International Journal of Thin Films Science and Technology

http://dx.doi.org/10.18576/ijtfst/11S105

Impact of Kegel Exercises and Transcutaneous Tibial Nerve Stimulation on Low Back Pain in Women with Stress Urinary Incontinence: A Randomized Controlled Trial

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Received: 22 Nov. 2021, Revised: 12 Jan. 2022, Accepted: 22 Jan. 2022
Published online: 1 Feb. 2022

Abstract: Background: Low back pain (LBP) was evidenced to be associated with stress urinary incontinence (SUI), both of which are common problems in women. **Aim:** This study aimed to determine the impact of Kegel exercises and transcutaneous tibial nerve stimulation (TTNS) on LBP in women with SUI. **Methods:** Forty-five females complaining of LBP associated with SUI were randomly chosen from the outpatient clinic at Deraya University. Their ages varied from 35 to 45 years, their body mass index (BMI) was 25-30 kg/m^2, with a number of parities $\leq$ three normal vaginal deliveries. They participated in the study after, at least two years from the last delivery. They were divided into three equal groups at random (A, B&C). Group A received standard LBP protocol, group B received (TTNS) and Kegel exercises and group C received the standard LBP therapy, TTNS and Kegel exercises. Evaluation for the three groups was done before and after the interventions by ultrasonography imaging, urinary distress inventory-6 (UDI-6) & modified Oxford scale to assess pelvic floor muscle (PFM) function, while visual analog scale (VAS), Oswestry disability index questionnaire (ODIQ) & Pain Pressure Algometry (PPA) were used to assess LBP. **Results:** Analysis indicated a significant improvement in LBP in the three groups as well as PFM thickness and force in the groups B and C, whereas, there was no statistically significant difference in the group A post-treatment. Comparison between groups post treatment showed significant differences in VAS, ODIQ and UDI-6. For (PPT), PFM thickness & force and modified Oxford scale, there was no statistically significant difference between the groups B & C, while there were significant differences between the groups A&B and A&C. **Conclusion**: Combining Kegel exercises with standard LBP treatment and TTNS is effective in reducing LBP as well as improving PFM function in women with SUI.

Keywords: Kegel exercises; Low back pain; Stress urinary incontinence; Transcutaneous tibial nerve stimulation.

1 Introduction

Urinary incontinence (UI) is termed, according to the International Association of Urinary incontinence, as an involuntary leakage of urine [1]. Stress urinary incontinence (SUI) is an involuntary leaking of urine due to conditions of increased intra-abdominal pressure as sneezing or coughing [2]. It has a vast impact on multiple aspects of the women's daily life [3], and though it affects around 50% of the females over 45 years, a few seek professional help [2]. Low back pain (LBP), on the other hand, is one of the most frequent and significant musculoskeletal disorder [4]. It represents the most common reason for visiting healthcare providers [5].

According to a study, LBP was reported in 71.9% of patients having UI [6]. One proposed mechanism is that pelvic floor muscles, among others, contribute to spinal stability [4] through mechanically supporting the spine and pelvis, and by modulating intraabdominal pressure [7]. Consequently, any impairment of those muscles could negatively affect the lumbopelvic stability, and so is the postural function [7]. The biomechanical link between pelvic floor dysfunction and LBP could be confirmed by the higher incidence of increased lumbar curvature, anterior pelvic tilting, changed thoracic curvature, sacral rotation,

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together with altered both lumbar and pelvic mobility in the women with UI, compared to the women without the condition [6]. As a result, optimizing the pelvic floor support could positively affect cases of LBP. Similarly, it was proved that PFM exercising is beneficial in LBP treatment with UI patients [8].

