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The short-term effects of posterior tibial nerve stimulation on anorectal physiology in patients with faecal incontinence: a single centre experience

Nick A. Heywood, James S. Pearson, James E. Nicholson, Clare Molyneux, Abhiram Sharma, Edward S. Kiff, Peter J. Whorwell and Karen J. Telford

Abstract

Background: Posterior tibial nerve stimulation (PTNS) is a novel treatment for patients with faecal incontinence (FI) and may be effective in selected patients; however, its mechanism of action is unknown. We sought to determine the effects of PTNS on anorectal physiological parameters.

Methods: Fifty patients with FI underwent 30 min of PTNS treatment, weekly for 12 weeks. High-resolution anorectal manometry, bowel diaries and Vaizey questionnaires were performed before and after treatment. Successful treatment was determined as a greater than 50% reduction in FI episodes.

Results: Fifty patients with FI were studied; 39 women, median age 62 years (range 30–82). Compared with pretreatment, there were reductions in episodes of urgency (16.0 *versus* 11.4, $p = 0.006$), overall FI (14.5 *versus* 9.1, $p = 0.001$), urge FI (5.4 *versus* 3.2, $p = 0.016$) and passive FI (9.1 *versus* 5.9, $p = 0.008$). Vaizey score was reduced (16.1 *versus* 14.5, $p = 0.002$). Rectal sensory volumes (ml) decreased (onset 40.3 *versus* 32.6, $p = 0.014$, call 75.7 *versus* 57.5, $p < 0.001$, urge 104.1 *versus* 87.4, $p = 0.004$). There was no significant change in anal canal pressures (mmHg) (maximum resting pressure 41.4 *versus* 44.2, $p = 0.39$, maximum squeeze pressure, 78.7 *versus* 88.2, $p = 0.15$, incremental squeeze pressure 37.2 *versus* 44.1, $p = 0.22$). Reduction in FI episodes did not correlate with changes in physiological parameters ($p > 0.05$). Treatment success of 44% was independent of changes in manometric parameters ($p > 0.05$).

Conclusions: PTNS has a measureable physiological effect on rectal sensory volumes without an effect on anal canal pressures. It also reduces FI episodes; however, this effect is independent of changing physiology, suggesting that PTNS has a complex mechanism of action.

Keywords: Faecal, faecal incontinence, incontinence, neuromodulation, PTNS, stimulation

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Correspondence to:
Nick A. Heywood
Department of General Surgery, University Hospital of South Manchester, 2nd Floor Acute Block, Southmoor Road, Wythenshawe, M23 9LT, UK
nick.heywood@nhs.net

James S. Pearson
University Hospital of South Manchester, Manchester, UK

James E. Nicholson
Lancashire Teaching Hospitals NHS Foundation Trust, Preston, UK

Clare Molyneux
Abhiram Sharma
Edward S. Kiff
University Hospital of South Manchester, Manchester, UK

Peter J. Whorwell
University Hospital of South Manchester & Manchester University, Manchester, UK

Karen J. Telford
University Hospital of South Manchester, Manchester, UK

Introduction

Faecal incontinence (FI) is a common problem with a prevalence of between 0.4% and 18% of the adult population,[1,2] depending on how incontinence is defined in studies. It carries with it significant physical and psychological comorbidity.[3] Bowel diaries and scoring systems are commonly used to determine the severity of faecal incontinence and the response to treatment[4,5] and high-resolution anal manometry (HRAM) has become the preferred investigation of choice for patients with FI. However, there is considerable overlap of manometric measurements when comparing continent and incontinent individuals and anorectal manometry is an unreliable predictor of outcomes after intervention.[6–8]

Posterior tibial nerve stimulation (PTNS) is a form of neuromodulation used in the treatment of urinary incontinence and FI, safely performed in an outpatient setting.[9] A number of studies report symptom improvement of FI after PTNS,[10–12] however most published studies are uncontrolled and many use wide varieties of scoring systems and outcome reporting to define success.

