Efficacy of Bilateral Transcutaneous Posterior Tibial Nerve Stimulation for Fecal Incontinence

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ABSTRACT

Context: Posterior tibial nerve stimulation is a new second-line treatment for refractory fecal incontinence.

Objective: To assess the efficacy of bilateral transcutaneous posterior tibial nerve stimulation (BTPTNS) for treatment of fecal incontinence in Japanese patients and its impact on quality of life.

Design: A prospective observational-interventional study was conducted from May 2015 to June 2017 in patients with fecal incontinence in whom conservative treatment had failed. All patients received a 30-minute session of stimulation twice weekly for 6 consecutive weeks. Evaluation at baseline and at 6 weeks involved the Wexner score, Fecal Incontinence Quality of Life (FIQL) questionnaire, and anal manometry. Patients recorded episodes of incontinence in a weekly diary.

Main Outcome Measures: Reduction of 50% or greater in incontinence episodes, decreased Wexner score, and improved FIQL scores.

Results: Twenty-two patients with a median age of 64.1 years (range, 26-81 years) and men:women ratio of 9:13 completed BTPTNS. Mean episodes of fecal incontinence were significantly reduced from 4.7 to 1.5 ($p < 0.05$). An improvement of 50% or better in episodes of fecal incontinence was achieved in 77.2% of patients. The median Wexner score significantly decreased from 10.2 to 6.9 ($p < 0.05$). The median FIQL score improved from 2.7 to 3.1 ($p = 0.06$), and significant improvement was seen in the embarrassment domain (2.2 vs 2.8, $p < 0.05$). Resting and squeezing anal pressures revealed no significant changes.

Conclusion: Our findings suggest that BTPTNS is safe and well tolerated and may improve symptoms of fecal incontinence. This technique offers an additional noninvasive, less expensive form of treatment.

INTRODUCTION

Fecal incontinence is an underestimated disorder because it is often underreported by patients and underrecognized by health practitioners. Estimates of prevalence in the community-based adult population vary from 1.4% to 19.5%.[1] Because prevalence and severity rise with age, fecal incontinence is expected to be a larger problem in an increasingly aging society. Moreover, fecal incontinence is embarrassing, causing great discomfort that can lead patients to stigmatization, social isolation, and poor self-esteem with profound implications for their quality of life.[2] Conservative treatment, including dietary modification, constipating medications, lifestyle advice, biofeedback, and pelvic floor exercises, may be helpful to a considerable number of patients.[3] The following invasive treatments are usually recommended if conservative treatment fails: Neuromodulation, injection of bulking agents, sphincteroplasty, artificial bowel sphincter, dynamic graciloplasty, and colostomy.[4] However, these surgical procedures are complex, with variable outcomes and significant morbidity.[5]

New technologies have evolved since the early 2000s, with techniques of neuromodulation offering high efficacy combined with low morbidity. Nerve stimulation for treatment of fecal incontinence has gained popularity, although the exact mechanism and the role of anorectal physiology in the treatment of fecal incontinence have not yet been completely defined.[6,7] It may involve higher cortical centers and increased anal canal representation in the somatosensory cortex, with improved awareness of continence resulting in symptom control and better quality of life.[8] Posterior tibial nerve stimulation is a recent, minimally invasive, less expensive form of neuromodulation (first used to treat patients with urinary incontinence), and its sustained safety and efficacy have been established in numerous publications.[9,10] It is now gaining traction as a second-line treatment of refractory fecal incontinence and is based on the same principle of nerve stimulation as sacral neuromodulation (SNM).[11] It has been applied percutaneously[11-18] and transcutaneously,[19-24] but the results are limited by the methods of stimulation and the heterogeneity of patients enrolled in the studies. The aim of this study was to assess the efficacy of bilateral transcutaneous posterior tibial nerve stimulation (BTPTNS) for treatment of fecal incontinence in Japanese patients and to evaluate its impact on their quality of life.

