NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic augmentation cystoplasty (including clam cystoplasty)

An 'overactive bladder' or detrusor hyper-reflexia causes symptoms of urgent need to urinate, urge incontinence, frequent urination and waking at night to urinate. One of the causes is bladder muscle (detrusor) overactivity, in which the detrusor contracts unexpectedly during bladder filling. Laparoscopic augmentation cystoplasty (including clam cystoplasty) is reconstructive surgery to increase the size of the bladder and is done via small incisions. The procedure involves sewing or stapling a tissue graft from a section of the small intestine (ileum), colon or other substitutes, to the urinary bladder.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make 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 June 2009.

Procedure name

- Laparoscopic augmentation cystoplasty (including clam cystoplasty)

Specialty societies

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

Description

Indications and current treatment

Laparoscopic augmentation cystoplasty (including clam cystoplasty) is performed in both children and adults and is indicated for a number of conditions including:

- Anatomically/structurally contracted bladder (tuberculous contracted bladder, radiation cystitis and schistosomiasis)
- Neurogenic bladder (spina bifida, spinal cord injury and multiple sclerosis)
- Overactive bladder

Non-surgical treatments for these conditions include bladder training, anticholinergics, 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.

The proposed advantage of a laparoscopic approach is less intraoperative blood loss, quicker recovery, less pain, a shorter stay in hospital and smaller scars.

What the procedure involves

The procedure was first reported in 1995[1]. It aims to increase the size of the bladder and avoid vesicoureteric reflux by reducing the intravesical pressure. Pressure generated by the bladder muscle during voiding is usually less than 25 cm H_2O in people with normal bladder function.

Bowel preparation and prophylactic antibiotics are given prior to the operation. The procedure is performed with the patient under general anaesthesia and in the low-lithotomy position. Laparoscopic surgery is performed via 4 or 5 ports placed in a fan-shaped arrangement. The bladder is distended with saline and usually bivalved in the sagital plane. Normally a loop of ileum is selected and sutured on to the bivalved bladder. The anastomosis or ‘patch’ is then tested for water tightness by filling the augmented bladder with saline. A drain is inserted and wounds closed. A suprapubic catheter (SPC) may be placed in addition to the urethral catheter. Cystoplasty may be combined with urinary diversion e.g. Mitrofanoff procedure in which a catheterisable stoma is created for bladder emptying.

Approximately 2–3 weeks after surgery, tests are performed to ensure that the patch is leak-proof.

Once a watertight reservoir is demonstrated the remaining catheter is removed. It may take 3 months for an augmented bladder to establish itself. Patients are normally advised to stay well hydrated.

The procedure aims to reduce urgency and urge incontinence, prevent nocturia and reduce voiding frequency. However, most people need to perform ISC as voiding is often not possible, even when continence has been restored. Patients must carry out intermittent self-catheterisation (ISC) or pass urine on a regular basis, at least every 6 hours to prevent cystoplastic rupture.

In both the open and laparoscopic procedures mucus is secreted from the bowel patch and bladder washouts may be required to avoid stone formation and infection. There may be increased risk of malignancy in the transposed section of bowel. Lifelong follow up with regular cystoscopy may be recommended. There is also a risk of metabolic acidosis and B12 deficiency.

Variations of the procedure are also known as ileocystoplasty, sigmoidocystoplasty, enterocystoplasty and bladder augmentation.

OPCS code

M36.1 Enlargement of bladder, Caecocystoplasty

M36.2 Enlargement of bladder, Ileocystoplasty

M36.3 Enlargement of bladder, Colocystoplasty

List of studies included in the overview

This overview is based on 51 patients from 3 case series[2,3,4] and 5 case reports[5,1,6,7,8].

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.

Efficacy

Bladder function

A case series of 23 patients (mixed paediatric and adult population) treated with laparoscopic cystoplasty reported a significant increase in mean bladder volume from 111 ml before surgery to 778 ml 12 months after the procedure ($p < 0.01$)[2] (4 patients lost to follow-up). A case series of 6 paediatric patients reported an increase in mean bladder volume from 48 ml before surgery to 260 ml at follow-up (average follow-up 13–16 months)[4]. A case report of 1 adult patient reported an increase in bladder volume from 85 ml before surgery to at least 250 ml 4 weeks after the procedure[5]. A case report of 1 adult patient reported an increased bladder volume from 150 ml before surgery to 315 ml 3 months after the procedure[1]. A case report of 1 paediatric

patient showed improved bladder capacity using pre- and post-operative imaging studies[8].

A case series of 17 adult patients reported significant improvement in bladder control using the Bladder Control Scale (BLCS) from a mean score of 14.9 before surgery to 1.6 at follow-up (average follow-up 17 months) ($p = 0.0002$)[3].

A case series of 23 patients treated with laparoscopic cystoplasty reported a decrease in mean maximum detrusor pressure from 92 cm H_2O before surgery to 15 cm H_2O 12 months after the procedure[2] (4 patients lost to follow-up). A case series of 6 paediatric patient reported a decrease in mean maximum detrusor pressure from 35 cm H_2O before surgery to 12 cm H_2O at follow-up (average follow-up 13–16 months)[4].

Continence

A case series of 23 patients treated with laparoscopic cystoplasty reported that all 19 patients included at follow-up were continent (day and night) between ISC every 4–5 hours. In this study, 39% (9/23) were described as incontinent before the procedure[2]. A case series of 6 paediatric patient reported that all patients were generally dry for 2–3 hours between catheterisations within a month of the procedure[4]. A case report of an adult patient with worsening voiding dysfunction prior to surgery found that she was continent between catheterisations with urinary volumes of approximately 400 ml after the procedure[5]. A case report of an adult patient with a history of lifelong incontinence reported that she was dry between ISC every 4 hours at 3-month follow-up[1]. A case report of a paediatric patient with a history of urinary tract infections and urinary incontinence was completely dry between ISC every 4 hours 6 weeks after a combined ileocystoplasty and Mitrofanoff appendicovesicostomy[6]. A case report of an adult patient who initially presented with a microbladder and micturition every 8–10 minutes was symptom-free at 20-month follow-up, although the patient had nocturnal incontinence for a few weeks after the procedure[7].

Safety

Five long-term/serious complications were reported in the literature:

- A male paraplegic patient presented with multiple bladder stones in the augmented pouch 13 months after surgery. He was managed with cystolithotomy[2].
- Another male patient suffered a spontaneous rupture of pouch 15 months after augmentation due to neglected ISC. The rupture was repaired and a urethral catheter inserted. The catheter was removed after 4 weeks and the patient has had no further sequelae[2].
- A trocar-induced rectus sheath haematoma was reported during a sigmoidocystoplasty. This was controlled laparoscopically[3].
- A self-limited paralytic ileus was reported and managed conservatively[3].
- One case series reported a leak from the ileal anastomosis on the 2nd and 3rd post-operative day caused by the tip of the urethral catheter traversing overlying suture lines of the patch and intestinal anastomosis. This resolved rapidly when the Foley catheter was replaced and bowel rest and parenteral nutrition were extended for a few extra days[4].

Two case series[3,4] reported mean intraoperative blood loss of 232 ml and generally less than 170 ml. Two case reports showed intraoperative blood loss of approximately 100 ml[5,6]. A case report showed 1 patient who required a transfusion of 2 U of packed red blood cells despite an estimated blood loss of only 250 ml during the procedure[1].

A case series of 6 paediatric patients reported no change in mean Valsalva leak-point pressure (a measure of strength of urethral sphincters) from 35 cm H_2O before surgery to 36 cm H_2O at follow-up (average follow-up 13–16 months)[4].

A case series reported no change in bowel function using the Bowel Control Scale (BWCS) from a mean score of 6.4 before surgery to 5.3 at follow-up (average follow-up 17 months) ($p = 0.3$)[3]. This indicates no change in bowel function despite the removal of a segment of bowel for bladder augmentation.

A case series reported minor bowel disturbances in 6 patients (bouts of diarrhoea and constipation)[2].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic clam cystoplasty. Searches were conducted of the following databases, covering the period from their commencement to 4 June 2009 and updated to 25 August 2009: 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 idiopathic and neurogenic detrusor overactivity, overactive bladder, urge incontinence and urinary incontinence.
Intervention/test	Laparoscopic clam cystoplasty, ileocystoplasty, augmentation cystoplasty, bladder augmentation, Bramble cystoplasty and enterocystoplasty
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.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search. However, the procedure is included in the British Association of Urological Surgeons (BAUS) Female & Reconstructive

Urology Surgical Procedures Data-Set, which was initiated in September 2008.

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.