Neither the exact mechanism of action of PTNS nor its effect on physiology is fully understood. PTNS is proposed to act by direct modification of the peripheral nerve roots which share the same spinal roots as the neuronal innervation to the pelvic floor (L4–S3), or by central stimulation of cortical pontine activity.[13–15] Few studies in the published literature report these effects specifically. Aside from the randomized controlled trial by Knowles and colleagues comparing treatment success of PTNS with sham electrical stimulation,[16] only one recent study has measured HRAM before and after PTNS treatment, which included relatively small numbers. It found a significant correlation between increased maximum squeeze pressures and reduced Wexner score,[17] but the effect on other physiological parameters was unclear.[13] Consequently, we sought to determine the effects of PTNS on physiological parameters in a larger cohort of patients.

Materials and methods

Patients referred to our institution with faecal incontinence were seen by a coloproctologist who obtained a full history and performed clinical examination. Specialist assessment included anorectal physiology. Patients who had failed conservative management, including lifestyle modification, pharmacological or biofeedback treatment, were considered for PTNS. All patients were discussed at a specialist pelvic floor multidisciplinary team meeting and suitable patients were counselled by a pelvic floor physiotherapist and informed written consent was obtained. Pretreatment HRAM was performed and patients were asked to complete bowel diaries and the Vaizey incontinence score for 2 weeks prior to treatment. Bowel diaries were completed for total number of bowel motions, urgency episodes, total incontinence episodes, urge incontinence episodes and passive incontinence episodes. Patients underwent a 30 min PTNS treatment once weekly for 12 weeks using the Urgent PC Neuromodulation system (Uroplasty Ltd, Manchester, UK). On completion, post-treatment HRAM was performed, Vaizey score was repeated and bowel diaries completed for the subsequent 2 weeks.

Successful treatment was defined as a greater than 50% reduction in total incontinence episodes.[16] Using this definition, we aimed to compare the changes in physiological parameters, as measured by anorectal manometry, between patients who had treatment success and those who did not.

Posterior tibial nerve stimulation

Patients were positioned in a sitting position with their right foot resting on a stool. The needle electrode was percutaneously sited 5 cm cephalad to the medial malleolus and 2 cm posterior to the tibia with the tip of the needle approximately 2 cm deep to the skin. A surface electrode was placed near the medial aspect of the calcaneus of the ipsilateral limb and both were connected to the stimulator. Correct placement of the needle was identified by running the test programme and eliciting a motor (toe flex, dorsiflexion) or sensory (tingling sensation travelling to the heel, arch or toes) response through incrementally increasing the amplitude of the stimulus. In the case of non-response, the needle was repositioned and placement rechecked until a response was obtained. Once a tolerable response was confirmed, stimulation was delivered for 30 min.

High-resolution anal manometry

Equipment. HRAM was performed using a standard water perfused catheter with a nonlatex balloon attached to the end. It incorporates 10 circumferential sensors at 0.8 cm intervals and has an external diameter of 14 Fr (customized single-use anorectal 10ch catheter, S7-R10-1003; Mui Scientific, Mississauga, Canada; balloon #BS6, volume = 400 ml max; Mui Scientific). Prior to the investigation, sensors were zeroed to atmospheric pressure at the level of the anal verge. Data acquisition, visualization and signal processing were performed using a commercially available manometry system (Solar GI v9.3; Medical Measurements Systems, Enschede, The Netherlands).

Protocol. HRAM was performed in the left-lateral position following informed written consent. Prior to catheter insertion, a digital rectal examination was performed with subjects asked to ‘squeeze’ and ‘push’ in order to confirm their understanding of these instructions.

Table 1. Comparison of bowel diaries in the 2 weeks before and after treatment with posterior tibial nerve stimulation performed using the paired *t* test, significance at the 0.05 level.

