Original article

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Faecal incontinence in patients with a sphincter defect: comparison of sphincteroplasty and sacral nerve stimulation

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Abstract

Aim Sphincteroplasty (SP) is used to treat faecal incontinence (FI) in patients with a sphincter defect. Although sacral nerve stimulation (SNS) is used in patients, its outcome in patients with a sphincter defect has not been definitively evaluated. We compared the results of SP and SNS for FI associated with a sphincter defect.

Method Patients treated by SNS or SP for FI with an associated sphincter defect were retrospectively identified from an Institutional Review Board approved prospective database. Patients with ultrasound evidence of a sphincter defect were matched by age, gender and body mass index. The main outcome measure was change in the Cleveland Clinic Florida Faecal Incontinence Score (CCF-FIS).

Results Twenty-six female patients with a sphincter defect were included in the study. The 13 patients in each group were similar for age, body mass index, initial CCF-FIS and the duration of follow-up. No differences were observed in parity ($P = 1.00$), the rate of concomitant urinary incontinence ($P = 0.62$) or early postoperative complications. Within-group analysis showed a significant reduction of the CCF-FIS among patients having SNS (15.9–8.4; $P = 0.003$) but not SP (16.9–12.9; $P = 0.078$). There was a trend towards a more significant improvement in CCF-FIS in the SNS than in the SP group (post-treatment CCF-FIS 8.4 *vs* 12.9, $P = 0.06$). Net improvement in CCF-FIS was not significantly different between the groups ($P = 0.06$).

Conclusion Significant improvement in CCF-FIS was observed in patients treated with SNS but not SP patients. A trend towards better results was seen with SNS.

Keywords Sacral nerve stimulation, sphincteroplasty, faecal incontinence, sphincter defect

What does this paper add to the literature?
This report describes a significant improvement in faecal incontinence among patients with a sphincter defect when treated with sacral nerve stimulation compared with sphincter repair.

Introduction

The prevalence of faecal incontinence (FI) varies between 0.5% and 8.3%, depending on the specific group being assessed [1,2]. A recent large cohort study has shown an incidence of FI close to 20% in a group of almost 6000 American women, accounting for the often understated prevalence for psychosocial reasons [3]. Thus the true prevalence is underestimated through embarrassment and reluctance to accept the problem [4].

Most patients can be conservatively managed by diet, antidiarrhoeal medication, biofeedback and physiotherapy while some patients will require some form of surgical intervention. Invasive treatments include sphincteroplasty (SP), neuromodulation by stimulation of the sacral or posterior tibial nerves, radiofrequency, tissue remodeling, and injection of bulking agents [5]. SP has been the most popular for treatment for sphincter defects, especially when obstetrically related [6]. It is not influenced by the presence of other pelvic injury [7,8], but concomitant damage to the pudendal nerves can be related to failure [9].

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Sacral nerve stimulation (SNS) for FI [10] was initially intended for patients with an intact sphincter, but it has also been used in the presence of a sphincter defect where it improves symptoms [5]. Although the mechanism of action is unknown, there are three current theories: (i) activation of a somatovisceral reflex with inhibition of colonic activity and an increase in internal sphincter tone, (ii) modulation of afferent information from the rectum acting on the defaecatory reflex and (iii) directly increasing external sphincter tone [11].

Few studies have compared SNS with SP for FI. A recent Cochrane review highlighted the lack of randomized controlled studies evaluating the surgical treatment for FI in the last decade [12]. The object of the present study was to compare the results of SP and SNS for FI in patients with a sphincter defect using a validated scoring system.

Method

Study population

Following Institutional Review Board approval, a retrospective review of a prospectively maintained Institutional Review Board approved database was undertaken for all patients treated for FI at one institution over a 10-year period. Patients with sonographic evidence of a sphincter defect were identified and treatment groups were matched by age and the pretreatment Cleveland Clinic Florida Fecal Incontinence Score (CCF-FIS) and subsequently stratified for SNS and SP. Patients with no sonographic documentation of a sphincter defect or those with missing preoperative or postoperative CCF-FIS values were excluded from the analysis. The surgical technique for anterior overlapping SP and SNS has been described previously [13]. Although a larger series has been published from our centre, the sample in the current study does not overlap with that of the previous study for several reasons [13]. First we specifically studied patients with a sphincter defect confirmed by sonography allowing measurement of the size. Second, the patients had a preoperative and postoperative CCF-FIS assessment. Third, the matching process limited the sample size to that of the current report.

Sphincteroplasty

All patients received anterograde mechanical bowel preparation by combining a clear liquid diet on the day before the surgery with polyethylene glycol and bisacodyl (15 mg) given on the evening before surgery. The patient was placed in the prone jack-knife position and a 120° curvilinear incision was made just outside the external sphincter. The rectovaginal septum was dissected and the scar at the site of the defect was isolated. An overlapping repair of the edges of the mobilized sphincter was performed.

Sacral nerve stimulation

SNS was conducted in two phases. The first was performed under local anaesthesia with fluoroscopic guidance. The test electrode was inserted percutaneously into the third sacral foramen and the best response elicited on either side was selected. Two weeks later the patient was reassessed and if there was improvement of more than 50% in the CCF-FIS a permanent electrode was implanted.

