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Original Article

Effects of Special Pelvic Floor Muscle Training on the Quality of Life in Women with Urinary Incontinence, A Clinical Trial

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ABSTRACT

Background: Stress urinary incontinence (SUI) is the involuntary loss of urine which occurs with physical exertion and an increase in intra-abdominal pressure. Pelvic floor muscle training (PFMT) is generally recommended to reduce SUI. This study aimed to compare the effects of three different exercises in women with urinary incontinence by abdominal and pelvic floor muscle retraining.

Methods: A total of 81 patients with urinary incontinence (UI) were randomly allocated to the pelvic muscle training by biofeedback (BF), pelvic muscle training by biofeedback plus abdominal exercise (BF+AbdExs), and only abdominal exercise (AbdExs). All participants received 12 weeks of treatment. The outcome measure was maximal vaginal squeeze pressure and Quality of life (QOL) Questionnaire. Data analysis was performed using ANOVA and Kruskal-Wallis tests.

Results: The mean age of patients was 49.4±8.4 years. The scores of QOL, pelvic floor muscle strength, and endurance increased in all groups after the treatment. The mean score of QOL in group BF+Abd.Exs ranged from 65.2 to 93.6, while in groups BF and AbdExs, it ranged from 61.8 to 85.6 and 63.6 to 79.1 respectively. More aspects of QOL improved significantly in the BF+ AbdExs group than in other group. However, the difference in pelvic floor muscle strength and endurance was not statistically significant among the three groups ($p>0.05$)

Conclusion: An increase in pelvic floor muscle strength was associated with AbdExs, which improved QOL. Thus, the AbdExs seems to induce co-contraction in pelvic floor exercise. However, AbdExs alone is not adequate for improving incontinence.

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Introduction

Urinary incontinence (UI) is a multifactorial syndrome defined as any involuntary loss of urine [1]. It is a common problem with prevalence of 15-55% [2]. This variation is due to differences in target populations and study design. Half of women with UI will have symptoms of stress urinary incontinence (SUI) alone, with a further 30% having mixed SUI and urge urinary incontinence (UUI) [3].

The number of pregnancies, high body mass index, hypertension, diabetes mellitus, and postmenopausal status are among the risk factors for incontinence [4-6]. UI is not life-threatening; however, there is a consensus on the fact that UI can negatively affect quality of life (QOL) in many aspects such as physical activities, social interaction, as well as even sexual and psychological well-being [6]. In general, women with UI report physical limitations in some activities, such as domestic activities, which negatively influence the emotional aspects of life. Further, there are other problems such as

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fear of loss of bladder control, hygienic condition, the smell of urine, as well as the need for wearing pads and changing clothes. Family members and caregivers also experience diminished QOL [7].

SUI occurs with physical activity and increase in intra-abdominal pressure. Coughing, sneezing, straining, jumping, and running are commonly associated with the leakage [4]. Indeed, the SUI occurs when the urethral sphincter complex and pelvic muscles cannot resist forces resulting from increases in intra-abdominal pressure [8].

Kegel developed the idea of pelvic floor muscle (PFM) exercises [8]. It is postulated that pelvic floor muscle training (PFMT) decreases the mechanical stress in order to enhance bladder neck support by raising the strength and endurance of the pelvic floor muscles, resulting in improved stress incontinence [9]. In general, PFMT is muscle contraction and relaxation. It has proven to be the most effective, non-invasive, inexpensive and safest therapy as the first line of treatment for urinary incontinence [10]. The effectiveness of exercise therapy has been demonstrated in many randomized controlled trials [9, 11-13]. However, muscle training is time consuming (8-12 weeks) and it is affected by many factors such as muscle co-contraction and strength of pelvic floor muscles [9, 14]. In addition, many patients cannot contract their muscles correctly because these muscles are deep and small. Some studies have focused on the relationship between PFM, deep abdominal muscles, and diaphragm muscle [15, 16]. Also, Thompson believed that abdominal muscles become more active than PFM in UI and suggested that they should be considered in PFMT [16, 17]. Spasford claimed that abdominal muscle training may be useful in treating urinary incontinence [18]. Currently, there is less evidence available whether women suffering from UI with the ability to contract the PFM on demand benefit from PFMT alone or in combination with abdominal exercise (AbdExs). Therefore, the question is if the AbdExs improves QOL of women with UI or not.

