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ORIGINAL ARTICLE

Sacral nerve stimulation—hidden costs (uncovered)

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Abstract
Aim The aim of this study is to determine the occurrence of surgical revision in a cohort of patients treated with sacral nerve stimulation (SNS) for faecal incontinence and constipation and to establish the types of procedures performed and indications for surgery.
Method From the years 2002 to 2014, 125 patients were identified who had undergone permanent SNS therapy with 36 (28.8 %) patients requiring surgical intervention postimplantation. These cases were retrospectively reviewed (range of follow-up 1–99 months).
Results Over a total of 1512 months of SNS treatment, 51 unplanned surgical procedures were required in 36 patients. At present, 48 procedures have been performed at an average of 2.6 years following implantation and three patients are awaiting surgery. Lead-related problems accounted for 30 (58.8 %) procedures at an average of 1.7 years affecting 22 patients. Battery and implantable pulse generator-related problems attributed to 13 procedures (25.5 %) in 12 patients at an average of 5.0 years. Battery depletion occurred in seven patients at an average of 5.4 years. Surgical revision was required to replace, remove, or resite various components of the SNS system. Indications for surgery included lead damage, pain and loss or lack of SNS efficacy. Explantation was warranted in six patients due to poor SNS efficacy, pain, infection and facilitation of a magnetic resonance imaging scan. This was performed at an average of 1.6 years.
Conclusion A considerable proportion of patients treated with SNS therapy require surgical revision. These unplanned procedures are associated with substantial unexpected costs that financially burden SNS services.

Keywords Sacral nerve stimulation · Hidden costs · Complications

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Introduction

Sacral nerve stimulation (SNS) is a minimally invasive surgical technique used in the management of a number of conditions [1, 2]. Its origins stem back to 1981, when Tanagho et al. [3] first demonstrated the potential clinical benefits. Since then, SNS has been used for the treatment of disorders, such as urinary and faecal incontinence, constipation and pelvic pain [2, 4]. The underlying mechanisms by which this intervention works are still obscure and as yet not completely understood [1]. It is suspected that electrical stimulation of the sacral nerve roots results in alterations to the complex nervous pathways; such modifications consequently affect the physiological function of the pelvic organs and pelvic floor [2, 5–7].

Treatment with SNS is recognised to yield varying symptomatic responses amongst patients [1, 8]. Therefore, to try to optimise the likelihood of positive clinical outcomes, standard practice regulates that patients must initially undertake a 2-week trial of temporary SNS, known as percutaneous nerve evaluation (PNE) [1, 2]. During this test phase, a temporary percutaneous lead is inserted percutaneously into either the third or fourth sacral foramen (S3 or S4) and connected to an external pulse generator [1, 2]. This generates the electrical

impulses that are transmitted through the electrode and delivered to the nerve root. Only if significant symptomatic improvement is demonstrated will the patient be eligible for permanent SNS therapy [1, 2]. Significant improvement was defined by an improvement in incontinence scores and quality of life scores with a threshold level set at 70 %. This procedure involves implantation of a permanent lead and formation of a subcutaneous pouch positioned in the outer upper quadrant of the buttock for an implantable pulse generator (IPG), which is controlled externally by a handset [1, 2]. Regular reprogramming of the device is often required to maintain optimal efficacy [9].

Following this operative procedure, adverse effects that are commonly reported include painful stimulation, leg cramp, infection at the site of the implant, loss of stimulation and poor efficacy [9–11]. These complications are usually resolved with minimal nonsurgical methods, such as medication and reprogramming [9, 10]. However, some adverse events such as lead migration or fracture, battery depletion and severe pain at the IPG site often require surgical management [2, 9, 12]. Within our patient cohort, we aim to establish the occurrence of adverse effects requiring surgical revision post-SNS implantation. Ascertaining the indications for surgery, the frequency and the types of procedures, will enable clinicians to better inform future SNS patients preoperatively of the likelihood of further surgical intervention related to the SNS system following implantation. Additionally, these extra unplanned procedures have wider financial implications as they are associated with unexpected expenses that are often overlooked, financially burdening SNS services.

The aim of this study was to determine the occurrence of surgical revision in a cohort of patients treated with SNS for faecal incontinence and constipation and to establish the types of procedures performed and indications for surgery.

Methods

We identified all patients who had undergone permanent SNS therapy at our unit for the treatment of bowel disorders, such as faecal incontinence and constipation from the year 2002 to 2014 from a prospectively maintained database. A total of 125 patients were found with long-term follow-up over these 12 years. All procedures were performed by three surgeons in the same colorectal pelvic floor unit at a University Teaching Hospital. In particular, we focused our search on patients who had experienced complications requiring further surgical intervention involving the SNS system; 36 patients were identified. The clinical case notes of each of the subjects involved were retrospectively reviewed, gathering detailed histories which included clinical response to SNS therapy, adverse events and complications that had arisen postimplantation. The details of and indications for these operative procedures were evaluated.

Results

Demographics

Of the 125 patients in our unit who had permanent SNS therapy, 36 patients (28.8 %) were identified who experienced adverse effects post-SNS implantation requiring further surgical intervention related to the device. At present, three of these patients are awaiting surgical revision. The cohort comprised of 34 female (94.4 %) and 2 male (5.6%) patients with a mean age of 54.3 years (range 26–81). The indications for SNS therapy were for the management of faecal incontinence in 34 patients (94.4 %) and constipation in 2 patients (5.5 %). Prior to implantation of the permanent sacral nerve stimulator, these patients underwent PNE; two trials were required for six of these patients. Following significant objective and subjective symptomatic improvement during these test periods (>70 % improvement in Vaizey score and Manchester health questionnaire), permanent implantation was performed. For the vast majority (33 patients), this operative procedure was carried out under general anaesthesia (GA) and for three patients, it was performed under local anaesthesia (LA). The permanent electrode was positioned in the patient's right or left S3 or S4. The average duration of treatment with SNS therapy at the latest follow-up appointment was 45.8 months (3.8 years).

Adverse effects requiring unexpected surgical intervention

During a total of 1512 months of SNS therapy, 51 unplanned surgical procedures were required in 36 patients following permanent SNS implantation. The average number of additional surgical procedures per patient was 1.4. At present, 48 procedures have been performed; these have been carried out at an average of 31.5 months (2.6 years) post-SNS insertion, and three patients are awaiting surgery. The vast majority of procedures have been indicated due to lead related problems summarised in Table 1. These accounted for 30 procedures (58.8 %) affecting a total of 22 patients (61.1 %), with 2 of these patients awaiting surgery. These involved replacement, removal or adjustment of the lead due to damage, impedance, pain or poor SNS efficacy. The average length of time that the procedures were carried out was 20.1 months (1.7 years, range 1–54 months) post-SNS implantation.

Battery and IPG-related problems shown in Table 2 accounted for a total of 13 operative procedures (25.5 %) in 12 patients (33.3 %). These were required to replace, remove or resite the IPG unit or battery pack due to pain around the

Table 1 Summary of lead-related surgical procedures

Indication	Number of procedures	Details
Lack or loss of SNS efficacy/impedance	22	• 18 replacements • 1 lead moved to the contralateral side • 1 removal • Adjustment
Trauma/damaged lead	4	• Damage incurred from falls
Discomfort/pain	4	• 2 replacements • 1 repositioning • 1 lead moved to the contralateral side
Total	30	

SNS sacral nerve stimulation

Table 3 Explantation and reimplatation procedures

	Indication	Number of affected patients	Number of procedures
Explantation			
	Loss or lack of SNS efficacy	3	
	Pain	3	4
	Infection	1	1
	Facilitate MRI scan	1	1
	Total		6
Reimplatation			
	Infection	1	1
	Facilitate MRI scan	1	1
	Total		2

SNS sacral nerve stimulation, *MRI* magnetic resonance imaging

battery/IPG site or depletion of the battery. The indications for surgical intervention were very similar to those encountered in the lead-related procedures. Overall, the average length of time when these unexpected operative procedures were performed was 60.1 months (5.0 years) following permanent SNS implantation. Battery depletion was noted in seven patients (19.4 %) occurring at an average battery life of 65.2 months (5.4 years).

Explantation of the entire SNS system noted in Table 3 was warranted in six patients (16.7 %) mainly due to failure of SNS in alleviating symptoms, loss of efficacy and pain. These were carried out at an average of 18.8 months (1.6 years). In two cases, the SNS system had to be explanted and reimplanted at a later date; in one patient, this was required to facilitate magnetic resonance imaging (MRI) for a separate medical problem and in another patient, this was due to postoperative infection.

Failures

In addition to these findings, failure of SNS therapy was evaluated amongst the entire cohort of 125 patients. This was defined as lack of symptomatic improvement, patient dissatisfaction or use of an alternative therapy for faecal incontinence or constipation. The failure rate was found to be 7.2 % (nine patients); all except for one of these patients were female with an average age of 48.1 years (range 38–60) at the time of permanent SNS implantation. Explantation of the SNS device was performed in 4 patients (44.5%) at an average of 28 months (2.3 years) postimplantation. Following unsuccessful SNS therapy in the treatment of faecal incontinence, management of some of the patients employed other surgical approaches, such as percutaneous tibial nerve stimulation and colostomy formation. Temporary SNS trials were also carried out in patients to try to establish whether stimulation of the contralateral side would yield better symptomatic responses. Despite SNS failing to improve continence significantly in these patients, two out of the nine patients have opted to continue treatment due to the therapeutic benefit that they experience for symptoms related to other disorders that they are affected by, which in these cases include urinary incontinence and rectal pain.

Table 2 Summary of battery and IPG-related surgical procedures

	Procedure	Number of procedures	Details
Battery	Replacement	7	• 7 depletions
	Resiting	3	• 2 pain
IPG	Replacement	1	
	Resiting	2	• 2 pain
	Total	13	

SNS sacral nerve stimulation

Discussion

Spanning over the last 12 years, this study demonstrates our institution's experience of SNS therapy for adults with faecal incontinence and constipation. The surgical revision rate of 28.8 % shown in our long-term study was comparatively similar to rates reported in the literature, falling within the range of 16 to 41 % [2, 11–14]. These procedures were performed at an average of 2.6 years postpermanent SNS implantation, surgical intervention tends to be mandated less and less as time goes on from implantation [12].

Lead-related surgical interventions represented the most common operative intervention in our patient cohort,

accounting for 58.8 % of the procedures. Loss or lack of SNS efficacy attributed a high proportion of these, which were due to a variety of causes including impedance, lead migration, dislocation or suboptimal placement of the lead. Abnormal measurements of impedance between the electrodes are likely to be due to a fractured lead subsequently resulting in a loss of connectivity or from damage to the insulation coating around the lead [9]. However, in cases where the measurements of impedance testing remain within the normal parameters, but patients continue to lack sensation of stimulation or require very high stimulation amplitudes to experience minimal sensation, the fault is likely to lie with migration or misplacement of the permanent lead [9]. Even the most minimal of migrations, such as 2 mm, have been reported to significantly alter the therapeutic effects of SNS [9, 15]. In our cohort, trauma and lead damage incurred as a result of falls was another indication for lead-related surgical correction in four of our patients. In addition to this, surgical intervention was required in another four patients for the replacement, removal or adjustment of the lead due to pain localised to this site. This is recognised as a common complication, reportedly affecting 5.7 % of patients during their first year of SNS therapy [12].

Battery and IPG-related problems are frequently reported in the literature, accounting for 27.1 % of the unplanned procedures in a third of our patients [9, 11, 16]. Battery depletion accounted for 13.7 % of the unplanned surgical procedures required in our cohort, affecting one in five of our patients with an average battery life of 5.4 years. The rate of battery depletion is determined by the set stimulation parameters of the device, such as the amplitude and mode of stimulation [9]. The approximate battery life of the Medtronic InterStim® I and Medtronic InterStim® II IPG systems implanted in our patients are reported by the manufacturer to be 7 and 5 years, respectively [17]. Although the Medtronic InterStim® II neurostimulator has a shorter life span than its preceding model, the alterations applied such as its smaller size (<50 %) and lighter weight (<37 %) are designed to reduce the frequency of IPG-associated complications [17, 18]. As demonstrated by our results, with SNS therapy, patients often experience pain at the site of the implant and painful or uncomfortable stimulation [2, 9, 12]. To help establish whether the source of the pain is in relation to stimulation or the IPG unit, the implant is switched off to determine the stimulus [9]. The permanent implantable unit attributes to a high proportion of the costs associated with SNS therapy; therefore, the overall cost-effectiveness of this intervention is affected by battery life and the frequency of repositionings and replacements of the implant [19].