METHODS

A prospective observational-interventional study was conducted from May 2015 to June 2017 and was approved by our local hospital's ethics committee. Informed consent was obtained from all patients. Enrollment criteria included patients with at least 6 months of fecal incontinence because of various causes (previous anal surgery, obstetric, or idiopathic) who did not respond to conservative treatment (constipating medication, pelvic floor exercises, and biofeedback). Patients were treated with BTPTNS as second-line therapy. Exclusion criteria included age younger than 18 years, inability to provide informed consent or to complete detailed bowel diaries, and refusal to participate in the study. Patients

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with diabetic or peripheral neuropathy and those who could not attend weekly sessions in the hospital also were excluded.

All included patients were evaluated by a trained medical professional from our Coloproctology Department. A detailed medical history was obtained from each patient, and a physical examination including an assessment of the anal sphincter was performed. Manometry, using a 12-channel microballoon sensor (Star Medical Inc, Tokyo, Japan), was conducted to determine the anal canal resting and squeezing pressures. The anal canal pressure at rest and at maximal voluntary contraction was recorded by each of the microballoons. Manometry was repeated after 6 weeks of treatment and was performed by the same medical professional. At baseline and at 6 weeks, all patients completed the Cleveland Clinic Florida Fecal Incontinence Score, also known as the Wexner score. This instrument is used to calculate the type and frequency of incontinence using the subscales of solid, liquid, gas, wears pad, and lifestyle alteration. These 5 items are each evaluated using a 5-point Likert scale with the following semantic anchors: 0 = never; 1 = rarely; 2 = sometimes; 3 = usually; and 4 = always. A score of 0 is perfect continence, and a score of 20 is complete incontinence.[25] All patients also completed at baseline and at 6 weeks the Fecal Incontinence Quality of Life (FIQL) questionnaire, which is composed of 29 items to assess 4 domains: Lifestyle (10 items), coping/behavior (9 items), depression/self-perception (7 items), and embarrassment (3 items).[2] The average number of weekly incontinence episodes was calculated using detailed bowel diaries that all patients kept from baseline to 6 weeks.

All patients received a 30-minute session of BTPTNS twice a week for 6 consecutive weeks in an outpatient setting, according to the department-defined protocol. Two adhesive-surface electrodes were used, with one placed on the skin behind the medial malleolus and the other placed on the skin 10 cm cephalad from the first electrode.[19] Tibial nerve stimulation was done using a transcutaneous electrical nerve stimulation device (Intelect Advanced EMG module, DJO Global Inc, Vista, CA). The optimal position of the electrode was determined by observing the rhythmic plantar flexion of the toes during stimulation. Stimulation was carried out at an amplitude level that elicited the optimal response. The low-voltage stimulator we used has an adjustable current setting ranging from 0 to 60 mA, a fixed pulse width of 200 μs, and a fixed frequency of 10 Hz. The primary outcome measures were a reduction of 50% or greater in fecal incontinence episodes, a decrease in the Wexner score, and an improvement in the FIQL domain scores.

Table 1. Patient characteristics (N = 22)

Characteristic	Number
Sex (men:women)	9:13
Median age, y (range)	64.1 (26-81)
Median duration of fecal incontinence, y (range)	5.3 (0.5-23)
Median no. of vaginal deliveries (range)[a]	1.7 (1-3)
Anal sphincter defect (yes:no)	3:19
Incontinence cause	
Previous anal surgery	8
Obstetric	6
Idiopathic	8

[a] Female patients only.

Statistical analysis was performed using SPSS software (Version 17.0.0 for Windows/PASW Statistics 17, SPSS Inc, Chicago, IL). Quantitative variables were expressed as mean and standard deviation for normally distributed data, and as median and range for nonparametric distributions. Qualitative variables were given as numbers and percentages. Student's *t*-test was performed to compare paired normally distributed variables, and the Mann-Whitney *U* test was used for nonparametric variables. The χ^2 test was used to compare discrete variables. The Pearson correlation test was used to compare quantitative variables. A p value < 0.05 was considered statistically significant.

