



Percutaneous versus transcutaneous tibial nerve stimulation in the treatment of faecal incontinence

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Abstract

Objective: A prospective study was done to compare the efficacy of percutaneous versus transcutaneous tibial nerve stimulation for patients with Faecal Incontinence (FI) who had failed conservative treatment.

Methods: Thirty-eight patients were randomly divided into two groups: percutaneous group (PTNS) and transcutaneous group (TTNS). Subjects underwent thrice sessions weekly for 12 consecutive weeks. Assessments were done at baseline and at the end of treatment using a bowel habit diary and Faecal Incontinence quality of Life questionnaire (FIQOL).

Results: The results of the study showed that there was a significant reduction in the mean of total weekly FIEs, mean urge FIEs and mean passive FIFs for PTNS and TTNS groups at the end of the treatment compared with baseline, p -value <0.05 . The percentage of improvement was 42.8% for the PTNS group and 37.5% for the TTNS group. Regarding (FIQOL) measures, the results of the study showed that there was an improvement in all (FIQOL) measures for patients in both PTNS and TTNS groups. In comparing both groups, there were no significant differences between PTNS and TTNS regarding mean of total weekly FIEs, mean urge FIEs, mean passive FIFs and FIQOL measures p -value >0.05 .

Conclusion: PTNS was given for 12 weeks did not provide significant clinical benefit over stimulation applied by the transcutaneous route for the treatment of patients with FI. Further studies are recommended to determine its efficacy over long-term duration.

Keywords: Percutaneous route, Transcutaneous route, Tibial nerve stimulation, Faecal incontinence

Introduction

Faecal incontinence (FI) is the involuntary loss of feces as defined by International Urogynecology Association (IUGA) and International Continence Society (ICS) [1]. FI is a common debilitating disorder both physically and psychosocially, that has a substantial negative impact on quality of life (QOL), not only for the patients but also on their families. FI causes shame and extreme embarrassment, depression, physical discomfort, and disruption of activities of daily living [2-4].

FI affects individuals of all ages but is more common in women owing to trauma from childbirth and in older people. Women over the age of 40 are commonly affected due to pelvic floor dysfunction after obstetrical trauma. Although FI is relatively

common, it is difficult to obtain prevalence data about it. Patients are often unwilling to volunteer information about FI to their health practitioner, possibly because of embarrassment or their belief, as it is a normal part of the aging process [5,6].

FI is a complex and multifactorial medical disorder that best managed by a multidisciplinary team comprising: primary care, continence specialist nurse, occupational therapist, physical therapy and secondary care specialists such as neurologists, gastroenterologists, and geriatricians [7]. Management of FI is challenging because of a widespread lack of expertise, high prevalence, and multiple etiologies. Conservative therapy is the first-line treatment for patients with FI. Several conservative treatment options are available, but the durability over

time is often poor, the success rate of conservative treatment measures is nearly about 50% [8]. A more invasive approach can be necessary [9]. However, the surgical treatment options may carry a significant risk of complications and have well-established high long-term failure rates [10-13].

Nowadays, neuromodulation is one of the fastest growing areas in medicine. It is an attractive therapeutic option when conservative measures fail. It has to some extent obviated the use of overlapping sphincter repair and more extensive surgical procedures, which had high morbidity and poor long-term efficacy [14]. Neuromodulation is an intermediary therapy that is bridging the gap between conservative strategies and invasive surgery in centers where expertise exists [15]. The peripheral neuromodulation of the sacral nerve plexus can be done through tibial nerve stimulation with less invasive and technically simpler neuromodulatory therapies. Percutaneous tibial nerve stimulation (PTNS) is a less invasive peripheral neuromodulative technique involves electrical stimulation via a needle placed adjacent to the tibial nerve just above the ankle. Transcutaneous tibial nerve stimulation (TTNS) is a non-invasive peripheral neuromodulative involves electrical stimulation, which is delivered via two-pad electrodes placed over the tibial nerve just above the ankle [16-18]. Our purpose of the study was to assess which neuromodulative technique, PTNS or TTNS is clinically more effective and feasible for the patients with FI.

