Original Article

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# Percutaneous Tibial Nerve Stimulation and Biofeedback Pelvic Floor Muscle Training Effects on Urinary Frequency and Quality of Life in Young Women with Overactive Bladder

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**ABSTRACT**

**Background & Objective:** The over active bladder syndrome is one of the women 's health problem that it usually accompanied by frequency and nocturia with or without urgency urinary incontinency. The aim of the study was to compare the effect of percutaneous tibial nerve stimulation with biofeedback-assisted pelvic floor muscle training on quality of life and frequency of urination in young women with overactive bladder.

**Materials & Methods:** In this double-blind randomized clinical trial, 60 females aged 18 to 45 years with overactive bladder were randomly divided into two equal groups. The first group underwent biofeedback-assisted pelvic floor muscle training plus Kegel exercises three times a week for twelve sessions. The second group underwent percutaneous tibial nerve stimulation plus Kegel exercises, performed three times a week for twelve sessions using a two-channel stimulator with device. The frequency of daily urination was the primary outcome. Quality of life, severity of overactive bladder symptoms, severity of urinary incontinence symptoms, frequency of nocturnal urination, and urgency were secondary outcomes. The criterion for the rate of success was <0.05.

**Results:** In comparison between groups, a statistically significant difference was observed in the number of daily urinations, nocturnal urinations, and urgency, in favor of the percutaneous tibial nerve stimulation group ($p<0.01$). Meanwhile, in terms of urinary incontinence, this advantage was in favor of the biofeedback group ($p<0.01$). No significant difference was observed in terms of quality of life and severity of overactive bladder symptoms between the two groups.

**Conclusion:** Percutaneous tibial nerve stimulation and biofeedback-assisted pelvic floor muscle training are two minimally invasive, easy, and cost-effective methods that can reduce the frequency of urination and increase the quality of life, and probably reduce the risk of surgery in these patients.

**Keywords:** Overactive bladder, Percutaneous tibial nerve stimulation, Biofeedback, Pelvic floor muscle exercises

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## Introduction

Overactive bladder syndrome (OAB) is defined by the International Continence Society (ICS) as presenting with urinary urgency—the key symptom of OAB—usually accompanied by frequency (eight or more times within 24 hours) and nocturia (one or more times), either with (wet-OAB) or without (dry-OAB) urgency urinary incontinence (UUI) (1). The pathophysiology of OAB remains elusive, but several theories have been proposed to explain it: neurogenic, involving decreased inhibitory impulses from the CNS, increased afferent impulses, and enhanced efferent or motor nerve stimulation; myogenic, which includes changes in detrusor myocyte characteristics; and urotheliogenic, involving alterations in the bladder membrane (2). The overall prevalence of OAB is 16.9%, affecting approximately 33 million adults in the United States, and it increases with age. Chung et al. reported that the prevalence of OAB rises from 10.8% among individuals aged 40-44 to 27.9% among those over 60 years of age (3).

OAB impacts every aspect of a patient's individual and social life. The negative effects on patients' quality of life (QoL) include avoiding social interactions, isolation, depression, anxiety, embarrassment, diminished self-confidence, sexual dysfunction, and reduced physical activity (2-3). A study by Mauseth, S.A., et al., demonstrated that the pressures of OAB on the functional and social aspects of QoL are even more severe than those associated with diabetes (4).

The American Urological Association has defined three lines of treatment for OAB. The first-line treatment includes lifestyle changes and behavioral therapies, such as pelvic floor muscle training (with or without biofeedback), dietary adjustments, weight loss, constipation management, and bladder retraining (5). Biofeedback is a learning or retraining method where participants receive visual, auditory, and tactile feedback to increase motivation and awareness of their muscle functions, helping to inhibit bladder detrusor muscles and control urgency (6). The second-line treatment comprises pharmacological therapies like antimuscarinic drugs or beta-3 adrenergic receptor agonists, recommended for at least three months to improve symptoms by relaxing the bladder detrusor muscles (5,7). However, a review study indicates that about 43-83% of patients discontinue these medications within the first 30 days due to side effects. The third line of treatment, intended for those resistant to the first two lines, includes more invasive options such as intramuscular injections of botulinum toxin, various forms of neuromodulation (deep and superficial stimulation of the posterior tibial nerve, sacral nerve stimulation, pudendal nerve stimulation), and surgery (7,8).

Neuromodulation is a method that controls bladder function through indirect stimulation. Percutaneous tibial nerve stimulation (PTNS) is one of the less invasive neuromodulation techniques. The tibial nerve, comprising L4-S3 fibers—which are the same segments that innervate the bladder and pelvic floor muscles—suggests that manipulation of peripheral input to spinal motor neurons can increase segmental inhibitory tone (9).

