NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of transabdominal artificial bowel sphincter implantation for faecal incontinence

Faecal incontinence occurs when a person loses the ability to control their bowel movements, resulting in unplanned leakage of faeces. It can happen as a result of congenital problems with the anal sphincter (the ring of muscle that keeps the anus closed), or following childbirth, injury to or disease of the nervous system or spinal cord, prolapse of the rectum or pelvic organs, surgery involving the colon or anus, or pelvic radiotherapy. In this procedure, an inflatable circular cuff is placed under the skin around the anus, so it fits around the neck of the anal sphincter. A pump is implanted under the skin in the lower half of the abdomen which aims to allow movement of fluid to and from the cuff, to open or close the anus and allow bowel movements to be controlled.

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

- Transabdominal implantation of an artificial anal sphincter for faecal incontinence

Specialty societies

- Association of Coloproctology of Great Britain and Ireland.

Description

Indications and current treatment

Faecal incontinence occurs when a person loses control of their bowel and is unable to retain faeces in the rectum. Faecal incontinence can be caused by a wide variety of conditions that affect either the anatomy or function of the anal sphincter. Perineal injury during vaginal delivery is a common cause of faecal incontinence in women. Faecal incontinence can also be caused by neurological or spinal disease/injury (for example, stroke, multiple sclerosis or spinal cord injury). It may also occur following pelvic organ and/or rectal prolapse, colonic resection or anal surgery, or pelvic radiotherapy. For some patients faecal incontinence may be the result of surgical correction of congenital anorectal conditions, such as anorectal atresia or Hirschprung's disease, or the result of other anorectal surgery. Frail older people, people with diarrhoea, people with severe cognitive impairment or learning disabilities, and people with urinary incontinence are also at risk.

Faecal incontinence is associated with a high level of physical disability and social stigma. Its true incidence may be under-reported due to the sensitive and embarrassing nature of the condition.

Typically, first-line treatment for faecal incontinence is conservative, such as antidiarrhoeal medication and dietary management. This may be followed by pelvic floor muscle training, biofeedback therapy and electrical stimulation.

If conservative treatments have been unsuccessful, surgery, such as sphincter repair, may be recommended in patients with severe faecal incontinence. In patients for whom local surgery fails or is inappropriate, other surgical options include sacral nerve stimulation, stimulated graciloplasty (creation of a new sphincter from other suitable muscles) or implantation of an artificial anal sphincter (anorectal or transabdominal). More severe cases may require a permanent colostomy.

What the procedure involves

The procedure involves the implantation of three device components. The first is a sphincter cuff (consisting of an expander and a gel filled pillow) that is implanted around the anus. The control pump and balloon reservoir are then inserted into the abdominal space. All the components are joined together by tubing that allows the flow of saline solution between each component.

The inflatable cuff keeps the anal canal closed. To evacuate the bowel, the patient needs to press the control pump's button against the abdominal wall. This deflates the cuff and opens the anus by pumping fluid from the sphincter cuff to the balloon reservoir. The sphincter remains open until the patient wishes to close it by pressing the button on the pump. This opens the pump allowing fluid to automatically return to the cuff. As the balloon reservoir refills

the sphincter cuff gently squeezes the upper anal canal/lower rectum producing angulation between the rectum and anal canal.

Under general or other appropriate anaesthesia,a lower mid-line incision is made, extending from the pubic symphysis to the umbilicus. A small ‘window’ is then cut in the pelvic peritoneum and the inflatable sphincter cuff is a sphincter cuff (consisting of an expander and a gel filled pillow) is placed around the neck of the anal sphincter. The expander component of the cuff is placed behind the anorectal junction and the gel –filled pillow placed in front. The two components are then secured using a strap.

A subcutaneous pouch is then created for the control pump, usually in the right iliac fossa. A balloon reservoir is placed within the peritoneal cavity in the pelvis. The connecting tubes from the sphincter cuff and the pressure regulating balloon reservoir are brought through the abdominal wall from the pelvis. These tubes are connected to the control pump and the abdomen is closed.

The aim of this procedure is to reduce the rate of infection and complications associated with the anorectal approach.

Efficacy

The evidence is based on one case series of 12 patients. At a median follow-up of 59 months (range: 30–72 months), 75% (9/12) of patients had a functioning implant, with 5 of the 9 patients requiring surgical revision. Four patients required surgical revision to replace the operating pump and one due to disruption of the strap.

Continence (assessed using the Cleveland Clinical continence score) was evaluable in 10 patients. The median Cleveland Clinic continence scores improved from 16 (range: 7–20) before to 3 (range: 0–7) after surgery.

Safety

Three patients (25%) had the device removed because of complications. One patient developed pseudomembranous colitis in the perioperative period. Two other patients had the device removed because of infection after revision surgery.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to transabdominal artificial bowel sphincter implantation for faecal incontinence. Searches were conducted of the following databases, covering the period from their commencement to 16 April 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 faecal incontinence.
Intervention/test	Transabdominal implantation of an artificial anal sphincter.
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 12 patients from one case series study.

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

- Artificial anal sphincter implantation. NICE interventional procedures guidance 66 (2004). Available from www.nice.org.uk/IPG66

- Stimulated graciloplasty for faecal incontinence. NICE interventional procedures guidance 159 (2006). Available from www.nice.org.uk/IPG159

- Injectable bulking agents for faecal incontinence. NICE interventional procedures guidance 210 (2007). Available from www.nice.org.uk/IPG210

- Sacral nerve stimulation for faecal incontinence. NICE interventional procedures guidance 99 (2004). Available from www.nice.org.uk/IPG99

Clinical guidelines

- Faecal incontinence: the management of faecal incontinence in adults. NICE clinical guideline 49 (2007). Available from www.nice.org.uk/CG49

Table 2 Summary of key efficacy and safety findings on transabdominal artificial bowel sphincter implantation for faecal incontinence

Study details	Key efficacy findings	Key safety findings	Comments
Finlay G et al (2004)[1] Study type: **Case series** Country: UK Study period: Not stated Study population: The principal cause of faecal incontinence was idiopathic faecal incontinence (6 patients), obstetric sphincter injury (3 patients) and imperforate anus (3 patients) n = **12** Age: 47 years (range 19–73 years) Sex: 83% (10) females, 17% (2) males Inclusion criteria: All patients were or had been incontinent to solid stool on at least 5 days each week. All patients had undergone at least one surgical procedure that had failed to alleviate their symptoms. Technique: The prosthetic anal sphincter cuff was implanted at the anal canal junction and the pump implanted in a subcutaneous pouch in the iliac fossa. Follow-up: **Median follow-up 59 months (range 30–72 months)** Conflict of interest: All authors have declared having a shareholding in the company which holds the patent for the device used in this procedure.	***Operative success*** Implantation was achieved in all 12 patients. However the authors stated that the device was removed in 3 of the first 6 patients. The device was then modified and, with the benefit of clinical experience, no devices were removed in the next 6 patients. 75% (9/12) patients had a functioning implant after a median follow-up of 59 months. 5 of the 9 patients required further surgical revision: • due to disruption of the strap (1 patient) • to replace the operating pump (4 patients). ***Continence*** (assessed using the Cleveland Clinical continence score (maximal incontinence score of 20). Results are based on 10 evaluable patients. Continence score pre-procedure; 16 (range 7–20) Continence score 1 year post-procedure; 3 (range 0–7).	Three patients required device removal due to complications. A patient was readmitted to hospital soon after discharge with severe pseudomembranous colitis that failed to respond to conservative measures. The patient was found to have a perforation of the right colon which required emergency total colectomy and removal of the device. Another patient developed a streptococcal infection at the pump site 5 months after implantation, and required device removal. The third patient developed a disruption of the strap that joined the two components of the sphincter. This led to loss of bowel control. The strap was subsequently re-sutured during a further laparotomy, but the device became infected and was removed 4 months later. Two patients required a admission to hospital for bowel washout (as a result of faecal impacation).	First clinical paper published on this procedure. Limited evidence reported on efficacy outcomes. Early complications led to changes in protocol in terms of antibiotics as well as device modification. Patients with severe faecal incontinence.

Validity and generalisability of the studies

- The case series included in Table 2 is the first clinical report using the transabdominal artificial bowel sphincter implantation for faecal incontinence.
- It is based on a small number of patients and with a median follow-up of 59 months (minimum 30 months).
- The authors noted that early complications led to device modifications during the course of the study.
- High complication rates have been reported with other methods of anorectal implantation of artificial anal sphincters. The full clinical guideline on faecal incontinence notes that in 14 case series with a total of 402 patients, 20% (95% confidence interval [CI], 13% to 27%) of patients had complications associated with wound infection, while 50% (95% CI, 44% to 55%) had other complications.

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 D Bartolo, Dr Hunt,Mr E Kiff, Professor R Phillips, Professor J Monson, Professor N Mortenson, Mr P Sagar, Professor N Williams (Association of Coloproctology of Great Britain and Ireland).

- It is in effect a stenosing procedure that relies on delaying the passage of a formed stool.
- The technology is very similar to anorectal implantation of an artificial anal sphincter, which has been in use for several years.
- There are only preliminary data available on this technique.
- It should be associated with less infection and less risk of migration through the skin than the perineal procedure.

- Key efficacy outcomes are lower pressure occlusion - potentially less to go wrong; but more invasive placement and not sufficiently distal to obviate some mucous leakage.
- Artificial anal sphincter implantations have not been carried out in large numbers because of the high explant (removal) rate related to infection.
- A theoretical difficulty may be replacing the device (as with other artificial anal sphincters), but while replacement is relatively easy through the perineum, this procedure requires a low rectal dissection through an abdominal incision.
- Safety concerns will be similar to those associated with other artificial sphincters, such as erosion and septic complications, however it is argued that the design of the device should reduce the complication rate.
- Long term follow-up is important.
- Most cases of faecal incontinence are now treated with sacral nerve stimulation and there are few indications for this technique.

Issues for consideration by IPAC

- The clinical guidance on faecal incontinence refers to artificial anal sphincters and IPG 66.
- The manufacturer states that 24 patients have had the procedure with up to 11 year follow-up.

References

1. Finlay, IG.Richardson W and Hajivassiliou, C.A. (2004) Outcome after implantation of a novel prosthetic anal sphincter in humans.British Journal of Surgery 91.11 1485-92.

Appendix A: Additional papers on transabdominal n artificial bowel sphincter implantation for faecal incontinence

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
Hajivassiliou CA and Finlay IG. (1998) Effect of a novel prosthetic anal neosphincter on human colonic blood flow. British Journal of Surgery 85: 1703–07.	11 patients.	The study does not report on safety and efficacy outcomes in patients with faecal incontinence	The study does not report on safety and efficacy outcomes in patients with faecal incontinence

Appendix B: Related NICE guidance for transabdominal artificial bowel sphincter implanation for faecal incontinence

Guidance	Recommendations
Interventional procedures	**Artificial anal sphincter implantation. NICE interventional procedures guidance 66 (2004).** 1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake artificial anal sphincter implantation should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended. • Audit and review clinical outcomes of all patients having artificial anal sphincter implantation. 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence. 1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence. **Stimulated graciloplasty for faecal incontinence. NICE interventional procedures guidance 159 (2006).** 1.1 Current evidence on the safety and efficacy of stimulated graciloplasty for faecal incontinence is limited, but appears sufficient to support the use of this procedure for carefully selected patients in whom other treatments have failed or are contraindicated, provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 This procedure should be performed only in specialist units by clinicians with specific training and experience in the assessment and treatment of faecal incontinence.

Guidance	Recommendations
	Injectable bulking agents for faecal incontinence. NICE interventional procedures guidance 210 (2007). 1.1 Current evidence on the safety and efficacy of injectable bulking agents for faecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups. 1.2 Clinicians wishing to inject bulking agents for the treatment of faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG210publicinfo). • Audit and review clinical outcomes of all patients receiving injectable bulking agents for faecal incontinence (see section 3.1). 1.3 The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence. The Institute may review the procedure upon publication of further evidence. **Sacral nerve stimulation for faecal incontinence. NICE interventional procedures guidance 99 (2004)** 1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for faecal incontinence 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 The procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment of faecal incontinence.

Guidance	Recommendations
Clinical guidelines	**Faecal incontinence. NICE clinical guideline 49 (2007)** 1.8.8. If a trial of sacral nerve stimulation is unsuccessful, an individual can be considered for a neosphincter, for which the two options are a stimulated graciloplasty or an artificial anal sphincter. People should be informed of the potential benefits and limitations of both procedures. Those offered these procedures should be informed that they may experience evacuatory disorders and/or serious infection, either of which may necessitate removal of the device. People being considered for either procedure should be assessed and managed at a specialist centre with experience of performing these procedures. If an artificial anal sphincter is to be used, there are special arrangements that should be followed, as indicated in NICE interventional procedures guidance 66. 1.8.9 People who have an implanted sacral nerve stimulation device, stimulated graciloplasty or an artificial anal sphincter should be offered training and ongoing support at a specialist centre. These people should be monitored, have regular reviews and be given a point of contact.

Appendix C: Literature search for transabdominal artificial bowel sphincter implantation for faecal incontinence

IP 645: Transabdominal implantation of an artificial anal sphincter for faecal incontinence		
Database	**Date searched**	**Version searched**
Cochrane Library	15/4/08	Issue 1, 2008
CRD databases (DARE & HTA)	15/4/08	-
Embase	15/4/08	1980 to 2008 Week 15
Medline	15/4/08	1950 to April Week 1 2008
Medline in Process (MiP)	15/4/08	1950 to Present
CINAHL	15/4/08	1982 to date (via Dialog)
British Library Inside Conferences	11/4/08	-
The National Research Register (NRR) Archive	11/4/08	-
Controlled Trials Registry	11/4/08	-

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

1 Prosthesis Implantation/
2 "Prostheses and Implants"/
3 (Prosthe$ adj3 Implant$).tw.
4 (Artificial$ adj3 Implant$).tw.
5 Prosthe$.tw.
6 Artificial$.tw.
7 Implant$.tw.
8 Endoprosthe$.tw.
9 or/1-8
10 Anal Canal/
11 ((Anal$ or Anus$) adj3 Canal$).tw.
12 ((Anal$ or Anus$) adj3 Sphincter$).tw.
13 (Anorectal$ adj3 Disease$).tw.
14 (Anorectal$ adj3 Junction$).tw.
15 (Puborectali$ adj3 Muscle$).tw.
16 or/10-15
17 Fecal Incontinence/
18 Anus Diseases/

19 Encopresis/
20 ((Fec$ or Faec$) adj3 Incontinen$).tw.
21 ((Anal$ or Anus$) adj3 Diseas$).tw.
22 Encopre$.tw.
23 ((Anal$ or Anus$) adj3 Incontinen$).tw.
24 or/17-23
25 PAS.tw.
26 24 and 25
27 9 and 16 and 24
28 26 or 27
29 Animals/
30 Humans/
31 29 not (29 and 30)
32 28 not 31