Strengthening PFM leads to increased pelvic support, providing stability to lumbopelvic structures, and decreased pain associated with lumbopelvic stability [8]. This could be achieved through various approaches. Of them, Kegel exercises are the most widely used approach for augmenting muscles strength and improving the tone [8]. A different approach includes using a neuromodulator, in the form of transcutaneous posterior tibial nerve stimulation (TTNS) to regulate neural activities, resulting in boosting the PFM condition, controlling the lower urinary tract, and facilitating sphincteric action [9]. So, the purpose of this research was developed to determine the effect of Kegel exercises and PTNS on LBP in women with SUI.

2 Materials and Methods

2.1 Trial Design

This trial was designed as a randomized controlled trial. The study was approved by the Ethical committee of Faculty of Physical Therapy, Cairo University (No: P.T.REC/ 012/002738). This study complies with the Helsinki Declaration principles for human research. Each patient signed a written consent form after being given a thorough description of the trial. The study was conducted at the outpatient clinic of Deraya University from November 2020 till December 2021.

2.2 Eligibility Criteria:

The included females were diagnosed with LBP combined with SUI based on the following criteria: their ages ranged from 35 to 45 years, their BMI was 25-30 kg/m^2, with a number of normal deliveries ≤ three times, and having a regular menstruation. They participated in the study complained of both UI &LBP from 6 months and more, mild and moderate SUI and after at least two years from their last delivery.

2.3 Exclusion Criteria

Women with prior history of disc prolapse and sacroiliac joints, symphysis pubic joint as well as lower limb problems, genital prolapse, leg length discrepancy, sever SUI, urinary tract infection, diastasis recti, diabetes, intrauterine device, and surgery related to the spine, abdomen or pelvis as well as skin disease that interferes with the usage of TTNS, chest and/or cardiac disease and using any drugs for pain or UI were excluded from the study participation.

2.4 Evaluation Procedures:

Evaluation of all groups (A, B & C) was done before and two months after the treatment.

2.4.1 Assessment of Pelvic Floor Function

2.4.1.a Ultrasound imaging unit (Mindary DP10, B- mode, Serial number; bn- 75013216, China) with a convex transducer was used at a frequency of 5 MHz for evaluating the thickness and voluntary PFM contractions' force (strength) of all patients. It has a good inter-rater reliability for measuring PFM thickness and force (ICC, 0.81, 0.7123) respectively, as well as a good intra-rater reliability (ICC, 0.98, 0.9841) respectively [10].

The measurements were taken with a full bladder while the woman was in crock position, with the lumbar spine neutrally positioned, and the hips and knees bent to 60°. The ultrasound transducer was inserted transversely across the midline of the abdomen directly superior to the symphysis pubis, with an angle of about 60° from vertical [11]. Further assurance of the examination plane was done by asking the woman to relax the PFM and then perform maximum contraction. A marker (X) was placed on the image of the bladder at the junction of the hyper and hypoechoic structures. Another marker was placed at the end of the muscle, and then the measurement was taken as the distance between the two points [12].

After that initial practice, women performed three maximal PFM contractions so that displacement of the posterior bladder wall, as a result of a pelvic floor muscle contraction, could be measured. A clearly defined edge, at the point of the greatest observed displacement being visible throughout the movement, was selected for the measurement. The image was captured at the moment of maximum displacement. At this time, the woman relaxed the PFM. The investigator then measured the displacement to its current position in the stilled image and was blinded to the measurement value until after the caliper had been fixed at the end point. The transducer was not moved during the procedure to ensure the field of vision remained constant between rest and maximal contraction, (Fig.1). The mean of the three measurements by the same investigator was used for statistical analysis [13].