Interventional procedures

- Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedures guidance 64 (2004). Available from http://guidance.nice.org.uk/IPG64

Clinical guidelines

- Urinary incontinence: the management of urinary incontinence in women. NICE clinical guideline 40 (2006). Available from http://guidance.nice.org.uk/CG40

Table 2 Summary of key efficacy and safety findings on Laparoscopic bladder augmentation cystoplasty (including clam cystoplasty)

Abbreviations used: BLCS, Bladder Control Scale; BWCS, Bowel Control Scale; CISC, clean intermittent self-catheterisation.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
El-Feel A et al (2009)[2] Study type: **Case series** Country: Egypt Study period: Jun 2001 – Oct 2006 Study population: Patients with hypocompliant bladder showing a maximum detrusor pressure >= 40 cm H_2O and bladder compliance of < 15 ml/cm H_2O that failed to respond to other nonsurgical treatments. Augmentation also indicated for hypocompliant bladder showing evidence of vesicoureteral reflux in association with small bladder capacity (< 150 ml) and/or frequent episodes of pyelonephritis, or when the state of hypocompliant bladder was associated with intractable urgency or urge incontinence. n = **23** Age: mean = 27 years (range 12 – 56 years) Sex: 82.6% male (19/23) Inclusion criteria: See above. Exclusion criteria: Uremic patients with serum creatinine > 2 mg%; patients who were not able to perform CISC (handicapped or non-compliant); and patients with inflammatory bowel diseases or short bowel syndromes. Diagnostic cystoscopy was performed during initial assessment to exclude other bladder pathologies. Technique: Laparoscopic augmentation ileocystoplasty with extracorporeal preparation of ileal pouch. Follow-up: **mean 39 months (range 5 – 72 months)** Conflict of interest: None	All cases were completed laparoscopically with no conversion to open. *Mean bladder volume* Prior to surgery (n = 23): 111 ml At time of catheter removal following surgery (n = 19): 311 ml ($p < 0.01$) 12 months after surgery (n = 19): 778 ml ($p < 0.01$) *Maximum detrusor pressure* Before augmentation (n = 23): mean = 92 cm H_2O 12 months after surgery (n = 19): mean 15 cm H_2O All 19 patients who completed follow-up were able to attain daytime and nighttime continence when they followed regular CISC every 4–5 hours. 31% (9/23) were described as incontinent prior to the procedure.	16 patients with asymptomatic pyuria were treated with antibiotic therapy for at least 6 weeks as a prophylactic measure. No reports of febrile infections No clinical or laboratory evidence for metabolic acidosis during follow-up. Minor bowel disturbances in 6 patients (bouts of diarrhoea and constipation). Two patients reported long-term complications after they were initially missed during follow-up: • A male paraplegic patient presented with multiple bladder stones in the augmented pouch 13 months after surgery. He was managed with cystolithotomy. • A male patient suffered a spontaneous rupture of pouch 15 months after augmentation due to neglected CISC. The patient presented with generalised peritonitis associated with raised serum creatinine and leucocytosis. Exploration revealed rupture of the pouch at its dome with intact vesicoileal anastomosis. The rupture was repaired and a urethral catheter inserted. The catheter was removed after 4 weeks and the patient had no further sequelae.	4 patients lost to follow-up. Mean operative time: 202 minutes Mean hospital stay: 5 days Mean urethral catheter duration: 11 days All 23 patients were on oral anticholinergic drugs and CISC; 2 patients with detrusor sphincter dyssynergia were also managed with sphincterotomy using cold knife.

Abbreviations used: BLCS, Bladder Control Scale; BWCS, Bowel Control Scale; CISC, clean intermittent self-catheterisation.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Rackley RR et al (2003)[3] Study type: **Case series** Country: USA Study period: June 1999 – June 2002 Study population: Patients with reduced bladder capacities due to neurogenic causes. Conditions of included patients: Sensory urgency syndrome: 1 Multiple sclerosis: 8 Spinal cord injury: 5 Transverse myelitis: 1 Spina bifida: 1 Detrusor instability: 1 n = **17** Age: mean 39.9 years (range 18–62) [calculated by IP] Sex: males 17.6% (3/17) Inclusion criteria: See above Technique: Laparoscopic augmentation cystoplasty (5 ileocystoplasties, 3 sigmoidocystoplasties, 1 colocystoplasty, and 8 cecocolocystoplasties with a continent, catheterisable ileal stoma) Follow-up: mean **17 months** Conflict of interest: not stated	*Bladder control (BLCS score)* Before surgery: mean 14.9 +/– 5.0 At follow-up: mean 1.6 +/– 1.8 (p=0.0002; indicates significant improvement) *Bowel control (BWCS score)* Before surgery: mean 6.4 +/– 6.5 At follow-up: mean 5.3 +/– 6.0 (p = 0.3; indicates no change in bowel function despite the removal of segment of bowel for bladder augmentation)	*Blood loss* Mean 232 ml (range 60–550 ml) [calculated by IP] *Complications* Tocar-induced rectus sheath haematoma during a sigmoidocystoplasty and a self-limited paralytic ileus. The former was treated laparoscopically and the latter was managed conservatively.	Bladder control and Bowel control assessed by patient questionnaire; neither questionnaire nor scoring system were described.

