



## Posterior tibial nerve stimulation for fecal incontinence: Where are we?

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### Abstract

Neurostimulation remains the mainstay of treatment for patients with faecal incontinence who fails to respond to available conservative measures. Sacral nerve stimulation (SNS) is the main form of neurostimulation that is in use today. Posterior tibial nerve stimulation (PTNS) - both the percutaneous and the transcutaneous routes - remains a relatively new entry in neurostimulation. Though in its infancy, PTNS holds promise to be an effective, patient friendly, safe and cheap treatment. However, presently PTNS only appears to have a minor role with SNS having the limelight in treating patients with faecal incontinence. This seems to have arisen as the strong, uniform and evidence based data on SNS remains to have been unchallenged yet by the weak, disjointed and unsupported evidence for both percutaneous and transcutaneous PTNS. The use of PTNS is slowly gaining acceptance. However, several questions remain unanswered in the delivery of PTNS. These have raised dilemmas which as long as they remain unsolved can considerably weaken the argument that PTNS could offer a viable alternative to SNS. This paper reviews available information on PTNS and focuses on these dilemmas in the light of existing evidence.

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**Key words:** Posterior tibial nerve stimulation; Percutaneous; Transcutaneous; Faecal incontinence; Efficacy of treatment; Neurostimulation

**Core tip:** Posterior tibial nerve stimulation though in its infancy, holds promise to be an effective, patient friendly and cheap treatment for faecal incontinence refractory to available conservative options. However, several questions remain unanswered and pose dilemmas regarding the delivery of this treatment. Solving these dilemmas could hold the key for unlocking the pathway for this treatment to be brought into the limelight.

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### INTRODUCTION

Neuromodulation is here to stay. Neurostimulation remains at present the first choice treatment for fecally incontinent patients who have failed to improve with biofeedback, except for the small minority in whom where there is an underlying surgically repairable sphincter defect<sup>[1-3]</sup>. The first reported use of the sacral nerve stimulation (SNS) for faecal incontinence (FI) was just under two decades ago<sup>[4]</sup>. However, over the past decade not only has the use of neurostimulation increased exponentially but the remit of neurostimulation has widened to include the stimulation of other nerves- primarily the posterior tibial nerve<sup>[5]</sup>. SNS for faecal incontinence remains a time tested treatment with more than 50 series reporting on its use. A large meta-analysis has confirmed

on its use in improving the symptoms of FI as well as improving the quality of life of the patients<sup>[6]</sup>. Posterior tibial nerve stimulation (PTNS) for faecal incontinence is relatively new with just under 20 studies being reported<sup>[7]</sup>. PTNS has been used mainly in the management of urinary incontinence<sup>[8,9]</sup>. Shafik *et al*<sup>[5]</sup> has been credited with attempting PTNS for faecal incontinence. PTNS can be performed either by using a more invasive percutaneous approach<sup>[5]</sup> where an inserted 34 gauge needle forms the route of stimulation or by the less invasive transcutaneous “Qualtero” approach<sup>[10]</sup> where cutaneous pads replace the needle. Studies that have been done looking at the efficacy of the percutaneous PTNS approach are far more than those which have looked at the less invasive transcutaneous approach. Though there have been no studies so far which have directly compared these two routes of stimulation, indirect evidence points to a better efficacy for the percutaneous approach<sup>[11]</sup>.

PTNS is usually delivered unilaterally, at the nerve’s most superficial position which lies just above and behind the medial malleolus. The area of the nerve stimulated is quite small as the grounding electrode is usually placed in the instep. No evidence exists as to any dominance of the left or right tibial nerve unlike the pudendal nerve<sup>[12]</sup>.

## DILEMMAS IN TREATMENT

### **Treatment protocols dilemmas**

There remains a lack of an effective and standardised treatment protocol for both percutaneous and transcutaneous PTNS (Table 1).

