ORIGINAL CONTRIBUTION

Evaluation of the Use of Posterior Tibial Nerve Stimulation for the Treatment of Fecal Incontinence: Preliminary Results of a Prospective Study

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PURPOSE: Neuromodulation therapies have been used with success in patients with fecal incontinence. Intermittent percutaneous tibial nerve stimulation is a new, minimally invasive treatment option for these patients. This study was designed to evaluate the results of intermittent percutaneous tibial nerve stimulation in patients with fecal incontinence.

METHODS: Sixteen patients (11 females; mean age, 59 ± 7.9 years) with severe fecal incontinence were treated with percutaneous tibial nerve stimulation. All patients completed a defecation diary, the Wexner Fecal Continence Scale, a fecal incontinence quality-of-life questionnaire, and a visual analog scale before treatment and during each phase of the study. Endoluminal ultrasound and anorectal physiologic studies were also performed in each patient.

RESULTS: Continence was improved in 10 of 16 patients after the first phase. Six patients did not continue to the second phase of treatment because of a lack of initial response. During the second phase, 7 of 16 continued to show improvement. After a six-month period without any treatment, 5 of 16 continued to have good continence. Overall, percutaneous tibial nerve stimulation significantly improved fecal continence. The Wexner score improved from a mean of 13.2 ± 4.1 at baseline to 9 ± 5.2 at the end of the first phase ($P < 0.0005$), to 8 ± 5.7 at the end of the second phase ($P = 0.001$), and to 9.1 ± 5 after 6 months without treatment ($P = 0.001$). Significant improvement was observed in three main domains of the fecal incontinence quality-of-life scale: coping/behavior, depression, and embarrassment. Scores on the visual analog scale improved from a mean of 4.6 ± 1.5 at baseline to 7 ± 2.5 at the end of the first phase ($P = 0.002$) and to 7.2 ± 2.5 after 6 months without treatment ($P = 0.001$).

CONCLUSION: Percutaneous tibial nerve stimulation is a minimally invasive and effective treatment option for patients with fecal incontinence.

KEY WORDS: Peripheral neuromodulation; Fecal incontinence; Percutaneous stimulation; Tibial nerve.

Fecal incontinence, which affects an estimated 2.2% of the population, can occur passively or be preceded by urgency.[1] It may result from traumatic damage to the anal sphincter mechanism, idiopathic degeneration of the sphincter muscle, spinal injury, or other neurologic causes.[2]

Some patients can be helped with antidiarrheal medications such as loperamide and codeine as well as by biofeedback, although the benefit in this group might be temporary. Other possible treatments include injection of biologic materials,[3] direct surgical repair,[4] dynamic graciloplasty,[5] and implantation of an artificial bowel sphincter.[6] Experience with these techniques is limited, and none is free of complications.

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TABLE 1. Timetable of assessments and number of patients during each phase of study

	Pretreatment	*First phase (3 months)*	*Second phase (8 months)*	*6 mo without treatment*
No. of patients	16	16	16	16
Wexner continence scale	x	x	x	x
Defecation diary	x		x	x
FIQL	x	x	x	x
VAS	x	x		x
Endoanal ultrasound	x			
Anorectal manometry	x		x	

FIQL = Fecal incontinence quality of life index; VAS = visual analog scale.

Sacral neuromodulation seems to be an effective therapy with reports of low morbidity and sustained benefit, at least over the medium term. However, placement of the sacral stimulator is invasive, and the system requires trial runs with percutaneous needles placed through the back through the sacral foramina.[7]

Posterior tibial nerve stimulation (PTNS) was first described for use in urologic disorders,[8] and it was later adapted by Shafik *et al.*[9] for the treatment of fecal incontinence. This novel system permits minimally invasive neuromodulation of the spine roots of L-4 through S-3 and thus peripheral afferent nerve stimulation of the posterior tibial nerve (PTN).

The aim of this prospective study was to evaluate the results of PTNS in patients with fecal incontinence.

