NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of insertion of a magnetic-bead band for faecal incontinence

Faecal incontinence is an inability to control bowel movements, resulting in the involuntary passage of stools. Insertion of a magnetic bead band involves placing a ring of magnetic beads around the muscles of the back passage (the anal sphincter) to help keep the sphincter closed.

Introduction

The National Institute for Health and Care 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 August 2013.

Procedure name

- Insertion of a magnetic-bead band for faecal incontinence

Specialist societies

- Association of Coloproctology of Great Britain and Ireland.

Description

Indications and current treatment

Faecal incontinence is an inability to control bowel movements, resulting in the involuntary passage of stools. Causes include problems within the rectum (including constipation and diarrhoea), problems with the sphincter muscles (such as damage caused by childbirth), or nerve damage (such as multiple

sclerosis, stroke or spina bifida). Faecal incontinence can also occur in conditions such as dementia or severe learning disability. .

NICE clinical guideline 49 ‘Faecal incontinence: The management of faecal incontinence in adults’ states that ’there is no consensus on methods of classifying the symptoms and causes of faecal incontinence. It is most commonly classified according to symptom, character of the leakage, patient group or presumed primary underlying cause. For many people faecal incontinence is the result of a complex interplay of contributing factors, many of which can co-exist. Some factors may be relatively simple to reverse. Therefore, a detailed initial assessment and structured approach to management is needed, starting with addressing reversible factors and, only if this fails to restore continence, progressing to specialised options and investigations.’

Initial management of faecal incontinence includes interventions related to diet, bowel habit and toilet access, and medication (see Faecal incontinence: The management of faecal incontinence in adults [NICE clinical guideline 49]). Specialised management options depend on the underlying cause and include pelvic floor muscle training, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation, and rectal irrigation. The main surgical treatment is anal sphincter repair. Sacral nerve stimulation is sometimes used for people with faecal incontinence in whom sphincter surgery is deemed inappropriate. If a trial of sacral nerve stimulation is unsuccessful, a neosphincter may be considered (stimulated graciloplasty or an artificial anal sphincter).

What the procedure involves

Insertion of a magnetic-bead band for faecal incontinence aims to reinforce and improve the competence of the anal sphincter to prevent episodes of incontinence without creating obstruction, and with less morbidity than artificial bowel sphincter surgery. The magnetic-bead band does not need to be adjusted once it has been implanted.

The procedure is done with the patient under general anaesthesia, using stringent asepsis. A tunnel is created around the anal canal via an anterior incision in the perineal body. A sizing tool is inserted to assess the circumference of the anal canal and the size of implant needed. This may be verified with fluoroscopy. The sizing tool is then removed and the implant is placed around the upper anal canal in a circular fashion. Fluoroscopy may be used to confirm the correct position and the ends of the implant are tied together. The wound is then closed.

The implant consists of a ring of interlinked titanium beads, each with a weak magnetic force that holds the beads together. During defecation, the beads separate, allowing for the passage of stool. Magnetic attraction then brings the beads together to re-establish continence.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to insertion of a magnetic-bead band for faecal incontinence. Searches were conducted of the following databases, covering the period from their commencement to 25 July 2013: 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). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

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	Insertion of a magnetic-bead band.
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 30 patients treated by insertion of a magnetic-bead band for faecal incontinence from 2 case series and 2 non-randomised comparative studies (the first 3 studies include considerable patient overlap)[1–4].

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.

Table 2 Summary of key efficacy and safety findings on insertion of a magnetic-bead band for faecal incontinence

Abbreviations used: FI, faecal incontinence; SNS, sacral nerve stimulation

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Wong MTC (2012)[1]

Non-randomised comparative study

France
Recruitment period: 2008–10

Study population: patients with FI

n=28 (12 magnetic-bead band versus 16 SNS)

Age: mean 65 versus 62 years
Sex: 100% (28/28) female

Patient selection criteria: conservative treatment had been unsuccessful in all patients (lack of satisfactory response to dietary modification and antidiarrhoeal medication for at least 1 year, together with a lack of benefit from concurrent biofeedback therapy for at least 6 months).

Technique: Magnetic anal sphincter (MAS) device was used (Torax Medical Inc., USA).

