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Research Article

Revision trends of sacral neuromodulation for faecal incontinence

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Abstract...

Introduction: This study aimed to determine the incidence, trend and risk factors associated with revision or removal of a sacral nerve stimulation device for treatment of faecal incontinence in a New Zealand institution.

Methods: This is a single-centre retrospective cohort study conducted at a New Zealand university hospital from January 2008 through December 2022. Subjects who underwent sacral neuromodulation for faecal incontinence were identified from a prospectively maintained database.

Discussion: After a median follow-up period of 71 months, 35 of the 173 subjects (20.2%) analysed had required at least one revision procedure. Reasons for revision included infection, implant site discomfort/pain or lead fracture/ migration. The most frequent indication for early revision was implant discomfort/pain, which occurred after a median of 8 months. For maintenance reasons, a battery change was required after a median duration of 78 months. 35 (20.2%) subjects subsequently required explanation of the sacral nerve stimulation device. On secondary analysis, no risk factors to predict loss of efficacy of treatment could be identified from our cohort.

Conclusion: Our study recorded a revision rate of 20.2%. No risk factor for loss of efficacy of treatment was identified, highlighting the need for further research to aid in patient selection for successful and cost-effective sacral nerve stimulation device implantation in the treatment of faecal incontinence.

Keywords: Sacral neuromodulation; Faecal incontinence; Revision.

Introduction

Sacral Neuromodulation (SNM) has become an accepted treatment for end-stage Faecal Incontinence (FI) [2], a debilitating condition affecting 10-15% of New Zealanders [2]. It has offered a therapeutic option when conservative measures such as diet optimization, constipating medications and behavioural therapy are not successful [3-5].

SNM consists of an Implantable Pulse Generator (IPG) that is attached to an electrical lead. This lead is typically placed through the S3 foramen and is tunnelled under the skin to connect to the IPG implanted under the skin in the upper, lateral gluteal region. SNM's mechanism of action in faecal incontinence management is unclear but thought to involve multiple pathways [6]. These include mediating atypical voiding

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reflexes via a blockade of C fibre activity [7], and controlling visceral and somatic afferent pathways at the spinal, supraspinal, and postganglionic levels [7]. These effects are produced by continuous low-level electrical stimulation to the sacral nerve roots by the electrode lead [8].

While effective, SNM is an expensive undertaking. A previous study at our institution showed that the component costs alone in this two-stage procedure exceeded NZ$ 20,000 per patient [9]. Moreover, SNM reintervention/revision and removal occurs frequently [10]. One of the main reasons has been loss of efficacy of treatment, with the incidence of surgical revision of SNM reported to be anywhere from 21% to 45% in the published literature [11,12].

Given the high cost of surgical reintervention and relatively high explanation rate, continued investigation into risk factors associated with SNM revision and explanation is paramount to guide clinical decision-making [10,13]. Delineation of these factors may aid in perioperative counselling, patient selection, clinical decision-making, and reduction in health-care costs.

The primary aim of this audit was to quantify our revision and explanation rate. Secondary aims included attempting to define any possible trend in revisions. Finally, we sought to identify patient characteristics associated with multiple surgical revisions and explanation of SNM, which have been previously used as a proxy to indicate loss of efficacy of treatment [14,15], with the aim to further understand the nuances around optimal patient selection for SNM in treatment of this debilitating condition.

Methods

Locality and ethics approval was obtained from the Auckland District Health Board (ADHB) local ethics office for a low/negligible risk audit (Ref. 101247).

Data was drawn from a prospectively maintained de-identified database of all subjects undergoing SNM at our institution. The period was from February 2008 when our SNM program commenced, to December 2022 to allow for at least 36months' follow up.

Patients considered for SNM treatment were adults with end-stage Faecal Incontinence (FI) refractory to conservative treatment. Suitability for SNM treatment was carefully assessed. This included a detailed history, examination and bedside testing including but not limited to high resolution manometry, 3D endoanal ultrasound and proctoscopy. A defecating portogram under fluoroscopy was often included and a baseline bowel diary collected over a two-week period. Thereafter, suitable candidates were discussed at the departmental pelvic floor multi-disciplinary team meeting attended by surgeons, allied health professionals, pelvic floor radiologists and senior clinical nurses.