MATERIALS AND METHODS

Criteria for inclusion in the study were as follows: age of 18 to 80 years old, severe incontinence with a Wexner score of 10 or higher, more than four fecal leaks within 28 days (recorded in a defecation diary), duration of incontinence of longer than 6 months before inclusion in the study, failure of conservative treatment (*e.g.,* fiber plus loperamide, biofeedback, or bulking agents), and integrity of the external anal sphincter. Patients were excluded from the study if they were younger than 18 years old or if they had any of the following disorders: severe cardiopulmonary disease; lesion of the PTN; severe distal venous insufficiency; use of a cardiac pacemaker or implantable defibrillator; inflammatory bowel disease; uncontrolled diabetes with peripheral nerve involvement; immunosuppression; active anal fissure, fistula, or abscess; or pregnancy. In patients who had previously undergone some form of anal repair, the external anal sphincter had to be circumferentially intact on endoluminal ultrasound.

Patients whose Wexner score after the first phase of treatment did not decrease to less than 40% of the initial score did not continue neuromodulation therapy. However, they did complete follow-up until the end of the study to facilitate the intention-to-treat analysis.

Before treatment all patients completed a defecation diary and the Wexner Fecal Continence Scale (range of scores = 0–20, where 0 = perfect continence and 20 = complete incontinence) as previously described.[10] Quality of life was assessed using The American Society of Colon and Rectal Surgeons quality-of-life questionnaire for fecal incontinence (29 items and four domains: lifestyle, coping/behavior, depression/self-perception, and embarrassment)[11,12] and a visual analog scale (VAS) for global quality of life (range of scores = 1–10, where 10 = best quality of life).

Defecation diaries and the VAS were repeated at eight months of treatment (second PTNS phase) and at six months without treatment (phase without PTNS); the Wexner continence scale, The American Society of Colon and Rectal Surgeons quality-of-life questionnaire, and the VAS were repeated at three months (first PTNS phase), eight months (second PTNS phase), and at six months without treatment (phase without PTNS).

Endoanal ultrasound was performed only before PTNS, for the purpose of patient selection. Physiologic testing consisted of resting and squeeze manometry and rectal sensation to latex balloon distention; this testing was performed before PTNS and at the second PTNS phase. Anal manometry was performed using a step-by-step pull-through technique with an eight-channel water-perfused system (Albyn Medical, Barcelona, Spain). Air insufflations into a rectal balloon were used to determine the rectal sensory threshold, urge, and maximum tolerated rectal volume. Table 1 shows a timetable of the assessments and the number of patients evaluated in each phase.

Application Technique

PTNS was applied according to the method of Stoller.[13] Patients lie supine with the soles of the feet together and their knees abducted and flexed ("frog position"). A 34-gauge stainless-steel needle is inserted approximately 3 cm to 4 cm cephalad to the medial malleolus, between the posterior margin of the tibia and the soleus muscle tendon. An adhesive electrode is placed on the same leg near the arch of the foot. Both the needle and electrode are con-

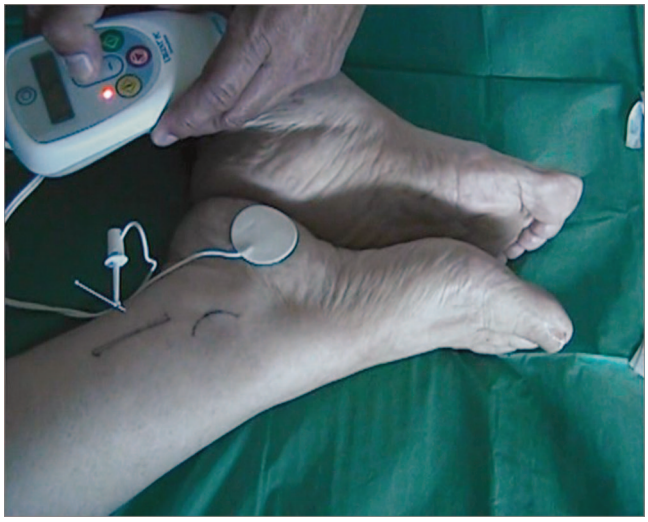

FIGURE 1. Technique of application of posterior tibial nerve stimulation.