Explantation of the SNS system has been noted in the literature to occur in approximately 10 % of patients who are treated with SNS [2, 11, 16, 20]. It accounted for 11.8 % of the surgical procedures in our cohort with a total of six patients affected. Explantation was performed at an average of 1.6 years post-SNS implantation. Lack or poor SNS efficacy and pain attributed to the majority of these procedures. One of our patients acquired a postoperative infection and had the SNS system explanted 2 weeks following implantation. Reimplantation was performed 5 months later in this case. Infection is recognised as a common adverse effect following SNS implantation, reportedly affecting between 2 and 10 % of patients with 50 % of these cases requiring full explantation [2, 12, 21, 22]. In one of our patients, explantation was performed to help facilitate an MRI scan and the SNS device was reimplanted at a later date. Although there have been reports of a few successful cases in which this imaging modality was performed with an implanted sacral nerve stimulator in place with no resultant complications, in one case, this has led to a patient sustaining serious neurological damage [9, 23, 24]. Therefore, it remains common practice for patients to undergo explantation of the SNS system prior to having an MRI scan; despite the stimulator being switched off the potential risk and danger remains that the magnetic fields may cause interference, inducing strong currents in the electrode lead [9].

Failure of SNS treatment affected of a total of nine patients in our unit, representing 7.2 % of our entire patient cohort. Despite achieving positive clinical outcomes from the temporary PNE trials, in a reported 10 % of patients following implantation of the permanent stimulator SNS fails to deliver significant symptomatic improvement [21, 25]. This was the reason for failure of SNS therapy for 8 (6.4 %) of our patients and intolerable painful stimulation was the indication in the ninth patient. In the vast majority of cases loss of SNS efficacy tends to manifest within the first year postimplantation [26–28]. Explantation was performed for four of our affected patients at an average of 28 months (2.3 years) postimplantation. When considering why failure occurs in these patients, some potential explanations that have been proposed for this unfavourable response to permanent SNS therapy could include an initial placebo effect, worsening of symptoms due to disease progression or the possibility of conditioning to SNS [9]. It is also proposed that tined quadripolar lead insertion for temporary stimulation may reduce the loss of SNS efficacy between initial and final stimulation and is an independent predictor of success of stimulation [29].

Our results clearly demonstrate that a considerable proportion of patients who undergo permanent SNS therapy will require further surgical intervention in relation to the SNS device and system. The costs associated with these unplanned operative procedures attribute to a substantial proportion of the expenses required to run SNS services [19, 30]. Healthcare resources are burdened by these unexpected procedures, as they place demands on both time and costs involved in planning operating lists, running operating theatres and taking up hospital beds. Many of the surgical revisions are

performed under GA requiring inpatient care, which results in longer hospital stay and longer recovery times, increasing the postoperative costs of these interventions. Replacements of faulty components of the SNS system, such as the battery or the IPG unit are expensive and account for significantly high costs. The financial demands also extend to the clinicians, surgeons, specialist nurses and other healthcare professionals included in the multidisciplinary team that are involved in supporting and treating patients with SNS therapy.

Conclusion

Our study has confirmed that the surgical revision rate in patients treated with SNS therapy is significant. There is a crucial need for patient counselling prior to implantation on the potential risks of needing further surgical procedures. In addition to this, to help improve management of the financial demands associated with these surgical revisions, awareness of the likelihood of postoperative surgical revisions must increase. NHS commissioning services should not overlook these hidden surgical expenses but should account for them in their analyses and evaluations to help plan ahead appropriately.

Compliance with ethical standard

Conflict of interest The authors have read and understood International Journal of Colorectal Disease policy on declaration of interests and declare that there are no conflicts of interest.

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