All patients require a successful 2-week Percutaneous Nerve Evaluation (PNE) trial with a unipolar lead (Model 3057, Medtronic, MN) with success defined by at least a 50% reduction in symptom severity and number of weekly FI episodes recorded on a bowel diary. After a successful trial, patients were offered permanent SNM implantation (Interitem II/Interitem X System, Medtronic, MN). This Implantable Pulse Generator (IPG) device was performed with a quadripolar lead (Model 3889 or 3093, Medtronic, MN) positioned within the S3/S4 foramen often under Image Intensifier (II) guidance. The key procedural steps have been previously described [5]. Specifically, our institution had adopted Mutzel's work which called for ten procedural steps to optimize the key aspects of the procedure. All subjects (100%) had insertion under Image Intensifier (II) guidance with 92.5% inserted into the S3 foramen. They were operated on by four experienced colorectal surgeons in an equal distribution.

After implantation, patients are reviewed at least once yearly, with a self-referral of symptom hotline to a Senior Clinical Nurse established for additional support.

Clinical and demographic data were extracted from the medical record of all the patients. Recorded patient characteristics included age at Basic Evaluation of SNM, sex and ethnicity. Bowel function variables included aetiology of FI and past pelvic floor operations. Technical factors included whether there was use of Image Intensifier (II) to aid lead placement, the foramen level of insertion (S3/S4). Procedure dates were extracted from clinical records for patients in the Colorectal Unit database.

Revisions (defined as all surgical reintervention under anaesthetic) or explanations were then studied as outcomes of interest. Reasons for revision and explant such as lead migration, lead fracture, implant site discomfort/pain or infection were extracted from clinical operation notes.

In this study, multiple surgical revisions and/or explanation of SNM were taken as a proxy to indicate loss of efficacy of treatment. Individuals who had multiple revision surgeries or complete device explanation were aggregated in a singular primary outcome and then compared with the other subjects which acted as a control. Possible risk factors for poor response were then analysed for a possible association with this outcome of interest. Indications of interest were compared to determine if there were any significant associations. Finally, Kaplan-Meier survival analysis was performed to visualize cumulative first-reinterventions, explants and battery replacements over the available follow-up time.

Sample size calculation

While this was a retrospective cohort study, an attempt at power calculation had suggested a sample size for this study of 83 patients. This assumed an α=0.05 and 1-β=0.8, with a significance level of $P<0.05$. The sample size was calculated using an online software program (http://clincalc.com/stats/samplesize.aspx), based on a previous audit of the initial experience at our institution which suggested a revision rate of 20.6%, compared with Eggers published aggregate rate of 35.2% [12].

Data analyses were accomplished using SPSS for Windows (Version 28.0, IBM, NY). When testing differences between groups, t-test or Mann-Whitney U test was used to compare continuous variables. Categorical variables were compared by χ^2 test. Parametric data are presented as mean ± SD, whereas nonparametric data are presented as a median with interquartile ranges. When sufficiently meaningful data were obtained through a univariate analysis, a multivariate analysis

was conducted using the Cox proportional hazards regression model. Statistical significance was considered at a p value of <0.05.

Results

Between 2008 and 2022, a total of 201 patients underwent Percutaneous Nerve Evaluation (PNE) of SNM (Stage 1), of which 173 patients (86.1%) proceeded to permanent implantation (Stage 2) (Figure 1).

Demographic data are presented in (Table 1). The median age was 63 years (range 27-85) and 182 were female (91%). 77% identified as New Zealand European with 7.7% Māori.

After a median follow up of 71 months, our cohort of 173 subjects who proceeded to permanent implantation (Stage 2) showed that 35 of the 173 subjects (20.2%) had required at least one revision procedure.

Pattern of reintervention/revision

Reasons for revision included infection, implant site discomfort/pain or lead fracture/ migration. The most frequent indication for early revision was implant discomfort/pain, which occurred after a median of 8 months (Table 2).

Kaplan Meier (K-M) analysis suggested that the probability of being reintervention free at 5 years was >70%, the probability of avoiding explants remained >60% at 12 years and the probability of maintaining the same battery remained >90% at 6 years (Figure 2).

Explanation

35 subjects (20.2%) ultimately required explanation of SNM after a median period of 41 months. 10 out of these 35 patients had undergone more than one surgical revision prior to explanation.

Among the 35 patients (20.2%) who subsequently required complete explanation of SNM, the most common indications for device removal were lack of symptomatic improvement (N=17, 49%). Refractory pain at the implantation site only occurred in 3 subjects (8.5%) with infection mandating removal occurring in 1 subject (3%). The rest of the subjects requested removal after tolerating a >6 month period with the SNM turned off, suggesting no difference with or without SNM (N=14, 40%).

Risk factors for poor response

Univariate analysis had initially suggested that subjects who had multiple revisions or their SNM device subsequently removed were younger, with a median age of 59 years compared to a median age of 66 years in those subjects without removal (Table 3). However, age nor age <55 years did not reach significance on multivariate analysis. The groups were otherwise similar in terms of gender (p=0.23), race/ethnicity (p=0.56), foramen cannulated (p=0.39) or the recorded aetiology of faecal incontinence (p=0.96).

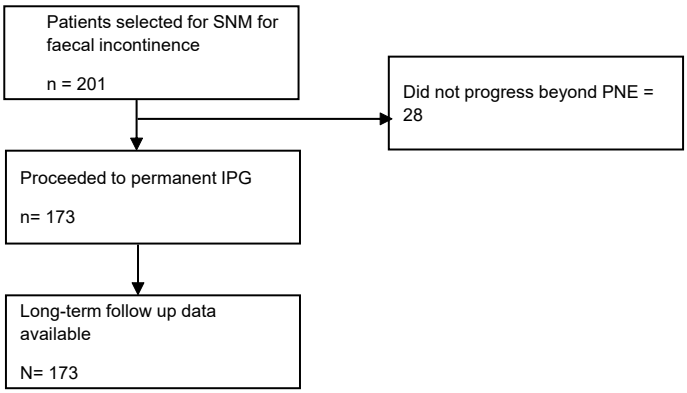

Figure 1: Study inclusion flow diagram.
SNM: Sacral Neuromodulation; PNE: Peripheral Nerve Evaluation; IPG: Implantable Pulse Generator.

Table 1: Demographics.

Patient demographics						
	Total	**PNE only**	**PNE + IPG implant**	**IPG explanted**	**IPG retained**	**p-value (<0.05)**
n	201	28	173	35	138	
Age, median (IQR)	63 (16)	59 (12)	63 (13)	62 (13)	64 (14)	
Female	182 (90.5%)	22 (78.6%)	160 (92.5%)	32 (91.4%)	128 (92.8%)	0.0637
Ethnicity						
NZ European	155 (77.1%)	24 (85.7%)	131 (75.7%)	28 (80.0%)	103 (74.6%)	0.91
Other European	23 (11.5%)	2 (7.1%)	21 (12.1%)	4 (11.4%)	17 (12.3%)	
Maori	15 (7.5%)	1 (3.5%)	14 (8.1%)	2 (5.7%)	12 (8.7%)	
Other	8 (3.9%)	1 (3.5%)	7 (4.1%)	1 (2.9%)	6 (4.3%)	
Aetiology of FI						
Obstetric Sphincter Injuries	40 (19.9%)	6 (21.4%)	27 (15.6%)	6 (17.1%)	21 (15.2%)	0.04
Non obstetric Sphincter Trauma	28 (13.9)	2 (7.1)	27 (15.6%)	5 (14.3)	22 (16.0)	
Low Anterior Resection Syndrome	8 (4.0)	1 (3.6)	8 (4.6%)	4 (11.4)	4 (2.9)	
Radiation damage	4 (2.0)	0 (0)	5 (2.9%)	2 (5.7)	3 (2.2)	
Connective Tissue Disorder	6 (3.0)	2 (7.1)	4 (2.3%)	1 (2.9)	3 (2.2)	
Spinal Injury	5 (2.5)	3 (10.7)	3 (1.7%)	1 (2.9)	2 (1.4)	
Multi-factorial	95 (47.3)	8 (28.6)	93 (5.4%)	16 (45.7)	77 (55.8)	

PNE: Percutaneous Nerve Evaluation; IPG: Implantable Pulse Generator.

Table 2: Revision trends.

	No of pt (%)	No. of surgical reintervention	Time to intervention (Median months, IQR)
Total with permanent SNS	173		
Explanation after permanent SNS	35 (20.2%)		41 (73)
Reasons			
Success	14		
Failure	17		
Pain	3		
Infection	1		
Revisions	74 (42.7%)	96	66 (32)
Reasons			
Battery replacement		57	78 (30)
Lead changes		20	31.5 (19)
Stimulator discomfort		14	8 (3)
Changing to MRI compatible lead		5	

SNS: Sacral Nerve Stimulator.

Table 3: Risk factors for loss of efficacy (Univariate Analysis).

Factors		Multiple Revisions/ Explant (N=61)	Control (N=112)	p value (<0.05)	Odds Ratio	95% CI
Age, median (IQR)		59 (7)	66 (14)			
Less than 55 yrs old, N (%)		20 (32.7%)	19 (16.9%)	0.02	2.388	1.183 to 4.825
Sex, N (%)						
	Female	54 (88.5%)	105 (93.7%)	0.23	0.5143	0.1897 to 1.403
	Male	7 (11.5%)	7 (6.3%)			
Ethnicity, N (%)						
	NZ European	45 (73.8%)	92 (82.1%)	0.5694		
	Other European	7 (11.5%)	9 (8%)			
	Maori	6 (9.8%)	6 (5.4%)			
	Others	3 (4.9%)	5 (4.5%)			
No of previous pelvic floor surgeries, median (IQR)		0 (1)	1 (1)			
Image Intensifier use for lead placement		61 (100%)	112 (100%)			
Foramen cannulated						
	S3	55 (90.1%)	105 (93.8%)	0.39	0.6111	0.2144 to 1.974
	S4	6 (9.9%)	7 (6.2%)			
Incontinence aetiology	Obstetric Sphincter Injuries	7 (11.5%)	18 (16.1%)	0.9598		
	Non obstetric Sphincter Damage	10 (16.4%)	19 (17.0%)			
	LARS	4(6.5%)	4 (3.6%)			
	Radiation damage	2 (3.3%)	3(2.7%)			
	Connective Tissue Disorder	2 (3.3%)	3 (2.7%)			
	Spinal Injury	2 (3.3%)	3 (2.7%)			
	Multi-factorial	34(55.8%)	62 (55.4%)			

Discussion/Conclusion

A recent systematic review of 36 studies reporting outcomes of SNM treatment for FI noted a 35% aggregate surgical revision rate [17], with 19.7% subsequently requiring explanation of the implant [18]. Similarly, our data identified a revision rate of 20.2% with a similar explanation rate of 20.2% after a median follow up period of 71 months.

This revision rate has persisted despite careful our institution's efforts to maintain careful patient selection as a key component in ensuring successful outcomes. Every patient referred for SNM for faecal incontinence is reviewed by a dedicated colorectal surgeon in our Pelvic Floor Clinic, thoroughly assessed and then discussed at the department's pelvic floor multi-disciplinary team meeting.

The patients' responses from their Percutaneous Nerve Evaluation (PNE)are analysed within the context provided by the clinical examination and investigations prior. Equally, our multi-disciplinary team also accept that the traditional criteria for success (≥50% improvement in diary variables) may not

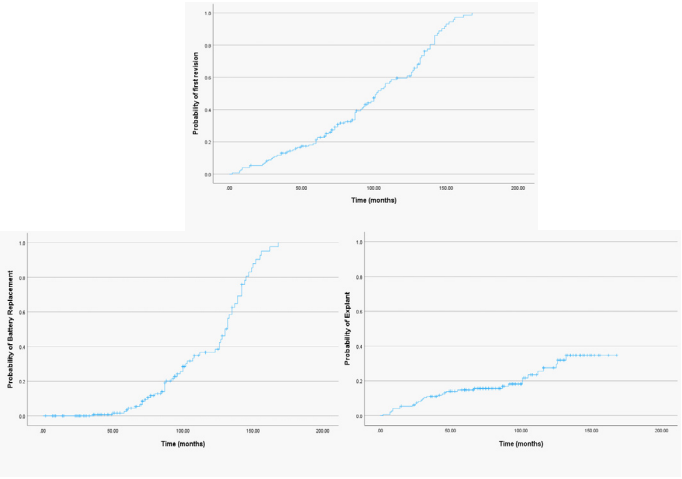

Figure 2: Kaplan Meier risk of first-reintervention, battery replacement and explanation of permanent IPG.