nected to a stimulator (Urgent PC®, Uroplasty Ltd., Geleen, The Netherlands) with an adjustable pulse intensity (0–10 mA). Fixed parameters are a pulse width of 200 microseconds and a frequency of 20 Hz. The stimulator contains a 9-V battery. The amplitude is slowly increased until plantar flexion of the large toe or fanning of the other toes occurs. If this response cannot be obtained or pain occurs near the insertion site, the stimulation device is switched off and the procedure is repeated. In most patients the motor response was accompanied by a sensory response characterized as a radiating sensation spreading in the sole of the foot. The current was set at a well-tolerated level. Elevation of the current was allowed whenever this sensation faded because of adaptation. In the first PTNS phase, patients underwent 12 weekly outpatient treatment sessions, each lasting 30 minutes. Patients who had a good response were offered the opportunity to undergo the second phase of PTNS, which consisted of treatment every other week for two months, then every three weeks for two months, and finally one session in one month. Subsequently they did not undergo any treatment for six months to determine what would happen during that period (phase without PTNS). Unilateral stimulation was performed (Fig. 1).

Statistical analysis was performed using SPSS® 9.0 software (SPSS Inc., Chicago, IL). Variables are presented as the mean and standard deviation or as the median and the range from the 25th to the 75th percentile (P_{25}–P_{75}) if distributions were nonnormal. For the prospective analysis of variables that were assessed before and after PTNS, Student's *t*-test for paired samples was used whenever the required hypothesis had been verified. Otherwise, Wilcoxon's signed rank test for paired samples was used. The Friedman test was used to analyze variables assessed at more than two time points (*e.g.,* at pretreatment and at three months). A P value <0.05 was considered statistically significant.

This study was approved by the local hospital ethics committee, and all patients provided informed consent.

RESULTS

Sixteen patients (11 females; mean age, 59 ± 7.9 years) with severe fecal incontinence were treated with PTNS. The median duration of incontinence was 24 (range, 6–816) months. Table 2 details the patients' characteristics.

There were no cases of bleeding either during or immediately after the procedure, which was well tolerated by all patients. All patients finished the first PTNS phase; good results (as defined) were achieved in 10 of 16 patients. During the second phase, 7 of 16 patients continued to have good continence. After six months without any treatment, only 5 of 16 patients continued to have good continence.

Globally PTNS treatment significantly improved fecal continence, with the Wexner continence score improving from a mean of 13.2 ± 4.1 at baseline to 9 ± 5.2 at three months (first PTNS phase; $P < 0.0005$), to 8.1 ± 5.7 at eight months (second PTNS phase; $P = 0.001$), and to 9.1 ± 5 after six months without treatment ($P = 0.001$; Table 2 and Fig. 2).

Regarding the defecation diary, a decrease was found in each item analyzed globally except the number of defecations (Table 3). However, a strong positive linear correlation was observed between the total number of defecations and the number of leaks ($r = 0.9$) in each analyzed phase, and this correlation reached statistical significance ($P < 0.01$). Besides, a clear decrease in the number of leaks, in relation to the total number of defecations, occurred in each analyzed phase ($P = 0.003$). Such a difference was found between the pretreatment stage and the second PTNS phase ($P = 0.010$) and between the pretreatment stage and the phase without PTNS ($P = 0.018$).

In all, 18.8% of patients had taken antidiarrheal medication before treatment, but only 12.5% reported taking it during the second phase and the phase without PTNS.

Patients' perceptions of how incontinence affected their lives also improved over the course of treatment. Before treatment 37.5% of patients reported that incontinence affected them. This percentage decreased to 25% during the second phase and remained at that level during the phase without PTNS. Furthermore, there was significant improvement in three of the four main domains of the fecal incontinence quality-of-life measure: depression, coping/behavior, and embarrassment (Table 4).