Shafik *et al*<sup>[5]</sup> in 2003 reported giving 30 min of percutaneous PTNS stimulation on alternate days for a period of four weeks. Though there is now a general consensus that patients require 12 wk of continuous treatment and that each treatment episode should last 30 min, there is no uniformity on how this should be given. Studies have given a single 30 min session of PTNS once a week for 12 wk while others have given two 30 min sessions a week for 6 wk<sup>[13-15]</sup>. Three prospective studies of percutaneous PTNS from the same institution have used either once a week or twice a week patterns of treatment with no apparent differences in efficacy<sup>[16-18]</sup>. The superiority of one approach over the other remains yet remains to be demonstrated. The National Institute of Clinical Excellence (NICE) suggests both patterns could be adapted depending on patient response<sup>[19]</sup>. It is logical that the onset of symptom improvement for the patient will only occur later on into the treatment using the once a week regime compared to the twice a week regime. The once a week treatment can help alleviate hospital workloads and may be more acceptable to the patient. However, the onset of symptom improvement for the patient on a once a week regime could be delayed which may have a potential for more patient dropouts. All percutaneous PTNS studies so far have utilised unilateral stimulation. There remains the unexplored question as to whether bilateral percutaneous PTNS could be more effective-

given that a recent pilot study on bilateral transcutaneous PTNS has shown better efficacy compared to unilateral stimulation<sup>[14,20]</sup>.

The same treatment protocol dilemma exists for transcutaneous PTNS as well. Queraltó provided patients with unilateral daily stimulation for 20 min for 4 wk and showed an 80% improvement in incontinence severity scores<sup>[10]</sup>. Eléouet *et al*<sup>[21]</sup> reported 63% improvement following a 20 min of unilateral twice daily stimulation for 1 mo. Vitton *et al*<sup>[22,23]</sup> attempted transcutaneous PTNS once daily for 3 mo on two groups of patients and reported a 41% and 54% improvement in symptoms. George *et al* attempted unilateral transcutaneous PTNS twice a week for 6 wk and reported a 45% improvement in symptoms<sup>[11]</sup>. Leroi *et al*<sup>[24]</sup> reported no improvements in the transcutaneous arm compared to the sham group following 20 min twice daily sessions for 3 mo. Thomas *et al*<sup>[25]</sup> suggested in a pilot study that daily stimulation may offer a better response compared to a twice weekly regime. A more recent variation has been the application of transcutaneous PTNS as a daily bilateral stimulation for 6 wk which has been reported to be more effective than the unilateral approach<sup>[14,20]</sup>. Only in one study was the transcutaneous PTNS stimulation provided in a hospital setting<sup>[11]</sup> while all the other studies required patients to apply the stimulation themselves at home after being trained.

### **Stimulation endpoint dilemmas**

The stimulation end point for the transcutaneous PTNS was to look for a motor response which was visualization of rhythmic flexion of toes during stimulation<sup>[10]</sup>. Intensity of stimulation was then turned down to just below the threshold required for motor contraction. This seems to be a common end point for stimulation in most of the transcutaneous PTNS studies except the published RCT<sup>[11]</sup> where a sensory and a motor response was sought and a study by Vitton *et al*<sup>[23]</sup> where a sensory response was looked for.

However, the end point for stimulation for percutaneous PTNS remains uncharted with no specific end points described to confirm effective stimulation. Percutaneous PTNS can cause both a sensory and a motor response. The motor response is flexion of the big toe or fanning of all toes; the sensory response is a tingling sensation felt on the foot radiating to all of the toes<sup>[26]</sup>. The original paper by Shafik *et al*<sup>[5]</sup> looked for a motor response following stimulation. However, subsequent studies introduced a sensory response as an endpoint for stimulation<sup>[16-18]</sup>. The voltage used and the intensity of stimulation to achieve a sensory response remains lower than the intensity required to achieve a motor response<sup>[26]</sup>. This could imply that the voltage used for eliciting a sensory response alone could be sub-optimal without the full potential of the treatment being realised. This could in turn be reflected in lower treatment response rates.

Using the presence of either a motor or a sensory response could imply different treatment levels for differ-

**Table 1** Posterior tibial nerve stimulation evidence summary *n* (%)

Ref.	Patient ( <i>n</i> )	Type of PTNS	Time, frequency and duration of therapy	Follow-up	Stimulation endpoints	Efficacy	Study classification
Shafik <i>et al</i> <sup>[5]</sup>	32	Pct	30 min, alternate days 4 wk	22 mo	Motor	27 (84)	Nonrandomised controlled
Queralto <i>et al</i> <sup>[10]</sup>	10	Tct	20 min, daily 4 wk	4 mo	Motor	8 (80)	Prospective uncontrolled
Mentes <i>et al</i> <sup>[43]</sup>	2 <sup>1</sup> (spinal)	Pct	30 min, alternate days 4 wk	3 mo	Motor	2 (100)	Prospective uncontrolled
Vitton <i>et al</i> <sup>[22]</sup>	12 <sup>2</sup> (IBD)	Tct	20 min, daily 12 wk	3 mo	Sub sensory	5 (42)	Prospective uncontrolled
Babber <i>et al</i> <sup>[44]</sup>	8	Pct	30 min, weekly 12 wk	3 mo	Not specified	7 (87)	Prospective uncontrolled
De La Portilla <i>et al</i> <sup>[41]</sup>	16	Pct	30 min, weekly 12 wk	6 mo	Motor and sensory	10 (62)	Prospective uncontrolled
Vitton <i>et al</i> <sup>[23]</sup>	24	Tct	20 min, daily 12 wk	15 mo	Sub sensory	13 (54)	Prospective uncontrolled
Govaert <i>et al</i> <sup>[42]</sup>	22	Pct	30 min, twice weekly 6 wk	12 mo	Motor and/or sensory	18 (82)	Prospective uncontrolled
<sup>3</sup> Boyle <i>et al</i> <sup>[18]</sup>	31	Pct	30 min, weekly 12 wk	14 mo	Motor or sensory	21 (68)	Prospective uncontrolled
Findlay <i>et al</i> <sup>[45]</sup>	13	Pct	30 min, weekly 12 wk	4 mo	Sub motor	12 (92)	Retrospective uncontrolled
Eléouet <i>et al</i> <sup>[21]</sup>	32	Tct	20 min, twice daily 4 wk	6 mo	Motor	20 (63)	Prospective uncontrolled
<sup>3</sup> Allison <sup>[17]</sup>	90	Pct	30 min, twice weekly or weekly; 6 or 12 wk	21 mo	Motor or sensory	69 (77)	Prospective uncontrolled
<sup>3</sup> Hotouras <i>et al</i> <sup>[16]</sup>	100	Pct	30 min, twice weekly or weekly; 6 or 12 wk	6 mo	Motor or sensory	85 (85)	Prospective uncontrolled
Leroi <i>et al</i> <sup>[24]</sup>	144	Tct	20 min, twice daily 3 mo	3 mo	Sub motor	34 (47)	Randomised controlled trial
George <i>et al</i> <sup>[11]</sup>	11	Pct	30 min, twice weekly 6 wk	6 mo	Motor and sensory	9 (82)	Randomised controlled trial
	11	Tct	30 min, twice weekly 6 wk	6 mo	Motor and sensory	5 (45)	
Thomas <i>et al</i> <sup>[25]</sup>	15	Tct	30 min, daily 6 wk	6 wk	Sensory	3 (20)	Prospective randomised
	15	Tct	30 min, twice weekly 6 wk	6 wk	Sensory	0 (0)	
Moreira <i>et al</i> <sup>[46]</sup>	10	Pct	30 min, weekly 12 wk	3 mo	Not specified	6 (60)	Prospective uncontrolled
<sup>3</sup> Hotouras <i>et al</i> <sup>[30]</sup>	150	Pct	30 min, twice weekly or weekly; 3 mo	26 mo	Motor or sensory	60 (52)	Prospective uncontrolled

<sup>1</sup>Study included spinal injury patients; <sup>2</sup>Study included patients with inflammatory bowel disease (IBD); <sup>3</sup>Studies from the same institution - possibility of duplication of results. PTNS: Posterior tibial nerve stimulation; Pct: Percutaneous posterior tibial nerve stimulation; Tct: Transcutaneous posterior tibial nerve stimulation.

ent patients. In addition, patients with diabetes mellitus or with peripheral neuropathy could have an impaired sensory response or none at all. The published RCT used the presence of both a motor and sensory response as the end point for effective stimulation<sup>[11]</sup>. The presence of a combined motor and sensory response on PTNS has been reported to be better associated with a successful outcome than the presence of either a motor or a sensory response alone<sup>[27]</sup>. However, this could cause patient discomfort as higher voltages required for achieving a motor response may have the potential to cause discomforting sensory stimulations in some patients. The CONFIDENT multicentre randomised controlled trial (ISRCTN 88559475) presently underway in the United Kingdom utilises either a sensory or a motor response as

an endpoint for stimulation.

### Efficacy dilemmas

Percutaneous PTNS for FI remains a relatively new and untested treatment with only 12 studies, one randomised controlled trial<sup>[11]</sup> and one review<sup>[28]</sup> having been published to date on its use. The only published RCT on PTNS only reports on a 6 mo follow-up<sup>[11]</sup>. There remains no doubt regarding the short term efficacy of PTNS which are comparable to that of SNS. However, the true test of the effectiveness of PTNS would be its efficacy in the medium and long term. This is crucial as this could validate its effectiveness as a treatment option for faecal incontinence rather than a stepping stone towards SNS. There is a dearth of information on such results though

early reports from Hotouras *et al*<sup>[15,16]</sup> who has published on the largest group of PTNS patients so far ( $n = 100$ ) reports a possible sustained efficacy for PTNS after 42 mo of follow-up<sup>[29]</sup>. However, this group<sup>[16-18]</sup> provided percutaneous PTNS as the first line therapy for fecally incontinent patients without assessing whether they were refractory to other non-interventional treatments<sup>[19]</sup>. This could perhaps imply that some of their patients would have had improvement in symptoms with other less invasive treatments had this been attempted. The CONFIDENT multicentre randomised controlled trial (ISRCTN 8855947) which is presently underway across 14 centres in the United Kingdom may shed more light on the true short term efficacy of PTNS though only the percutaneous approach is compared to a sham route of stimulation. Though this study recruits patients who have been refractory to other less invasive therapies, the lack of any form of standardisation nationally for such therapies nationally remains notable.

The efficacy of transcutaneous PTNS remains even more untested with only a handful of studies which have looked at this approach to PTNS. Though several studies have reported symptoms improvements in patients a recent multicentre trial reported no improvements following stimulation and concluded that unilateral transcutaneous PTNS was no more effective than sham stimulation<sup>[24]</sup>. Patients were exposed to stimulation for 20 min twice daily for 3 mo<sup>[24]</sup>. However, a new pilot study has looked at bilateral transcutaneous PTNS and found it to be effective compared to unilateral stimulation<sup>[20]</sup>.

## FOLLOW-UP DILEMMAS

There remain no standardised follow-up and top-up regimes that can be used for percutaneous and transcutaneous PTNS. Most studies report efficacy only at the end of the 6 or 12 wk treatment period. The first percutaneous PTNS study reported a relapse of symptoms in 29% of patients with the majority of patients improving with further treatment though the exact regime for such follow up treatment was not reported<sup>[5]</sup>. Almost all studies on PTNS mention the need for “top-up” treatments. However there remains no clarity as to whether such top-up sessions should be offered only when patients report back due to recurrence of symptoms or whether such sessions should be offered at lengthening intermittent intervals after the intense initial treatment period. One study on percutaneous PTNS reported good efficacy with a median of one 12 monthly top-up session<sup>[15]</sup>. Regular percutaneous PTNS top-ups at lengthening intermittent intervals resulted in a sustained therapeutic effect for urological dysfunction<sup>[13]</sup>. New studies on PTNS make inroads into this aspect though this has to be verified through more independent trials<sup>[30]</sup>.

The same dilemmas exist for transcutaneous PTNS as well. The efficacy following transcutaneous PTNS lasts for about 3 wk post treatment<sup>[20]</sup>. Though there is no definite top-up regimes recommended there remains the

advantage that such treatments can be undertaken by the patient in the comfort of their own homes as well as the fact that the costs for such top-ups will be very low<sup>[20]</sup>.

In comparison to SNS where the treatment effects are short-lived following the withdrawal of treatment, PTNS appears to confer a slightly longer lasting effect (albeit with a declining efficacy). However, a recent study on SNS has shown persisting efficacy even after the device was switched off which may bring it to par with the longer effects of PTNS<sup>[31]</sup>.

The heterogeneity of follow-up regimes for PTNS makes it difficult to assess exactly the long-term effects of its treatment. Furthermore, only a few studies have performed rigorous assessment of “top-up” regimes to maintain efficacy. Further work needs to be done on the follow-up of patients who benefit from PTNS to accurately assess the duration of efficacy.

## COST IMPLICATIONS

The present worldwide financial crisis has thrown into stark view the cost implications of neurostimulation. The direct medical costs for PTNS remain nearly ten times cheaper compared than those for SNS<sup>[17,32,33]</sup>. In PTNS itself the costs between percutaneous and transcutaneous PTNS also varies significantly. Percutaneous PTNS requires a re-usable stimulator 9V stimulator (Urgent PC®, Uroplasty Inc., United States) along with 12 disposable single-use leads. The disposable kits with 12 individually packed sterile stimulation units and a disposable battery for the Urgent PC stimulator unit costs £480 and are sufficient for the full treatment of 12 sessions<sup>[26,34]</sup>. The cost for the Urgent PC stimulator unit (Uroplasty, Berkshire, United Kingdom) is £1000. However, the reusable nature of the stimulator unit can reduce the costs of multiple treatments.