2.4.1.b Urinary Distress Inventory-6 (UDI-6) was used to assess the influence of urine symptoms, irrelative symptoms, stress symptoms and obstructive/discomfort symptoms on one's life. It consists of 6 items: frequent urination, leakage related to feeling of urgency, leakage related to activity, coughing, or sneezing small amounts of leakage (drops), difficulty emptying the bladder, and pain

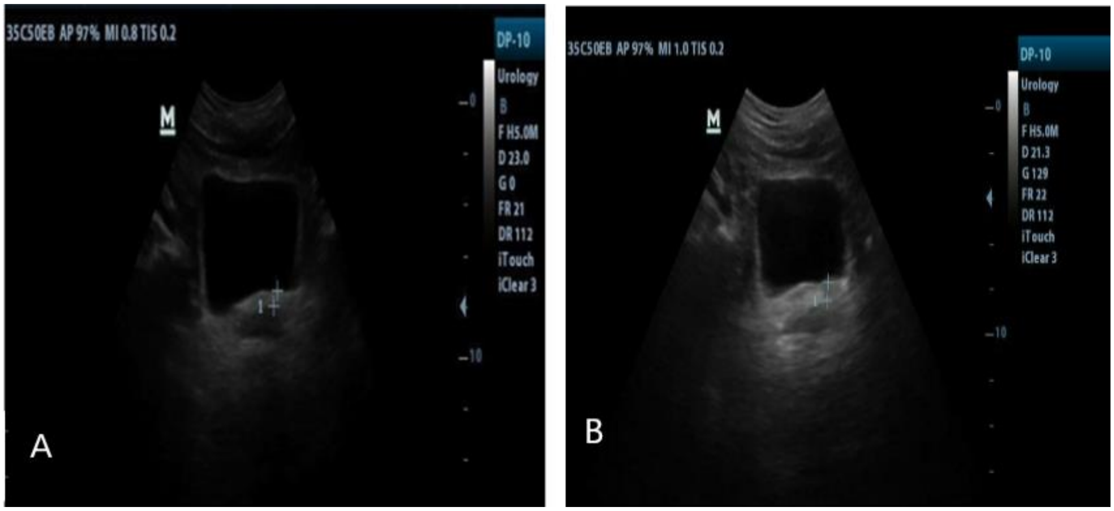

Fig. 1: Ultrasound image of PFM (A) at rest, and (B) at contraction.

or discomfort in the lower abdominal or genital area. Total score is calculated from 0 to 100. The higher the UDI-6 scores, the greater the disability [14].

2.4.1.c Modified Oxford scale was performed by digital vaginal palpation while the woman in crock-lying position to assess PFM strength. It consists of a six-point scale: 0 = no contraction, 1 = flicker, 2 = weak, 3 = moderate, 4 = good (with lift) and 5 = strong [15].

2.4.2 Assessment of Back Pain

2.4.2.a Pressure pain algometry was used to measure the pain pressure threshold (PPT) at lumbar region. The paravertebral measurement locations at the right and left side were chosen, and a pen mark was placed at 5-cm distance from the spinal column at various levels of the erector spinae mass at the third lumbar vertebra and at 4-cm distance at the level of fifth lumbar vertebra [16].

2.4.2.b Visual Analog Scale (VAS) was used to measure pain intensity. It is a horizontal line, usually 10 cm long, whose ends are labeled as the extreme “no pain” and “severe pain” [17]

2.4.2.c Oswestry disability index questionnaire (ODIQ), a 50-item patient questionnaire, was used to assess the amount of the restriction pain imposes on 10 domains; each section is scored on a 0–5 scale, where (5) represents the greatest disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and is expressed as a percentage. 0-20% indicates minimal disability, 21-40% for moderate disability, 41-60% for sever disability , 61-80% for a crippled, while 81-100% represents bed-bound patients [18].

Procedures

The treatment in the three groups was done three sessions per week for 2 months.