This study aimed to evaluate three different therapeutic strategies of exercise therapy (including treatment with electromyography biofeedback (BF) alone or BF in combination with abdominal exercise (BF+AbdExs) or only AbdExs in UI.

Methods

The present study is a clinical trial which was conducted at the outpatient clinic of urology in Alzahra hospital, Isfahan University of Medical Sciences between April 2015 and May 2016. The sample were determined according to the previous studies [15, 16]. At the beginning, all participants were examined by u urologist to confirm the inclusion criteria and severity of incontinence (mild, moderate, and severer). Women were eligible for the study if they had been diagnosed with UI, had ability to perform a pelvic muscle contraction (based on the digital examination), and had no prolapsed uterus. Patients with urinary tract infections, eversible cause of urinary incontinence (e.g. fecal impaction, drug effect), uncontrolled metabolic conditions (e.g. diabetes mellitus), serious chronic conditions which may have resulted in neurogenic bladder dysfunction, genitor urinary fistula, previous surgery for SUI, and neurological disease causing combination of bladder and sphincter dysfunction were excluded. At the initial visit, participants were individually taught the anatomy of the pelvic floor, lower urinary tract, and continence mechanism by an experienced physical therapist.

Eligible patients were randomly allocated into three groups, using random assignment individually (roll of die method, throwing a cube that had been removed from its three faces) (Figure 1).

The first group or BF group (n=33) were asked to do pelvic floor muscle contraction using electromyography (EMG) biofeedback (MyoII, EBNeuro, Italy) with an interavaginal probe [19]. Each patient performed 3 sets of exercise by biofeedback: each set consisted of 15 contractions held for 10s, which was followed by