Follow-up: median 18 (range 8–30) versus 22 (range 10–28) months

Conflict of interest/source of funding: one author has a consultancy agreement with Torax Medical Inc.</td>
<td>Number of patients analysed: 28 (12 vs 16)

Median incontinence scores (range)
<table>
<tr><td></td><td>Magnetic bead band</td><td>SNS</td></tr>
<tr><td>Baseline</td><td>16.5 (11–19)</td><td>15 (11– 18)</td></tr>
<tr><td>Follow-up</td><td>6 (3–15)</td><td>11.5 (0–14)</td></tr>
<tr><td>p value</td><td>0.001</td><td>0.0001</td></tr>
</table>
SNS patients needed a median of 4 adjustments of the stimulation parameters over a 12-month period.

Daily use of antidiarrhoeal medication at follow-up:
• Magnetic bead band=16.7% 92/12)
• SNS=37.5% (6/16)

Median FI quality of life score (higher scores indicate better quality of life)
<table>
<tr><td></td><td>Baseline</td><td>Follow-up</td><td>p value</td></tr>
<tr><td colspan="4">Magnetic-bead band</td></tr>
<tr><td>Lifestyle</td><td>2.5</td><td>3.6</td><td>0.002</td></tr>
<tr><td>Coping/ behaviour</td><td>1.5</td><td>3.2</td><td>0.006</td></tr>
<tr><td>Depression</td><td>2.6</td><td>3.7</td><td>0.007</td></tr>
<tr><td>Embarrassment</td><td>1.9</td><td>3.3</td><td>0.018</td></tr>
<tr><td>SNS</td><td></td><td></td><td></td></tr>
<tr><td>Lifestyle</td><td>2.0</td><td>3.5</td><td>0.0004</td></tr>
<tr><td>Coping/ behaviour</td><td>2.1</td><td>2.4</td><td>0.002</td></tr>
<tr><td>Depression</td><td>2.0</td><td>3.6</td><td>0.002</td></tr>
<tr><td>Embarrassment</td><td>2.0</td><td>2.3</td><td>0.002</td></tr>
</table>
NB: scores estimated from graphical presentation

There was a significant increase in anal canal resting pressure after insertion of a magnetic bead band, from 42.5 cmH_2O to 54 cmH_2O (p=0.027). There was no significant change in the SNS group.</td>
<td>Postoperative course and early complications
Magnetic-bead band
• No patient needed a stoma.
• Mild anal bleeding=16.7% (2/12) (resolved spontaneously before discharge)
• Faecal impaction=8.3% (1/12) (resolved with enemas)
• Device separation=8.3% (1/12) (the patient reported hearing a ‘crack’ during defecation approximately 1 month after implantation and passed the device 3 days later without evidence of ulceration.)
SNS
• All patients were discharged without incident after both the temporary percutaneous nerve evaluation test and permanent pulse generator implantation.

There was 1 device removal in each group: 1 patient in the magnetic-bead band group had spontaneous extrusion of the device, 1 patient in the SNS group had an infection at the pacemaker site 1 year after implantation and the device had to be removed. Both patients have since been managed conservatively and both have been offered an end colostomy.</td>
<td>Patient overlap with Lehur et al, 2010 and Wong et al, 2011.

Follow-up issues:
• No patients were lost to follow up.
Study design issues:
• Single centre.
• Data were reviewed from prospectively maintained databases.
• Consecutive patients.
• SNS was the first line of treatment. If SNS failed or was deemed unsuitable, insertion of a magnetic-bead band was selected.
• Quality of life was assessed using the 20-point Cleveland Clinic incontinence (Wexner) score and the 29-item validated Faecal Incontinence Quality of Life (FIQoL) questionnaire.
Study population issues:
• The 2 groups were similar with regard to age, preoperative functional scores, aetiology, and duration of incontinence.
• The cause of FI was obstetric in 39% (11/28) of patients, idiopathic in 36% (10/28) and anorectal surgery in 25% (7/28).</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; SNS, sacral nerve stimulation

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Wong MTC (2011)[2]

Non-randomised comparative study

France
Recruitment period: 2008–10

Study population: patients with end-stage FI

n=20 (10 magnetic-bead band versus 10 artificial bowel sphincter)

Age: median 65 versus 66 years
Sex: 100% (20/20) female

Patient selection criteria: all patients had end-stage FI that had not responded to prolonged medical treatment and pelvic floor retraining for at least 1 year. Exclusion criteria included: history of significant chronic defecatory motility disorder; underlying systemic disease as a source of FI; previous anorectal posterior compartment surgery; rectal resection; current overt rectal or vaginal prolapsed; complex anal or rectovaginal fistulas; active pelvic infection; history of pelvic radiation; history of anal, rectal or colon cancer within 2 years; an electric or metallic implant within 10 cm of the proposed area of device placement.

Technique: Magnetic anal sphincter (MAS) device (Torax Medical Inc., USA) the Acticon Neosphincter (American Medical Systems, USA) artificial bowel sphincter were used.

Follow-up: median 8 (range 6–13) versus 22.5 (range 6–72) months

Conflict of interest/source of funding: one author is a consultant for American Medical Systems and Torax Medical Inc.</td>
<td>Number of patients analysed: 20 (10 vs 10)

Median duration of surgery (minutes)
• Magnetic-bead band=62
• Artificial bowel sphincter=97.5 (p=0.03)

Median length of hospitalisation (days)
• Magnetic-bead band=4.5
• Artificial bowel sphincter=10 (p<0.0001)

Median incontinence scores (range)
<table>
<tr><th></th><th>Magnetic bead band n=10</th><th>Artificial bowel sphincter n=10</th></tr>
<tr><td>Baseline</td><td>17</td><td>16.5</td></tr>
<tr><td>Follow-up</td><td>6</td><td>5</td></tr>
<tr><td>p value</td><td>0.0002</td><td>0.0001</td></tr>
</table>
Median FI quality of life score (higher scores indicate better quality of life)
<table>
<tr><th></th><th>Magnetic bead band n=10</th><th>Artificial bowel sphincter n=10</th></tr>
<tr><td>Baseline</td><td>1.9</td><td>1.8</td></tr>
<tr><td>Follow-up</td><td>3.4</td><td>3.6</td></tr>
<tr><td>p value</td><td>0.0052</td><td>0.0089</td></tr>
</table>
There was a significant increase in anal canal resting pressure after insertion of a magnetic bead band, from 35 cmH_2O to 58.5 cmH_2O (p=0.027). In the artificial bowel sphincter group, there was no significant difference between preoperative anal resting pressure of 34 cmH_2O and 41 cmH_2O when the anal cuff was open but there was a significant increase from baseline value to closed anal cuff pressures (75 cmH_2O, p=0.0007). When comparing the median final steady-state pressures, the artificial bowel sphincter closed and cuff pressure was significantly higher than the magnetic-bead band anal resting pressure (89 vs 58.5 cmH_20, p=0.0147).</td>
<td>There was no significant difference in early postoperative complications (within 30 days of surgery) between the 2 groups (4 versus 2, p=0.63)

Magnetic-bead band
• No patient needed a stoma.
• Mild anal bleeding=20.0% (2/10) (resolved spontaneously before discharge)
• Faecal impaction=10.0% (1/10) (resolved with enemas)
• Device separation=10.0% (1/10) (the patient reported hearing a ‘crack’ during defecation approximately 1 month after implantation and passed the device 3 days later without evidence of ulceration.)
Artificial bowel sphincter
• No patient needed a stoma.
• Faecal impaction=20.0% (2/10) (resolved with enemas before discharge)

4 patients in the artificial bowel sphincter group needed revisions, after a median duration of 47.5 months (as a result of leakage from the anal cuff [3] and pressure-regulating balloon [1]). Two of these patients subsequently needed explantation because of perineal infection (1) and pain (1) that occurred 1 and 6 months after device revision, respectively.</td>
<td>Patient overlap with Lehur et al, 2010 and Wong et al, 2012. The first 8 patients in this series were part of the initial feasibility study.

Follow-up issues:
• No patients were lost to follow-up.

Study design issues:
• Single centre.
• Data were reviewed from prospectively maintained databases.
• Quality of life was assessed using the 20-point Cleveland Clinic incontinence (Wexner) score and the 29-item validated Faecal Incontinence Quality of Life (FIQoL) questionnaire.