Materials and methods

Research design

A prospective randomized study was done at King Khalid Hospital, Al Majmaah, KSA. The Declaration of Helsinki principles were followed in this research; the study protocol was submitted to the Institutional Review Board of the Basic & Health Science Research Center at Majmaah University, and an ethical approval was obtained under the number MUREC-Mar11 /COM-2018/3. Patients provided an informed written consent form before entering study.

Inclusion and exclusion criteria

Inclusion criteria included; patient ages ranged between 35-75 years, patients with a number of episodes of FI \geq two episodes per week, FI with solid or liquid stool disrupting lifestyle, patients with failed previous sacral nerve surgery (SNS) and patients who were resistant to conservative therapy. Reasons for exclusion were; any patient with pacemakers, implanted defibrillators, a history of heart problems, nerve damage or tendency to excessive bleeding. Patients with complete spinal cord injury, congenital anorectal malformations, and previous rectal surgery within last 12 or 24 months for cancer were excluded. Patients with inflammatory bowel disease, chronic diarrhea, stoma, active perianal sepsis, multiple sclerosis and spina bifida, pregnant or intention to become pregnant were also excluded.

Randomization

Random assignment of patients was conducted in two stages: First; researcher screened potentially eligible patients and report all patients who fulfilled the inclusion criteria of the study and had no exclusion criteria. Second, assigning the patients to either the PTNS group or TTNS group. Random process involved opening an opaque envelope prepared with random number generation using Excel to generate the allocation sequence by an independent person (registration clerk) who was not involved in any part of the study.

Outcome measures

Patients underwent baseline evaluation including details about current medication, previous medical, surgical and obstetric history, general physical examination, digital rectal examination, endo-anal ultrasound, defecography, anorectal manometry and rectal sensation testing. The goal of evaluation was not only to identify reversible causes and contributing factors for FI but also to determine the severity of the symptoms and their impact on the individual's quality of life (QOL).

Primary and secondary outcome measures

Primary outcome measures were the number and percentage of patients achieving more than \geq 50% reduction, in faecal incontinence episodes (FIEs) per week. Secondary outcome measures were the reduction in total (FIEs), urge (FIEs) and passive (FIEs) per week. Successful outcome measured by entries in a self-completed daily bowel diary.

Quality of life measures

Quality of life (QOL) measures were assessed using the FIQOL at the baseline (pre), and at the end treatment (post). FIQL questionnaire was designed to evaluate the impact of FI on four aspects of patients' QOL: lifestyle; coping behavior; depression or self-perception; and level of embarrassment. Each aspect was measured on a scale, scored between one and four, where one is highly affected, and four is not affected [19]. Validity and reliability of the FIQL have been established and recommended as a useful tool to assess FI [20,21]. Participants were given a self-administered questionnaire that included questions about patient demographics, alcohol consumption, preexisting medical conditions, prior surgical history and all known risk factors for FI.

Treatment procedures

Apparatus

PC neuromodulator equipment consisted of a stimulator and lead set. The lead with an adhesive surface electrode and needle electrode clip with 34-gauge stainless steel needle electrode was used for PTNS application. Two adhesive electrodes were used for TTNS. An alcohol swab was used to clean area of electrode placement. The lead set transferred the electrical current from the PC stimulator to the tibial nerve.

Parameters

Parameters used were; continuous mode, fixed-pulse frequency of 20 Hz, a pulse width of 200 μ , duration of every session was 30 minutes. Subjects underwent thrice sessions weekly for 12 consecutive weeks. For PTNS application, stimulation was selected within a range of 1.0 to 10 mA. For TTNS, the appropriate electric current intensity level was selected within a range of 18 to 38 mA.

Application

Patients were provided an illustrated information describing the procedure and the sensations they are likely to experience, including possible side effects. The patient sat in a comfortable position with the legs placed so that the medical aspect of the ankle was easily accessible.