Clinical variables

Preoperative demographic variables including age, gender and body mass index were recorded. The American Society of Anesthesiologists (ASA) classification and the follow-up period were also documented. Endoanal ultrasound findings and pudendal nerve terminal motor latency (PNTML) were determined. Confounders likely to affect the outcome in each group were specified *a priori*. They included the degree of the angle of the external sphincter defect and risk factors for FI including previous anorectal surgery, previous sphincter repair, vaginal delivery and abnormal PNTML. The pre- and postoperative CCF-FIS were obtained. The scores were obtained from chart review and telephone interview. Patients with an incomplete dataset were excluded from the functional outcomes analysis.

Results

The primary outcome was defined as the change in CCF-FIS between the preoperative and postoperative states in each group. Secondary outcomes included the comparison of changes in CCF-FIS and the final CCF-FIS following treatment. An intention to treat model of analysis was used whereby patients having SNS who required removal of the device were analyzed within the SNS group.

Statistical analysis

Comparison of continuous variables was performed using Student's t test or the Mann–Whitney U test according to the distribution, whether parametric or non-parametric. Categorical variables were compared with the chi-squared test. Paired analysis was performed

using Wilcoxon's signed-rank test. To perform a paired assessment of each intervention in affecting the CCF-FIS, an analysis of covariance (ANCOVA) was performed. All tests were two-tailed and significance was determined at a P value of less than 0.05. All statistical analyses were performed using SPSS version 20.0 (IBM, Armonk, New York, USA).

Results

Twenty-six female patients were identified between 2004 and 2014 who met the study inclusion criteria including 13 patients who had received a previous SNS matched by age and CCF-FIS with 13 who had had a SP. The groups were similar in age, body mass index, initial CCF-FIS, ASA classification and follow-up (Table 1). There were no significant differences in the degree of the external sphincter defect or any associated internal sphincter lesion (Table 2). The groups were also similar with respect to the number of previous vaginal deliveries, anorectal procedures and previous repair.

PNTML was performed in 77% of patients in the SNS group and 85% in the SP group. There were no differences between the two groups regarding the presence of unilateral or bilateral abnormalities ($P = 0.36$). Two patients in the SNS group and one in the SP group had unilateral alterations in the PNTML. Early postoperative complication rates were low and similar between the two groups (one patient in each group had wound infection). Two patients in the SNS group had the device removed for late infection. A significant improvement in CCF-FIS was observed between baseline and postoperative assessment in the patients treated with SNS (15.9–8.4; $P = 0.003$). No significant difference was identified between the baseline and postoperative score after SP (16.9–12.9; $P = 0.078$) (Fig. 1). When the change in the CCF-FIS score was compared between the two groups, there was no evidence on ANCOVA that either procedure was superior in reducing the CCF-FIS although there was a strong trend towards a lower CCF-FIS after SNS (8.4 *vs* 12.9; $P = 0.06$).

Discussion

Anterior overlapping SP was described as early as 1971 and involved superimposing the disrupted muscle [14]. Although it has been the most often used first-line approach for FI in patients with a sphincter defect, initial success rates of around 90% [15,16] have declined greatly over time [9,17–21]. In the present study, SNS significantly improved continence in most patients with sonographic evidence of a sphincter defect. In contrast there was only a trend towards a significant difference in CCF-FIS after SP, although this may have been due to the small number of patients in the study.

One of the earliest studies to demonstrate efficacy of SNS in FI patients with a sphincter defect was a five patient series [22] in which the authors describe progression to full continence in three. In a larger series of 28 FI patients with sonographic evidence of sphincter atrophy including 28% with evidence of an external sphincter defect [23], the CCF-FIS decreased from a median of 16–3 ($P < 0.001$), with demonstrable improvements seen in the subgroup of patients with a sphincter defect.

One of the features of the design of the present study was the matched pairing between patients having SP and SNS. This demonstrated a strong trend in favour of SNS. The difference of $P < 0.06$ was only just above the conventionally accepted chance of 0.05 and it is likely to be a type II error given the small number of patients. Previous studies have shown that a CCF-FIS of less than nine is associated with an improved quality of life compared with higher values [24]. In another retrospective study, patients with FI and an associated

Table 1 Demographic variables and follow-up in patients treated with sacral nerve stimulation (SNS) or sphincteroplasty (SP).

	SNS ($n = 13$)	SP ($n = 13$)	P value
Age (years), mean ± SD (range)	62.2 ± 10.7 (38–75)	57.2 ± 10.2 (40–74)	0.16
BMI (kg/m^2)	26.2	26.5	0.33
Initial CCF-FIS score (0–20), mean ± SD (range)	15.9 ± 2.7 (11–20)	16.8 ± 2.6 (10–20)	0.39
ASA score, mean (range)	2 (1–3)	2 (2–4)	0.79
Vaginal delivery (%)	8 (61.5)	12 (92.3)	0.29
Anorectal surgery (%)	8 (61.5)	7 (53.9)	0.76
Previous repair (%)	1 (7.7)	1 (7.7)	0.98
Follow-up (months), median (range)	13.9 (0.5–38.2)	10.1 (1.6–89.9)	0.72

ASA, American Society of Anesthesiologists; BMI, body mass index; CCF-FIS, Cleveland Clinic Florida Fecal Incontinence Score.

