Ulster Med J 2017;**86(1):**20-24

Clinical Paper

Outcomes of Sacral Nerve Stimulation For Faecal Incontinence in Northern Ireland

Irwin GW, Dasari BV, Irwin R, Johnston D, Khosraviani K.

Accepted: 11th July 2016
Provenance: externally peer-reviewed

Abstract

Background: Sacral nerve root stimulation (SNS) is an effective and developing therapy for faecal incontinence, a debilitating condition that can result in social and personal incapacitation.

Objectives: The objectives of this study are to assess the morbidity of the procedure, improvement in the incontinence scores and Quality of Life (QoL) following SNS.

Materials and methods: Patients were identified from the Northern Ireland regional SNS service from 2006 to 2012. Numbers of patients who had temporary placement and permanent placement were collated. Pre and postoperative assessment of severity of incontinence and QoL was performed using Cleveland Clinic Incontinence Score (CCIS) and Short Form-36 (SF-36) respectively. Statistical analysis was undertaken using Wilcoxon signed rank test. Morbidity was assessed by retrospective review of patient records.

Results: Seventy-five patients were considered for trial of a temporary SNS. Sixty-one proceeded to insertion of a temporary SNS and, of these, 40 elected to have a permanent SNS. There was a significant reduction in the pre-SNS and post-SNS Cleveland Clinic Incontinence Scores from median of 14 to 9 respectively (p=0.008). There was a significant improvement in Role Physical (p=0.017), General Health (p=0.02), Vitality (p=0.043), Social Functioning (p=0.004), Role Emotional (p=0.007), Mental Health (p=0.013) and Mental Health Summary (p=0.003). However, this is not reflected in the bodily pain and physical functional domains.

Conclusion: Permanent sacral nerve stimulation is effective and results in significant improvement of faecal incontinence scores and quality of life.

Keywords: Faecal incontinence, Sacral nerve stimulation, Quality of life

INTRODUCTION

Up to 1.4 percent of the population, aged over 40 years, in the United Kingdom is affected by major faecal incontinence,[1] a debilitating condition associated with a high level of physical and social disability. Prevalence increases with age and incontinence is reported in 7% of otherwise healthy adults over 65 years of age.[2] The aetiology of faecal incontinence is multifactorial with obstetric trauma one of the commonest causes. Other causes include sphincter damage secondary to perineal surgery for perianal fistulas and haemorrhoidectomy, idiopathic degeneration of the sphincter muscles, neurological conditions like pudendal nerve neuropathy, multiple sclerosis, diabetes mellitus, traumatic spinal cord injuries and congenital anorectal malformations.

The symptoms of faecal incontinence can be helped by changes in lifestyle and dietary habits. In particular, use of bulking and anti-diarrhoeal agents and biofeedback, can help in improving symptoms in a significant proportion of patients. When conservative measures fail to bring about improvement however, surgical options can be considered. Sphincter repair, graciloplasty, artificial anal sphincter, conventional and dynamic gluteoplasty, antegrade continence enema procedures and colonic conduit formation are well investigated surgical alternatives but the long term results are not promising. Failure of these treatment options often result in patients considering a permanent colostomy.

Sacral Nerve root Stimulation (SNS), was first developed in 1979 and used as a treatment for faecal incontinence in 1995. It is now established as a safe procedure that offers a unique opportunity to select appropriate patients through a temporary trial prior to permanent implant placement, and is an effective alternative therapeutic option in addition to the

Department of Colorectal Surgery, Belfast Health and Social Care Trust, Belfast City Hospital, 51 Lisburn Road, Belfast, BT9 7AB, UK

Kourosh.Khosraviani@belfasttrust.hscni.net

Correspondence to Mr. Kourosh Khosraviani

conventional procedures outlined.[3-5] In this study, we report the Northern Ireland experience with SNS in the management of patients with faecal incontinence and assess incontinence scores and QoL following permanent implant placement. The complications encountered as a consequence of the procedure are also reported.

PATIENTS AND METHODS:

All the patients aged 18-75 years who presented to clinic with one or more episodes of faecal incontinence per week and having failed conservative treatment were selected for temporary external stimulator placement. Endo-anal ultrasound, ano-rectal manometry and pudendal nerve terminal motor latencies were performed preoperatively with manometry repeated postoperatively. Patients with 50% reduction of incontinence score at 2 weeks follow-up were selected for permanent implant placement. Data were collected retrospectively from patient records.

