INFLUENCE OF POSTERIOR TIBIAL NERVE STIMULATION ON BLADDER FUNCTIONS IN DIABETIC PATIENTS WITH NEUROPATHIC MANIFESTATIONS

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ABSTRACT

Background: Peripheral neuropathy is a commonly reported complication of diabetes mellitus (Types I and II). Urological manifestations of autonomic neuropathy include, most often, diabetic bladder dysfunction (DBD).

Purpose: This randomised controlled trial study examines how posterior tibial nerve stimulation (PTNS) may influence bladder functions in patients with diabetic neuropathy.

Methods: Forty diabetic patients with polyneuropathy (males= 14 and females 26) whose ages ranged from 40 to 60 years participated in the present study. The history of urological complications could be traced back to five years or more. The participants were randomly assigned into Group A (Control Group) and Group B (Study Group). Group A received exercise for the pelvic musculature only, while Group B received the same design programme and PTNS. The scheduled sessions for both groups were three times weekly. The duration of the therapeutic interventions was six successive weeks. All patients were assessed by overactive bladder symptom score (OABSS).

Results: The findings suggested that there was a remarkable improvement in treating DBD as indicated by the improved OABSS for both groups. However, there was a significant post-therapeutic decrease in value of OABSS of Group B compared with that of Group A.

Conclusion: Adding PTNS to physical therapy exercise programmes has improved DBD in patients with diabetic polyneuropathy.

Keywords: Diabetic neuropathy, overactive bladder, posterior tibial nerve, overactive bladder symptom score.

I. INTRODUCTION

Diabetic neuropathy (DN) is a common neuropathy frequently observed in developed countries afflicting approximately 50% of patients with diabetes mellitus (DM). This complication aggravated the morbidity and mortality of uncontrolled DM and influenced life satisfaction and well-being for chronic patients (1). The prevalence of DN varies across reported case studies given the inconsistency of the inclusion criteria as well as the diverse operational definitions each study uses (2). Overactive bladder (OAB) and DM are serious health hazards that are encountered more often in geriatric populations. It was demonstrated that OAB is more frequent in diabetic patients (Type II) than their healthy peers (3).
Male patients (older than 45 years) with early-onset or chronic DM (Type II) encounter OAB symptoms and erectile dysfunction remarkably (4). Both sacral nerve stimulation and percutaneous tibial nerve stimulation (PTNS) approaches are second-line treatment modalities aiming to neuromodulate refractory OAB. Because of the minimally invasive nature and ease of applicability of this therapeutic intervention, neuromodulation is widely applauded, especially for sparing the patients squirming with embarrassment at exposing their genitals, commonly avoided with other treatment modalities (5).

II. METHODS

This randomised clinical trial study was performed in El- Sahel teaching hospital from July 2020 to April 2021 and was approved by the ethical committee of Cairo University. The enrolled participants were forty diabetic patients with polyneuropathy (males= 14 and females 26) whose ages ranged from 40 to 60 years. The participants were randomly assigned into Group A (Control Group) and Group B (Study Group).

Group A received pelvic floor exercise only,

Group B received the same design programme and PTNS.

The scheduled sessions for both groups were three times weekly. The duration of the therapeutic interventions was six successive weeks. All patients were assessed by OAB symptom score (OABSS).

Instrument for evaluation

The OABSS is a questionnaire designed to assess symptoms of OAB and computer an overall score. The questionnaire lists four questions on OAB symptoms with a score range as follows: that frequent urination at daytime scores 0–2, night-time urination scores 0–3, urgency urination score 0–5, and urgency incontinence scores 0–5.

III. INSTRUMENT FOR TREATMENT

Electrical stimulation device

Sonopuls-692 device (Enraf Nonius), manufactured in the Netherlands, is a complete unit for pain management and nerve stimulation. This device was used in this study for the application of PTNS. Sonopuls-692 provides 30 adjustable and rewritable pre-programmed suggestions for treatment. To induce the therapeutic effect, the generated electrical impulse transmits to the sacral nerve plexus through the main trunk of the tibial nerve.