There was a significant improvement in scores on the VAS, from a mean of 4.6 ± 1.5 at baseline to 7 ± 2.5 at the end of the first phase ($P = 0.002$) and to 7.2 ± 2.5 after six months without treatment ($P = 0.001$).

TABLE 2. Patient clinical, surgical, and endosonographic data and Wexner scores during each phase of study

		Patient Clinic/Surgical and Endosonographic Data		*Wexner Score*			
Case	*Sex*	*Antecedents*	*Endosonography*	*Pretreatment*	*First phase (3 months)*	*Second phase (8 months)*	*6 mo without treatment*
1	M	Fistulotomy	IAS defect	19	19	Discontinued	Discontinued
2	M	Repair anal atresia	IAS defect	20	10	9	9
3	F	Diabetes mellitus	Normal	15	7	10	10
4	F	Vaginal hysterectomy	IAS defect	13	11	Discontinued	Discontinued
5	F	Low anterior resection for rectal cancer Diabetes mellitus	Normal	12	7	3	3
6	F	Fistulectomy	IAS defect	13	7	0	8
7	F	Right colectomy for colon cancer	IAS defect	13	5	14	14
8	F	Not available	Normal	8	7	Discontinued	Discontinued
9	M	Circular anopexy	Normal	12	12	Discontinued	Discontinued
10	M	Sphincterectomy	IAS defect	8	1	7	7
11	F	Vaginal hysterectomy	Normal	10	4	3	3
12	F	Vaginal hysterectomy	Normal	18	12	3	10
13	M	Hemorrhoidectomies	IAS defect	7	2	2	2
14	F	Diabetes mellitus Hysterectomy	Normal	16	16	Discontinued	Discontinued
15	F	Hemorrhoidectomy, sphincterectomy, and endorectal repair of rectocele Diabetes mellitus	IAS defect	10	7	2	2
16	F	Implant bulking agent for passive incontinence	Normal Correct implants	18	17	13	13

F = female; IAS = internal anal sphincter; M = male.

In addition, significant improvement in squeeze pressure was noted between the baseline recordings and those measured at the end of the full treatment ($P < 0.007$; Table 5).

Statistically significant differences in the stimulation level necessary to obtain a sensory or motor response in patients' feet were not found. Therefore, 9 ± 2.7 V (equivalent to 4 mA) was used in the first PTNS phase, and 8 ± 4.03 V (equivalent to 3.5 mA) was used in the second phase.

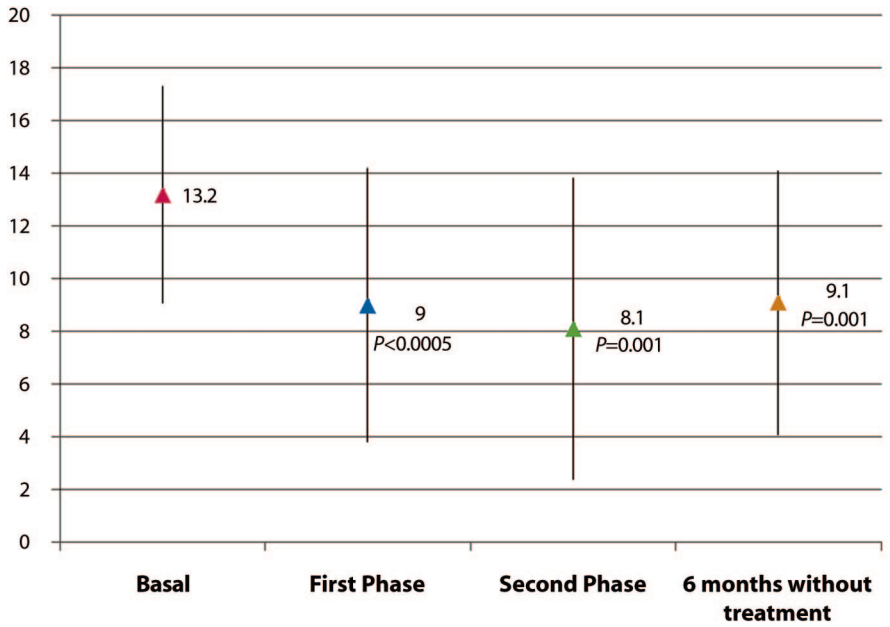

FIGURE 2. Evolution of the Wexner continence score over the course of treatment (N = 16). Data are the median (Min-Max). *P.* Friedman. $P < 0.005$ was considered statistically significant.

