



Laparoscopic augmentation cystoplasty (including clam cystoplasty)

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laparoscopic augmentation cystoplasty (including clam cystoplasty) is limited in quantity and quality but raises no major safety concerns, and the open procedure is well established. This procedure may therefore be used with normal arrangements for clinical governance, consent and audit.
- Patient selection and treatment should be carried out by a multidisciplinary team with specialist expertise in the management of urinary incontinence and experience in complex laparoscopic reconstructive surgery.
- 1.3 Clinicians undertaking laparoscopic augmentation cystoplasty (including clam cystoplasty) should submit data on all patients undergoing the procedure to the Female and Reconstructive Urology database run by the British Association of Urological Surgeons to allow monitoring of safety outcomes in the long term.

2 The procedure

2.1 Indications and current treatments

2.1.1 Laparoscopic augmentation cystoplasty (including clam cystoplasty) is indicated for a number of conditions including anatomically/structurally contracted bladder, neurogenic bladder and overactive bladder.

- 2.1.2 Current treatment options include bladder training, anticholinergic drugs, intravesical botulinum toxin injections, intermittent self-catheterisation (ISC) and sacral neuromodulation. In patients whose condition is refractory to non-surgical treatment, open augmentation cystoplasty is an established procedure.
- 2.1.3 Proposed advantages of a laparoscopic approach are less intraoperative blood loss, quicker recovery, less pain, a shorter stay in hospital and smaller scars.

2.2 Outline of the procedure

- 2.2.1 Laparoscopic augmentation cystoplasty (including clam cystoplasty, also known as ileocystoplasty, sigmoidocystoplasty, enterocystoplasty or bladder augmentation) increases bladder size and reduces intravesical pressure. Its aims are to reduce urgency and urge incontinence and reduce voiding frequency.
- 2.2.2 The procedure is typically carried out through 4 or 5 laparoscopic ports with the patient under general anaesthesia. The bladder is incised and an isolated piece of bowel, usually ileum, is sutured to this opening. A urethral and/or suprapubic catheter is left in the reconstructed bladder.
- 2.2.3 Once a 'watertight' reservoir has been demonstrated, 2 to 3 weeks after surgery, the urethral or subrapubic catheter is removed. Many patients require ISC and bladder washouts to reduce the risk of infection or stones in the augmented bladder. Patients need to empty the bladder at least every 4 hours (by passing urine spontaneously or by ISC) to prevent bladder rupture.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that 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 case series of 17 patients reported a significant improvement in bladder control on the Bladder Control Scale (scoring system not described) from a mean

preoperative score of 14.9 to 1.6 at an average 17-month follow-up (p=0.0002).

- 2.3.2 Case series of 23 and 6 patients treated by laparoscopic cystoplasty reported significant increases in mean postoperative bladder volume compared with preoperative volume from 111 ml to 778 ml and 48 ml to 260 ml at 12-month follow-up (p<0.01) and 13- to 16-month follow-up (significance not stated), respectively. Two case reports of 1 patient each reported increases in bladder volume from 85 ml preoperatively to 250 ml at 4-week follow-up and from 150 ml preoperatively to 315 ml at 3-month follow-up.
- 2.3.3 The case series of 23 and 6 patients reported postoperative decreases in mean maximum detrusor pressure from 92 cm to 15 cm water at 12-month follow-up and from 35 cm to 12 cm water at an average of 13- to 16-month follow-up, respectively (significance not stated).
- 2.3.4 The case series of 23 patients reported that all 19 patients with 12-month follow-up data were continent between ISC every 4 to 5 hours (39% [9 out of 23] of patients had been described as incontinent before the procedure). The case series of 6 patients reported that all patients were generally dry for 2 to 3 hours between catheterisations within 1 month of the procedure.
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as symptom relief, rapid recovery and shorter duration of hospital stay (compared with the open procedure), reduced need for analgesia, and cosmesis.

2.4 Safety

- 2.4.1 Multiple bladder stones in the augmented pouch 13 months after surgery were reported in 1 patient in the case series of 23 patients (these were treated by cystolithotomy).
- In the same case series of 23 patients, spontaneous rupture of the pouch 15 months after augmentation was reported in 1 patient who neglected to undertake ISC as recommended. The rupture was repaired and a urethral catheter was inserted for 4 weeks.

- In the case series of 17 patients, a trocar-induced rectus sheath haematoma was reported in 1 patient during a sigmoidocystoplasty (this was controlled laparoscopically). Paralytic ileus (managed conservatively) was reported in another patient in the case series of 17 patients (timing of event not stated).
- 2.4.4 Leakage from the suture line occurred in 1 patient in the case series of 6 patients: this resolved with conservative management.
- 2.4.5 The Specialist Advisers considered theoretical adverse events to include bleeding, sepsis, infection, damage to the bowel, intestinal anastomotic leaks (bowel or bladder), and metabolic disturbance.

3 Further information

Sources of evidence

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

Information for patients

NICE has produced <u>information for the public on this procedure</u>. 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 <u>Healthcare Improvement Scotland</u>.