowel obstructions (one patient developed septic shock and died)	Larger case series are included

Guru KA, Wilding GE, Piacente P et al. (2007) Robot-assisted radical cystectomy versus open radical cystectomy: assessment of postoperative pain. Canadian Journal of Urology 14:3753–6	Non-randomised comparative study n = 40	Patients who underwent robot-assisted radical cystectomy achieved similar pain control but required less opiates than those who underwent open radical cystectomy	Paper focuses on postoperative pain
Guru KA, Sternberg K., Wilding G.E. et al. (2008) The lymph node yield during robot-assisted radical cystectomy. BJU International 102 (2): 231-234.	Case series N = 67 Follow-up not stated	Mean operative duration of lymph node retrieval = 44 min (19-85) Mean lymph nodes removed = 18 (6-43) One reported postoperative 'vascular complication' requiring transfusion and return to operating room.	This complication has been reported in table 2. [May include patients reported in Yuh (2008) and and Butt (2008) (recruited during similar time period at same centre).]
Haber GP, Crouzet S., and Gill I.S. (2008) Laparoscopic and robotic assisted radical cystectomy for bladder cancer: a critical analysis. European Urology 54 (1): 54-62.	Systematic review N = not stated (48 studies included in review) Follow-up not stated	Oncological outcomes comparable to open surgery. Show lower perioperative morbidity.	Papers included either are already included in the overview or are smaller than those included. No new safety issues were identified.
Haber G, Campbell S., Colombo J. et al. (2008) Perioperative outcomes with laparoscopic radical cystectomy: "Pure laparoscopic" and "open-assisted laparoscopic" approaches. Urology 70 (5): 910-915.	Non-randomised comparative N = 54 (17 laparoscopic, 37 open-assisted laparoscopic) Mean follow-up = 25 months	Post-operative complications: 4 patients with urine leak and / or bowel leak 2 patients with small bowel obstruction 3 patients with ileus Late complications: 2 patients with vaginal fistula 1 patient with small bowel obstruction	Larger studies are included in table 2. Complications have been reported in table 2.
Hemal AK, Kolla S.B., and Wadhwa P. (2008) Evaluation of laparoscopic radical cystectomy for loco-regionally advanced bladder cancer. World Journal of Urology 26 (2): 161-166.	Case series N = 13 Follow-up = 18 months	Mean operative time: 310 min. At 18 month follow-up, 7 alive and cancer-free and 2 alive with metastases. Average blood loss 556 ml. No major intraoperative complication but one death in the postoperative sepsis.	Complications have been reported in table 2.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Hemal AK, Kolla SB, Wadhwa P et al. (2008) Laparoscopic radical cystectomy and extracorporeal urinary diversion: a single center experience of 48 cases with three years of follow-up. Urology 71:41–6	Case series n = 48 Mean follow-up = 38 months	Disease-free survival = 73% One conversion to open surgery because of severe hypercarbia Three 'major' complications: 2 rectal injury, 1 vein injury. One patient died in postoperative period of severe lower respiratory tract infection and septicaemia	A comparative study from the same centre is included (Hemal et al, 2007).
Huang J, Xu KW, Yao YS et al. (2005) Laparoscopic radical cystectomy with orthotopic ileal neobladder: report of 33 cases. Chinese Medical Journal 118:27–33	Case series n = 33 Follow-up = 1–21 months	No local recurrence at follow-up Metastasis = 3% (1/33) Postoperative complications = 18% (6/33) (2 pouch leakage, 1 pelvic infection, 2 partial small bowel obstructions, 1 neobladder-vaginal fistula)	Larger case series are included
Lane, B. R., Aron, M., Pritchard, C., Fergany, A. F., and Desai, M. M. (2008) Laparoscopic cystoprostatectomy in a heart transplant recipient. Surgical Laparoscopy, Endoscopy & Percutaneous Techniques 18 (3) 319-321.	Case report N = 1 Follow-up = 2 months	Disease free at 2-month follow-up. Blood loss minimised. No major complications.	Larger studies are included in table 2.