Study population issues:
• Patients were matched for age, comorbidities, duration of incontinence, preoperative functional scores, and anal manometry results.
• There was a statistically significant longer follow-up for patients treated by artificial bowel sphincter. The cause of FI was obstetric in 50% (10/20) of patients, idiopathic in 25% (5/20) and anal surgery in 25% (5/20).</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; SNS, sacral nerve stimulation

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lehur PA (2010)[3]

Case series

France, US and Denmark
Recruitment period: 2008–10

Study population: patients with documented FI of more than 2 episodes per week

n=14

Age: mean 63 years (range 41–74)
Sex: 100% (14/14) female

Patient selection criteria: age 19–84 years with a life expectancy >3 years and a documented history of faecal incontinence for at least 6 months; all patients must have previously attempted or not been candidates for conservative therapeutic approaches. An average of at least 2 FI episodes per week over a 3-week baseline diary period was required. Exclusion criteria included: history of significant chronic defecatory motility disorder; underlying systemic disease as a source of FI; previous anorectal posterior compartment surgery; rectal resection; current overt rectal or vaginal prolapsed; complex anal or rectovaginal fistulas; active pelvic infection; history of pelvic radiation; history of anal, rectal or colon cancer within 2 years; an electric or metallic implant within 10 cm of the proposed area of device placement.

Technique: Magnetic anal sphincter (MAS) device was used (Torax Medical Inc., USA).

Follow-up: median 6 months

Conflict of interest/source of funding: all the participating institutions received financial support from Torax Medical Inc. One of the authors is a consultant for Torax Medical Inc.</td>
<td>Number of patients analysed: 14

Mean number of weekly FI episodes (n=5):
• Baseline=7.2
• 6 months=0.7, p=0.05

Mean Wexner continence score (n=5) (scores range from 0 to 20 with higher scores indicating worse FI):
• Baseline=17.8
• 6 months=7.8, p=0.002

A significant improvement in solid and liquid stool control items of the Wexner continence score was also observed (p=0.008).

Mean FI quality of life score (n=5) (higher scores indicate better quality of life)
<table>
<tr><th></th><th>Baseline</th><th>6 months follow-up</th><th>p value</th></tr>
<tr><td>Lifestyle</td><td>2.2</td><td>3.4</td><td>0.0008</td></tr>
<tr><td>Coping/ behaviour</td><td>1.3</td><td>2.9</td><td>0.0008</td></tr>
<tr><td>Self-perception</td><td>2.0</td><td>3.5</td><td>0.002</td></tr>
<tr><td>Embarrassment</td><td>1.4</td><td>3.2</td><td>0.005</td></tr>
</table>
NB: scores estimated from graphical presentation

Mean obstructed defecation syndrome scores (n=5):
• Baseline=5.2
• 6 months=6.2, p=not stated

In 4 of the 5 patients with 6-month follow-up, there was a significant decrease in urgency episodes from a mean of 23.5 at baseline to a mean of 1 at 6-month follow-up (1 patient had an increase in urgency episodes).</td>
<td>No intraoperative complications associated with implantation of the device occurred.

Adverse events:
• Pain=14.3% (2/14) (1 was described as mild and resolved without any treatment; the other resolved after medication)
• Infection=14.3% (2/14) (1 patient developed infection 9 days after the procedure and was treated with systemic antibiotics without success. The implant was removed after 47 days and the patient had a stoma. The other patient had a superficial wound infection 7 days after the procedure that was successfully treated with systemic antibiotics. The patient then chose to have the device removed after 69 days because it did not meet her expectations: she opted for a stoma for personal reasons)
• Rectal bleeding=7.1% (1/14) (resolved without treatment)
• Obstructed defecation=7.1% (1/14) (2 days, resolved after treatment with enemas)
• Device separation=7.1% (1/14) (the patient reported hearing a ‘crack’ during defecation approximately 1 month after implantation. X-ray showed the device had separated and within a week the patient passed the device without evidence of ulceration. On review, the device was undersized at implant even though the largest available device was used.)</td>
<td>Patient overlap with Wong et al, 2011 and Wong et al, 2012.

Follow-up issues:
• 5 patients (36%) had completed 6 months follow-up (including 2 who had completed their 1 year follow-up).

Study design issues:
• Multicentre, prospective, observational clinical feasibility study.
• The FI quality of life scoring system was not described in detail in the paper.