Abbreviations used: BLCS, Bladder Control Scale; BWCS, Bowel Control Scale; CISC, clean intermittent self-catheterisation.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Shadpour P et al (2005)[4] Study type: **Case series** Country: Iran Study period: not stated Study population: Children with neurogenic dysfunction referred with total urinary and fecal incontinence secondary to myelomeningocele. n = **6** Age: mean 9.5 years (range 9 – 14) [calculated by IP] Sex: males 33.3% (2/6) Inclusion criteria: Patients had been refractory to medical management over a variable period of intermittent catheterisation, anticholinergics and conventional laxatives. Technique: Totally laparoscopic, combined freehand ileocystoplasty and Malone procedures for antegrade continence. Follow-up: mean **13 – 16 months** Conflict of interest: not stated	*Functional bladder capacity* Before surgery: mean 48 ml (range 32–73 ml) At follow-up: mean 260 ml (range 204–331 ml) *Maximum detrusor pressure* Before surgery: mean 35 cm H_2O (range 18–56 cm H_20) At follow-up: mean 12 cm H_2O (range 8–18 cm H_20) *Valsalva leak-point pressure* (a measure of strength of the urethral sphincters) Before surgery: mean 35 cm H_20 (range 20–53 cm H_20) At follow-up: mean 36 cm H_20 (range 23–52 cm H_20) Within 1 month of the procedure, patients were generally rendered dry for 2–3 hours between catheterisations and could void to completion by Valsalva and credÈ manoeuvers.	Intraoperative blood loss was generally <170 ml *Complications* One leak from the ileal anastomosis on the 2nd and 3rd post-operative day. This was caused by the tip of the urethral catheter traversing overlying suture lines of the patch and intestinal anastomosis and resolved rapidly when the Foley catheter was replaced and bowel rest and parenteral nutrition were extended for a few extra days.	Combined operation for urine and fecal incontinence. Malone procedure: the operation involves connecting the appendix to the abdominal wall and fashioning a valve mechanism that allows catheterisation of the appendix, but avoids leakage of stool through it. If the appendix was previously removed or is unusable, a neo-appendix can be created with a cecal flap. It is done to treat fecal incontinence unresponsive to treatment with medications. It is frequently done with a procedure to treat urinary incontinence as the two often co-exist, such as in spina bifida.

Abbreviations used: CISC, clean intermittent self-catheterisation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Meng MV et al (2002)[5] Study type: **Case report** Country: USA Study period: not stated Study population: Paraplegic patient with C6 spinal cord injury who developed worsening voiding dysfunction during the 2 years preceding presentation. Patient had previously been managed with CISC every 4 hours and remained dry n = **1** Age: 31 years Sex: Female Inclusion criteria: See above Technique: Totally laparoscopic enterocystoplasty Follow-up: **4 weeks** Conflict of interest: Not stated	Video urodynamic studies prior to surgery showed detrusor instability at bladder volumes 40 – 50 ml and a maximum bladder capacity of 85 ml. Following the procedure, the patient returned to work and normal activity 1 week after discharge and a cystogram at 4 weeks post-operatively demonstrated a bladder capacity of at least 250 ml. At the time of publication the patient was continent between catheterisations with urinary volumes approximating 400 ml.	Estimated blood loss of 100 ml. The patient remained hospitalised for 13 days due to prolonged ileus.	First report of pure laparoscopic ileal cystoplasty in humans (previous studies have exteriorised the bowel to facilitate bowel-to-bowel reanastomosis and ileal patch construction).

Abbreviations used: CISC, clean intermittent self-catheterisation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Docimo SG et al (1995)[1] Study type: **Case report** Country: USA Study period: Not stated Study population: Patient with a history of sacral agenesis and lifelong urinary incontinence. Patient was previously managed with CISC and anticholinergic agents without improvement in urinary incontinence. n = **1** Age: 17 years Sex: Female Inclusion criteria: See above Technique: Laparoscopic gastrointestinal bladder augmentation using the stomach Follow-up: **3 months** Conflict of interest: Not stated	Prior to surgery a voiding cystourethrogram revealed a thickened bladder with an elongated configuration, significant trabeculation and no vesicoureteral reflux. A cystometrogram showed a bladder capacity of 150 ml and bladder leak-point pressure of 23 cm H_20. 3 weeks after the procedure, the patient's suprapubic catheter was clamped and she began CISC. The patient was maintained on 5 mg oxybutynin daily. Urodynamic studies at 3 months revealed a bladder volume of 315 ml. The patient was dry between intermittent catheterisation every 4 hours.	The patient received a transfusion of 2 U of packed red blood cells for a haematocrit level of 19% despite an estimated blood loss of only 250 ml during the operation. Following the procedure there was persistent urine leak through the suction drain, which reached a plateau of 150 ml/day by day 5. This leak was sealed by day 13 postoperatively. The drain was then removed and the patient discharged.	First account in the literature of this procedure.

Abbreviations used: CISC, clean intermittent self-catheterisation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Gundeti MS et al (2008)[6] Study type: **Case report** Country: USA Study period: Not stated Study population: Patient presented with recurrent urinary tract infections and urinary incontinence despite management with anticholinergics and regular CISC. She had a myelomeningocele that had closed at birth, with subsequent spinal cord detethering at 9 years of age. n = **1** Age: 10 years Sex: Female Inclusion criteria: See above Technique: Paediatric robot-assisted laparoscopic augmentation ileocystoplasty and Mitrofanoff appendicovesicostomy (complete intracorporeal technique) Follow-up: **6 weeks** Conflict of interest: not stated	Urodynamic studies prior to surgery showed a small bladder capacity (220 ml) with poor compliance and a detrusor leak point pressure of 66 cm H_20. On renal ultrasonography she had bilateral grade1 (Society for Fetal Urology) hydronephrosis, with no demonstrated reflux on voiding cystourethrography. A technetium-99m dimercaptosuccinic acid renal scan showed a focal scar in the left upper pole with equal differential function. Following the procedure, oral intake started at 12 hours. The urethral catheter was removed at day 5 post-operatively and the patient was discharged with a suprapubic catheter and a feeding tube through her Mitrofanoff stoma. At 4 weeks, cystography showed an intact augmented pouch. CISC though the Mitrofanoff stoma was begun every 4 hours (volume of 200 – 250 ml in the day and 400 – 500 ml at night). The patient was completely continent day and night at 6 weeks post-operatively. She resumed her normal school activity and physical sports within 4 weeks.	Estimated blood loss < 100 ml. The patient's postoperative course in hospital was uncomplicated.	This is a combined procedure.

Abbreviations used: CISC, clean intermittent self-catheterisation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Sanchez de Badajoz E et al (1995)[7] Study type: **Case report** Country: Spain Study period: Not stated Study population: Patient presented with a microbladder and a markedly dilated left ureter. One month before the procedure he had undergone a right-side nephrectomy for tuberculosis. n = **1** Age: Not stated Sex: Male Inclusion criteria: See above Technique: Laparoscopy-assisted cystoplasty Follow-up: **20 months** Conflict of interest: Not stated	Following the procedure, intestinal transit returned the next day and the nasogastric tube was removed at 48 hours and the patient received and tolerated a liquid diet. The bladder catheter remained in place for 12 days post-operatively. The patient's frequency of micturition declined from every 8 – 10 minutes preoperatively to every 3 – 4 hours. During the first few weeks, the patient had nocturnal incontinence that slowly disappeared. At follow-up, the patient was symptom free. A urogram showed that the intestinal graft was bladder-shaped and that renal function was normal.		