Cleveland Clinic Incontinence Score (CCIS) was used to quantify the severity of incontinence and was assessed at 6 weeks and 12 months post-operative follow up. SF-36 questionnaires were completed retrospectively to compare the preoperative quality of life (QoL) with that at 6 weeks following surgery. Statistical analysis was undertaken using Wilcoxon signed rank test. Post-procedure morbidity was assessed by retrospective review of patient records.

Temporary and permanent procedures were carried out with the patient in a prone jack-knife position under general anaesthesia. The temporary wire was placed in the S3 and S4 foramen and the one that gave the maximum perianal spasm and toe flexion when the temporary wire was stimulated was used for the two weeks of the test. Electrodes for the permanent implant were placed in the same foramina to duplicate the response achieved during the test period. A Medtronic (Model No. 3023) [Pulse width: 210µs, Frequency: 14 Hz] stimulator was inserted in a subcutaneous pocket created above the iliac bone. One dose of prophylactic antibiotic was administered at induction of anaesthesia.

Before discharge, patients were counselled by the senior author and the stimulator programmed to the amplitude just below the threshold for individual patient sensation. Patients were reviewed at the clinic at 6 weeks, 3 months and one year following the procedure by the senior author. Severity of incontinence and QoL were assessed using CCIS and SF36v2 forms respectively. Patients were sent postal questionnaires with a postal and telephone reminder at 4 weeks.

RESULTS:

75 patients presenting to the colorectal clinic between 2006 and 2012 were identified as having been assessed as suitable for consideration of a sacral nerve stimulator. 70 (93.3%) of these patients were female. The major indication for assessment was faecal incontinence (72 patients, 96%). This was mostly urge incontinence or urge and passive incontinence (49.3%).

Preoperative Assessment

61 of the 75 patients were selected as appropriate for trial with temporary implant placement, 14 either declining the procedure, not having true faecal incontinence, or not having tried all conservative measures. Of these, 60 were female of whom 70% had at least one previous pregnancy. 64.2% had required perineal intervention during delivery, which included perineal tear, forceps delivery or episiotomy. 57.3% of the initial 75 patients considered for temporary placement of SNS had previously undergone perianal surgery, ranging from anal sphincter repair, haemorrhoidectomy and anal pull through (Table 1). The median age of patients was 42 years (range: 22-76 years). Patients were discharged on the same day following temporary wire placement and the following morning after placement of the permanent implant.

Table 1:

Number of patients with previous perianal surgery

Previous Perianal Surgery	Number of Patients
Anterior Sphincter Repair	18
Second Degree Tear Repair	1
Third Degree Tear Repair	12
Fourth Degree Tear Repair	1
Haemorrhoidectomy	4
Anal pull-through	2
Perineal Burn	1
Ano-vaginal Fistula	1
Reconstruction following Trauma	3

All the patients had either Ultrasound Scan (USS) or Magnetic Resonance Imaging (MRI) assessment of their anal canal. 61.7% of the patients who proceeded to a temporary wire had either a defect, scar or thinning of their anal sphincter, with the rest having no abnormality on imaging. Thirty-nine patients had a pudendal nerve assessment prior to temporary SNS assessment. This demonstrated bilateral delay in 33.3% of patients, right-sided delay in 12.8% of patients, left-sided delay in 5.1% of patients and 48.7% of patients' pudendal nerve assessments were reported as normal.

Temporary SNS

A temporary SNS was placed in 61 patients. Of these, 40 patients (65.6%) reported an improvement in their Cleveland Clinic Incontinence Score of greater than 50% and all of these patients proceeded to permanent SNS implant placement. There was no morbidity from the procedure itself, however, there were some technical failures reported with two patients having wire failure due to wire dislodgement and one patient suffering battery failure, giving a total complication rate of 4.9%.

Permanent SNS

Cleveland Clinic Incontinence Scores:

In the patients who proceeded to permanent implant placement there was a significant reduction in the pre-SNS and post-SNS Cleveland Clinic Incontinence Scores from median of 14 to 9 respectively (p: 0.008). There was no difference in improvement at 6 weeks or 12 month follow up and at their most recent follow up 78% of patients reported continued improvement from their baseline symptoms prior to placement of the SNS (Table 2).

Quality of Life:

When assessed by SF36 Questionnaire patients reported a significant improvement in Role Physical (p=0.017), General Health (p=0.02), Vitality (p=0.043), Social Functioning (p=0.004), Role Emotional (p=0.007), Mental Health (p=0.013) and Mental Health Summary (p=0.003) (Table 3). However, these improvements were not shared in the bodily pain and physical functional domains.

