Posterior tibial nerve electrical stimulation versus biofeedback on non-neurogenic detrusor over activity
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ABSTRACT

The purpose of this study was to compare the effects of posterior tibial nerve electrical stimulation versus biofeedback on non-neurogenic detrusor over activity. Thirty patients with overactive bladder (urge incontinence) participated in this study. Their age ranged from 25 to 40 years. Patients were randomly divided into two groups of equal number; Group (A): received posterior tibial nerve electrical stimulation of pulse width at 200 μs, with frequency of 20 Hz, with maximum tolerable intensity. The duration of each session 30 minutes, three days weekly, for 12 weeks. Group (B): received biofeedback for 30 min, three days weekly, for 12 weeks. All patients were assessed before and after the treatment course (36 sessions) according to the urodynamic parameters. These parameters are voided urine volume, residual urine volume and bladder stability. Results of this study revealed that, regarding voided urine volume, Group A showed significant increase compared to the Group B (p<0.05), while there was no significant differences in residual urine volume between both groups at different measuring periods (p>0.05), while there were significant reduction in bladder instability in favor of group A. On conclusion, both posterior tibial nerve electrical stimulation and biofeedback are effective in management of non-neurogenic detrusor over activity. However, posterior tibial nerve electrical stimulation seems to be more effective.

KEY WORDS: Posterior Tibial Nerve, Electrical Stimulation, Overactive bladder, Biofeedback, Urodynamic Parameters.

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INTRODUCTION

Detrusor over activity (DO) is the most common voiding dysfunction, which is also known as Overactive bladder (OAB), urge syndrome, hyperactive bladder syndrome, detrusor hyperreflexia, detrusor instability and detrusor hyperreflexia. OAB is a sudden involuntary contraction of the muscular wall of the bladder causing urinary urgency; an immediate unstoppable urge to urinate which is characterized by a group of four symptoms: urgency, urinary frequency, nocturia, and urge incontinence. DO can affects life socially, emotionally and behaviorally, and it will impact the everyday life of the Family. DO may lead to social isolation, depression, disturbed sleep, and impaired domestic and sexual function. It is comprised of a group of four symptoms: urgency, urinary frequency, nocturia, and urge incontinence. DO has been reported in both males and females, but it is more common in females. The frequent feeling of urgency may occur during the day, at night, or both. More than 40% of people with overactive bladder have incontinence, while about 40% to 70% of urinary incontinence is due to overactive bladder. Most people with the condition have problems for years.

Treatment of OAB is aimed at reducing the debilitating symptoms in order to improve the quality of life in affected patients. Anticholinergic therapy is the first therapeutic line of treatment for OAB because it reduces the contractility of the detrusor muscle. However, certain adverse effects limit the use of anticholinergic drugs, particularly dry mouth and constipation. Behavioral therapy focusing on dietary and lifestyle modifications (fluid restriction, avoidance of caffeine), bladder retraining and pelvic floor muscle exercises and electrical stimulation. 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. PTNS is a minimally invasive technique that is effective to suppress detrusor over activity and also improve bladder cystometric capacity.

Biofeedback pelvic floor muscle training has been widely used in treatment of stress urinary incontinence, idiopathic detrusor over activity, learned dysfunctional voiding and chronic pelvic pain. Only limited data has been reported on this treatment of overactive bladder (OAB) and voiding dysfunction in adults. Using PTNS and Biofeedback were found to have a great outcome in decreasing frequency, urgency, frequency of nocturia and improvement in quality of life. The present study was carried out to determine the effectiveness of posterior tibial nerve electrical stimulation (PTNES) versus biofeedback on non-neurogenic detrusor over activity.

MATERIALS AND METHODS

Subjects

This study was carried out on 30 patients (4 males and 26 females) with overactive bladder (urge incontinence). They were referred from urodynamics department by gynecologists or urologists after medical examinations and confirmation of their diagnosis. None of them received medical treatment regarding their urge incontinence during the study course. Exclusion criteria were infections, neurological problems, pelvic tumor, cardiac pacemakers, pelvic-abdominal surgeries, diabetes and history of low back pain. All patients were given a full explanation of the treatment protocol and they signed an informed consent at the beginning of the study. The patient's age ranged from 25 to 40 years. They were randomly divided into two groups of equal number; Group (A): received posterior tibial nerve electrical stimulation of pulse width at 200 μs, with frequency of 20 Hz and with maximum tolerable intensity. The duration of each session 30 minutes, three days weekly, for 12 weeks. Group (B): received biofeedback for 30 min, three days weekly, for 12 weeks also. All patients were assessed before and after the treatment course (36 sessions) according to the urodynamic parameters. These parameters are cystometric capacity and bladder stability.