The results of a systematic review and meta-analysis demonstrated that all physical and rehabilitation therapies improved daytime micturition frequency and nocturia in OAB patients (10). A study by Carlo et al. indicated that PTNS enhances quality of life, reduces the number of daily micturition, and decreases episodes of nocturia and urge incontinence more effectively compared to electrical stimulation with pelvic floor muscle training (11). Moreover, the results have shown that PTNS has both short-term and long-term effects in these patients, although there are contradictory reports regarding its control over urinary symptoms and quality of life (12,13). A study on the short-term effects of PTNS on women with OAB demonstrated significant improvements in urinary symptoms for patients with refractory OAB and reduced the costs associated with medications, and physician and nurse visits (10). Conversely, another study focusing on the long-term effects of PTNS reported that while it is an effective treatment, high discontinuation rates suggest that long-term PTNS treatment may be feasible for only a minority of women with OAB (13). Pelvic floor muscle training is another non-invasive method to improve symptoms of OAB (6). The effects of biofeedback-assisted pelvic floor muscle training (BFAPFMT) and PTNS as non-invasive treatments have been investigated separately in OAB (6,12,13); however, studies comparing these two therapeutic interventions in young women with OAB are limited. Although beneficial studies have been conducted, there are conflicting results regarding the superiority of these methods over other treatments. Also, most studies on the effects of PTNS on OAB have been conducted in women over 50 years of age, with very few in women under 50. Therefore, the aim of this study is to compare the effects of PTNS and BFAPFMT on the frequency of voiding in young women with overactive bladder as the primary outcome. Secondary outcomes, including quality of life, severity of OAB symptoms, severity of urgency incontinence (UI), frequency of nocturnal urination (Nu), and urgency, were evaluated before, after, and 6 weeks post-intervention.

## Materials and Methods

This study was conducted as a double-blind randomized clinical trial (IRCT20210624051692N1)

at the Rehabilitation School of Babol University of Medical Sciences in Iran. Female patients who visited Rouhani Hospital Women's Clinic displaying signs and symptoms of OAB—such as feeling a sudden urge to urinate that is difficult to control, frequent urination (eight or more times in 24 hours), waking up more than twice at night to urinate, and urgency incontinence—were examined by a physician and selected to participate in the study based on inclusion and exclusion criteria (1, 2).

Inclusion criteria included young women with OAB who scored 8 or higher on the Overactive Bladder Score Scale (OABSS) questionnaire, aged between 18 to 45 years old, and who had experienced one or a maximum of two vaginal deliveries (9, 14). Exclusion criteria encompassed stress incontinence, pacemaker use, Alzheimer's disease, superficial or deep infections at the electrode site, urinary tract infections, central neurological diseases (such as multiple sclerosis, stroke, Parkinson's disease), uterine prolapse above the second degree according to the POP-Q system (anterior and posterior compartment), pregnancy or suspected pregnancy or planning for it, cesarean delivery, uncontrolled diabetes mellitus, history of surgery to control incontinence, botulinum toxin injection, pelvic tumors, history of radiotherapy, use of anticholinergic drugs, and urinary congestion (6). The sample size was calculated to be about 60 participants, based on $\alpha$=5%, $\beta$=20%, s=3, and d=1.5.

Participants were randomly divided into two equal groups by computer. For the first group (n=30), Biofeedback-Assisted Pelvic Floor Muscle Training plus Kegel exercises was performed three times a week for twelve sessions using a biofeedback device. The second group (n=30) underwent Percutaneous Tibial Nerve Stimulation plus Kegel exercises, carried out three times a week for twelve sessions using a two-channel portable stimulator device. After completing questionnaires and a daily record of urination for three consecutive days, the patients underwent treatment. Questionnaires and daily urine recording tables were completed by the patients at the end of the twelfth session and one month after the end of the intervention.

All participants were informed about the purpose and content of the study, and all signed informed consent forms. The study protocol was approved by the medical ethics committee of Babol University of Medical Sciences (IR.MUBABOL.REC.1400.163).

**Randomization**

This randomized, double-blind clinical trial was conducted at the research center of the Rehabilitation School at Babol University of Medical Sciences in Iran. For random allocation, we utilized the online service from randomization.com. The participants, examined by a specialist and then referred to the research center, were divided into two equal groups by computer. In this process, the 60 enrolled patients were block-randomized in a 1:1 ratio into two groups equally by an independent researcher using computer-generated randomization of study numbers. Both the therapist and the patients were kept unaware of the placement in treatment groups, and the patients did not know the type of treatment they were receiving.

**BFAPFMT:** BFAPFMT utilizes surface electromyographic (EMG) techniques, registered with intravaginal probes, combined with biofeedback to elicit myoelectric activation of the muscles (6). BFAPFMT was performed in a supine position, with a vaginal probe placed around the levator ani muscle and a ground electrode on the anterior superior iliac spine. Patients were instructed to perform the following three movements for 15 minutes, while simultaneously observing the monitor screen for information on the severity and type of contractions, which were visually displayed: 1) resting the pelvic floor muscles for a minute to sense the muscles at rest; 2) performing ten maximal voluntary contractions (MVCs) for three seconds each; and 3) engaging in three tolerable contractions for 30 seconds. Additionally, these women were instructed to perform Kegel exercises. For the Kegel exercises, the patient lay in a supine position with a pillow under her knees, an empty bladder, and was asked to breathe slowly, focusing on her pelvic floor muscles while avoiding contraction of the thigh, abdomen, and buttock muscles. The patient then squeezed the pelvic floor muscles (PFM) for 5 seconds and rested for 5 seconds. Over time, the duration of the contraction was gradually increased to 10 seconds with an equivalent rest period. In this study, BFAPFMT was carried out three times a week for twelve sessions using a biofeedback device (6).

**PTNS**: This method involves placing a electrode at the ankle, near the tibial nerve. When stimulated, impulses from the tibial nerve travel to the nerve roots in the spine, helping to block abnormal bladder signals and prevent bladder spasms (9). In this study, PTNS was administered three times a week for twelve sessions using a two-channel portable stimulator device capable of parameter adjustments. The patient was positioned supine with the positive electrode placed on the medial surface of the calcaneus and the negative electrode positioned 5 cm above and 2 cm behind the medial malleolus. PTNS was performed bilaterally. The electrodes were connected to a TENS unit set to voltage of 9 volts, amplitude range of 0.5-10 mA, a frequency of 20 Hz, and a pulse width of 200 microseconds for 30 minutes. The stimulation intensity was kept below the pain threshold, ensuring visible dorsiflexion of the big toe and other toes (9, 15).

**Data collection**

Information was collected through standard questionnaires and a three-day bladder diary. These questionnaires were completed by all participants before the intervention, immediately after, and six weeks following the conclusion of the intervention (follow-up period).

**International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life Module (ICIQ-LUTSqol)**

The ICIQ-LUTSqol questionnaire is highly reliable and has good internal consistency and content validity (16). This questionnaire comprises 20 questions, each divided into two parts. The first part assesses the severity of symptoms related to lower urinary tract issues, while the second part evaluates the extent of emotional distress caused by these symptoms. Each question in the first part is scored from 1 to 4, and each question in the second part is scored from 0 to 10. The minimum total score for the ICIQ-LUTSqol is 19, indicating no symptoms and a better quality of life, while the maximum score is 76, reflecting very severe symptoms and poor quality of life. A higher score indicates a worse quality of life (16).

**International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF)**

This questionnaire, which has high reliability and validity, measures the symptoms of UI with four questions. It provides a summary of the cause, severity, and effects of incontinence symptoms. The total score of the questionnaire ranges from 0 to 21, with higher scores indicating a worse condition. The last question is designed solely to assess the type of incontinence and does not contribute to the total score (17).

**Overactive bladder score scale (OABSS)**

The OABSS questionnaire, which possesses acceptable validity and reliability (16), was used to assess the severity of bladder hyperactivity symptoms. This questionnaire includes four questions that address the main symptoms of bladder hyperactivity. The first and second questions, which pertain to the number of daily urinations (Du) and nocturnal urinations (Nu), are scored from 0 to 3. The third and fourth questions, concerning the number of urgency episodes and incontinence events, are scored from 0 to 5. The minimum score on this questionnaire is 1, and the maximum score is 16. A total score of 8 or higher indicates moderate to severe bladder hyperactivity (16).

**Three-Day Bladder Diary Table**

The number of Du and Nu episodes for 3 consecutive days was recorded by the participants in table.

**Ethical approval**

The study protocol was approved by the medical ethic committee of Babol University of medical sciences (IR.MUBABOL.REC.1400.163) in May 2021.

**Statically analysis**

SPSS 25 software was used for statistical analysis and plotting. An independent sample t-test was used to compare demographic characteristics between the two groups. The Mann-Whitney U test and Chi-square were also performed to compare the frequency percentage of some variables. A Repeated Measures ANOVA test was used to compare the effects of PTNS and BFAPFMT on the number of Du and Nu, QoL, number of urgency, severity of OAB symptoms, and severity and number of UI before, after intervention, and at the follow-up time. For comparison between groups, an independent sample t-test was used. In all tests, the significance level was set at $P<0.05$.