Manometry:

There was no significant improvement in the pre and post-operative median resting (26.2 mm Hg vs. 28.3 mm Hg) and squeeze (49.6 mm Hg vs. 57.2 mm Hg) pressures. Median follow up period was 39 months (range: 4-108 months).

Morbidity:

In 6 patients there was an initial suspicion of infection. Five of these patients were given antibiotics for erythema around the wound and 1 of these patients had wound breakdown. A further patient was found to have a sterile abscess. Ten patients (25%) initially reported pain at the site of permanent implant, however in 6 of these cases it resolved with reprogramming or spontaneously and 4 had persistent pain requiring analgesics for more than six weeks.

Technical issues & Follow up:

The device required reprogramming in 62.5% of cases, however, this was usually performed at an outpatient appointment. Reprogramming by a Medtronic representative was required in 10% of cases. Repositioning of the SNS was required in three patients including one case where the stimulator had to be replaced due to infection following wound breakdown. There was one episode of wire failure in this cohort and one episode of battery failure after the device had been in place for over five years.

DISCUSSION

Faecal incontinence is a debilitating condition associated with significant stigmatisation and embarrassment. Difficulty in travelling, working and maintaining interpersonal relationships frequently results in the patient suffering from social isolation, depression and a reduced quality of life. This has substantial economic implications on individuals, family members and the healthcare system.[2] Community costs in the Netherlands were measured at €2169 in 2005 and $4110 per year in the US in 2012.[6 7]

Conservative treatment is effective in more than half of patients but more intensive treatment is required in a proportion of them.[8] Various studies have reported short term success rates, varying from 33 to 100% [9], with sphincter repair procedures, such as post anal repair, perineal reefing and overlapping sphincteroplasty, although the results worsened with increasing length of follow-up. Total pelvic floor repair, which combines anterior sphincter plication with levatorplasty, and post anal repair is reported to be a viable option when compared to post anal repair or levatorplasty for idiopathic incontinence.[10]

Other procedures, such as neo-sphincter procedures, graciloplasty (stimulated or non-simulated) and artificial bowel sphincter insertion, are technically demanding with high initial costs.[8] Dynamic graciloplasty is associated with morbidity and mortality rates of 0 to 13% and 0.14 to 2.08% respectively.[11] Artificial bowel sphincter insertion has success rates of 70-88% with morbidity rates as high as 33% [12] and explantation rates of up to 40%.[13] Stoma formation has the associated costs of hospitalisation and maintenance.

SNS continues to develop as therapy for faecal incontinence.[14] It was initially used for the treatment of urinary urge

TABLE 2:

Cleveland Clinic Incontinence Score

Type of incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Never 0; rarely < 1/month; sometimes <1/week and >1/month; usually <1/day and >1/week; always >1/day[28]

Jorge J, Wexner S. Etiology and management of fecal incontinence. Dis Colon Rectum 1993;36:77-97. Reprinted with permission of Cleveland Clinic Florida.

incontinence and non-obstructive urinary retention.[15] These patients observed a simultaneous improvement in bowel symptoms and its use was consequently investigated extensively in the treatment of faecal incontinence and constipation. Matzel et al were the first to report its use in faecal incontinence in 1995.[5]

The mode of action of SNS remains unknown. The clinical effect may be due to voluntary somatic, afferent sensory and efferent autonomic motor stimulation achieved by sacral nerve root stimulation.[16] In addition, the pelvic part of the sympathetic chain and large myelinated alpha motor neurones that innervate the external anal sphincter and levator ani muscles are also stimulated. The resulting neuromodulation probably results in a change in sphincter function, hindgut function or a combination of these leading to improved continence.[17] There is no evidence as yet to suggest why some patients do not gain sufficient benefit to warrant permanent implantation.

TABLE 3:

Short form 36 quality of life assessment.

Subscale	Median pre op	Median post op✷	p-value
PF	39.2	47.5	0.059
RP	28.7	42.2	0.017
BP	41.4	43.75	0.051
GH	28.6	40.55	0.020
VT	39.6	45.8	0.043
SF	24.1	40.5	0.004
RE	20.9	32.6	0.007
MH	28.9	35.9	0.013

✷ at 6 weeks post operative follow up

In our series, 40 of the 61 patients (65.6%) had marked improvement in incontinence scores with temporary wire placement and went on to permanent implant placement. Three of these remaining patients in our series opted for permanent colostomy.

