ORIGINAL CONTRIBUTION

Bilateral Transcutaneous Posterior Tibial Nerve Stimulation for the Treatment of Fecal Incontinence

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BACKGROUND: Unilateral posterior tibial nerve stimulation has been shown to improve fecal incontinence in the short term. Posterior tibial nerve stimulation is believed to work by stimulation of the ascending afferent spinal pathways. Bilateral stimulation may activate more of these pathways. This may lead to an improved therapeutic effect.

OBJECTIVE: The aim of this study was to assess the efficacy of bilateral transcutaneous posterior tibial nerve stimulation for fecal incontinence.

DESIGN: This was a single-group pilot prospective study.

SETTING: The study was conducted from June 2012 to September 2012 at the authors' institution.

PATIENTS: Twenty patients with fecal incontinence were recruited consecutively. Conservative therapy had failed to improve the fecal incontinence in all 20 patients.

INTERVENTION: All patients received 30 minutes of daily bilateral stimulation for 6 weeks. The bilateral stimulation was administered by each patient at home. No further stimulation was given after 6 weeks, and the patients were followed up until their symptoms returned to the prestimulation state (baseline).

MAIN OUTCOME MEASURE: The primary outcome measure was a change in the frequency of incontinent episodes per week.

RESULTS: Seventeen patients completed 6 weeks of treatment. Two patients achieved complete continence. Ten (59%) achieved a ≥50% reduction in frequency of incontinent episodes. Overall, there was a significant reduction in median (interquartile range) frequency of incontinent episodes per week of 6 (8.25) to 2 (7.25) ($p = 0.03$). There was a significant improvement in the ability to defer defecation from 3 (4) to 5 (8) minutes ($p = 0.03$). There was no change in the St Mark's incontinence score. One domain of the Rockwood fecal incontinence quality-of-life score and of the Medical Outcomes Study Short Form 36 score improved significantly.

LIMITATIONS: This study was limited by its small size and its lack of blinding and control.

CONCLUSIONS: Bilateral transcutaneous posterior tibial nerve stimulation appears to be a cheap and effective treatment for fecal incontinence. It can easily be used by the patient at home.

KEY WORDS: Posterior tibial nerve stimulation; Fecal incontinence; Neuromodulation; Sacral nerve stimulation.

Fecal incontinence (FI) is a common problem[1]; most patients are treated with pads, anal plugs, antidiarrheal agents, and behavioral training. When these fail, further invasive treatments are necessary, such as neuromodulation, bulking agents, sphincteroplasty, neosphincters, and colostomy.

The most established first-line treatment used currently is sacral nerve stimulation (SNS).[2–4]

Unilateral posterior tibial nerve stimulation (PTNS) for FI was first described in 2003.[5] Since then, 11 noncomparative studies and 2 randomized controlled trials have been published.[6] Posterior tibial nerve stimulation has less risk of infection and lower initial direct medical costs than

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SNS. It can be applied by percutaneous or transcutaneous stimulation. Sacral nerve stimulation is delivered by using a single-use needle electrode and requires administration by a medical professional. Posterior tibial nerve stimulation is administered by using a reusable adhesive electrode pad and can be performed by the patient at home.

Neuromodulation is believed to work via stimulation of multiple afferent sensory pathways in the spinal cord. This has an effect on the pelvic viscera, lower gut, and sensory cortex.[7] Bilateral neuromodulation may activate a greater number of afferent sensory pathways; this could lead to an improved therapeutic effect. In a proportion of the patients, the pelvis is innervated asymmetrically[8] and unilateral stimulation may therefore not achieve optimal treatment outcome depending on the site used for stimulation. Bilateral stimulation has been shown to be superior to unilateral SNS in some, but not all, patients with FI[9] and bladder dysfunction.[10] There are no reports of bilateral PTNS in the published literature.

We aimed to assess bilateral transcutaneous PTNS for treating FI in a prospective pragmatic pilot study.

METHODS

Ethical approval was granted by the local ethics committee (NRES Committee London- Dulwich, reference number 12/LO/0589). Patients were recruited according to the inclusion and exclusion criteria shown in Table 1. Informed consent was obtained. A 2-week FI bowel diary was kept, which recorded the frequency of episodes of FI, the frequency of defecation, and the deferral time to defecation. A visual analog scale rated on the patient response to "how happy are you with the way your bowels have been functioning" was recorded. Patients placed a mark on a visual analog scale of 0 to 100; zero indicated that they were very unhappy and 100 indicated that they were very happy. The Rockwood FI quality-of-life score,[11] the St Mark's continence score,[12] and the Medical Outcomes Study Short Form 36 score were also recorded.[13] The BMI was calculated. The ankle circumference was also estimated; this was measured immediately above the malleoli.