TABLE 3. Data from defecation diaries

Number	Pretreatment	Second phase (8 mo)	6 mo without treatment	P value
Days in diary[a]	25.9 ± 4.6	27.5 ± 1.7	28 ± 0	–
Defecations[b]	51 (37–81.2)	49.5 (35.2–72.2)	51.5 (35–72.7)	0.025
Discharge[b]	8.5 (3.2–19.5)	5 (0–15.2)	3.5 (0–15.2)	<0.0005
Urgency[b]	21.5 (14.2–43)	22 (1.2–34.7)	18 (1.2–33.5)	0.037
Use of pads[b]	7.5 (0–26.5)	0 (0–13.5)	0 (0–6.7)	0.018
Soiling[b]	7 (2.5–20)	4.5 (1.2–7.5)	3 (0–8.2)	0.011

[a]Data given as mean ± standard deviation.
[b]Data given as median (25th–75th percentiles).

DISCUSSION

PTNS was first described in 1983 by McGuire *et al.*[14] in patients with urinary incontinence, using a transcutaneous electrode over the common peroneal nerve or the PTN. Later Stoller[13] adjusted this method by use of a percutaneous needle electrode, placing the ground electrode on the ipsilateral extremity. Since then, several publications have reported promising early results for urgency and frequency, nonobstructive urinary retention, and chronic pelvic pain.

Shafik *et al.*[9] proposed using PTNS for fecal incontinence, achieving functional success in 78% of patients. This was the first report of the effectiveness of PTNS for fecal incontinence. Queralto *et al.*[15] used transcutaneous electric stimulation of the PTN in ten patients with idiopathic anal incontinence, and eight of the ten patients showed a 60% mean improvement in their incontinence score after four weeks. This improvement remained stable over the 12-week follow-up period.

The PTN is a mixed sensory-motor nerve that contains fiber originating from spinal roots L-4 through S-3. It comprises the outflow of the sacral nerves, which modulate the somatic and autonomic nervous supply to the pelvic floor, innervating directly the bladder, urinary sphincter, rectum, and anal sphincter. The exact mechanisms behind neuromodulation, either central or peripheral, remain unclear. One theory suggests an improvement in blood flow to the pelvis. Another possibility is a change in the neurochemical environment of neurons along the sacral pathways.[8] Primate studies have shown that repetitive stimulation of the PTN exerts a strong inhibitory effect on nociceptive neurons of the spinothalamic tract.[16]

Sacral root stimulation also activates the S-3 reflex. However, with sacral root stimulation the symptoms of incontinence recur immediately after deactivation, whereas with PTNS symptom improvement lasts weeks to months. This fact was observed in our series, in which half of the patients who responded to initial treatment remained continent without any treatment for six months. However, we believe that sooner or later some sessions will be needed for good continence to continue.

The role of anorectal physiologic measurement in patient selection or outcome evaluation remains unclear. Large series using sacral neuromodulation show a significant increase in squeeze pressure and heightened rectal sensation.[7] Prestimulation and poststimulation manometric parameters were not significantly different in the study of Queralto *et al.*,[15] which evaluated transcutaneous electric stimulation of the PTN. Shafik *et al.*[9] showed improvement in rectometric parameters in patients treated with PTNS. In our study, only an increase in squeeze pressure was seen in the patients who had a beneficial response to PTNS.