RESULTS

Twenty-two patients with a median age of 64.1 years (range, 26-81 years) and a men:women ratio of 9:13 completed the scheduled BTPTNS treatment. The median duration of fecal incontinence was 5.3 years (range, 0.5-23 years). Eight patients had a history of previous anal surgery, 6 patients had obstetric-related incontinence, and 8 had idiopathic incontinence. Patient characteristics are summarized in Table 1. All women included in the study had experienced vaginal delivery, with a median number of 1.7 deliveries (range, 1-3). Endoanal ultrasonography was used to determine the percentage of defect vs no defect. The BTPTNS procedure was well tolerated by all patients, with no adverse effects and no skin lesions at the site of electrode placement.

The mean number of fecal incontinence episodes was significantly reduced from 4.7 at baseline to 1.5 at 6 weeks ($p < 0.05$). Moreover, an improvement of 50% or more in fecal incontinence episodes was achieved in 77.2% of the patients. The patients who did not experience any improvement in fecal incontinence were given transanal electrostimulation and SNM. The median Wexner score significantly decreased from 10.2 to 6.9 ($p < 0.05$). The median overall FIQL score improved from 2.7 to 3.1, but the change was not significant ($p = 0.06$). FIQL score improvements were seen in the domains of lifestyle (2.9 vs 3.4, $p = 0.22$), behavior (2.9 vs 3.2, $p = 0.54$), and depression/self-perception (2.6 vs 3.0, $p = 0.11$), but the changes were not significant (Table 2). However, there was a significant improvement in the embarrassment domain (2.2 vs 2.8, $p < 0.05$). Manometry did not reveal any significant changes before and after the BTPTNS treatment. The resting and squeezing anal pressures were 55.0 vs 55.9 cm H_2O ($p = 0.89$) and 193.5 vs 194.0 cm H_2O ($p = 0.98$), respectively (Table 3). The median follow-up period for all patients after treatment was 1 month.

DISCUSSION

The etiology of fecal incontinence is multifactorial. Predominant factors are presumed to be trauma to the anal

Table 2. Wexner score and Fecal Incontinence Quality of Life (FIQL) domain scores			
Test	**Baseline**	**6 weeks**	**p value**
Wexner score	10.2	6.9	< 0.05
FIQL domain			
Overall	2.7	3.1	0.06
Lifestyle	2.9	3.4	0.22
Behavior	2.9	3.2	0.54
Depression/self-perception	2.6	3.0	0.11
Embarrassment	2.2	2.8	< 0.05

Table 3. Anorectal manometric data				
Anal pressure, cm H_2O	**Reference range[a]**	**Baseline**	**6 weeks**	**p value**
Median resting pressure	Men: 69.5; Women: 68.5	55.0	55.9	0.89
Median squeezing pressure	Men: 194.8; Women: 167.4	193.5	194.0	0. 98

[a] These normal values are cited by Li et al.[1]

1. Li Y, Yang X, Xu C, Zhang Y, Zhang X. Normal values and pressure morphology for three-dimensional high-resolution anorectal manometry of asymptomatic adults: A study in 110 subjects. Int J Colorectal Dis 2013 Aug;28(8):1161-8. DOI: https://doi.org/10.1007/ s00384-013-1706-9.

sphincter morphology because of obstetric, pelvic, or anal surgery; radiotherapy; and/or weakness of the internal anal sphincter function. Moreover, the findings imply that fecal incontinence is a result of an unstable/uninhibited rectum.[26] Thus, determining the treatment with the most favorable outcomes becomes a challenge and must be individualized.[7] At present, SNM is the best established neuromodulatory treatment for fecal incontinence and has been used since 1995, with a reported success rate of 85% of patients achieving 50% or greater reduction of incontinent episodes at 24 months.[6,8] Although SNM has the most enduring results over time, with 50% of patients maintaining full continence after 10 years, it is considered an expensive treatment that requires a highly specialized and dedicated colorectal team.[27] Furthermore, it is associated with relatively high morbidity and carries some risks and disadvantages. The procedure involves 2 operations that are performed under anesthesia and possibly exposes the patient to unnecessary radiation while confirming the position of the electrode. Moreover, adverse events occur in 12% of cases, some of which (device infection and lead migration) may require a pulse generator replacement or reimplantation. This has been seen in 7% of cases.[28] Therefore, less invasive treatment options with peripheral nerve stimulation have emerged.