Application for PTNS group

A needle was inserted about five cm cephalic from the medial malleolus and 2 cm posterior to the margin of the tibia, creating a 60-degree angle between the needle and the foot. The tip of the needle was gently tapped to penetrate the skin. The needle electrode was advanced with a slowly rotating motion until about 2 cm of the needle tip is left exposed. The adhesive surface electrode was placed on the foot near the medial aspect of the calcaneus on the same leg as the inserted needle electrode. The current was slowly increased while observing the patient's foot for a response that flexion or fanning of the toes or an extension of the entire foot. Patients also felt a tingling sensation under the foot or a feeling of heaviness or numbness. If a response was not obtained, the procedure was repeated in the other leg with a new needle [17,18].

Application for TTNS group

Stimulation was done on the tibial nerve using two self-adhesive surface stimulation electrodes. Contact electrodes were placed on the patient's skin with electrode gel with the negative electrode behind the internal malleolus and the positive electrode 10 cm above the negative electrode. The adequate position of the electrode was determined by slowly increasing the electric current until sensory and/or motor responses were evident. Typical responses included sole foot sensation and/or great toe flexion [22].

Statistical analysis

Statistical analysis was done using statistical package for the social sciences; SPSS Inc., Chicago, IL, USA, version 22. Differences were assumed significant at p-value <0.05. Continuous variables were described in terms of mean and standard deviation while categorical variables were described by frequencies (number of cases), and relative frequencies (percentages).

Shapiro-Wilk test was used to detect a normal distribution of data. For parametric normally distributed data, Paired T-test was used to detect differences within groups, and Independent T-test was used to detect differences between both

groups. For non-parametrical, ordinal data, Wilcoxon signed rank test was used to detect differences within groups, while the differences between both groups were evaluated using Mann-Whitney U test.

Results

Figure 1 illustrated participating patients and dropouts through the study. 45 patients with FI were selected for participation. Seven were excluded (four did not meet the study criteria, and three refused to participate). 38 patients participated and randomized into two groups. Of these patients, three had not yet completed the sessions, and five had with drawn from the program (one became pregnant, two moved away, and two disliked the treatment). Data for thirty patients were available for final analysis (14 patients in PTNS group and 16 patients in TTNS group). Our findings were classified as follows.

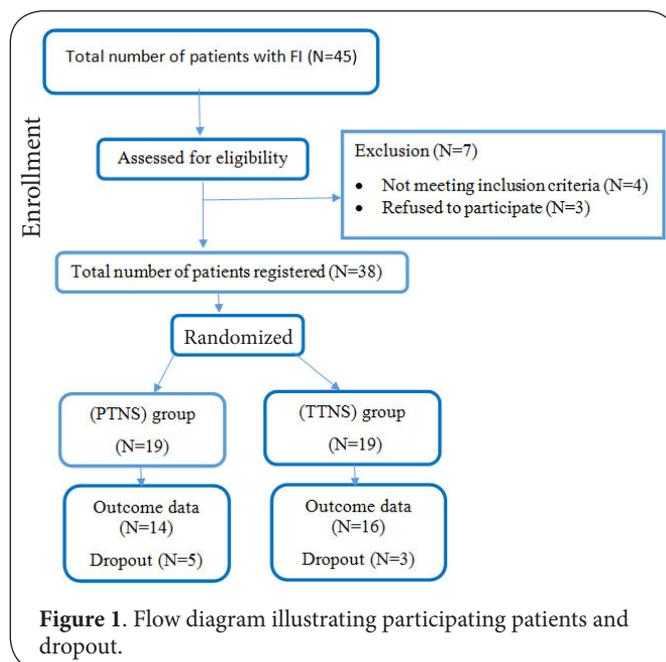


Figure 1. Flow diagram illustrating participating patients and dropout.

Patients' demographic data

The demographic data of all participants in each group shown in Table 1. There were no differences between the demographics of the patients composing the PTNS group and TTNS group. These results showed that both groups bear similar characteristics regarding age, sex, duration, type of FI, obstetric history, Type of previous treatment, p-value >0.05.