After receiving initial in-hospital teaching, all patients were taught to administer PTNS at home. Written instructions on the use of PTNS and a photograph demonstrating the electrode pad and lead position were also given. PTNS was performed on both ankles simultaneously for 30 minutes daily, for a 6-week period. PTNS was given by using a NeuroTrac Continence device (Verity Medical Ltd, United Kingdom) via two 50 mm × 50 mm electrode pads. The live pad was placed posterior and superior to the medial malleolus, and the ground pad was placed approximately 10 cm cephalad to this (Fig. 1). Continuous stimulation at a pulse width of 200 μs and a frequency of 10 Hz was used. The amplitude was set to produce a sensory stimulus in the ipsilateral foot at an intensity tolerable to the patient.

Each patient kept a 2-week bowel habit diary during the fifth and sixth week of therapy. The remaining questionnaires were completed at the end of the 6-week treatment. The PTNS devices were then returned, and patients were followed up by telephone consultation at 1 month after treatment had ceased. They exited the study when the frequency of incontinent episodes had returned to baseline. A study flow diagram is shown in Figure 2.

The primary outcome measure was the change in frequency of FI episodes per week. Secondary outcome measures were included the ability to defer defecation, measured in minutes, frequency of defecation, changes in the St Mark's continence score and quality-of-life

TABLE 1. Inclusion and exclusion criteria

Inclusion criteria	*Exclusion criteria*
Age 18–80 y	Spinal pathology, recent surgery
Fecal incontinence defined as at least 2 episodes per week of involuntary loss of either liquid or solid stool as defined by a baseline bowel diary	Peripheral vascular disease
Completed biofeedback and conservative therapy	Peripheral neuropathy
No previous neuromodulation	Previous anorectal surgery within the past year
	External rectal prolapse
	Active IBD
	Pregnancy
	Inability to apply the device independently

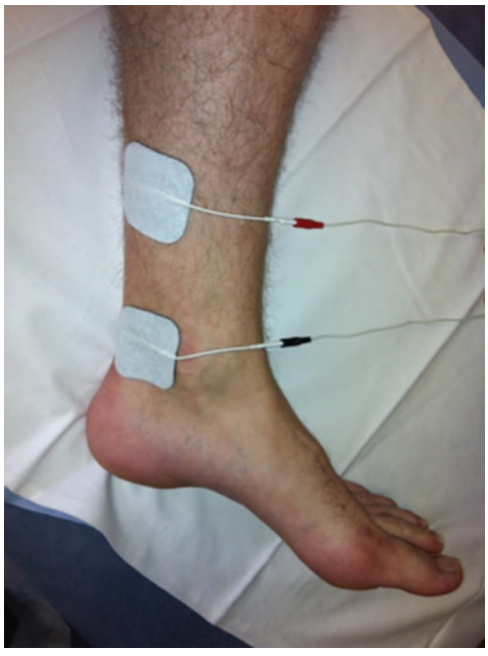

FIGURE 1. Photograph to show position of electrode pads.

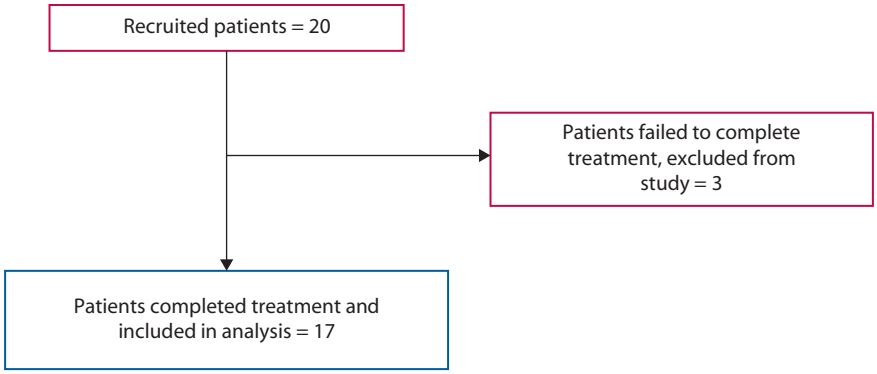

FIGURE 2. Study flow chart. Twenty patients were recruited. Seventeen patients completed treatment and included in analysis. Three patients who did not complete treatment were excluded from the study.

assessment. Patients were advised to abstain from the use of antidiarrheal agents during this study. All medication use was recorded.

