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SHORT COMMUNICATION

Sacral nerve stimulation versus percutaneous tibial nerve stimulation for faecal incontinence: a systematic review and meta-analysis

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Abstract

Aims Percutaneous tibial nerve stimulation (PTNS) and sacral nerve stimulation (SNS) are both second-line treatments for faecal incontinence (FI). To compare the clinical outcomes and effectiveness of SNS versus PTNS for treating FI in adults.

Method A literature search of MEDLINE, Embase, Science Citation Index Expanded and Cochrane was performed in order to identify studies comparing SNS and PTNS for treating FI. A risk of bias assessment was performed using The Cochrane Collaboration's risk of bias tool. A random effects model was used for the meta-analysis.

Results Four studies (one randomised controlled trial and three nonrandomised prospective studies) reported on 302 patients: 109 underwent SNS and 193 underwent PTNS. All included studies noted an improvement in symptoms after treatment, without any significant difference in efficacy between SNS and PTNS. Meta-analysis demonstrated that the Wexner score improved significantly with SNS compared to PTNS (weighted mean difference 2.27; 95% confidence interval 3.42, 1.12; $P < 0.01$). Moreover, SNS was also associated with a significant reduction in FI episodes per week and a greater improvement in the Fecal Incontinence Quality of Life coping and depression domains, compared to PTNS on short-term follow-up. Only two studies reported on adverse events, reporting no serious adverse events with neither SNS nor PTNS.

Conclusion Current evidence suggests that SNS results in significantly improved functional outcomes and quality of life compared to PTNS. No serious adverse events were identified with either treatment. Further, high-quality, multi-centre randomised controlled trials with standardised outcome measures and long-term follow-up are required in this field.

Keywords Faecal incontinence · Neuromodulation · Sacral nerve stimulation · Percutaneous tibial nerve stimulation · Systematic review · Meta-analysis

Introduction

Faecal incontinence (FI) is defined as the recurrent involuntary loss of faecal matter [1]. Neuromodulation for FI involves chronic, indirect or direct low-voltage stimulation of the sacral spinal nerves [2]. It is an alternative to conservative management and the more invasive surgical treatments. Sacral nerve stimulation (SNS) involves low-voltage stimulation of a sacral root by an electrode connected to an implanted pulse generator [2]. SNS has demonstrated persistent clinical efficacy and low mortality on long-term follow-up [2]. As the results for surgical repair for FI show a drastic deterioration during a 5-year follow-up [3], SNS has been suggested as an alternative or an adjunct to surgical repair [4]. National Institute for Health and Care Excellence (NICE) guidance currently recommends SNS for FI where surgical repair is considered inappropriate [5].

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Percutaneous tibial nerve stimulation (PTNS) involves modulation of the sacral nerve function by indirect low-voltage stimulation of the tibial nerve at the ankle via fine-needle electrodes connected to an external pulse generator [2]. Although SNS is a safe treatment, it requires two surgeries which may pose a risk to patient safety. On the other hand, PTNS has no reported adverse effects and is cheaper in the short term [2]. Therefore, a comparison between SNS and PTNS is essential to aid future healthcare provision and policy making in a financially restrained healthcare system. Previous systematic reviews have only addressed SNS and PTNS individually for FI [2, 6–8]. The aim of this review is to compare the clinical outcomes and effectiveness of SNS versus PTNS for FI in adults.

Methods

Search strategy

A systematic literature search was performed on MEDLINE, Embase, Science Citation Index Expanded and Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library. The following search headings were used in combination: "sacral nerve stimulation", "tibial nerve stimulation" and "faecal incontinence". Randomised controlled trials (RCTs) and nonrandomised studies comparing the effectiveness of SNS versus PTNS for treatment of FI in adults were included. Outcomes of interest included adverse events, functional outcomes and quality of life outcomes as highlighted in Table 1. The Cochrane Collaboration's risk of bias tool was used to assess the risk of bias of the included trials based on the following domains: allocation sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective outcome reporting and vested interest bias.