Primary outcome measures

With regards to Table 2, The number and percentage of patients achieved $\geq 50\%$ reduction in weekly FIEs in PTNS group was 6 out of 14, (42.8%) while the number and percentage of patients achieving $\geq 50\%$ reduction in weekly FIEs in TTNS group was 6 out of 16, (37.5%). No significant difference was

Table 1. Demographic characteristics of patients in PTNS and TTNS groups.

Variables	PTNS group	TTNS group	P-value
Age (Year) (mean ±SD)	58.57±10.26	57.13±10.85	0.711*
Duration (Month) (mean ±SD)	36.43±17.99	46.00±14.53	0.118*
Gender N (%)			
Female	10 (71.4%)	11 (68.8%)	0.875*
Male	4 (28.6%)	5 (31.3%)	
Previous Treatment N (%)			
Medical	4 (28.6%)	3 (18.8%)	
Biofeedback	3 (21.4%)	4 (25%)	
Pelvic floor ex.	2 (14.3%)	3 (18.8%)	0.704*
Fiber supplement	2 (14.3%)	2 (12.5%)	
Anal sphincter repair	1 (7.1%)	2 (12.5%)	
Other anal surgery	1 (7.1%)	1 (6.3%)	
Defecatory advice	1 (7.1%)	1 (6.3%)	
Obstetrics History N (%)			
Vaginal delivery	5 (35.7%)	1 (7.1%)	0.093*
Episiotomies	1 (7.1%)	1(7.1%)	
C-section	1 (7.1%)	1 (7.1%)	
Type of FI N (%)			
Passive	9 (64.3%)	12 (75.0%)	0.530*
Urge	5 (35.7%)	4(25.0%)	

* No significant difference

Table 2. Percentage of improvement in primary outcomes.

Variables	PTNS Group (N=14)	TTNS Group (N=16)	P-value
≤50% reduction FIEs N (%)	4 (28.6%)	7 (43.8%)	
≥50% reduction FIEs N (%)	6 (42.8%)	6 (37.5%)	0.374*
100% reduction in FIEs N (%)	4 (28.6%)	3 (18.7%)	

* No significant difference

observed between the PTNS and TTNS groups regarding the number of participants achieving ≥50%, 100% reduction in weekly FIEs (p-value >0.05).

Secondary outcome measures

As illustrated in **Table 3**, in PTNS group, there was a significant reduction in median value of FIEs per week into 6.50, p-value <0.001 with a median value of urge FI episodes reduced into 3.00, p-value <0.001 and the median passive episodes decreased into 2.50, p-value <0.001. For TTNS group, the results showed that there was a significant reduction in median value of FIEs per week into 7.00, p-value <0.001 with a median value of urge FI episodes reduced into 4.00, p-value <0.001 and the median passive episodes decreased into 3.00, p-value <0.001. The reduction of median value FI episodes in PTNS patients was more than TTNS regarding FIEs, Urge and passive FI episodes but with no significant difference as p value=0.40, p value=0.45, p value=0.13 respectively.

Statistical analysis of quality-of-life measures

Regarding FIQOL measures there was a significant improve-

ment in all domains (life style, Coping and behavior, Depression and self-perception, Embarrassment) at the end of treatment in PTNS and TTNS groups, p value <0.05. No significant difference was seen in the disease-specific (FIQOL) measures between the PTNS and TTNS in all domains following treatment, p value >0.05, as shown in **Table 4**.

Table 3. Secondary outcome measures.

Variables	PTNS Group	TTNS Group	P-value
FIEs (baseline)	11.5 (7)	11 (9)	0.94*
FIEs (post)	6.5 (7)†	7 (7) †	0.40*
Urge FIEs (baseline)	6 (7)	7 (6)	0.27*
Urge FIEs (post)	3 (7)†	4 (6)†	0.45*
Passive FIEs (baseline)	6 (6)	5 (7)	0.21*
Passive FIEs (post)	2.5 (7)†	3 (6)†	0.13*

Data are expressed as median(Range);

*No significant difference between groups;

†Significant differences within group

Table 4. Quality of life measures.

