Effect of 12-Weeks Posterior Tibial Nerve Stimulation in Treatment of Overactive Bladder

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ABSTRACT

Objective: the aim of this study is to investigate the effect of posterior tibial nerve electrical stimulation (PTN) on urodynamic parameters and its effect in treatment of overactive bladder Subjects: Sixty patients were included in this study. Their ages ranged from 20-70 years (mean age 52.96 ±15.18). They were randomly allocated into two equal groups. Procedures: Group (A) received 12 weeks posterior tibial nerve electrical stimulation with frequency 1-10 HZ, pulse width 200 μHZ, intensity according to patient tolerance, duration of treatment 15 min 3 times /week for 12 weeks, while group (B) received pelvic floor exercises for 15 min 3 times/week for 12 weeks. Results: The result of this study revealed that, the bladder volume at first desire to void for group (A) as well as for group (B), showed no statistical significant difference. Bladder stability in group (A) showed a highly statistical significant improvement with a percentage 48.69% while for group (B) is not significant , by comparing both groups post-treatment, there was a statistical significant difference between groups with high percentage of improvement of the bladder stability in group (A) more than group (B). Maximum flow rate was significantly improved post-treatment for group (A) with a percentage of improvement 25.2% , as well as for group (B) with a percentage of improvement 12.37%, and by comparing both groups post treatment there was a statistical significant improvement in (A) group more than in group (B) Conclusion: The results demonstrated that, there is objective effect of PTNS on urodynamic parameters especially bladder stability, and maximum flow rate, also PTNS is effective to suppress detrusor over activity in patient with overactive bladder.

Key words: Posterior Tibial Nerve; Electrical stimulation; Overactive bladder; Urgency.

INTRODUCTION

Urinary incontinence and overactive bladder are common conditions in adult population, with impact on physical, psychological, and social well-being, and represent an important burden to the economy of health services [1].

Overactive bladder symptoms include urgency, frequency, nocturia and urge incontinence and are frequent complaints of patients attending urology and gynecology clinics. In many patients, the cause is idiopathic with no obvious underlying neurological abnormality. Patients with overactive bladder also suffer from sleep disturbance, psychological distress from embarrassment due to incontinence and disruption to social and work life. Quality of life scores (QOL) are consistently reduced in this group of patients [2].

Neuromodulation has been reported to be effective for the treatment of stress and urgency urinary incontinence. The cure and improvement rates of pelvic floor neuroodulation in urinary incontinence are 30–50% and 60–90% respectively pelvic floor exercise with adjunctive neuromodulation is the mainstay of conservative management for the treatment of stress incontinence. For urgency and mixed stress plus urgency incontinence, neuromodulation may, therefore, be the treatment of choice as an alternative

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to drug therapy it can offer improvement in patient quality of life [3]. Electrical stimulation therapy can be considered a passive physiotherapy there is a twofold action of electrical stimulation when applied to the pelvic floor: contraction of pelvic floor muscles and relaxation with inhibition of bladder overactivity[4].

Stimulation of the tibial nerve was first described as a neuromodulatory treatment option by McGuire *et a*l [5] by stimulating the tibial nerve near the medial malleolus. The tibial nerve contains fibres originating from the spinal roots L4–S3; from this site also arises the somatic and autonomic nervous supply of the pelvic floor. It is believed that through this crossover tibial nerve stimulation works. Transcutaneous stimulation progressed to percutaneous stimulation is known as posterior tibial nerve stimulation (PTNS) and was initially known as Stoller afferent nerve stimulation.Posterior tibial nerve stimulation appears to be an easy and less expensive way to reach satisfactory results[6].

PTNS is a minimally invasive neuromodulation system designed to deliver retrograde electrical stimulation to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve. The posterior tibial nerve contains mixed sensory and motor nerve fibers that originate from L4 through S3, which modulate the innervation to the bladder, urinary sphincter, and pelvic floor. The specific mechanism of action of neuromodulation is unclear. Theories include improved blood flow and change in neurochemical balance along the neurons. Neuromodulation may have a direct effect on the detrusor or a central effect on the micturition centers of the brain [7] .