Jarrett MED (2004) in a systematic review of published literature found that 56% of 266 patients proceeded to permanent implant.[17] Uludag et al, Jarrett et al, Rosen et al and Leroi et al had permanent implantation rates of 77, 78, 80 and 55% respectively.[17-20] This shows that our rate was within the previously reported range and the differences of conversion may reflect variation in selection of patients and willingness to offer something to people with a very debilitating condition.

Various authors report improved continence scores and quality of life but using different scales of measurement (Wexner score, Cleveland clinic incontinence scores; SF-36, American Society of Colon and Rectal Surgeons questionnaire and Royal London Hospital questionnaire) perhaps due to the unavailability of a single validated scoring system to assess faecal incontinence.[14 21 22] This can make direct comparison between studies quite difficult.

Our study showed that, overall, there was a significant reduction in Cleveland Clinic Incontinence score from median 14 to 9 (p=0.008). This compares favourably with other studies which show a similar reduction in CCIS from a range of 12-18 to a range of 1-10.[14] The number of patients in these studies is very variable, as is the length of time of follow up, which could be as short as 6 months, making valid comparison difficult.[14] It is noted that the extent of improvement in these studies varies considerably and it is unclear whether there is a bigger improvement when starting from a higher or lower baseline, however, they are all statistically significant.

In keeping with our results, several studies have shown significant improvement in quality of life with effective SNS and specifically a long-term sustained clinical benefit in 80% of patients at 7 years.[23 24] It was pleasing to see that there was very little tailing off in improvement amongst our cohort.

In our study, two patients had no change in the CCIS at 6 weeks follow up. One of them had associated proctitis of unknown aetiology that might have contributed to persistent symptoms. Incontinence score in this patient was 20 preoperatively and at 6 weeks follow up. This is reflected in the physical function, general health and vitality sub scores of SF-36 that remained the same post operatively. Another patient with a migrated electrode had no improvement in incontinence scores at 6 weeks. Interestingly, all the sub-scores of SF-36 remained the same post-operatively except for social function (35 vs. 29.6). However, the incontinence scores improved from 10 to 8 after the electrode was reprogrammed. Another patient had painful serous collection around the implant for which the implant was replaced on the opposite side.

Other reported adverse events in the literature include implant related pain due to the lead running subcutaneously over the iliac crest to the abdominally placed generator, pain over the generator when it was set as the anode, unspecified pain, infection of the implant and superficial wound dehiscence.[17] By placing the implant in the upper outer quadrant of the buttock on the patient's dominant side, the stimulator is not felt when sitting down and there is decreased lead associated pain. The tined lead electrodes, although more expensive, inhibit axial movement of the lead and probably reduce the migration rates.[25]

Nearly half of all patients experience loss of efficacy at some point. 62.5% patients required reprogramming at least on one occasion, with 10% requiring a Medtronic representative to assist with reprogramming for either symptom control or discomfort. Alternative stimulator settings at higher frequency would increase treatment efficacy in patients experiencing loss of efficacy if alternative settings are tested.[26] When the stimulators have been in place for some time battery failure is not uncommon and may require exchange of the pulse generator, seen in the original cohort at a rate of 89% at an average of 7.4 years.[27]

This study reports our early experience with sacral nerve stimulation. Limitations of this study include small patient population and a limited follow up period of 12 months. Although the success rates are good at 12 months, longer-term efficacy needs further evaluated. Furthermore, this procedure was subject to limitations by the purchasing commissioners in Northern Ireland. Following on from this review of SNS results it is planned to make it available more widely.

CONCLUSIONS:

This study has shown that the use of SNS for faecal incontinence results in significant improvement in incontinence and quality of life scores. Patient selection based on the improvement in continence with minimally invasive temporary wire stimulation is effective at predicting those who will benefit over the medium term. There are relatively low rates of morbidity associated with the procedure.