Equipment

DANTIC UD5000/5500 Urodynamic Investigation System was used to perform multichannel cystometry. It is comprised of a trolley-mounted unit with integral printer and monitor; a mobile patient unit with built in H20 and CO2 pumps, a stand-mounted uroflow transducer and a stand-mounted puller mechanism. Measurements have been performed by the staff of urodynamic unit. All patients had been subjected to multichannel cystometry before starting the study and after 12 weeks. The urodynamic studies are valid and reliable. The variables measured were bladder stability (number of uninhibited detrusor contractions), voided urine volume and residual urine volume.

Chattanooga Vectra Neo 6000 was used to provide biofeedback PFMT and posterior tibial nerve stimulation. It was used for strengthening the pelvic floor musculature and inhibiting the involuntary detrusor muscle contraction.

Evaluation procedure

Patient's history was taken to be sure about inclusion and exclusion criteria of the participants. Urological examination was done to exclude any urinary tract infection that may cause the urinary incontinence. Finally, urodynamic evaluation was done to confirm the diagnosis of the idiopathic detrusor instability. This was done through measuring external urethral sphincter electromyography (EMG) and cystometry. The variables measured were bladder stability, voided urine volume and residual urine volume.

Measurement technique by Cystometry

A cystometric test measures how much urine the bladder can hold, how much pressure builds up inside the bladder as it stores urine, and how full the bladder when the urge to urinate begins. Patients had been instructed to empty the bladder as completely as possible before the test. Patients assumed on the examination couch the crotch lying position. Catherization with a single lumen catheter had been applied using a sterile technique and the Y-piece mounted on the catheter. One prong was connected with the manometer connecting tube and the
other had been applied via a damping tube to the infusion pump. Rectal balloon catheter inserted to record intra-abdominal pressure and the system had been emptied from air. Infusion of 37 oC warm, sterile normal saline (at a medium rate of 50 ml/min) filling of the bladder and recording had been started. The patient had been asked to cough as a provocative test for detrusor instability and he was instructed to void to measure the cystometric capacity. From the cystometrogram the following measurements had been recorded:

Storage phase: is the passive or filling phase of cystometry during which the bladder had been filled at a filling rate of about 50 ml/min, and it explains the relationships between levels of infused volumes, detrusor pressures, and the bladder compliance.

Voiding phase: is the active phase during which the patient had been instructed to void and it detects the following: the voiding time, the flow time, the maximum flow rate, and the detrusor pressure at maximum flow rate& detrusor contractility

Treatment Procedures

Before starting the treatment sessions, patients were asked to evacuate their bladders. All subjects in both groups were instructed briefly and clearly about the PTNS or biofeedback. All subjects received an orientation on how to train their pelvic floor muscles in order to maintain their confidence and cooperation. Sterilization procedures for patients and the equipment used were followed. In either group, the session lasted for 30 minutes and 3 times per week. The treatment duration in both groups was 12 weeks.

Procedure for group A (PTNS)

With the patients sitting in a frog leg position, a sensitive pressure point was identified approximately three-finger breadth cephalad-medially from the medial malleolus. This point was about one finger breadth posterior from the edge of the tibia. Two surface electrodes were applied. The first electrode is placed 2 cm posterior to the medial malleolus in the foot, with the second being 2 cm above the first. Placement of the electrodes was confirmed with the great toe flexion and or fanning of planter toe flexion of ipsilateral digits 2 through 5. Parameters set as following with the frequency of 20 Hz, pulse width at 200 μs for 30 min. Intensity was increased progressively until the response was achieved in the form of flexor muscle contraction of the first toe, fanning of all toes, or tingling sensation in the sole. The voltage remained at one point below the stimulus that generated the muscular contraction. Patients had to experience a tolerable but not painful sensation.

Procedure for group B (Biofeedback PFMT)

In a crock lying position, the vaginal/anal probe was completely inserted inside the vagina/anus after the lead wire was connected to the biofeedback unit. All patients where identified of the pelvic floor muscles and the awareness of correct contraction of the muscles. They were advised to avoid any known bladder stimulants and to increase daily water intake. Patients were trained to contract their pelvic floor muscles when the orders appear on the screen and to relax pelvic floor muscles in the intervals between each contraction. Visual feedback is monitored on the screen so every patient can notice his/her progress and correct contraction. Patients were asked to contract, hold for 10 seconds and relax for 10 seconds. For more strengthening for the PFM, they were asked to increase the time of contraction.

Statistical Analysis

All statistical measures were performed using the (SPSS) program. Prior to final analysis, data were screened for normality assumption, and presence of extreme scores. This exploration was done as a prerequisite for parametric calculation of the analysis of difference and analysis of relationship measures. Age and sex variables were compared using independent t tests. The current test involved two independent variables. The first one was the tested group, which had two levels; group (A) and group (B). The second one was the training periods, which had two levels (pre treatment and post treatment tests). As the tested variables were bladder stability, voided urine volume and residual urine volume. The two dependent variables were voided urine volume and residual urine volume. Accordingly, 2×2 Mixed design MANOVA was used to compare the tested variables of interest at different tested groups and measuring periods. MANOVA was conducted with the initial alpha level set at 0.05. Chi square was used to compare the detrusor instability at different tested groups and measuring periods.

Results

Data concerning the patients' demographic data (age, sex) as well as clinical characteristics (voided urine volume, residual urine volume and bladder instability) had been collected at the beginning of the study. Follow up evaluation of clinical characteristics had been performed after 12 weeks of treatment.

Demographic and clinical characteristics of the patients:

As shown in table (1), there were no statistical significant differences (P>0.05) observed between both groups concerning general characteristics (age, sex).
Table 1: Descriptive statistics and unpaired t-tests for the mean age of the patients with OAB for both groups.

<table>
<thead>
<tr>
<th>Items</th>
<th>Group A</th>
<th>Group B</th>
<th>Comparison</th>
<th>Level of significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>Mean ± SD: 36.86±4.24</td>
<td>Mean ± SD: 34.33±4.83</td>
<td>t-value: 0.325</td>
<td>P-value: 0.747</td>
</tr>
</tbody>
</table>

*SD: standard deviation, P: probability, S: significance, NS: non-significant.

Table 2: Descriptive statistics and multiple pairwise comparison tests (Post hoc tests) for the voided urine volume, residual urine volume in patients with OAB in pre treatment and post treatment tests for both groups.

<table>
<thead>
<tr>
<th>Dependent variables</th>
<th>Group A (N=15)</th>
<th>Group B (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre treatment</td>
<td>Post treatment</td>
</tr>
<tr>
<td></td>
<td>Pre treatment</td>
<td>Post treatment</td>
</tr>
<tr>
<td>Voided urine volume</td>
<td>359.46±160.036</td>
<td>390.86±130.00</td>
</tr>
<tr>
<td>Residual urine volume</td>
<td>41.53±13.51</td>
<td>33.06±6.93</td>
</tr>
</tbody>
</table>

Table (3): Multiple pairwise comparisons between pre treatment and post treatment tests values for all dependent variables

<table>
<thead>
<tr>
<th>Dependent variables</th>
<th>Voided urine volume</th>
<th>Residual urine volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>0.002*</td>
<td>0.0001*</td>
</tr>
<tr>
<td>Group B</td>
<td>0.01*</td>
<td>0.0001*</td>
</tr>
</tbody>
</table>

Multiple pairwise comparisons between group A and group B for all dependent variables

<table>
<thead>
<tr>
<th>Pre treatment test</th>
<th>Voided urine volume</th>
<th>Residual urine volume</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.13</td>
<td>0.618</td>
</tr>
<tr>
<td>Post treatment test</td>
<td>0.04*</td>
<td>0.454</td>
</tr>
</tbody>
</table>

*Significant at the alpha level (p < 0.05).

Table (4): Descriptive statistics and Chi square tests of the detrusor instability for each group at pre and post treatment.

<table>
<thead>
<tr>
<th>Detrusor instability</th>
<th>Frequency distribution</th>
<th>Group A</th>
<th>Group B</th>
<th>Group A vs. group B</th>
<th>Pre treatment</th>
<th>Post treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Unstable</td>
<td>Stable</td>
<td>Unstable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre treatment</td>
<td>15 (100%)</td>
<td>0 (0%)</td>
<td></td>
<td>15 (100%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Post treatment</td>
<td>2 (13.3%)</td>
<td>13 (86.7%)</td>
<td>6 (40%)</td>
<td>9 (60%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>X^2-value</th>
<th>P -value</th>
<th></th>
<th>Pre treatment</th>
<th>Post treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.000</td>
<td>1.00</td>
<td></td>
<td>24</td>
<td>0.0001*</td>
</tr>
</tbody>
</table>

*Significant at alpha level <0.05.