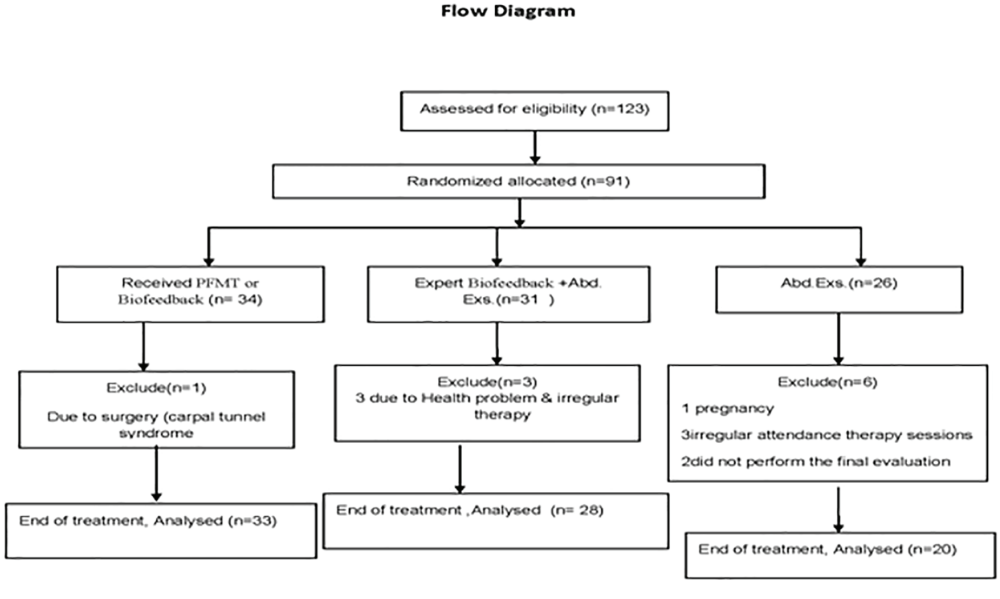

Figure 1: Randomization Flowchart

relaxation for 20s. The rest between sets was 5 minutes. In the second group (BF+AbdExs) (n=28), the patients received biofeedback exercises like the first group plus abdominal muscles exercise [20]. Abdominal training had two stages: In the first stage, the patients were in the crook lying position and performed 3 sets of isometric abdominal contraction, each set with 15 repetitions. The rest between each set was 5 minutes. The second stage had 3 sets, each set included 15 repetitions of curl-up exercise (the patients were in the crook lying position and were asked try to touch the furthest point of their legs with their fingertips on the right and left sides). The rest between each set was 5 minutes. The therapist controlled the pelvic and spinal movements. In the third group or AbdExs group (n=20), the patients were asked to do only Abd.Exs as described for the second group. All patients did the exercises three times a week for a total of 12 weeks. For ethical considerations, the third group was given the option of receiving the same program as the other groups after the trial. The therapist supervised the correct performance in all groups.

The outcome measures were obtained at the baseline and pos-treatment examinations. The outcomes included incontinence quality of life (I-QOL(Questionnaire and PFM strength as well as endurance before and after treatment. All patients completed I-QOL questionnaire in person. The Persian version of I-QOL consists of 22 items, each with a five -point Likert scale, where higher I-QOL scores indicate worse levels of QOL. This questionnaire is valid and the internal consistency reliability was reported to be 0.96 in the Persian version [21]. Pelvic-floor muscle function was examined through digital assessment by an urologist – a collaborator who was blind to the study. The patients were in supine position with hip and knee flexion. In this position, the evaluator introduced two fingers up to one third of the vagina. The patient was then instructed to lift and squeeze the pelvic floor muscle as hard as possible.

The muscle function was assessed by recording the following variables: strength or power (Oxford grading scale) and muscular endurance, based on the maintenance of muscle contraction; the strength was measured using six-point Oxford Grading Scale (OGS): 0, no contraction; 1, flicker; 2, weak; 3, moderate; 4, good; and 5, strong. The muscular endurance was assessed by the extent of muscle contraction in a second. This method of evaluation is standard assessment and was previously described by Laycock et al. [22, 23].

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences (code: 393829) and approval from Iranian registry of clinical trials was obtained (IRCT201506246083N9). Written informed consent was obtained from each patient before enrollment in the study.

Analysis was performed using SPSS software version 13 (SPSS Inc., Chicago, IL, USA). Kolmogorov-Smirnov test was performed to test the normality of data. Pelvic floor muscle strength and endurance were analyzed using one-way ANOVA. Also, the rate of satisfaction with treatment or I-QOL scores between groups was captured using Kruskal-Wallis test. All the statistical tests were 2-tailled at 0.05 significance level.

Results

Eighty-one of ninety-one patients completed the treatment. Forty-nine of them were SUI and 32 were mixed incontinence (symptoms of SUI and UUI with predominant SUI symptoms). The mean age of patients was 49.4±8.4 years. The characteristics of all three groups were comparable at pre-treatment (Table 1). Regarding demographic aspects at baseline, there was no difference in age (49.8±12.9 years), duration of incontinence, and severity of incontinence index between the three groups (P>0.05). According to the I-QOL Questionnaire, there was a significant decrease in the mean scores in all groups after the treatment (P=0.015). Most aspects of QOL improved significantly in the BF+AbdExs group as compared with the other groups (Table 2). The scores of pelvic floor muscle strength and endurance were elevated in all groups following the intervention (Table 2). However, the scores of pelvic floor muscle strength and endurance were not statistically significant different among the 3 groups after the intervention (P>0.05). Further, the score of QOL in between groups was statistically significant (P<0.05) (Table 3).