Parameter	Mean number pretreatment (SD)	Mean number post treatment (SD)	Mean percentage reduction	*p* value
Total bowel movements in 2 weeks ($n = 50$)	42.2 (22.0)	39.3 (21.7)	6.9	0.278
Urge episodes ($n = 41$)	16.0 (16.7)	11.4 (11.5)	28.8	0.006
Urge FI episodes ($n = 50$)	5.4 (7.5)	3.2 (5.3)	40.7	0.016
Passive FI episodes ($n = 50$)	9.1 (10.6)	5.9 (8.5)	35.2	0.008
Total FI episodes ($n = 50$)	14.5 (14.6)	9.1 (11.4)	37.2	0.001

FI, faecal incontinence; SD, standard deviation.

The procedure was performed using a modified London HRAM protocol as described by Carrington *et al.*[18] Briefly, the catheter was inserted into the anorectum with the most distal two pressure transducers being located outside the anal verge. Following a 3 min run-in familiarization phase, subjects underwent a 1 min rest phase and two 5 s 'squeeze' phases with a 30 s recovery phase between them. Rectal sensory volumes were examined by balloon insufflation and subjects were asked to indicate their first sensation (onset), desire to defecate (call), and maximum tolerated volume (urge) in ml. Mean resting pressure (MRP), maximum squeeze pressure (MSP) and incremental squeeze pressure (ISP) were recorded in mmHg.

Statistical analysis

Demographic and clinical data were collected and prospectively maintained on an electronic database for clinical audit purposes and analysed using SPSS Statistics version 22 (IBM, Chicago, IL, USA), with statistical support from a medical statistician. HRAM parameters, bowel diaries and Vaizey scores were compared using the paired *t* test. Comparisons between groups were performed using the independent samples *t* test and relationships between variables were tested using Pearson correlations. Significance was assumed at the *p* less than 0.05% level. As an evaluation of a new service, no sample size calculation was performed.

Ethical permissions

Our study was designed and conducted to audit a new service against the UK National Institute of Health and Care Excellence guidance and, after appraisal against the Health Research Authority decision tool, was not subject to ethical review.

Results

Demographics

A total of 50 patients completed the course of PTNS; 39 women and 11 men. The median age was 62 years (range 30–82). Twenty-two (44%) patients had urge, 22 (44%) had mixed and 6 (12%) had passive faecal incontinence. All 50 underwent HRAM before and after treatment and all returned completed bowel diaries. The parameter of 'urgency episodes' was added to the questionnaire after the first nine patients had undergone treatment, however it was still included for analysis. One patient's post-treatment Vaizey score was unavailable for analysis.

Bowel diaries

Compared with pre-treatment there was no significant difference in the mean total number of bowel movements after PTNS. There was a significant reduction in the number of urgency episodes (16.0 *versus* 11.4, $p = 0.006$), total FI episodes (14.5 *versus* 9.1, $p = 0.001$), urge FI episodes (5.4 *versus* 3.2, $p = 0.016$) and passive FI episodes (9.1 *versus* 5.9, $p = 0.008$) as shown in Table 1.

Overall, 33 patients had reduction in total FI episodes, 12 patients had an increase and in 5 there was no change. Using the definition of 'greater than 50% reduction in incontinence episodes', PTNS was successful in 44% (22/50) of patients.

Table 2. Pearson correlation between the change in Vaizey score with frequency of defecatory and FI episodes. Significance is at the 0.05 level.

Parameter	Change in total frequency	Change in total FI episodes	Change in urge episodes (n = 41)	Change in urge FI episodes	Change in passive FI episodes
Change in Vaizey score (n = 49)	0.378	0.295	0.189	0.27	0.309
p value	0.007	0.064	0.193	0.06	0.031

FI, faecal incontinence.

Table 3. Comparison of HRAM parameters before and after treatment with PTNS performed using the paired t test, significance at the 0.05 level.