Lin TX, Zhang C.X., Xu K.W. et al. (2008) Laparoscopic radical cystectomy with orthotopic ileal neobladder in the female: report of 14 cases. Chinese Medical Journal 121 (10): 923-926.	Case series N = 14 Follow-up = 30-60 months	Surgical margin tumour free. One patient had bone metastases 11 months after operation and died. Utero-pouch anastomotic stricture and pouch-vaginal fistula each in one patient; occasional day-time urinary incontinence and night-time incontinence in 1 and 2 patients, respectively.	Larger studies are included in table 2. Complications have been reported in table 2.
Lowentritt BH, Castle E.P., Woods M. et al. (2008) Robot-assisted radical cystectomy in women: technique and initial experience. Journal of Endourology 22 (4): 709-712.	Case series N = 20 Follow-up not stated	Median number of lymph nodes removed: 12 (one patient had node-positive disease). Surgical margins were negative in all patients. One conversion to open surgery due to hypercapnia associated with insufflation. Mean operative time: 350 min Mean estimated blood loss: 300 ml No blood transfusions required or major complications reported, but there was a lower extremity deep vein thrombosis requiring anticoagulation in one patient.	Larger studies are included in table 2. [The patients included are from the same unit of those included in the Woods study.]
Menon M, Hemal AK, Tewari A et al. (2003) Nerve-sparing robot-assisted radical cystoprostatectomy and urinary diversion. BJU International 92:232–6	Case series n = 17	All margins of resection were free of tumour Mean blood loss < 150 ml Performing the urinary diversion extracorporeally reduced the operative duration	Larger case series are included
Murphy DG, Challacombe B.J., Elhage O. et al. (2008) Robotic-assisted laparoscopic radical cystectomy with extracorporeal urinary diversion: initial experience. European Urology 54 (3): 570-580.	Case series N = 23 Mean follow-up = 17 months	Surgical margins clear in all patients; lymph nodes retrieved was 16; at follow-up one patient died of metastatic disease, one alive with metastases, 21 alive without recurrence; mean operative time was 397 min. Mean blood loss 278 ml (one patient required transfusion).	Larger studies are included in table 2
Park SY, Cho K.S., Ham W.S. et al. (2008) Robot-assisted laparoscopic radical cystoprostatectomy with ileal conduit urinary diversion: initial experience in Korea. Journal of Laparoendoscopic & Advanced Surgical Techniques Part (3): 401-404.	Case report N = 1 Follow-up = 11 days	No positive surgical margins but one positive lymph node (12 nodes dissected). No intraoperative complications reported.	Larger studies are included in table 2.
Pianezza ML, Slatnik J., and Evans H.J. (2008) Clear cell myomelanocytic tumour: minimally invasive treatment of a rare bladder tumour. Canadian Urological Association Journal 2 (3): 230-234.	Case report N = 1 Follow-up = 3 months	Positive surgical margins and no recurrence at 3-month follow-up. No complications reported.	Larger studies are included in table 2.
Rassweiler J, Frede T, Teber D et al. (2005) Laparoscopic radical cystectomy with and without orthotopic bladder replacement. Minimally Invasive Therapy &	Case series n = 48 Median follow-	At follow-up, 67% of patients showed no evidence of disease One patient required open reintervention because of bleeding	Larger case series are included

Allied Technologies: Mitat 14:78–95	up = 20 months	from the epigastric artery Long-term complications included one anastomotic stricture and one stenosis at the ureteral implantation of a sigmoid bladder	
Rawal S, Raghunath S.K., Khanna S. et al. (2008) Minilaparotomy radical cystoprostatectomy (minilap RCP) in the surgical management of urinary bladder carcinoma: Early experience. Japanese Journal of Clinical Oncology 38 (9): 611-616.	Case series N = 45 Follow-up not stated	Average lymph nodes removed: 14 and 16 (right and left side) Average blood loss: 1046 ml One patient died 18 days after surgery from septicaemia and acute renal failure. Other complications included rectal injury (1), wound infection (4), prolonged ileus (2), intestinal obstruction (1), ileoileal anastomotic leak (1), and neobladder leak (8).	Complications reported in table 2. Uncertain whether procedure uses a laparoscope.
Rhee JJ, Lebeau S, Smolkin M et al. (2006) Radical cystectomy with ileal conduit diversion: early prospective evaluation of the impact of robotic assistance. BJU International 98:1059–63	Non-randomised comparative study n = 30	Patients requiring transfusion: • robot-assisted = 57% (4/7) • open = 87% (20/23) p = 0.08 Mean hospital stay (days): • robot-assisted = 11 • open = 13 p = 0.52	Larger comparative studies are included
Tanaka K, Hara I, Takenaka A, Kawabata G, Fujisawa M. (2008) Incidence of local and port site recurrence of urologic cancer after laparoscopic surgery. Urology 71 (4) 728-734.	Case series N = 3 Follow-up = not stated	One patient was diagnosed with peritoneal carcinomatosis 11 months after surgery and died 3 weeks later.	Larger studies are included in table 2.
Tareen BU, Mufarrij P.W., Godoy G. et al. (2008) Robot-assisted laparoscopic partial cystectomy and diverticulectomy: initial experience of four cases. Journal of Endourology 22 (7): 1497-1500.	Case series N = 4 Follow-up not stated.	Patient with transitional cell carcinoma was found to have subsequent carcinoma in situ. Operative time: 163 – 252 min Mean blood loss: 35 ml No significant complications reported.	Larger studies are included in table 2.
Taylor GD, Duchene DA, Koeneman KS (2004) Hand assisted laparoscopic cystectomy with minilaparotomy ileal conduit: series report and comparison with open cystectomy. Journal of Urology 172:1291–6	Non-randomised comparative study n = 16	Mean postoperative analgesia (mg MSO_4 equivalents): • laparoscopic = 30.9 (8–76) • open = 149.3 (32–339) p = 0.01 Mean hospital stay (days): • laparoscopic = 6.4 (3–11) • open = 9.8 (6–19) p = 0.06	Larger comparative studies are included
Woods M, Thomas R., Davis R. et al. (2008) Robot-assisted extended pelvic lymphadenectomy. Journal of Endourology 22 (6): 1297-1302.	Case series N = 27 Follow-up not stated	Mean lymph node count: 12.3 (7-20) Mean operative time: 400 min Mean blood loss: 277 ml No intraoperative complications Post-operative complications: DVT (2), urine leak (2), cardiac arrhythmia (2), pulmonary embolus (1), clot retention (1), pelvic abscess (1), readmission for fever of unknown	Complications have been reported in table 2. [The patients included are from the same unit of those