Study population issues:
• Prior SNS therapy failed in 9 of the patients, and 2 patients had prior sphincteroplasty procedures.
• The cause of FI was obstetric in 50% (7/14) of patients, idiopathic in 29% (4/14) and neuropathic in 21% (3/14).</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; SNS, sacral nerve stimulation

Study details	Key efficacy findings	Key safety findings	Comments
Pakravan F (2013)[4] **Case series (conference abstract)** Germany Recruitment period: 2012 Study population: patients with severe FI **n=16** Age: mean 67 years Sex: 81% (13/16) female Patient selection criteria: not reported Technique: not reported **Follow-up: mean 184 days** Conflict of interest/source of funding: not reported	Efficacy findings from conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview.	There were no intraoperative complications. Adverse events: • Pain=31.3% (5/16) • Swelling and erythema in both gluteal regions within the second and third week after the implantation=31.3% (5/16) (resolved after conservative treatment) • Vaginal bleeding=6.3% (1/16) (resolved spontaneously) No explantations occurred during follow-up.	**Study design issues**: • Conference abstract – provides limited details of the study.

Efficacy

The efficacy data reported here is extracted from 3 studies with considerable overlap in patients treated by insertion of a magnetic-bead band.

Improved continence

A non-randomised comparative study of 28 patients treated by insertion of a magnetic-bead band or sacral nerve stimulation reported improved median continence scores in both groups from 16.5 and 15 at baseline to 6 and 11.5 (p=0.001 and 0.0001), respectively at follow-up (median follow-up 18 and 22 months respectively)[1].

A non-randomised comparative study of 20 patients treated by insertion of a magnetic-bead band or artificial bowel sphincter reported improved median continence scores in both groups from 17 and 16.5 at baseline to 6 and 5 (p=0.0002 and 0.0001), respectively at follow-up (median follow-up 8 and 22.5 months respectively)[2].

A case series of 14 patients reported a reduction in the mean number of weekly faecal incontinence episodes from 7.2 to 0.7 (p=0.05) at 6 months follow-up, in the 5 patients who had completed 6 months follow-up[3].

The case series of 14 patients reported that 1 patient chose to have the magnetic-bead band removed after 69 days because it did not meet her expectations: she opted for a stoma for personal reasons[3].

Quality of life

The non-randomised comparative study of 28 patients treated by insertion of a magnetic-bead band or sacral nerve stimulation reported statistically significant improvements from baseline in mean quality of life scores at follow-up for all 4 domains (lifestyle, coping/behaviour, depression, and embarrassment) in both groups (median follow-up 18 and 22 months respectively)[1].

The non-randomised comparative study of 20 patients treated by insertion of a magnetic-bead band or artificial bowel sphincter reported statistically significant improvements in median quality of life scores in both groups from 1.9 and 1.8 at baseline to 3.4 and 3.6 (p=0.005 and 0.009), respectively at follow-up (median follow-up 8 and 22.5 months respectively)[2].

The case series of 14 patients reported statistically significant improvements from baseline in mean quality of life scores at 6 months follow-up for all 4 domains (lifestyle [2.2 at baseline to 3.4 at follow-up, p=0.0008], coping/behaviour [1.3 vs 2.9, p=0.0008], self-perception [2.0 vs 3.5, p=0.002] and embarrassment [1.4 vs 3.2, p=0.005]) in the 5 patients who had completed follow-up[3].

Safety

Infection

Infection was reported in 14% (2/14) of patients in a case series of 14 patients. One patient developed infection 9 days after the procedure and was treated with systemic antibiotics without success. The implant was removed after 47 days and the patient had a stoma. The other patient had a superficial wound infection 7 days after the procedure that was successfully treated with systemic antibiotics[3].

Pain

Pain was reported in 14% (2/14) of patients in the case series of 14 patients. In 1 patient, the pain was described as mild and resolved after medication; in the other patient it resolved after medication[3].

Bleeding

Rectal bleeding that resolved spontaneously was reported in 1 patient in the case series of 14 patients[1]. Vaginal bleeding that resolved spontaneously was reported in 1 patient in a case series of 16 patients[4].

Obstructed defecation

Obstructed defecation was reported in 1 patient in the case series of 14 patients: it resolved within 2 days after treatment with enemas[3].

Swelling and erythema

Swelling and erythema in both gluteal regions within the second and third week after the procedure was reported in 31% (5/16) of patients: this resolved after conservative treatment[4].

