NICE guidance

Laparoscopic cystectomy

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG26.

1 Guidance

1.1 Current evidence on the safety and efficacy of laparoscopic cystectomy appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection for laparoscopic cystectomy should involve a multidisciplinary team experienced in the management of bladder cancer.

1.3 Clinicians undertaking laparoscopic cystectomy should have special training. The British Association of Urological Surgeons (BAUS) has produced training standards.

1.4 Clinicians should submit data on all patients undergoing this procedure to the BAUS Cancer Registry & Sections Audit with a view to further publication on long-term survival outcomes.

2 The procedure

2.1 Indications and current treatments

2.1.1 For most bladder cancer patients, the treatment will depend on whether or not the tumour has invaded the bladder's muscular layer. Tumours invading the muscular layer (as well as some 'high-risk', non-invading tumours) are usually treated by radical cystectomy or radiotherapy. When radical cystectomy is used reconstructive surgery is also required. Laparoscopic cystectomy is an alternative to radical cystectomy by open surgery.

2.2 Outline of the procedure

2.2.1 Laparoscopic cystectomy is carried out with the patient under general anaesthesia. The abdomen is insufflated with carbon dioxide and small incisions are made to allow the introduction of a laparoscope and surgical instruments. The ureters are isolated, ligated and divided and the vascular pedicles to the bladder are ligated, transected and stapled.

2.2.2 In men the prostate and seminal vesicles are dissected and removed with the bladder, and retrieved through an abdominal incision. In women, depending on the tumour burden and stage, the uterus and part of the vagina may need to be removed. Sometimes the ovaries are also removed.

2.2.3 Urinary diversion or formation of a neo bladder can be done laparoscopically or, more commonly, by an open procedure.

2.2.4 There are various ways of carrying out laparoscopic cystectomy and the procedure may be performed with computer (robotic) assistance.

2.3 Efficacy

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

2.3.1 A non-randomised comparative study of 65 patients reported a recurrence-free survival of 77% (23 out of 30) for laparoscopic cystectomy compared with 80% (28 out of 35) for open cystectomy at mean follow-up periods of 38 months and 46 months, respectively (p=0.2). A non-randomised comparative study of 42 patients reported no disease-related deaths in the 20 patients treated by laparoscopic surgery compared with 5% (1 out of 21) of patients in the open cystectomy group during a mean follow-up of 19.5 months and 19 months, respectively (p value not significant). A case series of 84 patients reported a disease-free survival of 83% (70 out of 84) at a mean follow-up of 18 months.

2.3.2 The study of 65 patients reported a lower mean requirement for analgesia in the

laparoscopic group than in the open cystectomy group (32 mg and 65 mg % morphine equivalent, respectively; p=0.001). The study of 42 patients reported a mean requirement for non-opioid analgesics of 2.2 vials a day in the laparoscopic group compared with 3.9 vials a day in the open cystectomy group (p<0.05).

2.3.3 The Specialist Advisers considered that key efficacy outcomes included need for blood transfusion, time to discharge, requirement for analgesia, time to return to full activity, histology clear margin rates, extent of lymph node dissection and cancer-specific 5-year survival. One stated that the procedure has not been performed for long enough or in sufficient numbers to be able to evaluate the incidence of local recurrence of cancer or subsequent metastases.

2.4 Safety

2.4.1 Conversion to open surgery was reported in 5% (1 out of 20) and 3% (1 out of 33) of patients in two non-randomised controlled trials, and 0% (0 out of 84) and 2% (2 out of 83) in two case series.

2.4.2 Fistulae (including vaginal, urinary and enterovesical) were reported in 1% (1 out of 83), 2% (2 out of 84), 3% (1 out of 33) and 8% (1 out of 13) of patients in the two case series of 83 and 84 patients, the non-randomised controlled trial of 54 patients comparing open cystectomy with robotically assisted cystectomies, and a further non-randomised controlled trial of 37 patients, respectively. Rectal injury was reported in 5% (1 out of 20) and 3% (1 out of 30) of patients in the non-randomised controlled trials of 44 and 65 patients, respectively. Other complications included abdominal abscess (8% [1 out of 13]), percutaneous drainage of abscess (3% [1 out of 33]), injury to artery (1% [1 out of 84]), urinary leakage (1% [1 out of 83]), urinary tract infection (10% [8 out of 84]) and haematoma (4% [3 out of 84]).

2.4.3 There was a case report of port site metastasis in a patient 10 months after laparoscopic cystectomy; the patient was reported to have high-grade, high-stage transitional cell carcinoma.

2.4.4 One Specialist Adviser considered that theoretical adverse events included difficulty controlling haemorrhage, bowel injury or obstruction, inadequate cancer

clearance and port site metastasis. The Specialist Advisers stated that anecdotal adverse events include bowel fistula, peritonitis and prolonged operative time. One Adviser stated that the laparoscopic technique may not allow as radical an excision as open surgery, particularly for lymph nodes.

2.5 Other comments

2.5.1 The Committee noted that the published evidence on laparoscopic cystectomy was in patients with bladder cancer. There may be other patients for whom the procedure might be beneficial: they should be referred by the specialist teams caring for them to units with experience in case selection and use of laparoscopic cystectomy (see sections 1.2 and 1.3).

2.5.2 The Committee noted that most surgeons had stopped doing bladder reconstruction laparoscopically as part of this procedure.

3 Further information

3.1 NICE has issued a cancer service guideline on urological cancers.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.