Urodynamic detrusor overactivity (UDO) is currently defined by the International Continence Society (ICS) as a condition in which the bladder is shown to contract either spontaneously or with provocation to contraction during filling while the subject is attempting to inhibit micturition, Urodynamic investigations are a functional assessment of the lower urinary tract, the purpose being to try to reproduce the symptoms and obtain an objective explanation for the dysfunction.

MATERIALS AND METHODS

Sixty patients of both gender were included in this study. They had overactive bladder (urge incontinence) and were randomly selected from the department of urodynamics of the The National Institute of Urology and Nephrology between years 2008-2010. Their ages ranged from 20 to 70 years (mean age 52.96 ±15.18). Weight ranged between 60-93 kg with a mean of 74.4 ± 9.41 kg in Group A, while it ranged between 60-90 kg with a mean of 76.36 ± 7.7 kg in Group B.Height ranged between 156-179 cm with a mean of 166.68 ± 5.9 cm in group (A), while it ranged between 155-176 cm with a mean of 166.2 ± 6.15 cm in group (B).Comparison of age, weight, and height revealed no statistically significant differences (P>0.05) between the two studied groups.

Patient Criteria

Inclusion Criteria: Patient age was > 19 years old; patient had ≥ six month history of documented overactive bladder; patient had failed other conventional therapy; patient was free of mechanical urethral obstruction as documented by cystoscopy or pressure flow criteria; patient demonstrated an understanding of neuromodulation therapy, its benefits, and its potential risks; patient had normal functioning of the upper urinary tract, urgency/ frequency syndrome; a tem-day washout period prior to treatment had be completed.

Exclusion Criteria: Pregnant patients or those intendings to become pregnant during the course of the study. Patients becoming pregnant during the course of the study were to be immediately terminated from the study. Patient having an active urinary tract infection, patient having abnormal cystoscopy, which is concerning for or indicative of malignancy, patient having a urinary fistula, patient had a bladder stone, patient had ankle injury or surgery causing inability to stimulate the tibial nerve or discomfort in using the foot cradle, patient having metal implant from surgery or a metallic foreign body in either leg below (distal to) the knee, patient had cochlear implants, patient having a hyperreflexic neurogenic bladder or urodynamically proven instability secondary to a known neurourologic cause (i.e. stroke, parkinson's, multiple sclerosis), patient had uncontrolled diabetes, patient having diagnosed peripheral neuropathy such as diabetes with peripheral nerve involvement.

Complete physical examination and history was taken for all patients, including previous urological symptoms like frequency, urgency, nocturia, or incontinence. The physical examination included neurological assessment of perianal sensation, anal sphincter tone, and a brief screening for any neurological factors such as, Parkinson's disease, multiple sclerosis, stroke, or previous operations (mainly pelvic surgeries). Detailed analysis of the present overactive bladder symptoms was done. Medical history including current drugs especially diuretics, and anti-diabetic drugs was done. Urologic examination done by the staff of urology department of the National Institute of Urology and Nephrology, excluded genitourinary infection that might cause urinary incontinence. Laboratory investigations, mainly fasting and postprandial blood glucose, complete urine analysis were carried out to exclude diabetes mellitus, urinary tract infection as well as renal infection. Urodynamic studies had been by the staff of urodynamic unit, confirmed the diagnosis of overactive bladder and urgency.

The patients were randomly divided into two equal groups. Group A included thirty patients with overactive bladder (urge incontinence). They received posterior tibial nerve electrical stimulation of faradic type, biphasic continuous rectangular, with frequency of 0-10 Hz, pulse width 200 μHz, 15 minutes daily, three days/week, with maximum tolerable intensity, for 12 weeks, plus the routine pelvic floor exercise. Group B included thirty patients who received the routine physical therapy program of pelvic floor muscle through pelvic floor exercises 15 min three times a week for 12 weeks.

Electrical stimulation was delivered to the posterior tibial nerve via a combination of electrode and generator components, including a small 34-gauge needle electrode, surface electrode, lead wires, and hand held electrical generator. The low-voltage stimulator had adjustable pulse intensity according to patient tolerance, a fixed pulse width of 200 microseconds and a frequency of 10Hz. The device produces an adjustable electrical impulse that travels to the sacral nerve plexus via the tibial nerve.

Urodynamic investigation system was used to perform the urodynamic investigations, as voiding cystometry . It comprises of a trolley-mounted unit with integral printer and monitor, a mobile patient unit with built in H_2O and CO_2 pumps, a stand-mounted urofloobeen subjected to multichannel cystometry before starting the study and at the end of the study (after 12 weeks).

Measurement was done by urodynamic Evaluation System This procedure was performed by using the

DANTIC UD5000/500 urodynamic investigation system. The urodynamic studies are valid and reliable, by testing the multichannel cystometry.

The variables measured. (a) Initial desire to void which reveals bladder sensation, **(b)** Bladder stability (number of uninhibited detrusor contractility), and **(c)** Maximum flow rate.

RESULTS

The result of this study includes (1st) Results of 1st desire to void in both groups and between Groups, (2nd) Results of Stability in both groups and between groups and (3rd) Results of Maximum flow rate in both groups and between groups: The collected data presented as before (pre) and after 12 weeks of treatment application (post), that to determine role of PTNS in patients with overactive bladder (urgency).

(a) Results of Initial desire to void:

There was no statisticaly significant difference (P>0.05) in initial desire to void for both groups A and B, after 12 weeks (post) when compared with the corresponding mean value before initiation of treatment (pre), with a percentage of improvement of 8.64% and 0.88% for Group A and B respectively.

Comparative analysis of testing initial desire to void between groups. Un-paired t-test of initial desire to void at pre treatment for Group A and group B revealed no statistical by significant differences (p>0.05) of mean value of initial desire to void among both groups at the beginning of the study.

Comparative Analysis of initial desire to void at end of the study (Post-treatment): Un-paired t-test of initial desire to void after application of treatment (post) for both Groups A and group B, revealed no statistical by significant differences (p>0.05) of mean value of initial desire to void among both groups after application of treatment.

(b) Results of stability

For Group A: The statistical analysis of the mean differences of stability by Wilcoxon matched pairs signed ranks test at pre and post treatment of electrical stimulation group revealed that there was a highly statistical by significant difference (<0.05) in stability post of treatment of PTN electrical stimulation group when compared with the corresponding mean value before initiation of treatment, with a percentage of improvement of 48.69% post treatment of electrical stimulation group.

For Group B: The statistical analysis of the mean differences of stability by Wilcoxon matched pairs signed ranks test at pre and post treatment of exercise group revealed the following results: There was no statistical by significant difference (P>0.05) in stability, post treatment of exercise group when compared with the corresponding mean value before initiation of treatment, with a percentage of improvement of 4.25% post treatment of exercise group.

Comparative analysis of testing stability between groups Pre and Post treatment

Pre-treatment: Mann-Whitney test of stability at pre treatment for PTN electrical stimulation group (Group A) and exercise group (Group B) revealed no statistical by significant differences (p>0.05) of mean value of stability among both groups at entry of the study.

Post-treatment: the statistical analysis of the mean differences of stability by Wilcoxon matched pairs signed ranks test at pre-treatment and after application of treatment (Post) of exercise group revealed the following results: There was no statistical significant difference (P>0.05) in stability, after application of treatment (Post) of exercise group when compared with the corresponding mean value before initiation of treatment (Pre). with a percentage of improvement of 4.25% after application of treatment (Post) of exercise group.

Table 1. Comparative analysis of the mean value of stability among Electrical stimulation group (Group A) and Exercise group (Group B) after application of treatment (Post)

Statistics	Stability after application of treatment	
	Electrical stimulation group (A)	Exercise group (B)
Mean	1.933	1.633
Standard Deviation	0.254	0.49
Mann-Whitney U-value	315	
Probability value	0.0411	

Table 2. The statistical analysis of mean differences of maximum flow rate before initiation of treatment (Pre) and after application of treatment (Post) of Electrical stimulation group (Group A)

Statistics	Maximum flow rate	
	Pre	**Post**
Mean	**12.51**	**15.663**
Standard Deviation	**6.263**	**3.861**
Mean Difference	**3.153**	
Paired t-value	**3.277**	
Probability value	**0.0027**	
Significance	**Significant**	
Percent of Change	**25.2 %**	

Table 3. Comparative analysis of the mean value of maximum flow rate among Electrical stimulation group (Group A) and Exercise group (Group B) after application of treatment (Post)

Statistics	Maximum flow rate after application of treatment	
	Electrical stimulation group (A)	Exercise group (B)
Mean	15.663	12.807
Standard Deviation	3.861	4.693
Un-Paired t-value	2.575	
Probability value	0.0126	
Significance	**Significant**	

(c) Results of Maximum flow rate

1-Results of maximum flow rate for group (A): As observed in Table 2. There was statistical significant difference (<0.05) in maximum flow rate, post

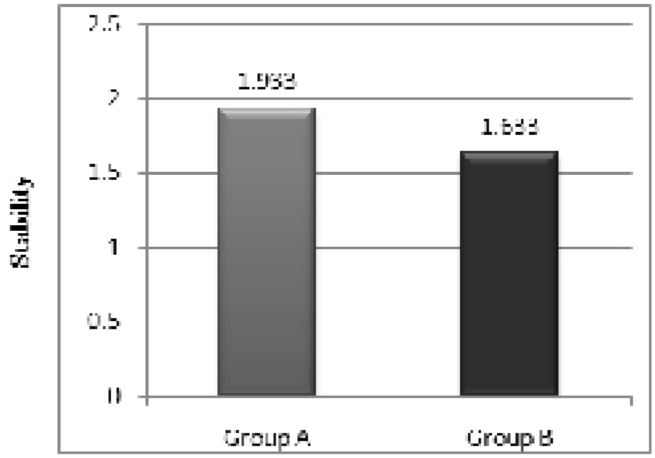

Figure (1): The mean values of stability after treatment (Post) for PTN Electrical stimulation group and Exercise group.

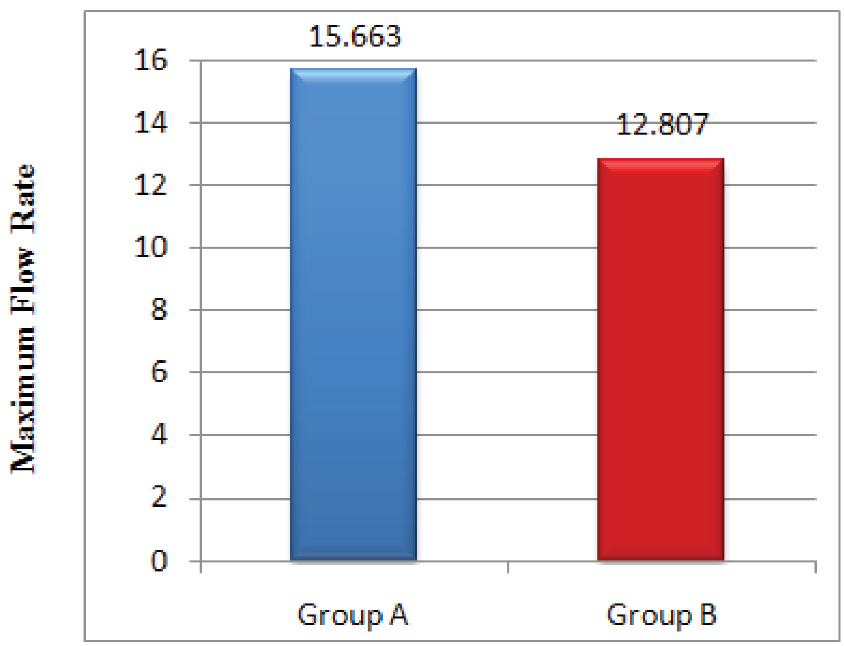

Figure (2): The mean values of maximum flow rate after treatment (Post) for Electrical stimulation group and Exercise group.

treatment of electrical stimulation group when compared with the corresponding mean value before initiation of treatment (pre), with a percentage of improvement of 25.2% post treatment of electrical stimulation group.

For Group B: There was statistical by significant difference (<0.05) in maximum flow rate, post treatment of exercise group when compared with the corresponding mean value before initiation of treatment (pre), with a percentage of improvement of 12.37% post treatment of exercise group.

Comparative analysis of testing maximum flow rate between groups pre and post treatment:

Pre-treatment: Un-paired t-test of maximum flow rate at pre treatment for electrical stimulation group (Group A) and exercise group (Group B) revealed no statistical by significant differences (p>0.05) of mean value of maximum flow rate among both groups at entry of the study.

Post-treatment: As observed in table 3 and figure 2, un-paired t-test of maximum flow rate post treatment for electrical stimulation group (Group A) and exercise group (Group B) revealed statisticaly significant differences (p<0.05) of mean value of maximum flow rate among both groups post treatment.

DISCUSSION

Electrical stimulation of the posterior tibial nerve with needle electrodes demonstrates suppression of detrusor contraction in patients with overactive bladder. Posterior tibial nerve electrical stimulation was chosen as the physiotherapeutic method because it is an interesting alternative for the treatment of overactive bladder, which is effective and without sideffects, despite the fact that pharmacological treatment is currently the first option for the treatment of patients with clinical symptoms of overactive bladder, but adherence to treatment is low, especially due to side effects which lead to discontinuation in 60% of cases. Posterior tibial nerve electrical stimulation is considered to be a simpler, less invasive, and easy to apply form of peripheral sacral stimulation that is well tolerated by patients and more affordable [8].

Posterior tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation for the treatment of voiding dysfunction in patients who have failed behavioral and/or pharmacologic therapies. Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention. Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. While the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-S3) which control the bladder detrusor and perineal floor [9].

PTNS offers a nondestructive alternative for patients with urge incontinence caused by over active bladder that is refractory to conservative treatment modalities. Detrusor overactivity inhibition is achieved by acute electrical stimulation of afferent somatic sacral nerve fibers by PTNS; the rational of treatment is based on the existence of spinal inhibitory systems that are capable of interrupting detrusor contraction [7]. The aim of this treatment modality is to achieve detrusor inhibition by electrical stimulation of somatic nerve fibers by means of PTNS.

One study used peripheral tibial nerve stimulation on urodynamic findings in patients with Parkinson's disease. The study group had storage issues, overactive bladder, and involuntary detrusor contraction. The results showed significant improvement in patient's symptoms [10]. In a prospective observational study, the efficacy of a tibial nerve stimulation device in patients with overactive bladder unresponsive to pharmacotherapy, fielded initial success rate was 54%, with improvements seen in voiding diary parameters, urodynamic parameters and quality of life scores [11].

In groups of 90 patients with overactive bladder, the result revealed that PTNS delayed onset of detrusor instability [DI] but could not abolish it [12]. Additional studies assessed patients treated with PTNS and concluded that PTNS is an effective, minimally invasive procedure to treat urge incontinence and idiopathic voiding dysfunction [13, 14, 15].

A study compared outcomes between patients treated with the percutaneous Stoller Afferent Nerve Stimulator (SANS) alone and patients that received both SANS plus a low dose of antichoinergic medication. All patients underwent 60 minutes of SANS treatment once a week for a total of eight weeks. The treatment response rate was 61.6% in the SANS group and 83.2% in the SANS plus medication group. The researchers noted that the best symptomatic improvements were seen in patients with urge incontinence [16].There is little difference in outcomes in incontinent patients randomly assigned to PTNS weekly Group 1 versus three times per week Group 2. The result showed 63% and 45% were completely cured after treatment for Group 1 and 2 respectively [17]. In our study we use 1-10 Hz pulse rate which did not lead to fatigue contraction of the leg muscles.

