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Sacral neuromodulation for faecal incontinence – 10 years' experience at a Scottish tertiary centre

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ABSTRACT

Introduction: Sacral nerve stimulation (SNS) is increasingly popular in the management of faecal incontinence. This paper reports the first 10-year experience of SNS in the management of faecal incontinence at a tertiary referral centre. Data was collected in a prospectively maintained database.

Results: In total 130 patients were referred. The majority were women (94%) under 75-year-old (98%). Seven patients were found to have full-thickness rectal prolapse at the initial work-up and proceeded to rectopexy. Eighty-three patients underwent temporary SNS testing with 73.5% positive outcome, of which 52 patients had permanent implant insertion. There were four failures of SNS (7%) following implantation despite successful temporary testing, seven infection, one lead migration and three post-operative pain/numbness. One patient subsequently developed colorectal cancer requiring SNS removal.

A higher frequency of episodes of incontinence was associated with positive SNS outcome ($p = 0.007$). There was no significant association between age, sex, type of faecal incontinence, previous anorectal/pelvic surgery, colonoscopic or USS findings and the likelihood of successful SNS.

Of the 52 patients with SNS implants, 27 patients were seen only once for follow-up; the remaining 25 patients were seen more than once – five of these were part of our initial cases of routine 6- and 12-monthly follow-up, 6 patients were seen for adjustment of voltages, whereas the remaining 14 patients were seen for complications of the implants. If the initial five patients were excluded, only 38% of patients would have been seen more frequently on an as-required basis.

Conclusion: SNS is a safe and effective option in the management of faecal incontinence. Of the initial work-up, endoscopy and examination-under-anaesthesia (EUA) or proctogram are essential and more likely to influence the likelihood of suitability of SNS testing. A patient-led drop-in approach to follow-up is feasible to allow patients to be seen on an as-required basis.

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Introduction

Faecal incontinence is the involuntary loss of faecal content. It is a complex multi-factorial problem which affects up to 10% of the adult population.[1] Being a multi-factorial problem, it is often difficult to manage, especially in moderate to severe cases where the symptoms are often not well-controlled with standard conservative measures. Conservative measures include dietary advice, lifestyle changes, stool-bulking agent such as methylcellulose, anti-diarrhoeal medication such as loperamide or co-phenotrope, pelvic floor physiotherapy and biofeedback therapy.

Patients with moderate to severe faecal incontinence often have socially disabling symptoms, with a detrimental impact on their psychological well-being and quality of life. Surgical options available are offered based on the main causative factor. Management options traditionally included sphincteroplasty, dynamic graciloplasty, artificial bowel sphincter, injection of bulking agent, or stoma formation. While bulking agents are a low risk intervention, their efficacy may be limited. Furthermore the more invasive option such as sphincter repair, gracilloplasty and artificial sphincters may be complicated by significant morbidity and may not offer a durable solution. Stoma surgery has been shown to significantly improve quality of life for patients with severe symptoms[2] but many patients are averse to such a radical solution.

Newer, less invasive techniques include radiofrequency ablation of sphincter muscles (SECCA), sacral neuromodulation and the magnetic sphincter augmentation continence restoration system (FENIX™ MSA). Studies on the SECCA technique have shown good outcomes with a 55%–84% improvement of incontinent scores. These studies are however of limited numbers of patients with short- to medium-term follow-up where the longest period of follow-up is up to five years.[3] The technique has not been widely adopted, possibly due to the limited evidence as well as due to the cessation of its production in 2006, only to be re-launched in 2008 by Mederi Therapeutics Inc.[3] Magnetic sphincter augmentation was adopted from the utilisation of magnetic beads in the management of gastro-oesophageal reflux. Its role in the management of faecal incontinence is still in its early days. Its use was first described in 2010 in 14 patients with a 90% reduction in incontinence episodes and 50% reduction in Wexner incontinence score.[4]

Sacral neuromodulation has been used for urological indications since the 1960s.[5] Its positive effect on patients with concurrent faecal incontinence was observed and its usage in faecal incontinence was formally reported in 1995 by Matzel et al. from Erlangen, Germany.[6] SNS was initially used in patients with intact sphincters with no surgical option for sphincter repairs or replacement. Subsequent studies have shown that its positive effect is not influenced by the presence of sphincter defect <120°.[7] Its success rate is also unaffected by the type of faecal incontinence or by previous surgery.[8,9] The popularity of SNS in the management of FI increased when it was shown to have a sustained long-term effect, with better outcome compared to best medical treatment.[10,11] SNS also provides comparable outcomes and sustained results when compared to sphincteroplasty; without the morbidities associated with sphincter surgery, SNS is certainly the more attractive option.[12] With such reports of success, two-staged sacral neuromodulation for faecal incontinence was introduced in Glasgow in 2005. The introductory period had been challenging due to initial apprehension and funding restrictions. With increasing evidence regarding its success and financial benefits in comparison to sphincter surgery and stoma formation,[13] the use of SNS increased over the 10-year period and the unit receives referrals from Greater Glasgow as well as external referrals from other health boards in the West of Scotland. We hereby report our first 10 years' experience in the use of SNS and examined the factors associated with successful SNS implantation.

Methods

One hundred and thirty patients were referred regionally for consideration of SNS implantation (Interstim, Medtronic, USA) between 2005 and 2015. Data was collected in a prospectively maintained database.

Prior to consideration for SNS, patients underwent either flexible sigmoidoscopy or colonoscopy to rule-out luminal pathology. Endoanal ultrasonography and anorectal manometry were carried out in all cases and either examination under anaesthesia or a defaecating proctogram was performed to exclude full-thickness rectal prolapse. Patients also had to have completed a trial of non-operative measures including stool bulking agents, anti-diarrhoeal medication, physiotherapy and biofeedback therapy. Investigations and non-operative management for outside referrals were usually carried out at the base hospital. Patients were asked to complete a two-week baseline bowel diary using a modified Wexner incontinence grading scale to record their experience of faecal incontinence and urgency. Only patients with at least one episode of faecal incontinence per week or with episodes of significant urgency (less than 1 min of warning time) were considered for the first stage of SNS testing with temporary wire insertion for a trial of peripheral nerve evaluation (PNE). This is to allow assessment of improvement of symptoms by at least 50%, which will qualify the patient for insertion of a permanent implanted pulse generator (IPG).

Inclusion/exclusion criteria for PNE

Inclusion Criteria	Exclusion Criteria
• Urge/passive/mixed faecal incontinence • Severe urgency (<1 min warning time) • ≥1 episode of incontinence on a weekly basis • Unsuccessful maximal medical therapy	• Age >75-year-old • Infrequent episodes of incontinence • External anal sphincter defect of >180° • Presence of full-thickness rectal prolapse • Stoma • Untreated secondary causes of incontinence – e.g. colitis, malignancy • Significant life-limiting co-morbidities

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