Table 1: Characteristics of the three groups

Variable / Group	BFµ	BF+AbdExs €	AbdExs €	P value
Age (mean &SD)	51.2±9.7	48.4±6.9	47.8±8.1	P=0.27
Duration (mean)¥	2.5±1.8	2.96±1.4	2.75±1.5	P=0.065
Severity (mean)	1.54±0.5	2±0	1.74±4	P=0.33

*Stress Urinary Incontinence, α: number, €: Abdominal Exercise, µ: EMG Biofeedback ¥: year

Table 2: Mean scores of Quality of Life, Oxford Grading Scale and endurance before and after the intervention

Groups	Variable	BFµ	BF+AbdExs. €	AbdExs€	P value
Before treatment	Score I-QOL.	61.8±19.1	65.2±17.1	63.6±18	P=0.053
	Scale OGSα	2.1±0.3	2.4±0.4	2.7±o.4	P=0.066
	Endurance (second)	2.9±0.4	3±0.3	3.1±0.3	P=0.071
After treatment	Score I-QOL	85.6±13	93.6±11	79.1±17	P=0.015
	Scale OGSα	4±0.7	3.8±0.7	3.6±0.4	P=0.059
	Endurance(second)	6.5±0.3	7±0.1	6.4±0.3	P=0.065

α: Oxford Grading Scale, €: Abdominal Exercise, µ:EMG Biofeedback

Table 3: Comparing Quality of Life between groups after treatment

Groups	Mean±SD	P value
BF$^{\mu}$	85.6±13	0.03
BF+AbdExs.$^{\epsilon}$	93.6±11	
BF$^{\mu}$	85.6±13	0.04
AbdExs.$^{\epsilon}$	79.1±17	
BF+AbdExs.$^{\epsilon}$	93.6±11	0.00
AbdExs.$^{\epsilon}$	79.1±17	

€: Abdominal Exercise, µ: EMG Biofeedback

Discussion

Biofeedback therapy during pelvic floor muscle re-education can improve bothersome symptoms in women with both SUI and UI. Our results indicated that based on I-QOL scores following a pelvic floor training program with biofeedback, the discomfort from urinary symptoms diminished significantly in women with SUI or UI. Improving patient QOL is one of the main purposes of each treatment. Accordingly, the most sensitive tool to evaluate patient QOL improvement is self-report Questionnaire [21] where patients report their opinions with the minimum shame and bias. The mean score QOL was better in those who were trained to do pelvic floor muscle training plus abdominal muscle exercise, with the differences being statistically significant in this group. Indeed, our study revealed that abdominal muscle exercise helps to strengthen pelvic floor muscles to improve QOL, although it cannot be a replacement. It means that the abdominal exercise is a supplementary treatment in UI.

Pelvic floor muscle training in patients with SUI has generally been suggested in previous studies, as these exercises have no side effects and are the first line of treatment of UI [24, 25].

However, these muscles are not directly accessible like most other skeletal muscles. Therefore, biofeedback with an intravaginal electrode seems to be a logical exercise treatment for urinary incontinence. There are three main ideas behind this study: first, use of tools for pelvic floor muscle training increases patient's motivation [26]. Secondly, using biofeedback, patients can regularly see and control each time they attempt to contract their pelvic floor muscles. Further, abdominal muscles can be a trigger for pelvic floor muscles thanks to being accessible and visible for the patient as well as synergic pelvic floor muscles. Therefore, abdominal muscles can be supplementary for pelvic floor muscles or at least help them.

The scores of muscle strength and endurance increased in all three groups, and there were no significant differences. Comparing numbers in all three groups, changes in biofeedback and biofeedback plus abdominal were more considerable than in abdominal training.

The results of our study supported studies of Damoalin C. and Hung HC [15, 16]. They believed that diaphragm and abdominal muscles help pelvic floor muscles in urinary incontinence. Unlike our study, the Kamel DM.'s study presented the idea that, for urinary incontinence, abdominal muscle training is a better option than pelvic floor muscles [20].

Some limitations occurred in the study: few patients (11%, flow chart) dropped out of the study, the subjects who did not understand how to contract PFM (elderly patients) were not included. We lacked assessment with objective instrument such as perineometry or pad test. Future research is thus recommended.

Conclusion

Three months of therapeutic pelvic floor muscle training can improve the QOL in patients with UI; abdominal muscle strengthening also helped pelvic floor muscles as a supplementary treatment in UI.

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Conflict of interest: None declared.

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