CONTEMPORARY APPROACHES TO MALE URINARY INCONTINENCE: A CONTROLLED RANDOMIZED COMPARATIVE STUDY

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ABSTRACT

Background: Urinary incontinence UI is an involuntary leakage of urine due to loss of bladder control which is a common and often embarrassing problem that may cause tremendous emotional distress. Prevalence and risk factors depend on baseline physiological mechanisms, including weakness of pelvic floor muscles, hyperactive bladder that may result in urge UI, poor urethral sphincter function associated with stress UI, and impaired structural and functional integrity of pudendal nerve activity, associated with Pelvic floor muscle weakness plays an important role in UI etiology. Pelvic floor muscles work to support the bladder neck in the intra-abdominal cavity and maintain urinary continence. Weakness of these muscles leads the bladder to shift to the extra-abdominal cavity and thus a change in the urethra-vesicle angle occurs.

Methods: Group (A) twenty participants who received behavioral training (BT) pelvic floor exercises (PFE) and interferential current, group (B) twenty participants who received BT, PFE and posterior tibial nerve stimulation, and group (C) twenty participants who received BT, PFE and placebo interferential current. Urodynamic and cystometric measures including bladder volume at first desire to void, maximum cystometric capacity, and pressure at maximum flow rate were measured before and after intervention.

Results: Results of this study revealed that there was a statistical significant difference in bladder volume at first desire to void, maximum cystometric capacity, and pressure at maximum flow rate in favor of participants who received a combination of BT, PFE and interferential current compared with those who received a combination of BH and PFE with either posterior tibial nerve stimulation or placebo interferential current.

Conclusion: Interferential current is better than posterior tibial nerve stimulation in the rehabilitation of urinary incontinence.

Keywords: Urinary Incontinence, Interferential current, Posterior Tibial Nerve Stimulation, Urodynamics

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INTRODUCTION

Urinary incontinence UI is an involuntary leakage of urine due to loss of bladder control which is a common and often embarrassing problem that may cause tremendous emotional distress. The severity of UI ranges from occasionally leakage of few drops of urine during cough or sneeze to having a sudden strong urge to urinate just before losing a large amount of urine. Certainly, there is increasing evidence that the prevalence of UI in men is lower than that of women nevertheless incontinence in men increases with age and appears to rise more steadily than it does in women.¹

Several studies indicated that UI among males takes places most frequently post prostatectomy as a complication of the surgical interference that may disrupt the control of passage of urine through the sphincters resulting in its leakage. In males the leakage of urine occurs as a result of increasing the intra-abdominal pressure and consequently compressing the urinary bladder.²,³

Several factors may contribute to increase the intra-abdominal pressure such as lifting heavy objects, acute and chronic cough, strenuous exercises and laughing. Weakness of the pelvic floor muscles is a prime cause of stress urinary incontinence. This weakness may result from surgical interference to the prostate gland with possibility of nerve injury complication. The main function of the pelvic floor muscles is to control orifices of the urethra and the colon preventing both urinary and fecal incontinence.⁴

The rationale of conservative treatment for urinary incontinence is based on strengthening of pelvic floor muscles to help the proper control of bladder sphincters and consequently control urinary incontinence; therefore there is a variety of physiotherapeutic modalities and techniques have been used in different physiotherapy treatment protocols for patients with urinary incontinence such as pelvic Neuromuscular electrical stimulation, interferential current (IC), behavioral training (BT), and pelvic floor strengthening exercises (PFE). Furthermore, Neumann et al 2006 found consistent evidence from a number of high qualities randomized controlled trials that pelvic floor muscle training alone and in combination with adjunctive therapies is effective in treatment of UI in women, nevertheless they concluded that further studies are needed to evaluate optimal treatment programs and training protocols.⁵

Based on clinical practice bases there is not yet a concurrence which the ultimate physiotherapeutic treatment protocol in regards to current parameter, treatment frequency as well as treatment duration. Nevertheless, literature revealed that medium frequency currents (MFC) are superior to low frequency currents (LFC) because MFC have a short electrical pulse which decrease the tissue impedance and eases spread of MFC through the tissues arriving at the motor threshold more comfortably. Thence application of MFC privileges wider range of current with stimulating more motor units and reaches deeper tissues without causing discomfort for the patient. Eventually, the amplitude modulation of MFC stimulates nerves and allows the current to develop electrophysiological responses in cells and tissues similar to that of LFC.⁶,⁷,⁸,⁹,¹⁰ Jerez-Roig et al 2013 in a systematic review stated that there were no studies compared different electro-stimulation current parameters thence there is no evidence of which parameters are the most effective one.¹¹ Therefore, this study was conducted to compare the effectiveness of IC with low beating frequency combined with BT and PFE versus BT and PFE combined with either PTNS BT or placebo IC.

Subjects, Material and Methods

Seventy five male participants were diagnosed as urinary incontinence by urologist and referred to Physical therapy unit in the National Institute of Urology and Nephrology in Cairo. The urologist made his diagnosis upon detailed history, clinical and physical examinations and using DANTIC UD 5000/5500 Urodynamic investigation system. All patients were invited to participate in the study if they met the following criteria.

Inclusion criteria

Participant should be free from
1- Urinary tract infections
2- Diabetes mellitus
3- Neurological diseases
4- Neoplasm
5- Cognitive disorders

Only sixty participants aged between 54 and 71 years with average (62.1±5.15) met the inclusion criteria and participated in the study. After the study, procedures had been clearly explained and discussed with each patient; an Arabic language consent form was signed and obtained from each participant. Age, height, weight and body mass index values were recorded as well as all the variables that might influence on urinary incontinence such as duration of the incontinence problem, smoking, alcohol consumption, presence of constipation, chronic coughing, allergy, heart disease, blood pressure problems and diuretic drug usage were screened for each participant. All
participants had been asked to evacuate their bladder before the treatment sessions started, so that they are relaxed and comfortable during the session. Each participant was trained and taught a program of pelvic floor exercises (PFE) composed of home exercises included three daily sessions from lying, sitting, and standing positions with 10 seconds of contraction followed by 10 seconds of relaxation and repeat the exercises for 15 repetitions per each session. Both contraction and relaxation times were progressively increased 1 second each week. Moreover, each participant was asked to interrupt his urinary stream during voiding once daily for the first 2 weeks.12 A daily bladder diaries and exercise logs were kept during the 12 weeks of treatment. In addition, bladder control strategies were taught to each participant to prevent stress incontinence by contracting pelvic floor muscles just before and during activities that caused leakage.13

Eventually, each participant received a fluid management handout defining normal intake, which consisted of drinking 6 to 8 (eight fluid-ounce) glasses daily, avoid caffeine and a plan to distribute fluid consumption throughout the day. Twelve visits of behavioral training (BT) were demonstrated with one week interval starting with explanation of continence-related anatomy and PFE, followed by teaching how to use anal palpation. Each Participant was instructed to pelvic floor muscles contraction without holding of breath or contracting of either abdominal, thigh, or buttock muscles. Henceforth the participants were randomly assigned into one of three groups.

**Group A treatment protocol (ICG)**

Twenty male participants received BT, PFE and IC. Each participant received 20 minutes of low beating frequency (5 Hz) IC at two pinots of applications first point on the abdomen just above the inguinal ligament, 3 cm apart while the second point on the medial side of thighs just below the inferior border of the femoral triangle. Each participant received three sessions per week for a period of 12 weeks.

**Group B treatment protocol (PTNSG)**

Twenty male participants received BT, PFE and posterior tibial nerve stimulation of faradic type, biphasic continuous rectangular, with frequency of 20 Hz, with maximum tolerable intensity from comfortable sitting position with the treatment leg elevated. A disposable sterilized fine needle electrode is inserted into the inner aspect of the leg just above the medial malleolus. A surface electrode (grounding pad) is placed over the medial aspect of the calcaneus of the same leg. Each participant received three sessions per week for a period of 12 weeks.

**Group C treatment protocol (PICG)**

Twenty male patients received BT, PFE and placebo IC sessions with a frequency of three sessions per week for a period of 12 weeks.

**Measurement protocol**

A double blind measuring protocol was applied for both participant and the staff of the urodynamic unit in the National Institute of Urology and Nephrology. A DANTIC UD 5000/5500 Urodynamic investigation system was used to perform the urodynamic investigation and measure the bladder volume at first desire to void (BVFDV), maximum cystometric capacity (MCC) and the pressure at maximum flow rate (PMFR) for each participant in the three groups pre-intervention and post-intervention. Measurements were done by the same staff for all participants throughout the procedures.

**Data Analysis**

All recorded data were collected and analyzed by using SPSS 20 statistics program. One way ANOVA was conducted to compare the age, body mass index, BVFDV pre-intervention and post-intervention, MCC pre-intervention and post-intervention, and PMFR pre-intervention and post-intervention between groups and within groups. A post Hoc analysis had been done for additional exploration of the differences among means in between groups. All comparisons were evaluated at 0.05 level of significance.

**RESULTS**

Table 1 shows the mean and standard deviation as well as F value and P value of age and body mass index for IC group, PTNS group and PIC group. While Table 2 shows the mean and standard deviation as well as F value and P value of urodynamic investigation which include BVFDV, MCC, and PMFR for the three groups pre-intervention and post-intervention.

One way ANOVA revealed no significant difference in both age and body mass index between the three groups (p > 0.05) (fig 1). Moreover, there is no significant difference in BVFDV, MCC, and PMFR between the three groups pre-intervention (p > 0.05).

On the other hand there is significant difference in BVFDV, MCC, and PMFR between the three groups post-intervention (p < 0.05).

Eventually, running post Hoc test LSD revealed significant difference in BVFDV, MCC, PMFR for the favor of participants who received a combination of BT, PFE and IC compared with
those who received a combination of BT and PFE with either PTNS or placebo IC (p< 0.05) (fig2)

Table 1 shows the mean and standard deviation as well as F value and P value of age and body mass index for interferential current (GA), posterior tibial nerve stimulation (GB) and placebo electrical stimulation (GC)

<table>
<thead>
<tr>
<th>Variable</th>
<th>GA</th>
<th>GB</th>
<th>GC</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61.8±5.3</td>
<td>62.6±5.1</td>
<td>61.9±5.2</td>
<td>.139</td>
<td>.871</td>
</tr>
<tr>
<td>Body mass index</td>
<td>31.1±3.4</td>
<td>31.3±4.2</td>
<td>31.4±3.4</td>
<td>.030</td>
<td>.970</td>
</tr>
</tbody>
</table>

Table 2 shows the mean and standard deviation as well as F value and P value of urodynamic investigation for interferential current (GA), posterior tibial nerve stimulation (GB) and placebo electrical stimulation (GC) pre intervention and post intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>GA</th>
<th>GB</th>
<th>GC</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder volume at first desire to void Pre</td>
<td>175.3±59</td>
<td>161.2±62</td>
<td>162±54</td>
<td>.653</td>
<td>.52 4</td>
</tr>
<tr>
<td>Post</td>
<td>223.3±4</td>
<td>179.7±6</td>
<td>191.7±5</td>
<td>3.51</td>
<td>.03 6</td>
</tr>
<tr>
<td>Maximum cystometric capacity Pre</td>
<td>414.2±1</td>
<td>394.7±43</td>
<td>334.8±11</td>
<td>2.29</td>
<td>.11 0</td>
</tr>
<tr>
<td>Post</td>
<td>515±108</td>
<td>438.3±39</td>
<td>358.3±11</td>
<td>8.71</td>
<td>.00 2</td>
</tr>
<tr>
<td>Pressure at maximum flow rate Pre</td>
<td>37.3±14</td>
<td>38.2±13</td>
<td>39.8±15</td>
<td>.168</td>
<td>.84 6</td>
</tr>
<tr>
<td>Post</td>
<td>58.6±15</td>
<td>47.1±14</td>
<td>43.7±17</td>
<td>4.94</td>
<td>.01 0</td>
</tr>
</tbody>
</table>

Graph 1: Pressure at maximum flow rate

Graph 2: Bladder Volume at first desire to void

DISCUSSION

Despite of small sample size (only twenty participants in each group) all the variables that might influence on the results such as urinary tract infections, diabetes mellitus, neurological diseases, neoplasm, and cognitive disorders were controlled as we excluded any participant who had been diagnosed with any of the previous conditions during designing our inclusion criteria. Therefore our inclusion criteria might be considered as the reason of decreasing our sample from seventy five down to sixty since the fact that fifteen participants failed to pass the inclusion criteria.

Moreover, other variables such as age and body mass index which might affect on our results were recorded and statistically analyzed, as revealed from our results there were insignificant difference in between the three groups in regards to age as well as the body mass (table 1).

All measurement procedures were conducted by the same staff of the urodynamic unit in the National Institute of Urology and Nephrology by using a high reliable DANTIC UD 5000/5500 Urodynamic investigation system to measure BVFDV, MCC and PMFR. Aiming to fulfill the highest level of transparency and avoiding any bias that might pollute our results. A restricted double blind protocol had been applied in all measurement procedures for each patient throughout the whole study. Neither the staff nor the participants were informed in which study groups they were belong.

This study was conducted to compare the effectiveness of IC with low beating frequency combined with BT and PFE versus BT and PFE combined with either PTNS or placebo IC on BVFDV, MCC and PMFR in elder patients.

Our treatment protocols were designed with the lowest risk and noninvasive intervention dealing with urinary incontinence through behavioral training, pelvic floor exercises, IC and percutaneous electrical stimulation nevertheless their interventions are underestimated for long
period of time especially when bladder symptoms are severe.

Moreover, PTNS was used as a part of the treatment protocols for group B; PTNS is an interesting alternative a physiotherapeutic method for the treatment of UI with no side effects. Additionally, PTNS is easy to apply form of peripheral sacral stimulation that is usually well tolerated by patients. The rationale of using PTNS based on the anatomical fact that posterior tibial nerve originates from L4 through S3 as a branch of the lumbosacral plexus as well as the pudendal nerve which originates from S2 to S4 and supplies the detrusor muscle; therefore stimulation of the posterior tibial nerve will cause neuromodulation of the lumbosacral plexus which reflects on the pudendal nerve and consequently the detrusor muscle as well.

The findings of this study revealed that combination of BT and PFE with IC have superior benefits in improving BVFDV, MCC, and PMFR in patients with UI compared with BT and PFE combined with either PTNS or placebo IC after 12 weeks of intervention.

Our findings are parallel to that of Oláh et al 1990, Laycock and Jerwood 1993, as they studied the effects of IC and PFE in patients with different intensities of urodynamic incontinence; they indicated that the program was more effective in cases with mild and moderate incontinence intensity rather than in those with severe incontinence. Based on the results of this controlled randomized study we can claim that interventional current stimulation of low frequency has privileges in management of moderate intensity post prostatectomy UI when it is combined with BT and PFE for a period of 12 weeks.

CONCLUSION

Interferential current of low frequency, BH and PFE are important interventions in management of moderate intensity post prostatectomy UI.

REFERENCES


Citation