Variables	PTNS Group	TTNS Group	P-value
FIQOL_ life style_ baseline	2.65 (0.70)	2.35 (1.00)	0.24*
FIQOL_ life style_ post	2.95(0.90) †	2.70 (1.10) †	0.09*
FIQOL_ Coping and behavior _ baseline	1.45 (1.00)	1.50 (0.90)	0.69*
FIQOL_ Coping and behavior _ post	2.70 (1.30) †	2.30 (1.90) †	0.06*
FIQOL_ Depression and self-perception _ baseline	2.75 (1.20)	2.65 (0.90)	0.21*
FIQOL_ Depression and self-perception _ post	2.80 (1.10) †	2.70 (0.90) †	0.08*
FIQOL_ Embarrassment_ baseline	2.40 (1.00)	2.20 (0.80)	0.35*
FIQOL_ Embarrassment_ post	2.75 (0.60) †	2.65 (0.90) †	0.09*

Data are expressed as median (Range);

*No significant difference between groups;

†Significant differences within group

Discussion

The clinical effects of PTNS compared with TTNS, in the treatment of patients with FI who had failed conservative management were assessed in the current study. The results of the study showed that there was a significant reduction in the mean of totally weekly FIEs, mean urge FIEs and mean passive FIFs in both PTNS and TTNS at the end of the treatment, p-value <0.05. Regarding (FIQOL) secondary outcome measures, the results of the study showed that there was an improvement in all quality-of-life measures for patients in both PTNS and TTNS groups. Patients in the PTNS group showed improvement in all of the quality-of-life measures, compared to patients in the TTNS group however with no significant difference, p-value >0.05.

The results are supported by theoretical explanation [23] that clarify PTNS may be more effective. In PTNS, an electric

field is created between a stick-electrode and a needle, which present directly over the tibial nerve creating direct stimulation to tibial nerve, so that the motor and sensory response easily evoked by low current. In TTNS route the electric field is created between both surface stick-electrodes; the current must overcome the impedance of skin before it affects tibial nerve and this requires larger current to evoke the motor and sensory responses than is required for percutaneous needle stimulation. In TTNS, if a larger amplitude is used to evoke the response, more afferent nerves in the skin are recruited and stimulated which can lead to painful sensations. While results in suboptimal stimulation, if the stimulation is introduced at a tolerated level. The reported percentage of improvement and efficacy of PTNS and TTNS in previous faecal incontinence studies varied from 54% to 84.3% [17,18,22,24-27].

The comparison with results of other TTNS and PTNS studies is difficult and complicated because of different outcome measures used, heterogeneous patient populations, different frequency and duration of treatment used. Only one study [23] compared the efficacy of PTNS versus TTNS in faecal incontinence patients. In that study, about 30 patients were classified randomly into three groups percutaneous; transcutaneous; sham transcutaneous, the frequency of treatment was twice weekly for six weeks. A bowel habit diary and St Mark's continence score were measured at baseline and after six weeks of treatment. The results their study showed that patients underwent percutaneous nerve stimulation had a more significant decline in the number of incontinence episodes and they were able to defer defaecation for a prolonged duration than those underwent transcutaneous and sham stimulation. Treatment duration and secondary outcome measures were different from our study. In addition, the improvement in PTNS was marked compared with TTNS while in our study the improvement in PTNS was more than TTNS but with no significant differences.

Conclusion

PTNS appeared to offer some benefits greater than those obtained from TTNS route but without significant differences; further studies are needed to involve follow up on long-term effects.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Authors' contributions	ISW	MKS
Research concept and design	✓	--
Collection and/or assembly of data	--	✓
Data analysis and interpretation	✓	--
Writing the article	✓	✓
Critical revision of the article	✓	--
Final approval of article	✓	✓
Statistical analysis	--	✓

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