**Voided urine volume, Residual urine volume:**
Statistical analysis revealed that there were no significant between subject effect (F = 2.591, p = 0.093) and group*time effect (F = 0.208, p = 0.813) but there were significant within subject effect (F= 34.06, p = 0.0001). Table (2) represents the mean ± SD and multiple pairwise comparisons for all dependent variables in both groups in different measuring periods. Multiple pairwise comparison tests revealed that there were significant increase of voided urine volume at post treatment measure in compare to pre treatment measure at the both groups (P < 0.05). While there were significant reduction of residual urine volume at
post treatment measure in compare to pre treatment measure in the both groups (p < 0.05).

Regarding between subject effects, multiple pairwise comparisons revealed that there were significant increase of in voided urine volume at post treatment test in group A in compare to group B (p < 0.05), with no significant differences in residual urine volume between both groups at different measuring period (p > 0.05). Table (3).

**Detrusor instability**

As shown in table (4), the effect of the tested group (first independent variable) on the detrusor instability by using Chi square revealed that the frequency distribution of the detrusor instability of the "pre treatment" between both groups revealed that there was no significant difference (X² = 0.000 and p = 1.00).

While, Chi square revealed that the frequency distribution of the detrusor instability of the "post treatment" between both groups showed that there was significant difference (X²= 24 and p = 0.0001*) and this significant reduction in detrusor instability in favor of group A.

**DISCUSSION**

Overactive bladder has a detrimental effect on quality of life; in most domains (physical functioning, social functioning, vitality, role limitations). The main goal of treating overactive bladder is to inhibit detrusor over activity and hence, to increase functional bladder capacity. Few studies have explored the effects of electrical stimulation on urodynamic parameters and these studies presented evidence that it causes improvements. Posterior tibial nerve electrical stimulation (PTNS) was chosen as the physiotherapeutic method because it is an interesting alternative for the treatment of OAB, which is effective and with no side effects, despite the fact that pharmacological treatment is currently the first option for the treatment of patient with clinical symptoms of overactive bladder, adherence to treatment is low, especially due to side effects which lead to discontiruation 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. Biofeedback PFMT can change the contractile and relaxation properties of the skeletal muscles through repeated exercise. Regular PFMT can strengthen the pelvic floor muscles and treat urge incontinence. The results of the study demonstrated that with a proper training program, patients with OAB or voiding dysfunction could achieve improvement in symptoms. The severity of frequency urgency symptoms can be reduced, and the cystometric capacity, bladder stability can be increased.

PTNS is an interesting alternative for the treatment of over active bladder, which is effective and without side effects. Furthermore, PTNS had good results with a significant improvement in maximum cystometric capacity and significant decrease in leakage episodes, frequency and nocturia.

These results were in agreement with Dmochowski and Gomelsky, who stated that percutaneous tibial nerve stimulation continues to display superiority to sham treatment and benefits similar to antimuscarinic therapy may be observed. This therapy is well tolerated and durable outcomes have been seen at 12 months of follow-up.

Wooldridge reported that a course of 12 PTNS sessions was prescribed and administered in the context of an independent community-based, nurse practitioner-led continence practice. The results of this analysis indicated that patients treated with PTNS therapy experienced statistically significant decreases in both day and night voids, and in episodes of urge incontinence. This study confirmed the results of previous studies indicating that PTNS therapy is a safe and effective treatment that can be successfully incorporated in a community-based setting.
Coyne, et al., concluded that posterior tibial nerve electrical stimulation was an effective, safe and noninvasive treatment that significantly improved the OAB symptoms and quality of life of the patients. Matzel et al., found that the improvement rate in stress incontinent patients was 66%, while it was 72% in patients with detrusor instability after applying electrical stimulation, and detrusor instability became stable in 89% of men with detrusor instability. In the disagreement with the results of the present study Zhao and Nordling demonstrated that PTNS in patients with interstitial cystitis had no significant clinical effect and it may give some response but less than through sacral root itself.

**Declaration of interest:** The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

**REFERENCES**


Fjorback et al., reported that PTNS had no effect or failed to suppress detrusor contraction on neurological detrusal over activity patients but the bladder volume during the first contraction and cystometric bladder capacity was increase.

On conclusion, posterior tibial nerve is considered an effective method compared to biofeedback in the treatment of non-neurogenic detrusor over activity.