Statistical Considerations

This was a nonrandomized pilot study and therefore a sample size calculation was not performed. Because the data were nonparametric, variance was expressed by the median and the interquartile range. The Wilcoxon rank test was used for comparison of paired data. Statistical analysis was performed by using SPSS computer software (IBM, version 20).

RESULTS

Twenty patients were recruited into this study. Three patients were excluded from the analysis. Two did not complete 6 weeks of treatment and did not return at 6 weeks. It was not clear why this occurred. One patient unwittingly entered the study in early pregnancy. She had a miscarriage during PTNS therapy. The ethics committee and study's sponsors were notified of this adverse event.

Seventeen patients were included in the analysis. Baseline data are shown in Table 2. There was a significant reduction in the frequency of FI episodes from a median (interquartile range) of 6 (8.25) per week at baseline to 2 (7.25) per week at 6 weeks ($p = 0.03$). At 6 weeks, only 2 patients had achieved complete continence. Ten patients (59%) achieved a reduction of incontinent episodes per week of 50% or more. The remaining 5 patients (29%) had less than 50% reduction of incontinent episodes. The median percentage reduction in frequency of incontinent episodes was 66% for the whole group.

The ability to defer defecation was significantly improved from a median (SD) of 3 (4) minutes to 5 (8) minutes ($p = 0.03$). The bowel satisfaction score improved significantly from a median of 10 (25) to 20 (52.5) (maximum score, 100; $p = 0.02$). There was no significant change in the St Mark's continence score (Table 3). Those patients who had experienced a reduction in the frequency of incontinent episodes returned to the baseline value at a median of 3 (1) weeks. Body mass index and ankle circumference had no significantly significant effect on the change in incontinent episodes.

A significant improvement was seen in the lifestyle domain of the Rockwood FI quality-of-life score. There was also a significant improvement in the general health domain of the Medical Outcomes Study Short Form 36 quality-of-life assessment (Tables 4 and 5).

DISCUSSION

Treatment of FI in patients in whom conservative therapy has failed is difficult. Existing surgical treatments tend to be invasive and expensive, and they often have mixed results. Transcutaneous PTNS has the advantage that it can be performed at home, by patients, after simple training. The therapy does not require expensive or invasive equipment. Although there is some inconvenience to the patient

TABLE 2. Baseline characteristics of the patients

Total number of patients	17
Age, y	61 (24.5)[a]
Sex	15 female
Duration of symptoms, y	7 (6)[a]
Type of FI	
Mixed	9
Urge	4
Passive	4
Vaginal deliveries	2 (1)[a]
Ankle circumference, cm	23 (2.5)[a]
BMI, kg/m^2	27 (5)[a]
Anal sphincter defect	5
External anal sphincter defect	2
Internal anal sphincter defect	2
Combined sphincter defect	1
Previous anorectal surgery	
Anterior sphincteroplasties	3
Delorme procedure	1

FI = fecal incontinence.
[a]Median values used; interquartile range is given in parentheses.

TABLE 3. Bowel diary data, St Mark's FI score, and visual analog score results

	Baseline	*Six weeks*	*p*
FI episodes per week	6 (8.25)	2 (7.25)	0.029
Defecations per week	12 (7.75)	14 (8.25)	0.30
Deferral time, min	3 (4)	5 (8)	0.027
St Mark's score	20 (5)	19 (4.5)	0.23
Visual analog bowel satisfaction scale	10 (25	20 (52.5)	0.018

Variance expressed as a median, interquartile range in parentheses.
FI = fecal incontinence.

who will have to find the time to perform the procedure, the direct and indirect costs are likely to be considerably lower than existing treatments that require surgery or numerous visits to and from a hospital. The stimulator used for transcutaneous PTNS costs approximately $80, and 4 reusable electrode pads cost $5. These would suffice for 6 weeks of daily treatment.

To the best of our knowledge this is the first study that has reported the outcome of bilateral transcutaneous PTNS for FI. This achieved a significant short-term improvement in the frequency of incontinent episodes and, importantly, in the ability to defer defecation. This study was limited by small numbers and the lack of a control.