Procedures

I) Evaluation

One evaluation procedure was done pre- and post-treatment after six weeks of treatment.

Overactive bladder symptom score (OABSS):

The overall score of OABSS is calculated. These symptoms correspond to the timing of the urinary condition during the past week. Patients were instructed to circle the score that best applies to their urinary condition so that frequent urination at daytime scores 0–2, night-time s urination cores 0–3, urgency urination score 0–5, and urgency incontinence scores 0–5. The maximal score, corresponding to the utmost severity, is 15.

II) Treatment plans

The patients were subdivided evenly into Group A and Group B (Study group). The scheduled sessions for both groups were three times weekly. The duration of the therapeutic interventions was six successive weeks.

Group A received pelvic floor exercise only, consisting of Kegel exercises, Bridging exercises and Squatting exercises. For performing Kegel exercises, bi-digital application of fingers was indicated. All cases were requested to contract the anal sphincter muscles around the therapist’s finger in the rectum. Meanwhile, the therapist placed the other hand on the lower abdomen for checking any inappropriate abdominal muscle contraction.
The bridging exercise required patients to take a supine position, bend the knees and displace the feet flat on the floor at approximately a hip-width distance. The patient’s arms were instructed to fall to the sides with downward palms. At last, the patients were requested to contract the pelvic musculature to lift the buttocks a few inches off the ground.

To do the squatting exercises, the patients should stand with the feet hip-width apart, flat on the floor, and bend at the knee to touch the floor, as low as it would be convenient and attainable. However, the spine was kept almost in a straight position, except for a slight forward-leaning. Emphasis was placed on tightening the buttocks and pelvis during the returning to standing position.

Strengthening exercises focused on recruiting the maximal muscle fibers by maintaining the contraction at an optimum hold. The initial contraction lasted for 5-10 seconds before resting for 10-20 seconds. The exercises were repeated 12-20 times. In contrast, endurance exercise aimed to maintain muscle contraction at 65-75% of its maximum strength. Therefore, the hold time was 20-30 seconds with an exact rest time. The exercises were repeated 8-10 times.

**Group B received the same design programme and PTNS.**

The PTNS was performed with a Sonopuls-692 (Enraf Nonius). Two adhesive electrodes were positioned nearly five centimeters above the medial malleolus, behind the medial tibial edge, and connected to the stimulator. Electrical stimulation was then applied by using charge-compensated 200-second pulses with a 10-Hertz pulse rate. The amplitude was toned to match the patient’s discomfort threshold. The duration of the therapeutic session was 20 minutes.

**Statistical Analysis**

The independent samples *t*-test was conducted to compare the two groups Chi-squared test was calculated for comparing sex distribution between groups. OABSS were compared between groups using Mann–Whitney U test and between pre-and post-treatment in each group. The statistical difference of the p-value corresponding to each statistical test was considered significant at p < 0.05. The statistical package for social studies (SPSS) v. 25 (IBM SPSS, Chicago, USA) was used for calculating all the indicated tests.

**IV. RESULTS**

**Subject characteristics:**

Table 1 demonstrated the descriptive statistics for the participants in groups A and B as regards age, weight, height, BMI and sex (P > 0.05).

<table>
<thead>
<tr>
<th></th>
<th>Mean±SD</th>
<th>Mean Difference</th>
<th>t-value</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (year)</td>
<td>52.8 ± 6.27</td>
<td>54.85 ± 4.64</td>
<td>-2.05</td>
<td>-1.17</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>79.85 ± 9.87</td>
<td>78.65 ± 10.05</td>
<td>1.2</td>
<td>0.38</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>164.15 ± 7.04</td>
<td>163.95 ± 8.72</td>
<td>0.2</td>
<td>0.08</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.63 ± 3.52</td>
<td>29.26 ± 3.21</td>
<td>0.37</td>
<td>0.34</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>12 (60%)</td>
<td>14 (70%)</td>
<td></td>
<td>(χ² = 0.43)</td>
</tr>
<tr>
<td>Males</td>
<td>8 (40%)</td>
<td>6 (30%)</td>
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Effect of treatment on OABSS

- **Within-group comparison**

There was a significant decrease in OABSS in both groups A and B more than pre-treatment (p < 0.05)
- Between groups comparison:
The difference in OABSS between groups pre-treatment was not significant (p > 0.05). Comparing post-treatment groups showed a significant decrease in OABSS (p < 0.05). Table 2 illustrates the statistical analysis for both comparisons.

Table 2. Measures of OABSS pre and post-treatment for the studied groups

<table>
<thead>
<tr>
<th></th>
<th>Interquartile range</th>
<th>U-value</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td></td>
</tr>
<tr>
<td>OABSS Pre-treatment</td>
<td>12.5 (14.75-10.25)</td>
<td>13 (14-12)</td>
<td>179.5</td>
</tr>
<tr>
<td>OABSS Post-treatment</td>
<td>10 (11.75-9.25)</td>
<td>5.5 (8-4)</td>
<td>25</td>
</tr>
</tbody>
</table>

V. DISCUSSION

The current study showed that treatment with PTNS for six weeks improves bladder functions in patients with diabetic neuropathy. Regarding OABSS, there was a significant decrease in the value of OABSS of both groups, but there was more improvement of Group B compared with that of Group A.

As recommended, the first treatment modality for managing OAB includes medication, with or without adjunct training for the bladder and the pelvic muscle (7). Electrostimulation is a conservative therapeutic modality, which relies much on equilibrating the excitatory and inhibitory impulses that regulate bladder incontinence. The application of this simulation could be parasacral, intravaginal/intranal or via the tibial nerve (8).

Following Fitz et al. (9), we evaluate the impact of training the pelvic musculature on the OAB. The OAB-V8 questionnaire was used as an instrument to evaluate urinary symptoms. The symptomatic bladder has shown a remarkable improvement, including the urinary leakage. Leakage was assessed by pad test, voiding diary, nocturia, and lessened discomfort. Fitz et al. (9) reported positive results by analyzing the responses generated from answering the I-QoL questionnaire in determining the quality of life.

This study went hand in hand with what Finazzi-Agrò et al. (10) concluded about the efficacy of applying PTNS. They applied PTNS to patients with detrusor overactivity incontinence for 12 weeks. The frequency of urination, episodes of urinary incontinence, severity of urge, voids during the night, and volume of voids have improved remarkably. The exact neurological mechanism by which symptoms wax and wane remains idiopathic, although PTNS has been proven effective in modifying the somatosensory pathway.

We also agree with Finazzi-Agrò et al. (11), who conducted tibial nerve stimulation on sixty patients with bladder dysfunction. These cases were recalcitrant to anticholinergic drugs and behavioural modification. The results revealed that PTNS improves symptomatic OAB in recalcitrant cases in the short run. This non-invasive treatment is cost-effective as it minimises the need for medical consultation and frequent follow-up visits.

The findings of this study also agree with Kurdoğlu et al. (12), who conducted a retrospective study in which 24 elderly patients diagnosed with OAB received 30 minutes of tibial nerve stimulation once a week for three months. The urgency episodes reduced, and the urge urinary incontinence and nocturia have improved. In this connection, Rostaminia (13) conducted a retrospective study in which 62 females with OAB underwent 12 sessions of PTNS and presented a decrease in urologic manifestations. Therefore, the PTNS is efficient in managing OAB in adult and geriatric populations.
VI. CONCLUSION

This study concluded that adding PTNS to Kegel exercises, bridging exercises, and squatting exercises improved the functionality in patients with diabetic bladder dysfunction.

REFERENCES:


