NICE guidance

Insertion of a magnetic bead band for faecal incontinence

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg483

1 Recommendations

1.1 Current evidence on the safety and efficacy of insertion of a magnetic bead band for faecal incontinence is limited in quantity and quality. The available evidence was considered in the context of the distress that faecal incontinence can cause and of the other treatment options, which may be limited. If further evidence supports the efficacy of this procedure, it has the potential to significantly improve quality of life for appropriately selected patients. Therefore insertion of a magnetic bead band for faecal incontinence may be used with special arrangements for clinical governance, consent and audit. NICE encourages the publication of outcomes on all patients, with specific consideration of entering all eligible patients into the HTA trial – 12/35/07 (see section 1.3).

1.2 Clinicians wishing to undertake insertion of a magnetic bead band for faecal incontinence should take the following actions.

- Inform the clinical governance leads in their NHS trusts.

- Ensure that patients understand the uncertainty about the procedure's efficacy (especially in the long term) and the risk of complications that may need removal of the band. They should inform them fully about other treatment options and about the value of research studies (when appropriate), and provide them with clear written information. In addition, the use of NICE's Information for the public is recommended.

1.3 Clinicians should offer all eligible patients entry into the HTA trial – 12/35/07. Data about all patients who do not enter the trial should be collected for local audit and review with a view to collaborative publication of outcomes.

1.4 The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence.

1.5 NICE will review the procedure when the results of the HTA trial are available. Research outcomes for any future studies should include disease-related quality of life.

2 Indications and current treatments

2.1 Faecal incontinence is an inability to control bowel movements, resulting in the involuntary passage of stools. Causes include problems in the rectum, 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.

2.2 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).

3 The procedure

3.1 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 inserted.

3.2 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. The sizing tool is then removed and the implant is placed circumferentially around the upper anal canal. Fluoroscopy may be used to confirm the correct position. The ends of the implant are tied together. The wound is then closed.

3.3 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 the passage of stool. Magnetic attraction then brings the beads together to re-establish continence.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. There was considerable patient overlap between the studies. For more detailed information on the evidence, see the interventional procedure overview.

4.1 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). 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).

4.2 The non-randomised comparative study of 28 patients 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). The non-randomised comparative study of 20 patients 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).

4.3 A case series of 24 patients reported that 70% (16/23) of patients were satisfied with the procedure and 61% (14/23) would recommend it to another person. A 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.

4.4 The specialist advisers stated that the key efficacy outcome is improved continence with accompanying improvement in disease-specific and generic quality of life.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Infection was reported in 14% (2/14) of patients in the 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. Perineal abscess was reported in 1 patient at 6 months postoperatively in the case series of 24 patients; the device was explanted.

5.2 Swelling and erythema in both gluteal regions 2 weeks after the procedure was reported in 31% (5/16) of patients in a case series of 16 patients. This resolved after conservative treatment.

5.3 Obstructed defecation was reported in 1 patient in the case series of 14 patients. This resolved within 2 days after treatment with enemas.

5.4 Rectal bleeding that resolved spontaneously was reported in 1 patient in the case series of 14 patients. Vaginal bleeding that resolved spontaneously was reported in 1 patient in the case series of 16 patients.

5.5 Pain that resolved after medication was reported in 14% (2/14) of patients in the case series of 14 patients. Pain (not further described) was reported in 31% (5/16) of patients in the case series of 16 patients.

5.6 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.

5.7 The specialist advisers listed erosion and discomfort as anecdotal adverse events. Theoretical adverse events were chronic pain, device migration, constipation and loss of magnetism.

6 Further information

6.1 For related NICE guidance see the NICE website.

Information for patients

6.2 NICE has produced information on this procedure for patients and carers (Information for the public). It explains the nature of the procedure and

the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence the guidance is based on is also available.

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Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation