

Is Permanent Sacral nerve Stimulation Implantation Under Local Anaesthesia Feasible and Effective?

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Abstract

Background: Sacral nerve stimulation (SNS) is a minimally invasive surgical technique that plays an important role in the treatment of disorders of the bladder and bowel. Permanent SNS implantation under local anaesthesia (LA) offers many advantages.

Objectives: To assess if implantation of permanent sacral nerve stimulation (SNS) under local anaesthesia (LA) is feasible and effective.

Patients and Methods: Using a prospective database, nine patients who had permanent SNS implantation under LA in our unit were selected and analysed.

Results: Four patients suffered from underlying cardiovascular disease and LA was deemed more appropriate to minimise perioperative risks. The decision to opt for LA in the other five patients was indicated due to patient preference. The average volume of lignocaine 1% used was 25 millilitres and operative length of time was 36 minutes, with the lead inserted into the right S3 foramen in all patients. Eight patients were discharged on the day of the procedure. Long term follow up revealed that SNS alleviated the symptoms in the majority of the patients, but the benefit gained fluctuated over time. Surgical revision was required in three of these patients, these included replacement of a lead, resiting of the implantable pulse generator, and explantation of the SNS device.

Conclusions: Implantation of permanent SNS under LA is a viable surgical option, associated with several advantages that apply to both patients and service provision. Performing this surgical procedure under LA avoids the perioperative risks involved with (general anaesthesia) GA and also offers the possibility of SNS treatment for patients in whom GA is medically contraindicated, ultimately widening the breadth of the cohort suitable for SNS treatment. Other potential benefits include reduction in time and costs involved in carrying out the surgery.

Keywords: Constipation, Faecal Incontinence, Local Anaesthesia, Sacral Nerve Stimulation

1. Background

Sacral nerve stimulation (SNS) is a minimally invasive surgical technique that plays an important role in the treatment of disorders of the bladder and bowel (1). Over time the scope of conditions that SNS benefits has broadened; it was originally indicated in patients with urinary incontinence and non-obstructive urinary retention in 1981 (2, 3). Its potential application for the improvement of symptoms of faecal incontinence was confirmed during clinical trials in 1995 (4). More recently, SNS has also been recognised to play an emerging role in the management of constipation (5). The exact mechanism by which SNS works is not completely understood (6). The improved clinical outcome has been suggested to arise, as a result of the modulative effect that the electrical current delivered via the electrode exerts on the sacral nerve root and its corresponding neuromuscular components (1, 7, 8).

To help identify patients who are likely to respond to and benefit from this intervention, candidates undergo a trial course of stimulation for two weeks (1). During this

period of assessment, a temporary percutaneously placed electrode is inserted into either the 3rd or 4th sacral foramen and connected to an external pulse generator (2, 6). This process can be carried out under either LA or GA, with correct positioning of the electrode assessed using a sensory response or a motor response in the latter (9, 10). Patients are encouraged to monitor their symptoms by completing bowel diaries (11). Depending on the indication for SNS, the appropriate questionnaires are completed and scores are calculated using bowel diaries and validated symptom specific severity and symptom specific quality of life (QoL) questionnaires. We have traditionally used the manchester health questionnaire (MHQ), vaizey incontinence score or Kess score (12-14) Subsequently if the trial is deemed successful, patients are eligible for implantation of a permanent percutaneous electrode and an implantable pulse generator (IPG) (6).

Standard surgical practice traditionally involves implantation of the permanent SNS apparatus under GA.

This tends to be the preferred method, due to the dissection involved and because the technique under LA is perceived to be uncomfortable (5, 10). Carrying out the process with a conscious patient would also rely on attaining a sensory response, in addition to the use of image intensifier to ascertain correct positioning of the permanent electrode for optimal stimulation (10).

Having to perform this procedure under GA however, makes SNS inaccessible to a subset of the population in whom either GA is contraindicated due to compromised medical fitness or in patients who are reluctant to undergo GA due to the risks involved. It is also important to consider that the prevalence of faecal incontinence increases in the elderly population; with increasing age these patients often have medical comorbidities (15-17) and an alternative anaesthetic approach would be beneficial in such patients. In addition the procedure is performed in the prone position increasing the risk to the anaesthetised patient.

A study by our group has reported a retrospective review of 111 patients with faecal incontinence that underwent a trial of temporary SNS, comparing the outcomes of those performed under LA with GA. The study demonstrated similar success rates in these groups and concluded that insertion of the temporary electrode under LA, with reliance on a sensory rather than a motor response for lead positioning is just as successful and reliable as performing the procedure under GA (18). Therefore our assumption was that the success achieved from temporary SNS under LA is likely to be valid for permanent SNS.

Performing this operative procedure with LA would not only broaden the scope of patients that SNS could potentially benefit, but would also have financial implications, as it would be less time consuming and less demanding on healthcare resources. Patients not only avoid the risks and complications associated with GA, they would only be required to attend the day case unit. This would result in shorter hospital stay and quicker recovery times, increasing the cost effectiveness of the procedure. Permanent SNS implantation under LA offers many advantages; it could potentially be a viable treatment option, associated with medical and economic benefits.

2. Objectives

To assess if implantation of permanent sacral nerve stimulation (SNS) under local anaesthesia (LA) is feasible and effective.

3. Patients and Methods

We identified patients from a prospective database in our unit who had undergone permanent SNS. From 2004 - 2014, a total of 126 patients underwent implantation of permanent SNS for faecal incontinence or constipation. Nine were found to have undergone the procedure under LA. The case notes of these patients were retrospectively reviewed.

All procedures were performed with the patient in prone position. Povidone Iodine was used for disinfection. Fluoroscopy was used to confirm the position of the tined electrode. Medtronic SNS stimulator was used for all cases.

4. Results

4.1. Temporary SNS

Of our group of nine patients, eight were female and only one was male. The mean age at which they had the temporary SNS implanted was 62 years. SNS was indicated as the next appropriate therapeutic intervention for management of faecal incontinence in eight of our patients and for constipation in one patient. All of the patients underwent a trial of temporary SNS, with the majority performed under LA, except for one patient whose surgery was carried out under GA. The mean volume of lignocaine 1% injected for these patients was 9.5 mL, with none of the patients requiring extra sedation during this process. The patient and temporary SNS trial details are presented in Table 1. During this test phase, our patients recorded their progress in bowel diaries. Questionnaires were completed and scores were allocated, prior to and post insertion of temporary SNS.

Table 1. Summary of Results of Temporary Lead Placement

Gender	Date of Birth	Age	Indication for SNS	Date of Implantation	Age	LA/GA	Volume of LA, mls	Was Sedation Required
Male	06/09/1949	64	Constipation	22/12/2011	62	LA	8	No
Female	05/04/1940	74	Faecal incontinence	20/06/2007	67	LA	7	No
Female	19/03/1947	67	Faecal incontinence	29/03/2007	60	GA	n/a	n/a
Female	27/02/1932	82	Faecal incontinence	13/02/2008	76	LA	13	No
Female	03/12/1957	56	Faecal incontinence	25/10/2007	49	LA	10	No
Female	26/06/1949	64	Faecal incontinence	27/09/2007	58	LA	10	No
Female	24/01/1950	64	Faecal incontinence	25/10/2007	57	LA	10	No
Female	19/08/1948	65	Faecal incontinence	18/02/2010	61	LA	10	No
Female	13/08/1942	71	Faecal incontinence	16/02/2010	67	LA	8	No

4.2. Permanent SNS

Following evaluation of their temporary trials, all nine patients successfully met the criteria for eligibility for permanent SNS implantation. Details of the surgery are displayed in Table 2. A LA approach was indicated in two of the patients (A and B) due to past medical complications associated with GA. Two of the patients (C and D) suffered from underlying medical conditions, which posed an increased risk of perioperative complications under GA; so the surgery was performed under LA to minimise this risk. Whereas in the other five patients (E to I), there were no specific medical contraindications to GA, but instead the decision to opt for LA was due to patient preference.

Intravenous sedation was required in one patient during the procedure. The position of the permanent electrode was the right S3 foramen for all nine patients. The average volume of lignocaine 1% that was used was 25 millilitres and the average length of time the operative procedure lasted was 36 minutes.

The effectiveness of permanent SNS for our patients, in

terms of improvement of symptoms and benefit gained, was largely positive. Immediately following implantation, eight of the patients experienced some degree of benefit and were very pleased with the results, one patient responded poorly despite experiencing excellent results with temporary SNS. The patients' results are summarised in Table 3. Overall, long term follow up revealed that seven of our patients continued to find SNS beneficial, but for two SNS failed to achieve good results in the long term (Table 3). Five patients reported pain as a side effect of the intervention. The location of the pain varied and included discomfort at the battery site, back, buttock and radiation to leg. No patient had removal of the implant due to pain.

Surgical revision was required in three of our patients post SNS implantation. One patient needed removal of a lead and replacement on the other side. SNS wire and battery was removed in one patient due to poor long term results and one patient had replacement of the device after battery depletion.

Table 2. Summary of Results of Permanent SNS Implantation

Date of Implantation	Age	Reason for Opting for LA	Volume of LA, mls	Site	Was Sedation Required	Duration of Procedure, min
02/05/2012	62	Past experience of cardiac arrhythmia during GA	50	Right S3	No	49
30/08/2007	67	Vasovagal episode post GA	20	Right S3	No	40
26/07/2007	60	Cardiac murmur detected during pre-operative assessment for permanent SNS	Unknown	Right S3	No	11
06/11/2008	77	Compromised medical fitness due to underlying cardiovascular disease (ischaemic heart disease (IHD), 2 cardiac stents, murmur)	Unknown	Right	Yes	51
18/06/2008	50	No specified reason, not medically CI, patient choice	10 ^a	Right S3	No	35
18/06/2008	58	No specified reason, not medically CI, patient choice	25	Right S3	No	26
18/06/2008	58	No specified reason, not medically CI, patient choice	18	Right S3	No	33
29/09/2010	62	No specified reason, not medically CI, patient choice	20	Right S3	No	44
03/02/2011	68	No specified reason, not medically CI, patient choice	35	Right S3	No	Unknown

^a15 mls 0.5% marcaine with 1 in 200,000 adrenaline solution.

Table 3. Permanent SNS Results and Follow Up

SNS Extremely Helpful; feels Like a Different Person	None	Excellent Result
Significant benefit experienced	Continued to suffer from occasional urgency and episodes of incontinence; occasional episodes of cramp and an uncomfortable sensation shooting down the patient's right leg	24 months post implantation symptoms worsened, high impedance in SNS lead; evision surgery: lead on the right side removed and a new permanent lead inserted into the left S3 running across the midline to the existing battery in the right buttock; ood response
Pleased with results; incontinence improved; no longer housebound	Occasional discomfort both at insertion and battery site	Battery exhausted after 34 months due to high output required to maintain adequate stimulation; new battery and wires inserted
Considerable improvement in continence	Good results; occasional shooting pain down the leg	very pleased with results and immense increase in quality of life; minor complaints: infrequent stabbing pain in her right buttock (located away from the stimulator site) still experienced occasional accident which limits activities
Good result; better bowel control; ery pleased	None	Leakage tended to occur when stools were of a looser consistency; anal bulking agent was administered to augment the anal sphincter with improvement in continence; experienced pain at battery site which eased with a steroid injection
Some improvement; urgency significantly less	Still troubled by occasional incontinence; Flare up of symptoms from Crohn's disease exacerbated incontinence issues	Although SNS was beneficial, the patient was still troubled by faecal leakage; injection of anal bulking agent with symptomatic improvement
Poor response to permanent SNS, despite excellent results with temporary SNS; lightly fewer episodes of	Experienced pain down the right leg	Battery and wires removed
Much improved faecal incontinence	None	Good long term results
Extremely pleased; significant improvement	Occasional episode of incontinence and leakage	Good response to SNS; handset broke down which had subsequently switched off the SNS battery so symptoms recurred; once the handset was fixed, the malfunction had minimal effect on symptoms

5. Discussion

This retrospective study has examined whether implantation of permanent SNS under LA is a feasible and effective treatment option. To our knowledge there appear to be few discussions in the literature that report the viability of this alternative anaesthetic approach for the insertion of permanent SNS.

For four of our patients SNS implantation under LA was favoured due to cardiovascular contraindications to GA. Patients who have underlying cardiac disease constitute a cohort at greater risk of perioperative complications when anaesthetised; therefore if the surgery were to be carried out under GA they would mandate more intense monitoring and management (19, 20). Performing the surgery under LA instead, reduces the risk of medical complications manifesting during perioperative stresses (21). If GA was the only anaesthetic option, this may have otherwise resulted in either a delay in or cancellation of implantation of permanent SNS in these four patients (20). Our other five patients were medically fit to undergo GA, but opted to avoid GA. This decision making

was likely to be influenced by awareness of the common adverse effects associated with GA, such as nausea, vomiting, disorientation and a slower recovery (22, 23). Ultimately our findings have shown that with LA the breadth of the cohort suitable for SNS treatment is widened.

The average length of time in which the procedure was carried out was 36 minutes. Under LA the duration of the procedure and the recovery time are shorter in comparison to GA, the patient's stay in hospital may be reduced and they are able to return home on the same day. This was the case for the majority of our patient's. One patient had a prolonged procedure and needed intravenous sedation during their surgery. This patient had an overnight stay in the hospital. However as observed in 8 of our patients, sedation is usually not required when performing this technique under LA.

Use of LA may reduce the duration of the procedure with positive impacts on the costs involved. In addition to this there may be other financial benefits associated with LA. The costs of carrying out this day case surgical procedure

under LA are less when compared to GA, as the demands on hospital resources and services are reduced. Overall permanent SNS under LA was found to be feasible and the potential to treat more patients per operating list is a promising outlook. Future studies should aim to investigate this anaesthetic approach further and on a larger scale.

Revisional surgery was required in three patients in this small cohort. One of the revisions was due to depletion of battery after 34 months. The old battery was removed and as high impedance was found at the time of replacement a decision was made to replace the tined lead at the same time. On retrospective analysis the high impedance was the likely cause of need for high voltage leading to early battery depletion. The other two surgical interventions were due to poor result in one case and deterioration of result in another due to high impedance. One patient needed injection of steroids and this helped with pain relief at battery site. We have successfully used this on advice of pin specialists in the past. One patient continued to have some passive faecal incontinence and we performed bulking of sphincters with a bulking agent with improvement in symptoms. Similar revision surgery rates are described in literature in other studies of SNS and we have recently described a revision rate of 20% in a larger cohort of patients (24, 25).

In conclusion, the findings of our study have demonstrated that implantation of permanent SNS under LA is both feasible and effective. This technique delivered benefits in terms of time and costs. Performing this procedure under LA broadens the scope of patients that SNS can benefit and also offers an alternative less disruptive approach for patients who wish to avoid GA. The LA option has the potential to broaden the scope in delivering SNS implant surgery to more patients afflicted by debilitating symptoms.

Footnote

Authors' Contribution: Concept and design: Abhiram Sharma, Karen Telford; data collection: Moez Zeiton, Sara Faily, James Nicholson; data analysis: Sara Faily, Moez Zeiton and Abhiram Sharma; manuscript writing and editing: Sara Faily, Moez Zeiton, James Nicholson, Karen Telford and Abhiram Sharma.

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