Device separation

Device separation was reported in 1 patient in the case series of 14 patients; the patient reported hearing a ‘crack’ during defecation approximately 1 month after implantation. X-ray showed the device had separated and within a week the patient passed the device without evidence of ulceration on clinical examination. On review, the device was deemed to be undersized at implant even though the largest available device was used[3].

Validity and generalisability of the studies

- Almost all the patients included in the studies are women.
- There is considerable patient overlap between the first 3 studies included in table 2[1–3]. The case series is a feasibility study and the 2 non-comparative

studies use some of the same patients matched with controls (treated by either sacral nerve stimulation or artificial bowel sphincter).

- One study is reported only as a conference abstract - efficacy findings from conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview. Safety outcomes only have been presented from this abstract[4].
- The non-randomised comparative study comparing insertion of a magnetic-bead band against artificial bowel sphincter reported a statistically significant longer follow-up for patients treated by artificial bowel sphincter. This makes it difficult to compare the efficacy of the 2 procedures at last follow-up[2].
- There is a lack of long-term follow-up.

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.

Interventional procedures

Related by indication

- Percutaneous tibial nerve stimulation for faecal incontinence. NICE interventional procedure guidance 395 (2011). Available from www.nice.org.uk/guidance/IPG395
- Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence. NICE interventional procedure guidance 393 (2011). Available from www.nice.org.uk/guidance/IPG393
- Transabdominal artificial bowel sphincter implantation for faecal incontinence. NICE interventional procedure guidance 276 (2008). Available from www.nice.org.uk/guidance/IPG276
- Injectable bulking agents for faecal incontinence. NICE interventional procedure guidance 210 (2007). Available from www.nice.org.uk/guidance/IPG210
- Stimulated graciloplasty for faecal incontinence. NICE interventional procedure guidance 159 (2006). Available from www.nice.org.uk/guidance/IPG159

- Sacral nerve stimulation for faecal incontinence. NICE interventional procedure guidance 99 (2004). Available from www.nice.org.uk/guidance/IPG99
- Artificial anal sphincter implantation. NICE interventional procedure guidance 66 (2004). Available from www.nice.org.uk/guidance/IPG66

Related by procedure

- Laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease. NICE interventional procedure guidance 431 (2012). Available from www.nice.org.uk/guidance/IPG431

Clinical guidelines

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

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 Steve Brown, Mr Thomas Dudding (Association of Coloproctology of Great Britain and Ireland)

- Neither specialist adviser has ever performed the procedure.
- Both specialist advisers consider the procedure to be definitely novel and of uncertain safety and efficacy.
- One adviser stated that sacral neuromodulation is the best comparator; the other stated that the artificial bowel sphincter is the main comparator and dynamic graciloplasty is also a comparator.
- Theoretical adverse events include infection, erosion, chronic pain, device migration, and loss of magnetism.
- Anecdotal adverse events include bleeding and infection.
- Adverse events reported in the literature include infection, wound dehiscence and device failure.
- The key efficacy outcome is improved continence.
- There is uncertainty about the efficacy.

- Training is required in device insertion. The procedure needs to be performed in centres that provide a full range of pelvic floor investigations and treatments (likely to be national commissioned designated centres).
- A trial is about to start (HTA-funded, principal investigator is David Jayne).
- One adviser considers the potential impact of the procedure on the NHS to be moderate, in terms of numbers of patients and use of resources; the other adviser considers the potential impact to be minor.

Patient commentators' opinions

NICE's Public Involvement Programme sent 5 questionnaires to 1 NHS Trusts for distribution to patients who had the procedure (or their carers). NICE received xxx completed questionnaires.

Section to be inserted if there is no patient commentary

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Section to be inserted if patient commentators raised no new issues

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Section to be inserted if patient commentators raised new issues

The patient commentators raised the following issues about the safety/efficacy of the procedure which did not feature in the published evidence or the opinions of specialist advisers, and which the Committee considered to be particularly relevant:

- [insert additional efficacy and safety issues raised by patient commentators and highlighted by IPAC, add extra rows as necessary].
- [Last item in list].

Issues for consideration by IPAC

Ongoing trials:

- NCT01920607; Medical and Economic Evaluation of a Magnetic Anal Sphincter for Patients With Severe Anal Incontinence (MOS STIC); RCT comparing magnetic anal sphincter with sacral nerve stimulation; Location=France; estimated enrolment=156; start date=November 2013; estimated completion date=May 2016.
- An HTA-funded trial is due to start in October 2013 (with 12 months setup period to include training and setup of 20 UK centres); estimated enrolment is 350 patients recruited over 30 months and randomised 1:1 magnetic anal sphincter versus sacral nerve modulation.