Table 2 Endoanal ultrasound findings and results of pudendal nerve terminal motor latency tests in 26 patients treated with sacral nerve stimulation or sphincteroplasty for faecal incontinence.

	SNS, 13	SP, 13	*P* value
Mean degree of external sphincter defect, degrees ± SD (range)	116° ± 25.7° (90–157)	106° ± 34.6° (45–180)	0.6
Internal sphincter associated defect (%)	7 (53.9)	5 (38.5)	0.47
Abnormal PNTML (%)	Bilateral 1 (7.7) Unilateral 2 (15.4%)	Bilateral 0 (0%) Unilateral 1 (7.7%)	0.36

PNTML, pudendal nerve terminal motor latency; SNS, sacral nerve stimulation; SP, sphincteroplasty.

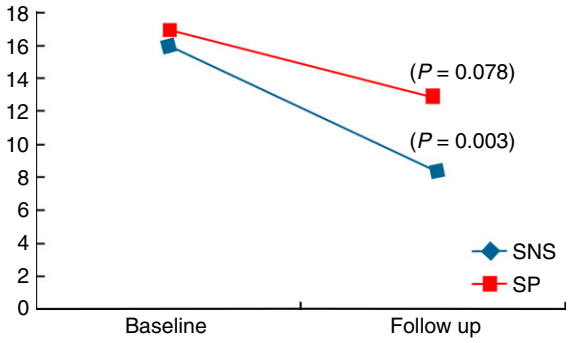

Figure 1 Preoperative and postoperative mean Cleveland Clinic Florida Fecal Incontinence Score after sacral nerve stimulation (SNS) and sphincterplasty (SP).

sphincter defect treated by SNS (n = 10) and SP (n = 14) were found to be similar clinically and manometrically [25]. The findings of the present study are similar and show that SNS is valid for patients with FI with an associated sphincter defect. Although the present study does not report the long-term results, large case series not limited to patients with a sphincter defect have reported a long-term improvement after SNS (over 50% in the frequency of weekly episodes of incontinence) for as many as 89% of patients with up to 50% becoming completely continent [26–28]. Although we are unable to recommend an algorithmic approach on whether to perform a sphincter repair before considering SNS in incontinent patients with a sphincter defect, the data of the present study would support this and data on the long-term outcome after SP would do also [9,17,19,21].

The severity of the sphincter defect was not significantly different in the two groups in the present study. In most previous studies SNS was only used for sphincter defects of less than 120° [22,29], but in the present study patients with a defect of more than 120° were included and were found to have improved continence after SNS. Despite these promising results, further studies will be needed properly to evaluate the role of SNS for patients with larger defects.

Factors associated with a successful outcome after SP have been stated to include the presence of a localized isolated defect, a sphincteric gap not exceeding 160°–180° and the absence of pudendal neuropathy [30]. Although preoperative manometric findings are not related to the postoperative results of repair, improvement in these measurements is a good objective indicator of regained continence [31]. In the present series, the two patient groups were comparable in the prevalence of pudendal neuropathy, controlling for some of the poorer outcome of SP with abnormal PNTML testing [32]. In contrast, the presence of pudendal neuropathy does not seem to influence the outcome of SNS [33].

In the present study, one patient in each group developed an early postoperative wound infection and two patients in the SNS group required removal of the device for infection. The small sample size of the study may explain some of the lower infection rates. In a large prospective trial of 120 patients a 5% rate of infection requiring removal of the device was reported [34], and in a recent retrospective study of 172 patients having sphincter repair a 20% rate of infection was reported [35]. Another retrospective review reported that 28.8% of patients experienced some form of adverse effect after SNS with an average of 1.4 additional procedures for each patient [36]. A larger study will be required to provide a more detailed assessment of the difference in adverse events between SNS and SP.

The most important limitations of the present study are its retrospective nature and the small sample size. We did not perform a power calculation as we aimed to identify all patients fitting the inclusion criteria so as to allow the matching of as many patients as possible. The

main limiting factor was ensuring that ultrasound and manometric records and documentation of the preoperative and postoperative CCF-FIS were available. Despite these defects, the present study indicates an improvement in FI following SNS as measured by a validated score whereas this is less clear following sphincter repair.

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Author contributions

All the authors made substantial contributions to concept and design, acquisition of data, analysis and interpretation of data, drafting the article, revising it critically for intellectual content and approval of the final version.

Conflict of interests

FGR, SAC, AJC, DRS, none. MZ, consultant, American Medical Systems (AMS); grant recipient AMS, Salix Pharmaceuticals, Cook Medical. BG, speaker in courses, Medtronic Corp. GD, none. SDW, fees for consulting, Incontinence Devices Inc., Mederi Therapeutics, Medtronic, and stock options for consulting, Renew Medical.

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