consistently correlate with the patients' global impression of change. For this subgroup of patients, absolute reductions in symptoms across multiple domains could represent more accurate predictors of the patients' global impression of change and may have a role in supplementing discipline-specific assessments [19]. This would serve to mitigate the potential for false positives, recently measured to be as high as 16% [20], which the authors feel may account for some of the explanation rate of 20.2% in our cohort.

Pain is one of the most common complications after SNM implantation. This has accounted for 7.5% of surgical reinterventions/revisions in our study. Traditionally, the IPG is either repositioned to the contralateral gluteal region or to the anterior abdominal wall. In our experience, we noticed that there was a decrease in pain complications after we discontinued the practice of fixation sutures after 2018. An adequately snug sub-Scarpa's pocket appeared to reduce the incidence of clinically significant post-operative pain mandating revision.

Our study was unable to identify any significant risk factors for poor efficacy of treatment. Initial observations suggested that patients who underwent SNM before the age of 55 were more likely to undergo device revision or removal. However, this did not reach significance on multivariate analysis, highlighting the presence of confounding factors. While young age has previously been reported as a risk factor associated with increased risk of revision or removal of SNM in urology patients [10], our study suggests that the complex interplay of factors in a patient with faecal incontinence makes any exercise in risk factor identification challenging.

Our study supports previous work that showed the aetiology of FI did not contribute towards success or failure of SNM treatment, which was taken to mean lack of improvement from SNM [21]. These two groups had similar proportions of patients with and without sphincter defects and we similarly found that the device had similar success in both patient groups. We eagerly await current work further evaluating SNM use in the treatment of Low Anterior Resection Syndrome (LARS), which is a debilitating multifactorial syndrome [22].

The strengths of this study include being one of the largest cohorts in the Australasian subcontinent. With Sacral NeuroModulation (SNM) increasingly being implanted in younger patient populations, longer term outcomes of SNM beyond the commonly reported five years is an underdeveloped area of research. Our cohort's median age of 63 in a developed country with an average life expectancy of 82 years suggests that this long follow-up period of a median 71 months with none loss to follow up allows an accurate depiction of complications post SNM.

This study, however, does have limitations, including those intrinsic to a retrospective and single centre study that is associated with selection bias. Our analysis was limited to what was available in the electronic medical record and hence was unable to identify more extensive data points for comparison. The inability to separate the impact of temporal effects over the study period is another limitation. It may be expected that, with longer follow-up periods of procedures that involve the use of medical devices, the rates of reintervention would be high. As device technology continues to evolve, especially with subsequent models of SNM having longer battery lives, the revision rate quoted in this paper may decrease in future. The use of median follow- up period could introduce bias, which we hope the corresponding Kaplan-Meier (K-M) analysis to define a common time-to-event focus may help to overcome. We were also unable to account for the iinfluence of patient's preferences on revisions, pain, or device malfunction. The importance of Patient Reported Outcome Measure (PROM) in the success of sacral neuromodulation in faecal incontinence is an area of active study and we look forward to further research in this area.

Despite careful patient selection and an evidence-based protocolized electrode placement technique as described above, our revision and explanation rates suggest that faecal incontinence remains a heterogenous condition that is tricky to treat. Its multi-factorial nature with physical and psychosocial implications presents a conundrum unlike many other colorectal conditions. While SNM remain an effective treatment modality, patients should be aware that ongoing follow-up and program modification may be required to continue maintaining optimal response.

This study further provides a better understanding of the nuances of patient selection for SNM, and hints at various risk factors related to multiple revisions and explanation. Many studies have attempted to shed more light into the holy grail of improving patient outcomes in a cost-effective manner. This remains elusive and deserves greater study in our quest to improve patient selection and to aid in pre-operative patient counselling.

Declarations

Conflicts of interest: None to declare.

Funding sources: None to declare.

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