Our results were supported by the following: the beneficial effect of acupuncture on symptoms such as urgency, frequency, and dysuria has been proved by different studies which compare the action on the S6 (posterior border of the tibia, 5cm above the tibial medial malleolus). It is traditionally known for its effectiveness in treatment of lower urinary tract dysfunction. With use of the technique in other parts of the body no symptoms relief has been obtained [18].

PTNS produce improvement in bladder instability, voiding frequency and bladder capacity by urodynamics evidence [19]. PTNS in patients with over active bladder symptoms (urgency ,frequency) had a good results and urodynamics parameters were improved after treatment and showed statistically significant decrease in leakage episodes ,frequency and nocturea [5, 20, 21, 22] .

Objective results based on frequency volume charts, voiding volume, number of leakage episodes, incontinence severity, number of pads used, and quality of life was reported after application of PTNS [23, 24, 25, 19, 26].

PTNS has proving to be effective and well tolerated in adults and produced modification in urodynamic pattern in patients with non-neurogenic bladder dysfunction [27,28].There was an objective effect of PTNS on urodynamic parameters (significant improvement in maximum cyctometric capacity and involuntary detrusor contraction, and this improved bladder overactivity is an encouraging argument favouring PTNS as a non invasive treatment in clinical practice [29] .

The results of a single case study concluded that PTNS increased cyctometric capacity in spinal cord injury patients but detrusal overactivity was not found to recur immediately after stimulation was stopped. In another study of 37 patients there was significant increase in bladder volume at first involuntary detrusor contraction together with bladder maximum cyctometric capacity [30].

Peripheral nerve stimulation produces a statisticaly significant improvement in lower urinary tract symptomse specially day time and night time voiding frequency and volume,leakage episodes [31,21]. A study that include 23 children suffering from un responsive lower urinary tract symptoms revealed that PTNS produced improvement of overactivity symptoms and normalized the bladder cyctometric capacity, detrusor pressure at maximum flow rate and maximum flow rate [32] .

PTNS is a minimally invasive technique that is effective to suppress detrusor overactivity, and improve bladder cyctometric capacity [7]. PTNS has a subjective efficacy of 63–64% and an objective efficacy of 46–54% in a non-neurogenic patient with overactive bladder [6].

Percutaneous tibial nerve stimulation is reliable and effective for non-neurogenic, refractory lower urinary tract dysfunction in children. Efficacy seems better in dysfunctional voiding than in overactive bladder cases. There is evidence that percutaneous tibial nerve stimulation should be part of the pediatric urology when treating functional incontinence [33].

Our results were not supported by the following: In patients with interstitial cystitis PTNS had no significant clinical effect; it may give some response but lesser than through sacral root itself [34] .

PTNS had no effect or failed to suppress detrusor contraction in neurological detrusal overactivity patients, but the bladder volume during the first contraction and cyctometric bladder capacity was increased [35] .

Author study included ten women and five men (mean age, 60 years) with chronic pelvic pain and urinary symptoms who had failed other therapies. After 12 weekly PTNS treatments, mean of visual analogue scale score for urgency changed from 4.5 ± 1.0 at baseline to 2.7 ± 0.7 ($P < 0.05$).Mean visual analogue score for pain decreased from 8.1± 0.2 at baseline to 4.1 ± 0.6 after 12 weeks of treatment($P < 0.01$). They found no statistically significant changes in the number of voids or bladder volume from baseline after treatment [36].

CONCLUSION

This study has demonstrated that PTNS, which is a minimally invasive technique, is effective to suppress detrusor overactivity. Also, demonstrated objective effect of PTNS especially bladder stability, maximum flow rate, improved urodynamic parameters with PTNS, which is observed in this study, is an encouraging finding that further supports its use as an effective treatment modality in the clinical practice of detrusor overactivity. No serious adverse events or sideffects were observed during or after treatments, so posterior tibial nerve electrical stimulation is a new trend in the treatment of overactive bladder and urgency.

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