In our study we were unable to recognize, on the basis of clinical and manometric data and assessment scores, a specific group of patients who could benefit more from this therapy. This could be caused by the small sample size and by etiologic heterogenicity. It would be desirable in the future to arrange a controlled study to identify the patients who would benefit most from PTNS.

In the current study fecal incontinence improved in 44% of the patients who underwent full treatment. The exact cause of failure in the other 56% of patients is unknown. Failure could be related to the performance of the

TABLE 4. Fecal incontinence quality of life index during each phase of study

Domain[a]	Pretreatment	First phase (3 months)	Second phase (8 months)	6 mo without treatment	P value[b]
Lifestyle	2.7 ± 0.9	2.9 ± 0.7	3 ± 0.8	3 ± 0.7	$P = 0.086$
Coping/behavior	1.7 ± 0.5	2.1 ± 0.8	2.2 ± 0.8	2.2 ± 0.9	$P < 0.002$
Depression/self-perception	3.1 ± 0.9	3.2 ± 0.8	3.2 ± 0.9	3.2 ± 0.9	$P < 0.004$
Embarrassment	1.8 ± 0.7	2.3 ± 0.9	2.6 ± 1	2.6 ± 1	$P < 0.0005$

[a]Data given as mean ± standard deviation.
[b]$P < 0.005$ was considered statistically significant.

TABLE 5. Results of anorectal manometry before treatment and after second phase of study

	Pretreatment	*Second phase (8 months)*	*P value*[a]
MRP (mmHg)			
Median	16	24.2	NS
Minimum–maximum	8–64	14–145	
75th percentile	21.50	40.5	
MSP (mmHg)			
Median	44.7	63	<0.007
Minimum–maximum	20–124	39–209	
75th percentile	66.5	72.5	
First sensation (ml)			
Median	20	20	NS
Minimum–maximum	20–80	20–80	
75th percentile	20	20	
Urgency (ml)			
Median	60	40	NS
Minimum–maximum	40–180	40–100	
75th percentile	60	40	

MRP = maximum resting pressure; MSP = maximum squeeze pressure; NS = difference not significant.
[a]$P < 0.005$ was considered statistically significant.

technique, such as improper location of the stimulating needle in the leg or inadequate stimulation parameters. Alternatively, it could also be related to a disordered pudendal nerve reflex loop.

Furthermore, in a global sense, we were unable to show a statistically significant difference between items recorded in the defecation diary. This was probably a result of the small size of the sample, because the descriptive data showed a clear tendency toward improvement in the items considered. In fact, when considering the number of leaks in relation to the total number of defecations recorded in the different phases of the study, a lower number of leaks over the course of treatment was observed, and this decrease reached statistical significance.

We do not know whether application of the therapy in both tibial nerves would improve the efficiency and durability of the treatment. We also do not know whether patients can perform the treatment themselves at home, which would make it more convenient. Furthermore, some patients in whom percutaneous neuromodulation failed may still potentially benefit from central sacral neuromodulation.

PTNS is less invasive and less expensive than sacral root stimulation. In a study by Klingler *et al.*,[17] carried out in patients with urinary incontinence, the cost of PTNS treatment for each patient was $770 US (€895), compared with $8,849 US (€10,290) for implantation of the InterStim® neurostimulator (Medtronic, Minneapolis, MN).

It would be interesting to establish studies comparing this new therapy with the other forms of neuromodulation (*i.e.,* sacral and transcutaneous) to evaluate the efficiency, costs, and patient preferences for each. Likewise, it would be interesting to perform a study that includes a placebo group (*e.g.,* one with the neuromodulation electrode placed far from the trajectory of the PTN).

Peripheral neuromodulation for the treatment of fecal incontinence is a technology still in the relatively early stages of development. The results seen to date are both exciting and encouraging, but the optimal frequency of stimulation and ultimate durability of the response are among the questions about PTNS that have yet to be answered.

CONCLUSIONS

This study showed that PTNS is a minimally invasive procedure, is technically simple, and can be effective in the treatment of patients with fecal incontinence. However, it is believed that some additional sessions would be needed after the initial full treatment for good results to continue.

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