The costs for transcutaneous PTNS remain even smaller with the 50 mm × 50 mm self-re-usable adhesive surface electrode stimulation pads (Model VS.5050; Premier Medical Products, Bedford, United Kingdom) costing £1 per pair. The stimulator unit used is the NeuroTrac Continence Neurostimulator (Verity Medical Ltd, United Kingdom) costs \$80 and can be re-used as the percutaneous stimulator<sup>[20]</sup>.

SNS involves the *in-vivo* implantation of highly advanced technological devices and both the temporary and permanent wires were implanted under general anaesthesia. The higher costs for SNS arise due to the two-stage procedure along with associated pre- and post-operative care. The equipment only costs of SNS (2008 tariffs) were \$526 for the temporary implant and \$13500 for the permanent implant<sup>[35]</sup>. However, the actual charges levied for these procedures vary. Reports of costs for the initial temporary procedure for SNS vary from \$1300<sup>[35]</sup> to about \$5300<sup>[33]</sup>. Costs for the permanent implant procedure also varies from \$14500<sup>[35]</sup> to about \$21200<sup>[33]</sup>. Performing the initial stage of SNS under local anaesthesia appears to be more patient friendly and cheaper<sup>[36-38]</sup>.

One of the underlying concerns regarding PTNS remains on the follow up post treatment and the hidden costs for these which may outweigh the initial costs savings. Running an SNS service is expensive<sup>[39]</sup>. However, there remains the possibility that the costs for maintaining the efficacy of PTNS in patients may be higher as they remain yet unknown. Conflicting reports on the cost effectiveness of both procedures are available<sup>[7]</sup>. A two-year follow up of percutaneous PTNS in patients with faecal incontinence from one center reported that PTNS became cost effective after the first year of treatment<sup>[17]</sup>. However, another study which compared SNS to PTNS at 5 years post treatment for urological dysfunction reported that SNS therapy became much more cost efficient compared to PTNS<sup>[40]</sup>. Unlike SNS, running costs and long term follow up expenses for PTNS lacks clarity given the absence of a uniform and universally accepted follow up protocol along with the dearth of independent medium and long term follow up data on “successfully” treated PTNS patients.

### Future for PTNS?

There remains no question that SNS is less patient friendly and more expensive than PTNS in the short term<sup>[33]</sup>. Early attempts to make SNS more patient friendly have experimented at less invasive forms of SNS administration using a transcutaneous Percutaneous PTNS though minimally invasive does not require any operative procedures or a hospital inpatient stay. Patients also do not require a 3 wk trial phase which presently exists for SNS with insertion of a temporary SNS wire and a permanent implant subsequently if successful. Percutaneous PTNS has the potential to be delivered through a primary care setting using perhaps the abilities of specialist nurses who could provide these services on an outpatient basis. This could drive the costs of PTNS down even further.

Transcutaneous PTNS has the unique potential of being a treatment which is truly “by the patient, for the patient”. FI can be socially crippling with patients sometimes being unwilling to leave the safety of their own homes for fear of incontinent episodes<sup>[41]</sup>. Transcutaneous PTNS may hold promise as a treatment which patients can self-administer safely, cheaply and effectively in the comfort of their own homes<sup>[20]</sup>.

Presently PTNS appears to have the role as a stepping stone towards SNS in patients with faecal incontinence. Efficacy of transcutaneous PTNS has been used as a predictor for suggesting efficacy of SNS<sup>[42]</sup>. However, the question remains as to why patients should choose a potentially less patient friendly and clinicians should offer a more expensive and invasive treatment in the form of SNS when PTNS is available—albeit, in its infancy. This seems to have arisen as the strong, coherent, uniform and evidence based data on SNS remains to have been unchallenged yet by the weak, incoherent, disjointed and unsupported evidence for PTNS. A pilot study comparing SNS and percutaneous PTNS (UKCRN ID 10479/MREC ID 10/H 0808/38) may help shed more light on

direct comparison between the two treatments.

The true role for PTNS remains yet to be validated and time tested - as SNS has been. However, the question as to whether SNS and PTNS become “brothers in arms” in treating FI or whether this may yet turn out to be the “David *vs* Goliath” battle will be answered only once PTNS has come into its prime.

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