REFERENCES:

1. Perry S, Shaw C, McGrother C, Matthews RJ, Assassa RP, Dallosso H, *et al.* Prevalence of faecal incontinence in adults aged 40 years or more living in the community. *Gut.* 2002;50(4):480-4.
2. Malouf AJ, Chambers MG, Kamm MA. Clinical and economic evaluation of surgical treatments for faecal incontinence. *Br J Surg.* 2001;88(8):1029-36.
3. Hetzer FH. Fifteen years of sacral nerve stimulation: from an open procedure to a minimally invasive technique. *Colorectal Dis.* 2011;13(Suppl 2):1-4.
4. Schmidt RA, Bruschini H, Tanagho EA. Sacral root stimulation in controlled micturition. Peripheral somatic neurotomy and stimulated voiding. *Invest Urol.* 1979;17(2):130-4.
5. Matzel KE, Stadelmaier U, Hohenfellner M, Gall FP. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet.* 1995;346(8983):1124-7.
6. Deutekom M, Dobben AC, Dijkgraaf MG, Terra MP, Stoker J, Bossuyt PM. Costs of outpatients with fecal incontinence. *Scand J Gastroenterol.* 2005;40(5):552-8.
7. Xu X, Menees SB, Zochowski MK, Fenner DE. Economic cost of fecal incontinence. *Dis Colon Rectum.* 2012;55(5):586-98.
8. Jarrett ME, Varma JS, Duthie GS, Nicholls RJ, Kamm MA. Sacral nerve stimulation for faecal incontinence in the UK. *Br J Surg.* 2004;91(6):755-61.
9. Baig MK, Wexner SD. Factors predictive of outcome after surgery for faecal incontinence. *Br J Surg.* 2000;87(10):1316-30.
10. Deen KI, Oya M, Ortiz J, Keighley MR. Randomized trial comparing three forms of pelvic floor repair for neuropathic faecal incontinence. *Br J Surg.* 1993;80(6):794-8.
11. Chapman AE, Geerdes B, Hewett P, Young J, Eyers T, Kiroff G, et al. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg.* 2002;89(2):138-53.
12. Wong WD, Jensen LL, Bartolo DC, Rothenberger DA. Artificial anal sphincter. *Dis Colon Rectum.* 1996;39(12):1345-51.
13. Christiansen J, Rasmussen OO, Lindorff-Larsen K. Long-term results of artificial anal sphincter implantation for severe anal incontinence. *Ann Surg.* 1999;230(1):45-8.
14. Matzel KE. Sacral nerve stimulation for faecal incontinence: its role in the treatment algorithm. *Colorectal Dis.* 2011;13 (Suppl 2):10-4.
15. Tanagho EA, Schmidt RA. Bladder pacemaker: scientific basis and clinical future. *Urology.* 1982;20(6):614-9.
16. Carrington EV, Knowles CH. The influence of sacral nerve stimulation on anorectal dysfunction. *Colorectal Dis.* 2011;13 (Suppl 2):5-9.
17. Jarrett ME, Mowatt G, Glazener CM, Fraser C, Nicholls RJ, Grant AM, et al. Systematic review of sacral nerve stimulation for faecal incontinence and constipation. *Br J Surg.* 2004;91(12):1559-69.
18. Uludag O DC, Baeten CGMI. Sacral neuromodulation for faecal incontinence. *Dis Colon Rectum.* 2002;45(12):A34-A36.
19. Rosen HR, Urbarz C, Holzer B, Novi G, Schiessel R. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology.* 2001;121(3):536-41.
20. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. *Dis Colon Rectum.* 2001;44(6):779-89.
21. Hetzer FH, Hahnloser D, Clavien PA, Demartines N. Quality of life and morbidity after permanent sacral nerve stimulation for fecal incontinence. *Arch Surg.* 2007;142(1):8-13.
22. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut.* 1999;44(1):77-80.
23. Uludag O, Melenhorst J, Koch SM, van Gemert WG, Dejong CH, Baeten CG. Sacral neuromodulation: long-term outcome and quality of life in patients with faecal incontinence. *Colorectal Dis.* 2011;13(10):1162-6.
24. Mellgren A, Wexner SD, Coller JA, Devroede G, Lerew DR, Madoff RD, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum.* 2011;54(9):1065-75.
25. Hetzer FH, Hahnloser D, Knoblauch Y, Lohlein F, Demartines N. New screening technique for sacral nerve stimulation under local anaesthesia. *Tech Coloproctol.* 2005;9(1):25-8.
26. Duelund-Jakobsen J, Dudding T, Bradshaw E, Buntzen S, Lundby L, Laurberg S, et al. Randomized double-blind crossover study of alternative stimulator settings in sacral nerve stimulation for faecal incontinence. *Br J Surg.* 2012;99(10):1445-52.
27. Matzel KE, Lux P, Heuer S, Besendorfer M, Zhang W. Sacral nerve stimulation for faecal incontinence: long-term outcome. *Colorectal Dis.* 2009;11(6):636-41.
28. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum.* 1993;36(1):77-97.