The mechanisms of posterior tibial nerve stimulation in patients with fecal incontinence are not fully understood. Some authors have hypothesized that there is a sensory and motor neuromodulatory effect involved including rectal sensory perception, pelvic striate muscle activation (allowing generation of increased maximum squeeze pressure), and a reduction in unwanted spontaneous anal relaxation and rectal contractions.[11,12,29] The results of a recent randomized trial contradict these findings, owing to similar findings in the percutaneous, transcutaneous, and sham transcutaneous groups.[30]

In our study, the anal canal resting and squeezing pressures did not differ before and after treatment. These findings were not related to success and are consistent with the studies of Marti et al[13] and Queralto et al.[19] However, some studies have shown a significant improvement in anal pressures,[12,16,30] and Lopez-Delgado et al[16] suggest that changes in anal pressure indicate the effectiveness of the treatment. Furthermore, it is assumed that changes may be barely noticeable and of little clinical value; they are apparent only in the early stages of treatment and in a few parameters.[12] There is ambiguity concerning findings in manometry. Manometry may have a role in defining success, but further research is necessary.

The posterior tibial nerve originates from sensorimotor and autonomic fibers derived from the fourth and fifth lumbar vertebrae and the first, second, and third sacral nerves, and by stimulating this nerve at the ankle, it may be possible to indirectly modulate sacral nerve function.[11] Neuromodulation is believed to work via stimulation of multiple afferent sensory pathways at the spinal level.[29] This has an effect on the pelvic viscera, lower gut, and sensory cortex.[31] Positron-emission tomography has shown that sacral nerve stimulation increases blood flow centrally, and it seems that initial activity in the frontal cortex can be changed after chronic stimulation and may reflect improved awareness of continence, resulting in symptom control.[32] Bilateral neuromodulation may activate a greater number of afferent sensory pathways, which could lead to an improved therapeutic effect. In a certain portion of patients, the pelvis is innervated asymmetrically,[33] and unilateral stimulation may therefore not achieve an optimal treatment outcome.

Bilateral stimulation has been shown to be superior to unilateral SNM in some, but not all, patients with fecal incontinence[34] and bladder dysfunction.[35] Similar to these findings achieved from SNM, bilateral stimulation of the tibial nerve may also be superior to unilateral stimulation. In a study conducted by Thomas et al[20] in which BTPTNS was used, the authors found that 59% of the patients achieved a 50% or greater reduction in the frequency of incontinent episodes with a significant reduction in median frequency of incontinent episodes per week and a significant improvement in the lifestyle domain of the Rockwood FIQL score. In another study in which BTPTNS was applied, there was a significant improvement in episodes of incontinence on the Wexner scale and the visual analog scale assessment, a decrease in the number of episodes of incontinence per unit of time, and a statistically significant improvement in 3 variables of the FIQL score, including lifestyle, behavior, and embarrassment.[21]

In our study, the frequency of fecal incontinence per week significantly decreased from 4.7 to 1.5 ($p < 0.05$) before and after treatment. Moreover, 77.2% of the patients experienced a 50% or better improvement in the episodes of fecal incontinence, and the median Wexner score significantly decreased from 10.2 to 6.9 ($p < 0.05$). An improvement was also seen in the median overall FIQL score

from 2.7 to 3.1 ($p = 0.06$), which was not significant; however, a significant change in the embarrassment domain (2.2 vs 2.8, $p < 0.05$) was observed. These results are consistent with the results of other studies.

CONCLUSION

Our findings suggest that BTPTNS is a safe, well-tolerated procedure among patients with fecal incontinence and may improve their symptoms. This technique offers an additional noninvasive and less expensive option for treatment before more invasive modalities are performed. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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