Does the magnetic anal sphincter device compare favourably with sacral nerve stimulation in the management of faecal incontinence?

M. T. C. Wong, G. Meurette, V. Wyart and P.-A. Lehur

Clinique de Chirurgie Digestive et Endocrinienne, Institut des Maladies de l’Appareil Digestif (IMAD), University Hospital of Nantes, Nantes, France

Received 20 December 2011; accepted 1 February 2012; Accepted Article online 16 February 2012

Abstract

Aim The magnetic anal sphincter (MAS) is a recent surgical innovation for severe faecal incontinence (FI). With its place in the treatment algorithm of FI yet to be defined, we report a nonrandomized comparison between MAS and sacral nerve stimulation (SNS) in a single-centre cohort of patients with FI.

Method Data were reviewed from prospective databases. From December 2008 to December 2010, 12 women [median age 65 (42–76) years], having FI for a median of 6.5 years, were implanted with a MAS. Sixteen women, of similar age, preoperative function scores, aetiology and duration of incontinence, and implanted with a permanent SNS pulse generator during the same period, served as a reference group. The duration of hospital stay, complications, change in incontinence and quality of life scores and anal physiology were compared between the two groups.

Results The duration of follow up was similar [MAS = 18 (8–30) months vs SNS = 22 (10–28) months; \( P = 0.318 \)]. Four patients with MAS experienced a 30-day complication, and the device was removed from one patient in each group. A significant improvement in incontinence \( (P < 0.001) \) and quality of life scores \( (P < 0.04) \) occurred in both groups. Mean anal resting pressure increased significantly in patients implanted with a MAS \( (P = 0.027) \).

Conclusion In this single-centre nonrandomized cohort of FI patients, MAS was as effective as SNS in improving continence and quality of life, with similar morbidity. These results can now serve as a prelude to a randomized trial comparing the procedures.

Keywords Faecal incontinence, magnetic anal sphincter, sacral nerve stimulation, surgery, results, quality of life

What is new in this paper?

This nonrandomized comparative study has shown that implantation of the magnetic anal sphincter improves incontinence and quality of life to a similar degree as sacral nerve stimulation.

Introduction

Owing to the complex and multi-etiological nature of faecal incontinence (FI), current treatments do not necessarily address the needs of every patient [1–3]. As a result of active research in this field, new innovations are presently being tested. One is the magnetic anal sphincter (MAS) or FENIX™ (TORAX Medical, Inc., Shoreview, Minnesota, USA), a novel device that employs magnetic forces to augment the patient’s anal sphincter. This has recently acquired the CE-mark (European Commission approval) and, in addition, a recent multicentre feasibility study has shown promising short-term results with limited complications and efficient restoration of continence [4].

In an effort to define its place in the treatment algorithm of FI, we compared the outcome of patients implanted with the MAS and the artificial bowel sphincter (ABS). The study showed that in the short term, both devices were equally effective in restoring continence and quality of life [5]. We then aimed to assess, in a similar manner, the outcome of the MAS and sacral nerve stimulation (SNS), comparing prospectively a cohort of patients treated in our institution [6]. The results of this
study will serve to determine the feasibility of a larger randomized trial comparing these two treatments for FI.

**Method**

**Patients**

Data were reviewed from prospectively maintained databases. Patients were not randomized into treatment groups. Rather, SNS was the first line of treatment, with patients selected for MAS being those who had failed either the percutaneous nerve evaluation (PNE) test or definitive SNS, those who had been deemed unsuitable for SNS owing to physical or cognitive limitations, or those who simply had refused this option.

From December 2008 to December 2010, 28 consecutive patients with FI failed to respond to conservative treatment, defined as a lack of satisfactory response to dietary modifications and antidiarrhoeals for at least 1 year, together with a lack of benefit from concurrent biofeedback therapy for at least 6 months. All underwent PNE testing, and subsequently 16 of these patients were implanted with a permanent SNS pulse generator. During the same period, the remaining 12 patients (of whom three had failed the PNE test and three had suffered a loss of efficacy after a period of permanent SNS) were implanted consecutively with the MAS. No patient had been treated with SNS and MAS (i.e. there was no crossover). Both MAS (Group 1, \( n = 12 \)) and SNS (Group 2, \( n = 16 \)) groups were similar in terms of age, preoperative functional scores, aetiology and duration of incontinence (Table 1). Treatment outcomes, including length of hospital stay, complications and changes in functional scores (incontinence severity and quality of life) were prospectively recorded. Of note, patients implanted with the MAS were part of two earlier studies, with a shorter duration of follow-up of 6 and 8 months, respectively [4,5].

**Table 1** Relevant medical history of treatment groups.

<table>
<thead>
<tr>
<th>Patient data</th>
<th>Treatment group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MAS (Group 1) ((n = 12))</td>
<td>SNS (Group 2) ((n = 16))</td>
</tr>
<tr>
<td>Age (years)</td>
<td>65 (42–76)</td>
<td>62 (44–74)</td>
</tr>
<tr>
<td>Duration of FI (years)</td>
<td>6.5 (1–40)</td>
<td>7 (1–30)</td>
</tr>
<tr>
<td>Aetiology of FI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetric trauma</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Anorectal surgery</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Idiopathic</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Prior surgical intervention for FI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNS</td>
<td>6*</td>
<td></td>
</tr>
<tr>
<td>Sphincter repair</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Sphincter defects on ultrasound</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Concurrent pelvic floor disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectocele</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Cystocele</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Incontinence severity score [6]</td>
<td>16.5 (11–19)</td>
<td>15 (11–18)</td>
</tr>
<tr>
<td>FIQoL score components [7]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle</td>
<td>2.5 (1.2–4.0)</td>
<td>2.0 (1.5–3.9)</td>
</tr>
<tr>
<td>Coping behaviour</td>
<td>1.5 (1.1–4.0)</td>
<td>2.2 (1.1–3.0)</td>
</tr>
<tr>
<td>Depression</td>
<td>2.6 (1.5–3.5)</td>
<td>2.0 (1.7–3.8)</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>1.8 (1.0–2.8)</td>
<td>1.0 (1.0–2.0)</td>
</tr>
<tr>
<td>Anal physiology tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting anal pressure (cmH(_2)O)</td>
<td>42.5 (8–86)</td>
<td>34 (10–68)</td>
</tr>
<tr>
<td>Maximum squeeze pressure (cmH(_2)O)</td>
<td>38.5 (0–97)</td>
<td>34 (0–133)</td>
</tr>
<tr>
<td>Maximum tolerated rectal volume (ml)</td>
<td>130 (50–300)</td>
<td>160 (50–300)</td>
</tr>
<tr>
<td>Contraction duration (s)</td>
<td>19 (0–50)</td>
<td>20.5 (0–166)</td>
</tr>
</tbody>
</table>

Data are given as \( n \) or as median (range).

*Three patients only had peripheral nerve evaluation and failed to achieve more than 50% improvement in incontinent episodes. The remaining three who had a permanent pulse generator implanted had it explanted during magnetic anal sphincter (MAS) implantation.

FI, faecal incontinence; FIQoL, Faecal Incontinence Quality of Life; SNS, sacral nerve stimulation.
Preoperative assessment

A baseline bowel-habit diary was completed over a period of 3 weeks by all patients. This comprised five questions recording the number per unit time of episodes of defaecation, incontinence and urgency, and the ability to defer defaecation (duration in minutes) and the treatment sought during incontinent episodes. Urgency was defined as the need to rush to the toilet to avoid an ‘incontinent’ episode, with a delay to postponed defaecation of < 15 min [7]. In addition, patients also underwent routine anal ultrasound and anal physiological testing, together with the systematic assessment of incontinence and Quality of Life scores, using the 20-point Cleveland Clinic incontinence severity score and the 29-item, validated Faecal Incontinence Quality of Life (FIQoL) questionnaire [8,9]. All patients were informed in detail about the procedures, the postoperative follow-up course, possible complications and outcome, and all gave informed consent. The study was approved by the Institutional Review Board Committee.

Device description and operative technique

The operative techniques for the temporary PNE test and permanent implantation have been previously described [7]. All patients were tested with 3 weeks of external stimulation. A definitive pulse generator was implanted when a significant benefit was obtained, defined as a decrease of at least 50% in the number of episodes of FI or urgency compared with baseline, as documented in the bowel-habit diary and evident patient satisfaction. Both the PNE and permanent implantation procedures were performed under general anaesthesia, using a staged implantation technique with the tined electrode used for the PNE test.

The technique of implantation of the MAS has previously been described in detail [4]. Essentially, it consists of 14–20 titanium beads, each encasing a permanent magnetic core through which a titanium wire is threaded to form a ‘necklace’. The entire device is implantable and each magnetic core has a separation force of 100 g. The device is manufactured in different lengths based on the number of beads necessary to accommodate the individual anal canal circumference, measured using a special sizing tool of similar diameter to the implant. The aim is to position the device, with the beads in contact, in apposition at the level of the anorectal junction, thereby providing passive reinforcement to the patient’s anal canal (Fig. 1). During defaecation, the beads separate, allowing for the passage of stool and then they re-approximate passively to re-establish continence (Fig. 2).

Follow up

Perioperative complications and postoperative course were recorded. Following the surgical procedure, the MAS immediately started to work. It is passively opened by the passage of stool, with no need for the patient to adjust or deactivate the device at the time of defaecation, as it will return to its predefaecation state automatically after evacuation. After surgery, patients were hospitalized for at least 1 day for observation, and a routine X-ray was taken before discharge to document the position of the
MAS. Patients were subsequently reviewed at 3 and 6 months, and at yearly intervals thereafter, accompanied by an evaluation protocol including bowel-habit diaries and assessment of the incontinence severity score and the FIQoL score, as well as anorectal manometry readings at 6 months postimplantation. SNS settings were adjusted in accordance with symptom satisfaction during consultations or on an ad-hoc basis, with all changes recorded in the patient’s clinical notes.

Statistical analysis

Statistical analysis was performed with STATVIEW® 4.5 software (SAS Institute Inc., Cary, North Carolina, USA). The results were expressed as median with range (minimum and maximum). For statistical comparisons, the Mann–Whitney U-test was applied for quantitative variables appropriately. A value of $P < 0.05$ was considered significant. Owing to the small number of patients, comparisons were not made between groups for the postoperative outcome.

Results

The predominant aetiology for FI was previous obstetric trauma. Five patients (three from Group 1) had had an anal sphincter repair. Six (21.4%) patients (three from each group) had an anal sphincter defect of $< 90^\circ$ of the anal circumference, noted on ultrasound, involving the anterior quadrant. Twenty-two (78.6%) patients (11 from each group) with associated pelvic floor pathology (rectocele, cystocele or urinary incontinence) had undergone some form of attempted corrective surgery prior to treatment with either MAS or SNS. Of the 12 patients who underwent MAS implantation, three had failed PNE, three had suffered a loss of efficacy with permanent neurostimulation, four were deemed unsuitable for SNS owing to cognitive or physical limitations and the remaining two declined the option of SNS outright because of the need for rigorous follow up.

The aetiology for FI, significant history of pelvic floor pathology and prior surgical intervention for FI are presented in Table 1. Preoperative data for both groups, including age and duration of incontinence, were similar. Functional scores, including the incontinence severity and FIQoL scale scores, were also comparable (Table 1).

Postoperative course and early complications

There was no mortality and no patient required a stoma. Four patients in Group 1 (MAS) experienced an early postoperative complication. Two experienced mild anal bleeding that resolved spontaneously before discharge, one developed faecal impaction that resolved with enemas and one reported hearing a ‘crack’ during defaecation 1 month after implantation and passed the device without evidence of ulceration during a clinical examination 3 days later. Presumably the device snapped at the suture point, probably as a result of excessive straining. The patient has since made an uneventful recovery and is being managed conservatively. In Group 2, all patients were discharged without incident after both the temporary PNE test and permanent implantation.

Although the median duration of surgery for MAS implantation compared with the combined time for both the PNE test and permanent pulse generator implantation

Figure 2 Lateral radiographs of implanted patients showing the magnetic anal sphincter (a 15-bead device) (left panel) and sacral nerve stimulation (using the INTERSTIM® pulse generator implanted in the buttock region and connected to a tined (barbed) lead electrode inserted in the foramen of S3) (right panel).
were similar at 60 (35–116) min and 61 (45–82) min, patients in Group 2 required a separate admission for each stage of the procedure. Thus, the overall median length of stay was similar in Groups 1 and 2, at 4.5 (4–7) days and 4 (3–7) days.

Revisions and removals
All patients had at least 8 months of follow-up, which was similar in each group (MAS = 18 [8–30] months; and SNS = 2 [10–28] months). There was one device removal in each group. As previously described, one patient in Group 1 experienced spontaneous extrusion of the device. The patient in Group 2 developed an infection at the pacemaker site 1 year after implantation and the device had to be removed. Both patients have since been managed conservatively on a regimen of antidiarrhoeal medication and rectal lavage, and both have been offered the option of an end colostomy.

Function
No patient was lost to follow up, and complete data were available for analysis. There were significant improvements in the median incontinence severity score at follow up compared with baseline scores in both groups [Group 1 = 16.5 (11–19) to 6 (3–15), \( P = 0.001 \); and Group 2 = 15 (11–18) to 11.5 (0–14), \( P = 0.0001 \)] (Fig. 3). Patients were not required to be on a special diet after surgery, but were advised to keep their stool consistency soft, using a combination of dietary modification and medication. Group 2 patients required a median of four (two to six) adjustments of the stimulation parameters over a 12-month period. At the latest review, two patients in Group 1 required daily use of antidiarrhoeal medication compared with six patients in Group 2, with one patient from each group experiencing occasional constipation that responded to enemas and laxatives. There were significant improvements in all four components of the FIQoL score for patients in both treatment groups (Figs 4 and 5).

In Group 1 there was a significant increase in anal canal resting pressure after surgery, from 42.5 (8–86) cmH₂O to 54 (19–107) cmH₂O (\( P = 0.027 \)). There was no significant change in Group 2. Other parameters measured, including anal canal maximum squeeze pressure, maximum tolerated rectal volume and duration of voluntary external anal sphincter contraction, did not change significantly in either group (Table 2).
Discussion

Following the initial success of magnetic sphincter augmentation technology in treating gastro-oesophageal reflux disease [10,11], the technology has now been applied to FI. The MAS aims to provide sufficient support to keep the anal sphincter closed to the passage of faeces until an appropriate level of force is generated during defaecation, thereby opening the collar of magnetic beads that automatically re-approximate at the end of evacuation. We have been using this new device since 2008 and preliminary reports have continued to be encouraging following CE marking this year (P.-A. Lehur, unpublished data). This initial experience demonstrated a satisfactory outcome in some patients after failed SNS, with the MAS serving as a viable form of ‘salvage’ therapy in adequately motivated patients [12]. With these observations, we decided to compare the outcome of a cohort of patients receiving either the more established modality of SNS or the newer MAS, with the goal of determining if a more rigorous comparison between the two procedures would justify a future randomized controlled trial.

Although this series has demonstrated a similar operation time for MAS and SNS implantation, the difference remains that the latter requires two separate hospital stays, approximately 3 weeks apart. Despite infection being a concern in any perineal implantation, it is encouraging that the overall morbidity rates after implantation of the MAS has been similar to SNS. In addition, we have also shown that the MAS has a short learning curve and is less invasive as a technique of anal encirclement, with less morbidity than the ABS device [5]. Furthermore, the MAS has the advantage over both the ABS and SNS of functioning immediately after implantation without the need for additional manipulation by either the patient or the surgeon. In contrast, SNS patients continue to require adjustments to pulse generator settings following implantation, reaffirming the ‘high-maintenance’ nature of this treatment modality [12,13]. This is supported by a recent publication from Aarhus in Denmark, which showed that out of 176 patients implanted with the permanent pacemaker, 85.2% experienced either a suboptimal response or adverse events, with 17.6% eventually discontinuing treatment or having the device removed altogether [3].

While we acknowledge the obvious limitation of this nonrandomized, single-centre study, the baseline characteristics of Groups 1 and 2 were similar. Those MAS implantations that followed previous SNS implantation were performed in a cohort of patients treated before the start of this current study in December 2008. Our initial concern was that the MAS device might not sufficiently occlude the anal canal, but this was unfounded as Incontinence Severity scores were found to be similar to those after SNS. Not only did patients with the MAS have significantly raised anal canal resting pressures, but fewer patients in this group required regular use of antidiarrhoeal medication compared with patients in the SNS group. In contrast, SNS did not induce any significant change in anal pressure or rectal volumes. However, the impact on quality of life was similar in both groups.

Combined with data from a previous comparison of the MAS and ABS, we feel that the former has a role in the treatment of FI. While it was not the aim of this study to prove the superiority of one technique over the other, the results have nonetheless demonstrated that the MAS is a feasible option, being less invasive and less morbid than the ABS and serving as a possible ‘salvage’ therapy for patients who fail to improve after SNS or are deemed unsuitable for it. It is clear that we need to expand on our findings by comparing the outcome of patients implanted with the MAS or SNS under the rigour of a prospective randomized controlled trial, something that has not been performed to date. This will also enable us to assess more objectively the long-term efficacy of the MAS to define better its place in the treatment of FI.

Acknowledgement

This study was supported by the Centre d’études et de recherche en chirurgie (CEREC) in facilitating
administrative support. The authors have no sources of funding to declare, except P.-A. Lehur who has a consultancy agreement.

References