Abbreviations used: CISC, clean intermittent self-catheterisation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Lorenzo AJ et al (2007)[8] Study type: **Case report** Country: Canada Study period: Not stated Study population: Patient with a low-capacity, poorly compliant bladder after multiple surgical interventions trying to correct bilateral vesicoureteral reflux. n = **1** Age: 9 years old Sex: Female Inclusion criteria: See above Technique: Paediatric laparoscopic ileal cystoplasty (complete intracorporeal surgical technique) Follow-up: **Not stated** Conflict of interest: Not stated	Despite suspicion that the patient had a neurological problem, evaluation including lumbosacral magnetic resonance imaging failed to find any specific defect. Regardless of anticholinergic use and intermittent catheterisation, the patient developed chronic renal insufficiency and radiological evidence of bilateral upper tract deterioration. Urodynamic evaluation showed a very small bladder capacity with a high detrusor leak-point pressure and poor compliance. Improvement of upper tract dilation and bladder capacity shown by preoperative and post-operative imaging studies		

Validity and generalisability of the studies

- There were no RCTs or non-randomised controlled trials within the published literature. The evidence was limited to small case series and case reports.
- A number of different cystoplasty procedures were used (e.g. ileocystoplasty, sigmoidocystoplasty, enterocystoplasty, cystoplasty with cecum and proximal ascending colon), and it is unclear if these results can be generalised.
- The review includes papers describing procedures done entirely laparoscopically and others combined with extracorporeal preparation of the bowel.

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 Peter Rimington and Mr Prokar Dasgupta (British Association of Urological Surgeons [BAUS]).

- One Specialist Adviser had never performed this procedure (although he has performed the open version of this procedure) and the other one had performed it at least once.
- Neither of the Specialist Advisers commented on the status of the procedure. It is unclear if they thought it was novel or established practice.
- Both Advisers reported that less than 10% of specialists are engaged in this area of work.
- The main theoretical adverse events were considered to be bleeding, sepsis, infection, damage to other areas of the bowel, intestinal anastomotic leak, urine leak from suture line of bladder, metabolic disturbance, need for CISC, deep vein thrombosis and pulmonary embolism.

- Key efficacy outcomes for this procedure are considered to be relief of symptoms, rapid recovery and reduced hospital stay, minimal analgesia, rapid return to normal feeding and excellent cosmesis.
- The procedure requires advanced laparoscopic and reconstructive skills with special knowledge of intracorporeal bowel anastomosis.
- One Specialist Adviser stated that the procedure, if safe and efficacious, is likely to be carried out in a minority of hospitals, but at least 10 in the UK; while the other adviser stated that it is likely to be carried out in fewer than 10 specialist centres in the UK.
- One Specialist Adviser observed that this procedure needs to be evaluated as a tertiary procedure in patients with refractory overactive or small-capacity bladders where first-line treatments such as anticholinergics and second-line treatments such as botulinum toxin injections and neuromodulation have failed.
- One Specialist Adviser stated that the open version of this procedure is not common and therefore changing to the laparoscopic version will have very little impact on the NHS as a whole.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme sent 6 questionnaires to 1 Trust for distribution to patients who had the procedure (or their carers). NICE received no completed questionnaires.

References

Comment [J1]: In ref 5 the page range is incomplete.

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2. El-Feel A, Abdel-Hakim MA, Abouel-Fettouh H et al. (2009) Laparoscopic augmentation ileocystoplasty: results and outcome. European Urology 55: 721–8.
3. Rackley RR, Abdelmalak JB, Dub RE (2003) Laparoscopic augmentation cystoplasty with or without continent stoma formation. Topics in Spinal Cord Injury Rehabilitation 8: 35–45
4. Shadpour P, Simforoosh N, Magsudi R et al. (2005) Totally laparoscopic combined freehand ileocystoplasty and malone procedures. Journal of Endourology 19 :471–5.
5. Meng MV, Anwar HP, Elliott SP et al. (2002) Pure laparoscopic enterocystoplasty. Journal of Urology 167:1386
6. Gundeti MS, Eng MK, Reynolds WS et al. (2008) Pediatric robotic-assisted laparoscopic augmentation ileocystoplasty and Mitrofanoff appendicovesicostomy: complete intracorporeal – initial case report. Urology 72:1144–7
7. Sanchez de BE, Hurtado AM, Garrido AJ et al. (1995) Laparoscopy-assisted cystoplasty. Journal of Endourology 9: 269–72
8. Lorenzo AJ, Cerveira J, Farhat WA. (2007) Pediatric laparoscopic ileal cystoplasty: complete intracorporeal surgical technique. Urology 69: 977–81.

Appendix A: Additional papers on Laparoscopic bladder augmentation cystoplasty (including clam cystoplasty)

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
Hedican SP, Schulam PG, Docimo SG (1999) Laparoscopic assisted reconstructive surgery. Journal of Urology 161: 267–70	Case series n = 8 Follow-up: not stated	Comparable operative time and intraoperative blood loss to open procedures with "excellent cosmesis". Median post-operative stay was 8 days, but it is not clear when they assessed cosmesis / mean follow-up. Small bowel obstruction was reported in one case but was apparently unconnected to the laparoscopic procedure.	Difficult to identify efficacy and safety outcomes related specifically to the bowel augmentation of the bladder as opposed to the Mitrofanoff procedure Larger studies included in table 2
Noguera RJ, Astigueta JC, Carmona O et al. (2009) Laparoscopic augmentation enterocystoplasty through a single trocar. Urology 73:1371-4	Case report n=1 Follow-up = 21 days	Successful procedure – patient able to perform intermittent self catheterisation to complete emptying. Blood loss <100ml No intra / post operative complications	Larger studies included in table 2
Nunez MC, Cansino AR, Alonso GS et al. (2007) Laparoscopic augmentation enterocystoplasty: initial experience. [Spanish]. Actas Urologicas Espanolas 31: 17–22	Case report n = 2 Follow-up: 12 months and 5 months	No intraoperative complications. Both patients achieved lower bladder pressure and good continence following the procedure.	Insufficient detail in English abstract Larger studies included in table 2

Appendix B: Related NICE guidance for Laparoscopic bladder augmentation cystoplasty (including clam cystoplasty)

Guidance	Recommendations
Interventional procedures	**Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedures guidance 64 (June 2004)** 1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for urge incontinence and urgency-frequency appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 Patient selection is important. The diagnosis should be defined as clearly as possible and the procedure limited to patients who have not responded to conservative treatments such as lifestyle modifications, behavioural techniques and drug therapy. Patients should be selected on the basis of their response to peripheral nerve evaluation.
Clinical guidelines	**Urinary incontinence: the management of urinary incontinence in women. NICE clinical guideline 40 (October 2006)** **Assessment and investigation** • At the initial clinical assessment, the woman's urinary incontinence (UI) should be categorised as stress UI, mixed UI, or urge UI/overactive bladder syndrome (OAB). Initial treatment should be started on this basis. In mixed UI, treatment should be directed towards the predominant symptom. *Expert opinion concludes that symptomatic categorisation of UI based on reports from the woman and history taking is sufficiently reliable to inform initial, non-invasive treatment decisions. (See section 3.2 of the full guideline.)* • Bladder diaries should be used in the initial assessment of women with UI or OAB. Women should be encouraged to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days. *Bladder diaries are a reliable method of quantifying urinary frequency and incontinence episodes. The Guideline Development Group (GDG) concluded that a 3-day period allows variation in day-to-day activities to be captured while securing reasonable compliance. (See section 3.9 of the full guideline.)* • The use of multi-channel cystometry, ambulatory urodynamics or videourodynamics is not recommended before starting conservative treatment. • For the small group of women with a clearly defined clinical diagnosis of pure

	stress UI, the use of multi-channel cystometry is not routinely recommended. • Multi-channel filling and voiding cystometry is recommended in women before surgery for UI if: – there is clinical suspicion of detrusor overactivity, or – there has been previous surgery for stress incontinence or anterior compartment prolapse, or – there are symptoms suggestive of voiding dysfunction. Ambulatory urodynamics or videourodynamics may also be considered in these circumstances. *It has not been shown that carrying out urodynamic investigations before initial treatment improves outcome. Complex reconstructive urological procedures were developed for use in specific urodynamic abnormalities. Hence, the GDG concluded that urodynamic investigations should be used to demonstrate the presence of specific abnormalities before undertaking these procedures. The GDG considered that urodynamic investigations are also of value if the clinical diagnosis is unclear prior to surgery or if initial surgical treatment has failed. (See section 3.11 of the full guideline.)* **Conservative management** • A trial of supervised pelvic floor muscle training of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed UI. *There is good evidence that daily pelvic floor muscle training continued for 3 months is a safe and effective treatment for stress and mixed UI. (See section 4.2 of the full guideline.)* • Bladder training lasting for a minimum of 6 weeks should be offered as first-line treatment to women with urge or mixed UI. *There is good evidence that bladder training is an effective treatment for urge or mixed UI, with fewer adverse effects and lower relapse rates than treatment with antimuscarinic drugs. (See section 4.3 of the full guideline.)* • Immediate release non-proprietary oxybutynin should be offered to women with OAB or mixed UI as first-line drug treatment if bladder training has been ineffective. If immediate release oxybutynin is not well tolerated, darifenacin, solifenacin, tolterodine, trospium, or an extended release or transdermal formulation of oxybutynin should be considered as alternatives. Women should be counselled about the adverse effects of antimuscarinic drugs. *There is no evidence of a clinically important difference in efficacy between antimuscarinic drugs. However, immediate release non-proprietary oxybutynin is the most cost effective of the available options. (See section 4.4.1 of the full guideline.)* • Pelvic floor muscle training should be offered to women in their first pregnancy