References

1. Wong MT, Meurette G, Wyart V et al. (2012) Does the magnetic anal sphincter device compare favourably with sacral nerve stimulation in the management of faecal incontinence? Colorectal Disease 14: e323–9

2. Wong MT, Meurette G, Stangherlin P et al. (2011) The magnetic anal sphincter versus the artificial bowel sphincter: a comparison of 2 treatments for fecal incontinence. Diseases of the Colon & Rectum 54: 773–9

3. Lehur PA, McNevin S, Buntzen S et al. (2010) Magnetic anal sphincter augmentation for the treatment of fecal incontinence: a preliminary report from a feasibility study. Diseases of the Colon & Rectum 53: 1604–10

4. Pakravan F, Helmes C (2013) First experiences after 15 implantations of the magnetic anal sphincter in patients with severe fecal incontinence. Diseases of the Colon and Rectum 56: e128

Appendix A: Additional papers on insertion of a magnetic-bead band 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
Mantoo S, Meurette G, Podevin J et al. (2012) The magnetic anal sphincter: a new device in the management of severe fecal incontinence. Expert Review of Medical Devices 9: 483-490	Review 3 studies	The device has acceptable and comparable adverse effects to other therapies. FI and Fecal Incontinence Quality of Life scores are significantly improved in the short term.	Review without meta-analysis (all included studies are summarised in table 2)

Appendix B: Related NICE guidance for insertion of a magnetic-bead band for faecal incontinence

Guidance	Recommendations
Interventional procedures	**Percutaneous tibial nerve stimulation for faecal incontinence. NICE interventional procedure guidance 395 (2011).** 1.1 The evidence on percutaneous tibial nerve stimulation (PTNS) for faecal incontinence raises no major safety concerns. There is evidence of efficacy in the short term in a limited number of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake PTNS for faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG395/publicinfo). • Audit and review clinical outcomes of all patients having PTNS for faecal incontinence (see section 3.1). 1.3 This procedure should only be carried out in units specialising in the assessment and treatment of faecal incontinence, as one of a range of treatment options. 1.4 The Committee was advised that further research is in progress. Future research should clearly define the patient groups being treated and should explicitly address treatment schedules. Studies should report long-term outcomes and requirements for retreatment. NICE may review this guidance on publication of further evidence. **Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence. NICE interventional procedure guidance 393 (2011).** 1.1 The evidence on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence raises no major safety concerns. There is evidence of efficacy in the short term, but in a limited number of patients. Therefore, this procedure should only be used with special arrangements

	for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG393/publicinfo). • Audit and review clinical outcomes of all patients having endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence (see section 3.1). 1.3 This procedure should only be carried out in units specialising in the assessment and treatment of faecal incontinence, as one of a range of treatment options. 1.4 Further research into endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence should clearly define the patient groups being treated. It should also report the clinical impact in terms of quality of life and long-term outcomes. NICE may review the procedure on publication of further evidence. **Transabdominal artificial bowel sphincter implantation for faecal incontinence. NICE interventional procedure guidance 276 (2008).** 1.1 Current evidence on the safety and efficacy of transabdominal artificial bowel sphincter implantation for faecal incontinence is based on a small number of patients and is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake transabdominal artificial bowel sphincter implantation for 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, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having transabdominal artificial bowel sphincter implantation for faecal incontinence (see section 3.1).