Statistical analysis

The meta-analysis was performed as per the recommendations from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Review Manager™ Version 5.3 (The Cochrane Collaboration, Software Update, Oxford) was used to perform the pair-wise meta-analysis. The "random effects" meta-analytical model was used for the analysis.

Results

Eligible studies

Of 593 references identified through electronic searches of Science Citation Index Expanded ($n = 223$), Embase ($n = 178$), MEDLINE ($n = 172$) and CENTRAL ($n = 20$), 251 duplicates between databases were excluded. A further 333 references were excluded through screening titles and reading abstracts. Nine references were retrieved for further assessment. Of these nine references, after reviewing the studies in detail, five studies were excluded. In total, four studies, one RCT [9] and three nonrandomised prospective studies [5, 10, 11] were included in the review.

Patient characteristics

Overall, 302 patients were included in the review, of which 47 were males and 255 were females. Mean age across the studies ranged from 48 to 62.3 years. In the review, 109 subjects underwent SNS, whereas 193 underwent PTNS.

Table 1 Results of meta-analyses. Weighted mean difference (WMD) was used for the meta-analysis and reported with 95% confidence interval (CI). WMD was considered statistically significant at $P < 0.05$. Heterogeneity between the included studies was assessed using the chi-squared test (X^2 or chi^2). The amount of heterogeneity was quantified by *I*-square (I^2), with a value of less than 40% considered not important. A random effects model was used for all the meta-analyses

Outcome	Number of studies	Number of patients		WMD	95% CI	*P* value	HG *P* value	HG I^2 (%)
		PTNS	SNS					
Wexner score	4	192	101	2.27	1.12, 3.42	0.0001[a]	0.75	0
FI episodes/week	2	162	52	8.11	4.13, 12.09	< 0.0001[a]	0.39	0
FIQL-Lifestyle	2	37	54	0.13	− 0.95, 1.21	0.81	0.0005	92
FIQL-Coping	2	37	54	0.51	0.16, 0.86	0.004[a]	0.28	14
FIQL-Depression	2	37	54	0.4	0.11, 0.69	0.007[a]	1	0
FIQL-Embarrassment	2	37	54	0.5	− 0.38, 1.38	0.26	0.02	82

PTNS percutaneous tibial nerve stimulation, *SNS* sacral nerve stimulation, *FI* faecal incontinence, *FIQL* Fecal Incontinence Quality of Life, *WMD* weighted mean difference, *CI* confidence interval, *HG* heterogeneity

[a] Statistically significant results

Adverse events

Two studies included in the review reported adverse events for the interventions [9, 11]. Thin et al. noted that 2 patients in the SNS group suffered from stimulator site pain, whereas 2 separate patients receiving PTNS suffered from paraesthesia and mild discomfort in the foot [9]. Al Asari et al. noted no adverse events in the PTNS group [11]. Meanwhile, the study observed that 2 patients receiving SNS had a wound infection resulting in re-implantation of the electrode [11].

Functional outcomes

All studies included reported the Wexner score as a measure for functional outcomes. Meta-analysis noted that SNS significantly improved the mean Wexner score compared to PTNS (Table 1). Two studies reported the frequency of FI episodes per week [9, 10]. Meta-analysis demonstrated a significant decrease in episodes of FI per week with SNS versus PTNS (Table 1). There was no evidence for publication bias.

Quality of life

Two studies reported the QOL of patients with Fecal Incontinence Quality of Life (FIQL) domains [9, 11]. Meta-analysis noted a significant improvement in the FIQL coping domain and depression domain with SNS compared to PTNS (Table 1). There were no significant differences between SNS and PTNS with regard to changes in FIQL lifestyle and embarrassment domains (Table 1).

Discussion

Our review included one RCT and three nonrandomised prospective studies. On meta-analysis, SNS was noted to significantly improve the Wexner score, frequency of FI episodes/week, FIQL coping domain and FIQL depression domain. On risk of bias assessment, no study reported attrition bias, reporting bias or any vested interest. However, studies failed to blind participants and personnel, therefore exposing the studies to a risk of performance bias. Moreover, only one study blinded outcome assessment, attributing to the risk of detection bias across the studies [9].

This is the first meta-analysis comparing SNS versus PTNS. Three hundred two patients were analysed across four studies. It has been estimated that over 3100 patients would have to be recruited to undertake an adequately powered RCT to compare these two complex interventions [9]. Such a number would be arduous to recruit in a single trial as there is uncertainty as to whether a large trial comparing SNS versus PTNS is financially viable. Therefore, the current meta-analysis is an instrumental comparison between the two treatments. Even though SNS is currently the more favourable option of the two treatments, our review offers invaluable information to patients to make an informed decision regarding their treatment. The significant differences in changes in QOL measures in SNS compared to PTNS observed in this review are a crucial finding as previous studies have emphasised the positive impact of emotional improvement on FI [12].

The review highlighted that studies comparing SNS versus PTNS had varying lengths of follow-up period [9, 11]. Moreover, there were baseline differences between treatment groups in the study with regard to squeeze pressures and symptom severity [10]. The treatment protocol for PTNS was inconsistent across studies. In three studies described in this review, patients in the SNS arm were excluded from the final perprotocol analysis if they did not demonstrate a > 50% improvement in FI episodes on peripheral nerve evaluation [9–11], hence selecting patients that are more likely to benefit from SNS and thereby introducing a selection bias in the studies [9–11]. Our review noted that discrepancies were observed in the inclusion criteria across the studies. Moreover, age and severity of FI were inconsistent at baseline across studies.

Both SNS and PTNS have not been the subject of many RCTs, with PTNS being a relatively new treatment for FI. Therefore, researchers may be more likely to publish positive findings, with inherent risk of publication bias. Our review process noted that despite the aetiology of FI being multifactorial, most studies did not describe the aetiology of the patients in the study. Therefore, comparing treatments based on aetiology was impossible. SNS is more commonly associated with adverse events as highlighted in a study reporting adverse events such as wound infection and lead migration in 12% of the patients [2]. SNS, unlike PTNS, also exposes the patients to anaesthesia and radiation [8].

PTNS is currently recommended by NICE under strictly audited conditions and offered to patients in around eight to ten centres in the UK [2]. In a robust trial (CONFIDENT—Knowles et al.) of PTNS versus sham, however, no significant difference in outcome was observed. SNS has been widely accepted as a treatment for FI, with good results up to 5 years [2]. It is however a costly device with a lifespan of between 5 and 7 years, requiring regular follow-up, reprogramming and battery changes. PTNS however has its own challenges, with regular sessions lasting an hour at a time needed to maintain treatment efficacy, and rapid attenuation of effect between "top-ups". However, the encouraging short-term results and acceptability amongst patients for PTNS may suggest its use as a bridge for patients awaiting SNS and/or patients with less severe FI, needing magnetic resonance imaging (MRI), or those unable/unwilling to undergo an anaesthetic for electrode implantation surgery [9]. With significant benefits of SNS and PTNS being highlighted in separate studies and a definitive trial between the treatment modalities not being feasible, it

could be possible for healthcare providers to offer the treatments based on patient preference. SNS is offered as the first-line treatment for patients failing conservative therapy, and not fit or unwilling to undergo surgical repair [4]. If the less invasive PTNS can be demonstrated to be more cost-effective and superior in improving FI symptoms, healthcare providers would offer sufferers PTNS over the more expensive SNS to curb healthcare expenditure and financial deficits.

Further, high-quality, multi-centre randomised controlled trials with standardised outcome measures and long-term follow-up are required in this field. Future trials should explore which patients will benefit from neuromodulation alone or the use of neuromodulation as an adjunct to other surgical and nonsurgical treatments for FI. Furthermore, trials should evaluate the cost-effectiveness and long-term effectiveness of PTNS.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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