		origin (1) (one patient had multiple complications).	included in the Lowentritt study.]

Appendix B: Related NICE guidance for laparoscopic cystectomy

Guidance	Recommendations
Interventional procedures	**Laparoscopic cystectomy. NICE interventional procedures guidance 26 (2003)** 1.1 Current evidence on the safety and efficacy of laparoscopic cystectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic cystectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's Information for the Public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present. 1.2 Special training is required to perform the procedure. The British Association of Urological Surgeons has agreed to produce standards for training.
Cancer service guidance	**Improving outcomes in urological cancers. NICE guidance on cancer services (2002)** All patients with urological cancers should be managed by multidisciplinary urological cancer teams. These teams should function in the context of dedicated specialist services, with working arrangements and protocols agreed throughout each cancer network. Patients should be specifically assured of: • streamlined services, designed to minimise delays • balanced information about management options for their condition • improved management for progressive and recurrent disease. Radical surgery for prostate and bladder cancer

	should be provided by teams typically serving populations of one million or more and carrying out a cumulative total of at least 50 such operations per annum. While these teams are being established, surgeons carrying out small numbers (five or fewer per annum) of either operation should make arrangements within their network to pass this work on to more specialised colleagues. Radical surgery (cystectomy) should be available for patients with muscle-invasive tumours confined to the bladder. Although patients' general fitness should always be taken into account when radical treatment is being considered, age should not, of itself, be a bar to surgery. Each network should agree clear guidelines on treatment and follow-up of bladder cancer which ensure that cystectomy is considered for patients with muscle-invasive or high-risk recurrent disease. Cystectomy is a complex operation which should be undertaken only by specialist surgeons working in cancer centres. Ideally, all radical cystectomies undertaken in each network should be carried out by a single team. Teams providing this form of surgery should carry out a cumulative total of at least 50 radical operations (cystectomies or radical prostatectomies) for bladder or prostate cancer per year. This level of workload is currently unusual in the UK and a transition period is likely to be required for reorganisation of services before the criterion of 50 operations can be met. In the meantime, surgeons who currently carry out fewer than five cystectomies per year should refer patients to designated surgeons who will become more specialised in this type of surgery. Surgical outcomes should be carefully audited and centres should aim to achieve 30-day mortality rates of 3.5% or less. Suitable patients should be offered bladder reconstruction or an alternative form of urinary diversion; facilities for reconstruction should be available wherever cystectomy is carried out.

Appendix C: Literature search for laparoscopic cystectomy

Database	Date searched	Version searched
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	22/10/08	Issue 4, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	22/10/08	N/A
HTA database (CRD website)	22/10/08	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	22/10/08	Issue 4, 2008
MEDLINE (Ovid)	22/10/08	1950 to October Week 2 2008
MEDLINE In-Process (Ovid)	22/10/08	October 21, 2008
EMBASE (Ovid)	22/10/08	1980 to 2008 Week 42
CINAHL (Search 2.0, NLH)	22/10/08	1981 to present
Current Contents (CBIB)	21/10/08	1995 to date

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Laparoscopy/
2	Robotics/
3	Cystectomy/
4	1 or 2
5	4 and 3
6	(laparoscop$ adj3 cystectom$).tw.
7	(robot$ adj3 cystectom$).tw.
8	(laparoscop$ adj3 cystoprostatectom$).tw.
9	(robot$ adj3 cystoprostatectom$).tw.
10	5 or 6 or 7 or 8 or 9
11	2002$.ed.
12	2003$.ed.
13	2004$.ed.
14	2005$.ed.
15	2006$.ed.
16	2007$.ed.
17	2008$.ed.
18	or/11-17
19	10 and 18
20	Animals/
21	Humans/

22	20 not (20 and 21)
23	19 not 22