	Injectable bulking agents for faecal incontinence. NICE interventional procedure 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. • 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. **Stimulated graciloplasty for faecal incontinence. NICE interventional procedure 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. **Sacral nerve stimulation for faecal incontinence. NICE interventional procedure 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. **Artificial anal sphincter implantation. NICE interventional procedure 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. **Laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease. NICE interventional procedure guidance 431 (2012).** 1.1 The evidence on the safety and efficacy of laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease (GORD) is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake laparoscopic insertion of a magnetic bead band for GORD 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, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having laparoscopic insertion of a magnetic bead band for GORD (see section 3.1). 1.3 NICE encourages further research and collaborative data collection on laparoscopic insertion of a magnetic bead band for GORD. Clear descriptions of patient selection are particularly important. Perioperative and long-term complications should be reported, together with details of long-term efficacy, including the need for further procedures and medication to control symptoms of GORD. NICE may review the procedure on publication of further evidence.
Clinical guidelines	**Faecal incontinence: The management of faecal incontinence in adults. NICE clinical guideline 49 (2007).** *Surgery* 1.8.1 All people with faecal incontinence considering or being considered for surgery should be referred to a specialist surgeon to discuss: • the surgical and non-surgical options appropriate for their individual circumstances • the potential benefits and limitations of each option, with particular attention to long-term results • realistic expectations of the effectiveness of any surgical procedures under consideration. 1.8.2 People with a full-length external anal sphincter defect that is 90º or greater (with or without an associated internal anal sphincter defect) and faecal incontinence that restricts quality of life should be considered for sphincter repair. They should be given a realistic expectation of what this operation can achieve and information about possible adverse events, in both the short and long terms. 1.8.3 People with internal sphincter defects, pudendal nerve neuropathy, multiple defects, external sphincter atrophy, loose stools or irritable bowel syndrome should be informed that these factors are likely to decrease the effectiveness of anal sphincter repair. 1.8.4 People undergoing anal sphincter repair should not routinely receive a temporary defunctioning stoma. 1.8.5 People undergoing anal sphincter repair should not receive constipating agents in the postoperative period and should be allowed to eat and drink as soon as they feel able to. 1.8.6 A trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate. These may be patients with intact anal sphincters, or those with sphincter disruption. In those with a defect, contraindications to direct

	repair may include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor-quality muscle. 1.8.7 All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with faecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success. People being considered for sacral nerve stimulation should be assessed and managed at a specialist centre that has experience of performing this procedure. 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 sphincter16. 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. 1.8.10 Antegrade irrigation via appendicostomy, neo-appendicostomy or continent colonic conduit may be considered in selected people with constipation and colonic motility disorders associated with faecal incontinence. 1.8.11 A stoma should be considered for people with faecal incontinence that severely restricts lifestyle only once all appropriate non-surgical and surgical options, including those at specialist centres, have been considered. Individuals should be informed of the potential benefits, risks and long-term effects of this procedure. Individuals assessed as possible candidates for a stoma should be referred to a stoma care service.

Appendix C: Literature search for insertion of a magnetic-bead band for faecal incontinence

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	25 July 2013	Issue 7 of 12, July 2013
Database of Abstracts of Reviews of Effects – DARE (CRD website)	25 July 2013	Issue 2 of 4, April 2013
HTA database (CRD website)	25 July 2013	Issue 2 of 4, April 2013
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	25 July 2013	Issue 6 of 12, June 2013
MEDLINE (Ovid)	25 July 2013	1946 to July Week 3 2013
MEDLINE In-Process (Ovid)	25 July 2013	July 24, 2013
EMBASE (Ovid)	25 July 2013	1974 to 2013 Week 29
CINAHL (NLH Search 2.0/EBSCOhost)	25 July 2013	1981 to present
BLIC (Dialog DataStar)	25 July 2013	n/a

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

1	Fecal Incontinence/
2	((faecal* or fecal* or faeces* or feces* or fecally* or faecally* or rectum* or
	rectal* or anal or anus or stool* or bowel* or defecat* or defaecat*) adj3
	(incontin* or urge* or dysfunction* or disorder* or leak* or soil* or seep* or
	impact*)).tw.
3	FI.tw.
4	Anal Canal/
5	((Anal* or anus* or back) adj3 (canal* or passage*)).tw.
6	or/1-5
7	Magnets/
8	((Magnet* or sphincter*) adj3 augment*).tw.
9	(Magnet* adj3 (anal* or anus*) adj3 sphincter*).tw.
10	MAS.tw.
11	((Magnet* or titanium*) adj3 (bead* or band* or ring*)).tw.
12	(Magnet* adj3 sphincter*).tw.
13	FENIX.tw.
14	(continen* adj3 restor*).tw.
15	((control* or regulat*) adj3 (faec* or fec* or rectal* or bowel* or anal* or anus* or
	rectum* or sphincter*) adj3 (open* or movement* or motion*)).tw.

16	or/7-15
17	6 and 16
18	animals/ not humans/
19	17 not 18