In the largest published series to date, Hotouras et al[14] reported the outcomes of 60 patients with mixed FI who had undergone unilateral percutaneous PTNS. They described statistically significant improvements in the mean (range) frequency of incontinent episodes per week from 5 (0–35) to 1 (0–27), and in the ability to defer defecation from 1 (0–15) to 5 (0–25) minutes. When the outcomes of SNS are assessed on an intention-to-treat basis, approximately 70% can be expected to experience a 50% or greater reduction in the frequency of incontinent episodes.[15] With the use of an arbitrary 50% percentage reduction in symptoms as an end point, the results achieved by bilateral transcutaneous PTNS in this study are therefore comparable to those achieved by both percutaneous PTNS and by SNS. However it must be appreciated that, in this study and in those previously published on percutaneous PTNS, fewer patients appear to gain full continence with PTNS in comparison with SNS, and in many a 50% reduction in symptoms may not be sufficient enough to improve quality of life. The reduction of incontinent episodes with SNS appears to be more pronounced than PTNS in those who respond to treatment (ie, proceed to permanent implantation).[16,17]

TABLE 4. Rockwood fecal incontinence quality-of-life score[11]

Domain	*Baseline*	*End of treatment*	*p*
Lifestyle	2.1 (0.6)	2.5 (1.6)	0.01
Coping/behavior	1.3 (0.55)	1.5 (0.55)	0.07
Depression/self-perception	21. (1.25)	2.4 (0.8)	0.47
Embarrassment	1.3 (1)	1.7 (0.7)	0.19

Variance expressed as a median, interquartile range in parentheses.

TABLE 5. SF-36 quality-of-life scores

Domain	*Baseline*	*End of treatment*	*p*
Physical functioning	46.7 (18.8)	46.7 (12.5)	0.59
Role physical	35 (28.2)	35 (28.2)	0.76
Bodily pain	41.8 (22.5)	51.6 (25.2)	0.17
General health	41.5 (15.7)	46.2 (14.9)	0.04
Vitality	44.3 (17.8)	44.3 (14.2)	0.52
Social functioning	40.9 (32.5)	51.7 (27.1)	0.78
Role emotional	23.7 (31.6)	44.8 (31.36)	0.44
Mental health	43.6 (23.9)	45.9 (20.5)	0.61
Total physical score	40.7 (16.3)	47.6 (13.3)	0.15
Total mental score	43.2 (30.4)	44.9 (21.3)	0.88

Variance expressed as a median, interquartile range in parentheses.
SF-36 = Medical Outcomes Study Short Form 36.

Unilateral transcutaneous PTNS appears to be less efficacious than percutaneous PTNS as demonstrated in a recent randomized controlled study by George et al.[18] This conclusion is supported by a recent double-blinded randomized controlled trial by Leroi et al.[19] They compared unilateral transcutaneous PTNS with a sham and concluded that unilateral transcutaneous PTNS was no more effective than the sham. It is possible that transcutaneous PTNS can only be significantly effective when used in a bilateral fashion, although a significant placebo response may exist.

Disappointingly, there was no significant improvement in the St Mark's continence score, and patient satisfaction scores remained low despite a reduction in the number of incontinent episodes. Because only 2 patients achieved full continence, low satisfaction scores may reflect patients being dissatisfied with any level of incontinence, even if the frequency of episodes has been reduced. In addition, learned behavior such as pad use, lifestyle changes, and use of antidiarrheal agents may continue. Such behavioral factors may take a long time to change if they have become established. Thus, the St Mark's continence score and other measures of incontinence severity may be unsuitable to detect short-term changes in severity.

Once treatment had finished, the therapeutic effect lasted for a median of 3 weeks. It is difficult to measure this accurately. Assessment was performed by telephone consultation and relied on the patients' recollection of their recent symptoms. Objective assessment by using bowel diaries would only work if performed continuously; this would not be practical. Three weeks is similar to the duration of efficacy reported by others. Govaert et al[20] and Hotouras et al[14] described a less intensive treatment regimen, a so-called "top-up" treatment. Consideration needs to be given to how such a regimen could be applied to bilateral transcutaneous PTNS.

One patient had a miscarriage during PTNS. There are no reports of the use of PTNS during pregnancy in the published literature. A few case reports have described SNS during pregnancy.[21–24] All pregnancies were uneventful, with the exception of one that resulted in an infant with a chronic motor tic syndrome and a pilonidal sinus, and another that resulted in a premature delivery. Although it is unlikely that PTNS was responsible for the miscarriage, the authors suggest that PTNS should not be used by those who are pregnant. It may be advisable that all those of a child-bearing age should be undergo a pregnancy test before PTNS.

CONCLUSIONS

Bilateral transcutaneous PTNS appears to be an effective treatment for some patients with urge and/or passive FI. Further studies are required to compare the clinical outcome and cost-effectiveness of bilateral transcutaneous PTNS with existing, more invasive treatments.

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