	as a preventive strategy for UI. *There is evidence that pelvic floor muscle training used during a first pregnancy reduces the likelihood of postnatal UI. (See section 4.7 of the full guideline.)* **Surgical management** • Sacral nerve stimulation is recommended for the treatment of UI due to detrusor overactivity in women who have not responded to conservative treatments. Women should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation. Life-long follow-up is recommended. *The treatment options for women who have detrusor overactivity and have not responded to conservative therapy are all costly and associated with significant morbidity. There is a stronger body of evidence for the effectiveness of sacral nerve stimulation than for other procedures. Up to two-thirds of patients achieve continence or substantial improvement in symptoms after this treatment. (See section 5.1 of the full guideline.)* • Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI where conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate. *Many procedures have been described for the treatment of stress UI; although there is no strong evidence of superior effectiveness of any one, the best available data support the use of retropubic mid-urethral tape procedures, colposuspension and autologous rectus fascial sling. Retropubic mid-urethral tape procedures consume fewer hospital resources and are associated with faster recovery than the other two procedures. (See section 5.2 of the full guideline.)* **Competence of surgeons performing operative procedures for UI in women** • Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women. *The expertise of the surgeon is one of the factors that influence surgical outcomes. The best outcomes are achieved when surgeons and/or their multidisciplinary team have specialist training and regular practice in continence surgery. (See section 6 of the full guideline.)*

Appendix C: Literature search for laparoscopic clam cystoplasty

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	25/08/2009	Issue3, 2009	3
Database of Abstracts of Reviews of Effects – DARE (CRD website)	25/08/2009	-	0
HTA database (CRD website)	25/08/2009	-	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	25/08/2009	Issue 3, 2009	0
MEDLINE (Ovid)	25/08/2009	1950 to August Week 2 2009	2
MEDLINE In-Process (Ovid)	25/08/2009	August 24, 2009	1
EMBASE (Ovid)	25/08/2009	1980 to 2009 Week 34	6
CINAHL (NLH Search 2.0 or EBSCOhost)	25/08/2009	1981-present	1
Current Contents - CBIB	25/08/2009	-	8

Database	Date searched	Version/files
BLIC (Dialog DataStar)	04/06/2009	-

Trial sources searched on 04 06 2009

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 04 06 2009

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

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

1 Cystoplast*.tw.
2 enterocystoplast*.tw.
3 ileocytoplast*.tw.
4 ileocystoplast*.tw.
5 ((Bramble* or Clam* or augment*) adj3 (cystoplast* or ilecytoplast* or ileocystoplast*)).tw.
6 (Bladd* adj3 augment*).tw.
7 (Bladder* adj3 reconstruct*).tw.
8 or/1-6
9 exp Laparoscopy/
10 exp Laparoscopes/
11 exp Surgical Procedures, Minimally Invasive/
12 Laparoscop*.tw.
13 or/9-12
14 exp Urinary Incontinence/
15 Urinary Bladder, Neurogenic/
16 Urination Disorders/
17 Urinary Bladder Diseases/
18 Urinary Bladder, Overactive/
19 Urinary Bladder/
20 ((Urin* or bladder* or urge*) adj3 (disord* or incontinen* or micturit*)).tw.
21 ((Overactiv* or Neurogen*) adj3 Bladder*).tw.
22 (detruso* adj3 overactiv*).tw.
23 (urin* adj3 bladd*).tw.
24 or/14-23
25 8 and 24 and 13
26 Animals/ not Humans/
27 25 not 26
28 from 27 keep 1-65