## Results

In this double blind randomized clinical trial study, according to consort form (Figure1), 75 young women with OAB were randomly participated. 60 participants with ranging between 18 to 45 years old with a mean age of 36.12±8.17 years and an average of 4.10 years from the onset of symptoms were completed the stages of study. The mean body mass index in PTNS group was 26.71kg/cm$^2$ and in BFAPFMT group was 27.9971kg/cm$^2$. 36.6% of them in PTNS group and 53.4% of people in BFAPFMT group had at least one abortion. All the participants had one or maximum two vaginal deliveries. 20 participants in the BFAPFMT group and 18 participants in the PTNS group had two vaginal deliveries. The participants in both groups were match in terms of demographic characteristics ($P>0.05$) (Table1). A statistically significant improvement was found in all study parameters for both groups at the end of the treatment compared with the baseline values except Nu in the BFAPFMT group. The number of Du, severity and frequency of UI, urgency, symptoms of OAB and emotional distress caused by OAB in both groups were statistically significantly reduced and, consequently, QoL in both groups increased.

Compared to the baseline values, no significant difference was observed in terms of QoL and symptoms of OAB. The total scores of the first and second parts of the quality of life questionnaire, in both the PTNS and BFAPFMT groups, significantly decreased after the end of the intervention compared to before the intervention, which indicates the improvement of the quality of life and the reduction of emotional distress. It is caused by symptoms of overactive bladder. In the comparison between PTNS and BF groups, one month after the end of the intervention, there was no significant difference between the two groups in terms of quality of life compared to before the start of the intervention, and the quality of life improved in both groups compared to the end time. The intervention remained stable and did not find significant changes (Table2).

.Nu did not change statistically in the BFAPFMT group, while it decreased in the PTNS group and remained stable during follow-up. In comparison between PTNS and BFAPFMT methods, a statistically significant difference was observed in the number of

Du, Nu and urgency, in favor of PTNS group (P<001). While in terms of UI, this advantage was in favor of the BFAPFMT group, which remained stable during the follow-up. But in the PTNS group, the severity of UI symptoms increased again during follow-up. The results showed that 6 weeks after the end of the intervention in both groups, the improvement of the study parameters remained stable, but in the PTNS group, the number of Du and the severity of UI increased again, which was statistically significant (P<001)(Table 2,3)(Figure2-4).