Anorectal physiology parameter	Pretreatment mean (SD)	Post-treatment mean (SD)	Percentage change (%)	p value
Onset (ml) Normal range (20–40 ml) (n = 50)	40.3 (18.8)	32.6 (12.3)	−19.1	0.014
Call (ml) Normal range (40–75 ml) (n = 50)	75.7 (26.6)	57.5 (20.5)	−24.0	<0.001
Urge (ml) Normal range (60–120 ml) (n = 50)	104.1 (39.6)	87.4 (35.4)	−16.0	0.004
MRP (mmHg) Normal range (33–114 mmHg) (n = 50)	41.4 (20.3)	44.2 (21.5)	6.8%	0.368
MSP (mmHg) (n = 50)	78.7 (49.0)	88.2 (47.7)	12.1%	0.146
ISP (mmHg) Normal range (29–366 mmHg) (n = 50)	37.3 (45.1)	44.1 (37.8)	18.2%	0.217
Vaizey score (n = 49)	16.1 (4.6)	14.5 (5.2)	−9.9%	0.002

HRAM, high-resolution anal manometry; ISP, incremental squeeze pressure; MRP, mean resting pressure; MSP, maximum squeeze pressure; PTNS, posterior tibial nerve stimulation; SD, standard deviation.

When comparing patient groups of success *versus* failure using this definition, there was no difference in age (58.2 *versus* 59.8, p = 0.68), baseline Vaizey score (16.07 *versus* 16.18, p = 0.93) or number of incontinence episodes listed in Table 1 ($p > 0.05$).

A comparison of pre-PTNS and post-PTNS Vaizey scores and bowel diaries was performed. There was no correlation between the change in Vaizey score and change in total FI episodes, urgency episodes or urge FI episodes. However, a significant positive correlation was found between the change in Vaizey score and the change in total number of bowel movements (0.378, p = 0.007) and the change in passive FI episodes (0.309, p = 0.031) (Table 2).

High-resolution anal manometry parameters

Compared with pretreatment, there was a significant reduction in all rectal sensory volumes measured; onset of first sensation (19.1%), call to stool (24%) and urgency to defecate (16%). There was

Table 4. Comparison between those who had a reduction in total FI episodes by greater than 50% and those who did not. The mean difference is calculated by subtracting the post-PTNS variable from the pre-PTNS variable. Independent sample *t* test with significance at the 0.05 level.

Change in parameter	Total FI improved by >50%	*N*	Mean change (pre–post)	SD	*p* value
Onset (ml)	No	28	10.3	20.3	0.337
	Yes	22	4.4	22.4	
Call (ml)	No	28	21.5	22.8	0.324
	Yes	22	14.0	30.4	
Urge (ml)	No	28	20.9	42.7	0.392
	Yes	22	11.3	33.9	
MRP (mmHg)	No	28	–5.0	24.6	0.394
	Yes	22	0.2	16.0	
MSP (mmHg)	No	28	–10.6	52.9	0.839
	Yes	22	–8.0	34.8	
ISP (mmHg)	No	28	–5.6	41.3	0.817
	Yes	22	–8.2	34.6	
Vaizey score	No	27	0.5	2.9	0.009
	Yes	22	3.0	3.6	

FI, faecal incontinence; ISP, incremental squeeze pressure; MRP, mean resting pressure; MSP, maximum squeeze pressure; PTNS, posterior tibial nerve stimulation; SD, standard deviation.

also an increase in MRP (6.8%), MSP (12.1%) and ISP (18.2%), however these changes were not statistically significant (Table 3).

Table 4 explores the differences between patients with or without a successful outcome; that is, those with a reduction in total FI episodes of 50% or more and those without. When the changes in HRAM parameters were compared between these two groups, no significant difference was found. The decrease in Vaizey score, however, is significantly greater in those with a successful outcome ($p = 0.009$).

The relationship between HRAM parameters and bowel diaries and Vaizey score

There was a significant negative correlation between the change in MRP with the mean call to stool (–0.298, $p = 0.035$) and urgency to defecate (–0.336, $p = 0.017$). No other correlation between HRAM parameters was identified. There was no correlation between the change in Vaizey and the change in HRAM parameters (Table 5).

A correlation analysis was performed to explore the relationship between the change in HRAM parameters and the change in the frequency of FI episodes recorded in the bowel diaries. We found no significant correlation between the reduction FI episodes and the decrease in rectal sensory volume. There was also no correlation with anal sphincter pressure ($p > 0.05$ for all parameters).

Discussion and conclusion

This study shows that PTNS has a demonstrable effect on rectal sensation with reduction in volume for onset, call to stool and urgency. Furthermore, it also appears to offer significant benefit in some patients with FI with reduction in urgency and number of FI episodes.

Table 5. Pearson correlation between the changes in Vaizey score with HRAM parameters. Significance is at the 0.05 level.

Parameter	Change in onset	Change in call	Change in urge	Change in MRP	Change in MSP	Change in ISP
Change in Vaizey score (n = 49)	0.101	−0.01	−0.226	0.231	0.059	−0.57
p value	0.492	0.946	0.119	0.111	0.685	0.699

HRAM, high-resolution anal manometry; ISP, incremental squeeze pressure; MRP, mean resting pressure; MSP, maximum squeeze pressure.

A reduction in rectal sensory volumes of up to 24% was reported across all patients compared with pretreatment. There was a strong clinical impression that these patients reported earlier notice of an awareness to defecate post treatment. Higher volumes are considered to represent rectal hyposensitivity (RH) and are associated with both constipation and FI. Burgell and Scott suggest that RH may lead to constipation through faecal retention and rectal evacuatory dysfunction, and incontinence through association with functional constipation and impairment of reflexive or conscious contraction of the anal sphincters.[19] Diamant and colleagues' review of anorectal testing techniques discusses the perception of rectal distension as a requirement for continence, and that improved ability to detect rectal distension is needed for biofeedback treatment for FI.[20] Our physiological findings would support the fact that a reduction in rectal sensory volumes may result in patients having earlier sensation of the presence of stool prior to reaching a threshold at which defaecation can no longer be delayed. Consequently, this increased awareness of stool in the rectum would make all the difference for patients reaching the bathroom in sufficient time to avoid an episode of FI. This subtle but significant delay in the need to defecate might make all the difference to the way a patient manages their FI and is not adequately captured in current FI severity instruments.

When adjusted for success (>50% reduction in FI episodes) we found no significant difference in the reduction in volumes between those who had treatment success, and those who did not; only Vaizey score was significantly different. The change in Vaizey score correlated with change in passive FI, however the significance of the correlation of Vaizey score with total bowel movements is not known. The changes in anorectal physiology did not correlate with reduction in FI episodes or Vaizey score, suggesting a physiological effect on patients independent of outcome. This objective change may suggest that the PTNS mechanism of action is through modification of sensory pathways, which is partly supported by our finding of a change in sensory thresholds, and may suggest a more complex action with other effects that we are currently unable to measure with HRAM or rectal sensory volumes alone.

In a recent double-blind, multicentre, pragmatic, parallel-group, randomized controlled trial, Knowles and colleagues[16] found that PTNS conveyed no significant clinical benefit over sham electrical stimulation. They found it may confer benefit in certain patient subgroups, where they found a reduction in urge FI episodes. However, it was undertaken on an unselected group of patients with FI and the authors concluded that further studies would be required to determine any potential predictors of response to treatment. In our study, we found PTNS to be successful in 44% of patients, which is somewhat higher than the 38% reported by Knowles and colleagues using the same measure of success. Although our study was uncontrolled, it is interesting to note that the response rate in the control group in the Knowles study was 31%, suggesting that our success rate of 44% may be more than just a placebo effect. Indeed, a *post hoc* analysis of the CONFIDeNT study has shown a significant clinical effect of PTNS compared with sham when excluding patients with obstructive defaecation.[21] The response rate of 48.9% is more comparable to the findings in our study and initial differences in success are likely to be explained by improved patient selection. Our view is also supported by the fact that from the bowel diary assessment, we found a significant reduction in mean urgency, total FI and both mean passive and mean urge FI episodes without a reduction in the total number of defecatory episodes, suggesting that Pq\ytyty-hTNS is an effective treatment for FI.

There are few studies evaluating the direct physiological effects of PTNS, and although it is thought to reflexly neuromodulate the rectum and anal sphincters,[22] its exact mechanism of action is not fully understood.[13,17] Most studies utilize pretreatment anorectal physiology in the absence of a post-treatment comparison, correlating clinical outcomes with the pretreatment findings without examining the physiological effects of PTNS. In one such study of 88 patients with FI, Hotouras and colleagues[23] evaluated the impact of sphincter morphology and rectal sensation on clinical outcome. They found improvements in patients with normal sensation, that clinical outcomes were independent of damage to the anal sphincter complex and they had statistically significant improvement in clinical parameters. In patients with abnormal rectal sensations, they found improvements only in the ability to defer defaecation. However, this used pretreatment definitions of median maximum tolerable volumes to classify hypo-, normo- and hypersensate rectal sensations without post-treatment measurements.

To our knowledge, our study is the largest study in the literature evaluating anal manometry before and after PTNS treatment. A similar study by Lopez-Delgado and colleagues[17] described results in less than half the number of patients studied in our present study. They showed that, in 24 patients with FI, MRP and MSP were increased after treatment. These changes in pressure for all patients were not statistically significant. Although on further analysis, they found a significant increase in manometry pressures in those patients who showed improvement after PTNS, their definitions of successful outcomes were unclear. At 6 months (and after six top-up treatments), they found manometric improvement was more evident and there was a significant negative correlation seen between MRP/MSP and Wexner incontinence score. The outcomes of this self-selected group may suggest a role for top-up treatments, however due to the shorter follow-up period in our study, we cannot corroborate these findings. As with our study, there is also a considerable lack of long-term data on the effects of PTNS. Further follow-up would clarify the role of PTNS in the longer term. Several studies have shown it to have similar efficacy to SNS in the short term (6–12 months). PTNS, however, is much less invasive and can be performed in the outpatient setting, and in the short term, is a less expensive alternative.[24–26]

Repeated attendances to clinic for PTNS may have a potential placebo effect and we are not able to report the degree of change that may have occurred over this period without intervention. Previous work also suggests that FI symptom severity scores may vary considerably over time in untreated patients.[27] In a study of 45 patients undergoing biofeedback therapy for FI, Boselli and colleagues[28] found reduced rectal sensitivity thresholds after treatment without statistically significant change in manometry variables or correlation with clinical outcome. Considering this, it is difficult to conclude at this time that PTNS alone is responsible for our findings, and it remains possible that there is a placebo effect.

PTNS appears to have a measureable physiological action on rectal sensory volume without effect on anal canal pressures. This change in sensory threshold might confer a benefit, which is not identified by current instruments, such as a delay between sensation and the need to defecate. Additional studies will need to combine manometric and anatomical parameters with more detailed baseline profiles such as the presence or absence of irritable bowel syndrome. Furthermore, there is a need for better selection of patients and use of patient-reported outcomes that identify factors that affect how patients manage FI and its effects on quality of life. Further analysis of increasing numbers of patients undergoing PTNS may be able to identify subgroups who may benefit.

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and analysed during the current study are not publicly available due to patients being under the care of the NHS, but are available from the corresponding author on reasonable request.

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Conflict of interest statement

PW has acted as a consultant for, or received research grant support from, the following pharmaceutical companies in the last 5 years: Almirall Pharma, Boehringer–Ingelheim, Chr. Hansen, Danone Research, Ironwood Pharmaceuticals, Salix, Shire UK, Sucampo Pharmaceuticals and Allergan. PW is an associate editor for Therapeutic Advances in Gastroenterology. No other authors report any conflicts of interest.

ORCID iD

Nick A. Heywood https://orcid.org/0000-0002-1852-9426

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