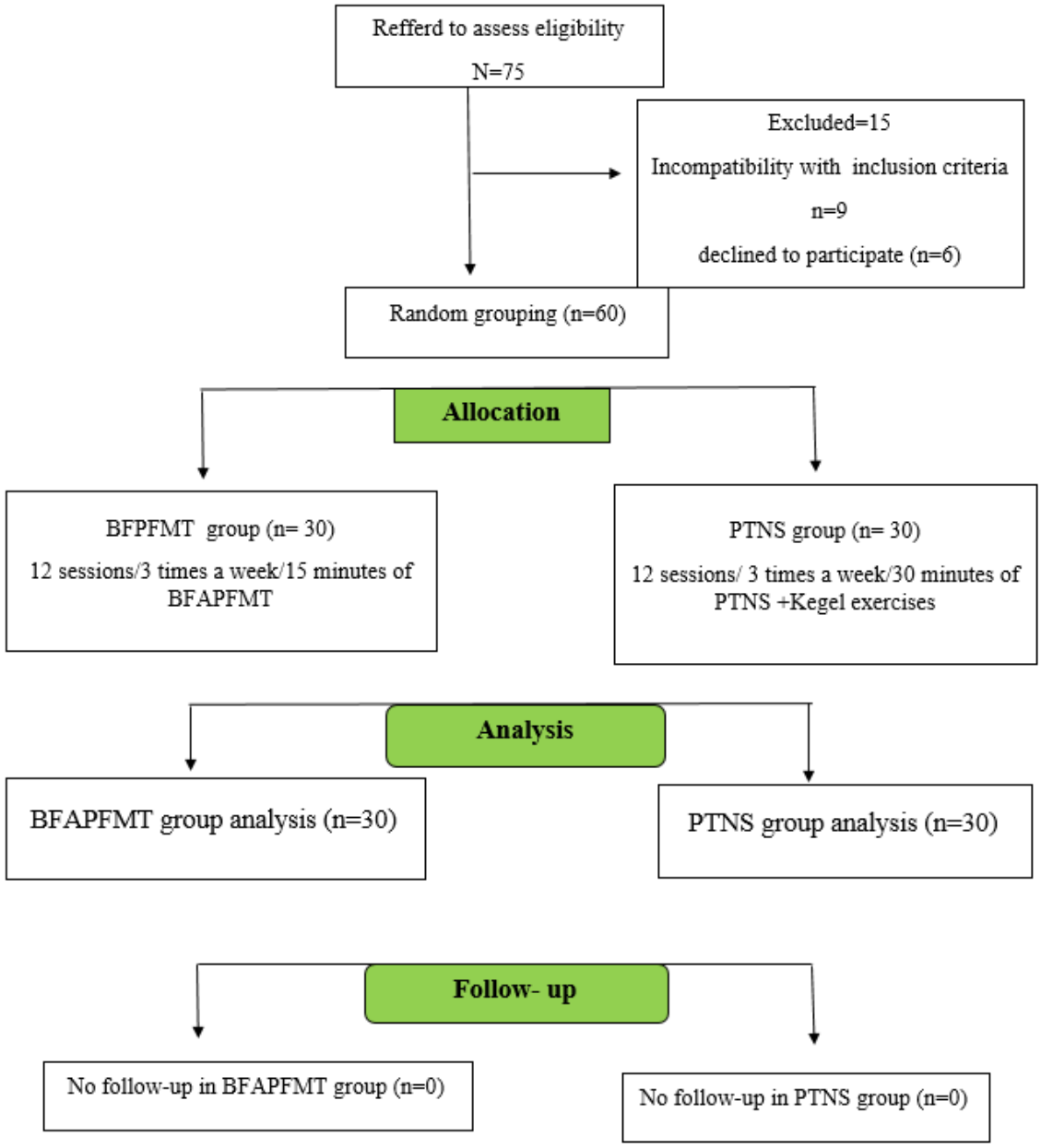


**Figure1. CONSORT participant's flow diagram. BFAPFMT: Biofeedback-Assisted Pelvic Floor Muscle Training; PTNS: Percutaneous Tibial Nerve Stimulation**

**Table 1. Demographic characteristics of the participants in two groups**

| Characteristics | | PTNS (M±SD) | BFAPFMT (M±SD) | P-Value* |
|---|---|---|---|---|
| **Age** | | 35.20±7.16 | 37.03±6.42 | 0.302 |
| **Height** | | 160.60±4.81 | 162.13±5.61 | 0.261 |
| **Weight** | | 68.93±8.67 | 73.27±9.86 | 0.076 |
| **BMI** | | 26.71±3.11 | 27.99±4.46 | 0.203 |
| **Duration of OAB** | | 3.20±2.48 | 5±4.85 | 0.078 |
| **Number of Delivery** | 1<br>2 | 12<br>18 | 10<br>20 | 0.592 |
| **Activity Levels** | Low<br>medium<br>Heavy | 11<br>16<br>3 | 9<br>14<br>7 | 0.380 |
| **Number of Abortions** | 0<br>1<br>2<br>3 | 19<br>10<br>1<br>0 | 14<br>8<br>6<br>2 | 0.841 |
| **Onset of Symptoms(years)** | <1<br>1-5<br>>5 | 8<br>18<br>4 | 7<br>13<br>10 | 0.201 |

* Independent sample t test; BMI: body mass index; PTNS: percutaneous tibial nerve stimulation; BFAPFMT: biofeedback-assisted pelvic floor muscle training; N: Number of participants

**Table2. Effect of PTNS and BFAPFMT on variables of study in before, after interventionand follow up in two groups**

| Variables | Group | Before (M±SD) | After (M±SD) | Follow up (M±SD) | P-Value* | Effect size |
|---|---|---|---|---|---|---|
| **ICIQ-LUTS** | PTNS | 53.83±9.96 | 38.90±9.60 | 39.06±9.90 | | |
| **part one** | BFAPFMT | 49.10±10.70 | 38.21±9.56 | 38.40±9.05 | <0.001 | 0.780 |
| P-Value** | | 0.082 | 0.781 | 0.787 | | |
| **ICIQ-LUTS** | PTNS | 137.47±35.07 | 73.61±31.63 | 73.96±31.13 | | |
| **part two** | BFAPFMT | 124.27±35.13 | 77.03±35.66 | 79.96±35.44 | <0.001 | 0.670 |
| P-Value** | | 0.151 | 0.696 | 0.489 | | |
| **ICIQ-UI** | PTNS | 12.40±2.50 | 6.52±3.24 | 7.66±3.03 | | |
| **SF** | BFAPFMT | 11.00±3.52 | 4.85±2.96 | 4.86±2.96 | <0.001 | 0.837 |
| P-Value** | | 0.082 | 0.042 | <0.001 | | |
| | PTNS | 10.65±2.24 | 6.04±1.96 | 6.00±1.83 | | |
| **OABSS** | BFAPFMT | 9.60±1.81 | 5.90±1.86 | 6.17±1.87 | <0.001 | 0.903 |
| P-Value** | | 0.051 | 0.767 | 0.729 | | |
| | PTNS | 11.77±3.17 | 7.17±1.59 | 9.27±2.24 | | |
| **Du** | BFAPFMT | 11.30±2.79 | 9.47±2.51 | 9.30±2.53 | <0.001 | 0.796 |
| P-Value** | | 0.548 | <0.001 | 0.957 | | |
| | PTNS | 1.70±0.70 | 0.93±0.52 | 0.90±0.54 | | |
| **Nu** | BFAPFMT | 1.57±0.62 | 1.43±0.67 | 1.30±0.70 | <0.001 | 0.526 |
| **P-Value**** | | 0.441 | 0.014 | 0.021 | | |

* Repeated Measure ANOVA Analysis; ** Independent sample t test

**Table3. Effect of PTNS and BFAPFMT on number of urgency and incontinence**

| Variable | Group | | Before | | After | | Follow up | |
|---|---|---|---|---|---|---|---|---|
| | | | N | % | N | % | N | % |
| **Urgency** | PTNS | Not at all | 0 | 0 | 1 | 3.3 | 0 | 0 |
| | | Less than once a week | 0 | 0 | 6 | 20 | 8 | 26.7 |
| | | Once a week or more | 3 | 10 | 18 | 6 | 18 | 60 |
| | | Once a day | 9 | 30 | 4 | 13.3 | 3 | 10 |
| | | 2-4 times a day | 8 | 26.7 | 1 | 3.3 | 1 | 3.3 |
| | | 5 times or more a day | 10 | 33.3 | 0 | 0 | 0 | 0 |
| | BFAPFMT | Not at all | 0 | 0 | 0 | 0 | 0 | 0 |
| | | Less than once a week | 1 | 3.3 | 2 | 6.7 | 4 | 13.3 |
| | | Once a week or more | 5 | 16.7 | 13 | 43.3 | 8 | 26.7 |
| | | once a day | 10 | 33.3 | 13 | 43.3 | 15 | 50 |
| | | 2-4 times a day | 6 | 20 | 2 | 6.7 | 3 | 10 |
| | | 5 times or more a day | 8 | 26.7 | 0 | 0 | 0 | 0 |
| **P-Value*** | | | 0.272 | | 0.014 | | 0.001 | |
| **Incontinency** | PTNS | Not at all | 0 | 0 | 5 | 16.7 | 3 | 10 |
| | | Less than once a week | 4 | 13.3 | 11 | 36.7 | 12 | 40 |
| | | Once a week or more | 13 | 43.3 | 10 | 33.3 | 13 | 43.3 |
| | | once a day | 5 | 16.7 | 4 | 13.3 | 2 | 6.7 |
| | | 2-4 times a day | 4 | 13.3 | 0 | 0 | 0 | 0 |
| | | 5 times or more a day | 4 | 13.3 | 0 | 0 | 0 | 0 |
| | BFAPFMT | Not at all | 2 | 6.7 | 7 | 23.3 | 6 | 20 |
| | | Less than once a week | 4 | 13.3 | 13 | 43.3 | 14 | 46.7 |
| | | Once a week or more | 13 | 43.3 | 8 | 26.7 | 8 | 26.7 |
| | | once a day | 7 | 23.3 | 2 | 6.7 | 1 | 3.3 |
| | | 2-4 times a day | 1 | 3.3 | 0 | 0 | 1 | 3.3 |
| | | 5 times or more a day | 3 | 10 | 0 | 0 | 0 | 0 |
| **P-Value*** | | | 0.343 | | 0.262 | | 0.184 | |

* Repeated Measure ANOVA Analysis

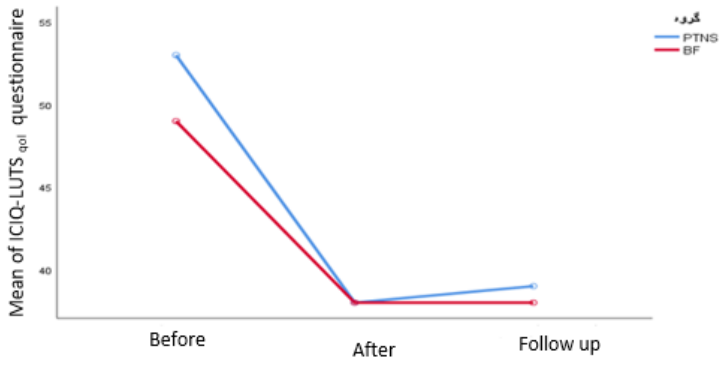


**Figure 2. The trend of changes in the mean of ICIQ-LUTS in before, after and follow up time in between two groups of patients with OAB**

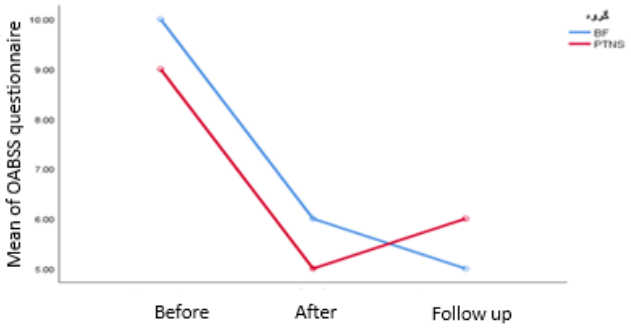


**Figure3. The trend of changes in the mean of Overactive bladder score scale (OABSS) in before, after and follow up time in between two groups of patients with OAB**

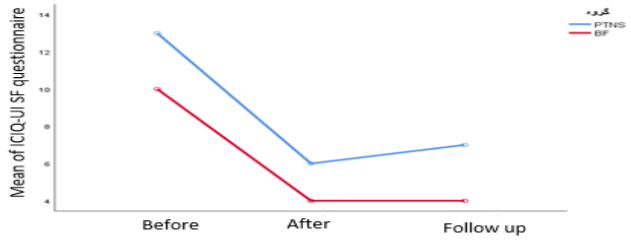


**Figure4. The trend of changes in the mean of ICIQ-UI SF in before, after and follow up time in between two groups of patients with OAB**

## Discussion

The results of our study showed that the number of Du, severity and frequency of UI, urgency, symptoms of OAB, and emotional distress caused by OAB were statistically significantly reduced in both groups, consequently increasing QoL. No significant differences were observed in terms of QoL and symptoms of OAB when compared to the baseline values. Additionally, our study revealed a statistically significant improvement in the number of Du in favor of the PTNS group after the intervention. The interventions for patients with OAB in both groups over six weeks were successful in improving the symptoms. According to a network meta-analysis of randomized controlled trials, PTNS is one of the effective modalities for reducing episodes of urgency incontinence and the number of pads used (18). However, some studies have reported that these improvements were temporary and not permanent. Our results were similar to those of Carlo Vecchioli et al., who compared PTNS versus electrical stimulation with PFMT in women with OAB (11). Conversely, our findings differ from those of Lucio et al., who found that adding transcutaneous tibial nerve stimulation to the BFAPFMT group offered no advantage over biofeedback alone. These differences might be attributed to variations in pelvic floor muscle strengthening protocols and the small number of samples in each group (19).

In the present study, all parameters remained stable in the BFAPFMT group at the follow-up time, but in the PTNS group, the frequency of Du and the severity of UI symptoms increased again, although they were still significantly lower compared to the baseline. Capitanucci ML et al. reported that monthly PTNS as maintenance therapy is essential to maintain positive outcomes and improve the symptoms of OAB (20). The results of Van Balken's study also showed that half of the patients' symptoms returned at the end of 6 weeks of treatment discontinuation. However, resuming PTNS monthly led to a return to pre-cessation recovery levels (21). Van Der Pal and colleagues reported that the best time to resume treatment with PTNS was 24 months after the initial treatment and stated that monthly maintenance therapy is also required during these 24 months (22).

The results of our study showed that both groups experienced significant improvements in QoL, but no significant differences were found between them. The total scores of the first and second parts of the quality-of-life questionnaire in both groups decreased significantly compared to before the intervention, indicating an improvement in QoL due to symptoms of overactive bladder. Furthermore, in the follow-up one month after the end of the intervention, no significant differences were observed between the two groups in terms of QoL compared to before the intervention. The improvement in QoL for both groups remained stable compared to the end of the intervention and did not show significant changes. This improvement in QoL in both groups is likely because of pelvic floor muscle training on retraining the strength of the pelvic floor muscles and preemptive contraction of these muscles. By increasing the strength of the pelvic floor muscles and improving the activity of the bladder muscles, the patients' urinary control is enhanced, thereby improving the frequency of emptying and increasing the quality of life. These results are consistent with other studies investigating the effects of PTNS and BFAPFMT on QoL in patients with OAB (23). A meta-analysis of 37 articles in 2016 demonstrated that BFAPFMT achieved better outcomes in improving QoL UI than the PFMT group alone (24).

Our study demonstrated that the rate of psychological distress significantly decreased by the end of the intervention compared to baseline and remained stable during the follow-up period. Van Balken et al. reported that poor mental health was not directly related to the severity of OAB symptoms but was considered a negative predictor of success in the PTNS method (21). Tadic et al. also noted that the rate of improvement—specifically, the reduction in the frequency of UI—is not associated with the early symptoms of depression. However, the improvement in psychological burden is significantly greater in individuals with a history of depression (25).

At the end of the interventions, both the PTNS and BFAPFMT groups showed improvements in the severity of OAB symptoms as measured by OABSS questionnaire scores, but there was no significant difference between the two groups. Alkis et al. conducted a study where TTNS was performed once a week and three times a week for 12 weeks in two different groups. Their study demonstrated that symptoms of OAB were significantly reduced in both groups, but the reduction in the three-times-a-week TTNS group was observed in the third week, whereas in the once-a-week TTNS group, it occurred in the fifth week. However, the final results of the treatment were the same in both groups (26). In another study by Gracia et al., it was shown that the severity of OAB symptoms and QoL in these patients improved by 90.5% (27). Meanwhile, Wibisono et al. found that improvement rates in unilateral PTNS groups ranged from 37.3% to 81.8%. They argued that bilateral PTNS may activate a greater number of afferent sensory pathways, potentially leading to greater efficacy (28).

In our study, analyses of the ICIQ-UI SF questionnaire at the end of treatment revealed that both groups experienced a significant reduction in UI, but this difference was more pronounced in the BFAPFMT group compared to the PTNS group. Bilateral transcutaneous posterior tibial nerve stimulation has been recognized as a cost-effective treatment for fecal

incontinence and can be administered by patients at home (29). Burgio et al. observed about an 80% reduction in UI in women who engaged in pelvic floor muscle strengthening with biofeedback (30). In contrast to our findings, Rafet et al. reported no superiority between the PTNS and BFAPFMT groups in improving the symptoms of urinary incontinence; however, both groups did see a significant reduction in UI (31).

ur study demonstrated that the interventions we used for reducing symptoms of OAB in two groups over six weeks were successful in improving the symptoms. However, some studies have reported that these improvements were temporary and not permanent. The frequency of Nu did not change statistically in the BFAPFMT group, while it decreased in the PTNS group and remained stable during the follow-up period. F. Albanezi et al., in a study investigating the effect of 12 weeks of TTNS and PFMT on sleep quality and number of Nu in women with OAB, stated that the frequency of Nu decreased significantly in both groups, but no significant difference was observed between the two groups (32). Conversely, Bykovience et al. reported that the number of Nu episodes at 6 weeks after the intervention was not significantly improved in any of the PFMT, PFMT with TTNS, or the control group (33). In our study, PTNS was also more effective than BFAPFMT in reducing urgency. Contrary to our findings, the number of urgency episodes in the TTNS group was not greater than that in the BFAPFMT group in studies by Bykovience et al. and Polat Dunya C et al. (31, 33).

**Limitations**

Due to the spread of COVID-19 at the time of the study, it was not possible to monitor patients for long-term follow-up. To evaluate the effectiveness of PTNS and BFAPFMT and to eliminate bias effects, it is suggested that a double-blind clinical trial study be conducted with three treatment groups, including the addition of a control or sham group. It is also recommended to use objective tools to measure variables.

## Conclusion

The results of our study indicated that PTNS has a significant effect on reducing urgency, which is one of the main and key symptoms of OAB in young women. An additional advantage of PTNS is that it does not require stimulation of specific parts of the body, such as the genital system, which can be seen as a benefit in improving symptoms in patients with OAB. It appears that persistence in symptom improvement may be one of the advantages of BFAPFMT. Thus, PTNS and BFAPFMT are accessible treatments that are minimally invasive, easy to administer, and cost-effective methods that can enhance the management of OAB symptoms. These conservative treatments could also potentially reduce the need for surgical interventions in young women with overactive bladder. Unlike most previous studies, this study specifically targeted young women with OAB. Future research should aim to conduct more extensive studies in this demographic with a larger sample size.

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## Authors' Contribution

Y.J: Study concept, design and writting, Sh. B: Data acquisition, case selection, R.M K: Data analysis, drafting, A. Gh: editing, data acquisition, M. E: Drafting of manuscript: Critical revision of the manuscript

## Conflict of Interest

The authors declare that they have no conflict of interest.

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## Ethics Approval and consent to participate

The study protocol was approved by the medical ethic committee of Babol University of medical sciences. (IR.MUBABOL.REC.1400.163)

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