2.5.1 Kegel exercises were performed for groups (B) and (C). Each patient was shown how to do Kegel exercises correctly while lying in crock position with a neutral lumbar spine, which entailed squeezing PFM for a few seconds and then relaxing. The first step in doing Kegel exercises was identifying the muscles and the right muscle contraction, followed by both fast and slow contractions. Slow contractions of Kegel exercises that assist in pelvic floor strengthening were: (1) lifting the PFM for ten seconds and (2) holding the muscles tight while counting to ten, doing three repetitions of ten contractions (hold for 10 seconds and relax for 10 seconds) with a two-minute break in between. All individuals were told to relax their abdominals and gluteal muscles, not to hold their breath, and not to strain during PFM contractions. Then, the number of repetitions was gradually increased, try to reach 300 repetitions in day. [19].

2.5.2 Transcutaneous tibial nerve stimulation (TTNS), using EMS electrical stimulation device, model 5200, IOT Japan, was administered to the groups B and C for 20 minutes, while the patient was lying supine on the bed with her head resting on a pillow. The electrodes were secured using tape, one was just posterior to the ankle’s medial malleolus and the other was roughly 10 cm above that. To guarantee that the electrodes activate the tibial nerve, a 10 Hz current frequency with pulse length of 200 µs was delivered initially, with a gradual increase in the intensity to confirm a rhythmic hallux flexion movement [20].

2.5.3 Standard LBP treatment was performed for groups (A) and (C). It consisted of paravertebral therapeutic ultrasound (IOT, Japan), administrated to the low back area for 10 minutes each session, at a frequency of 1 MHz, with an intensity of 1 W/cm^2 and a duty cycle of 50%. Static abdominal exercises as well as bridge, posterior pelvic rocking, McKenzie extension and knee to chest exercises were performed for ten repetitions each session [21].

2.5.4 Statistical methods: Prior to analysis, the normality of data was checked using Shapiro-Wilk test. Levene’s test for homogeneity of variances was conducted to test the homogeneity between groups. ANOVA test was conducted for comparing of the subject characteristics between groups. Mixed MANOVA was conducted to investigate the effect of time (pre versus post) and the effect of treatment (between groups), as well as the interaction between time and treatment on mean values VAS, ODIQ, PPT, PFM thickness as well as force, and UDI-6. Kruskal-Wallis test was conducted for comparing the median values modified Oxford scale between the three groups and was followed by Mann–Whitney U test to identify the significant difference between the two groups. Wilcoxon Signed Ranks Test was conducted for comparing pre and post treatment values in each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

3 Result

3.1 Participant Characteristics:

The mean ± SD for the age (years) and BMI (kg/m²) of the groups (A, B and C) were 39.8± 3.51 & 28.18 ± 1.71, 40.93 ± 3.61& 28.38 ± 1.60 and 40.66 ± 3.57& 27.81 ± 1.97, respectively. There was no significant difference between groups in the age or BMI ($p > 0.05$).

3.2 Effect of Treatment on VAS, ODIQ, PPT, PFM Thickness as Well as Force and UDI-6:

Mixed MANOVA revealed that there was a significant interaction of treatment and time ($F = 14.79$, $p = 0.001$), a significant main effect of time ($F = 140.25$, $p = 0.001$), and a significant main effect of treatment ($F = 5.14$, $p = 0.001$).

3.2.1 Within Group Comparison

There was a significant decrease in VAS and ODIQ and a significant increase in PPT at both spinal sides post treatment compared to pretreatment in group A, B and C ($p < 0.05$), (Table 1). There was no significant difference in the PFM thickness & force and UDI-6 between pre and post treatment in the group A ($p > 0.05$). While there was a significant increase in PFM thickness & force and a significant decrease in UDI-6 post treatment compared to pre-treatment in the groups B and C ($p < 0.001$) (Table 2).

There was no significant difference in the modified Oxford scale scores between pre and post treatment in the group A ($p > 0.05$). While there was a significant increase in the modified Oxford scale post treatment compared to pre-treatment in the groups B and C ($p < 0.001$), (Table 3).

3.2.2 Between Group Comparison

There was a significant decrease in VAS and ODIQ and a significant increase in PPT of both spinal sides in the group B compared to group A ($p < 0.05$), a significant decrease in VAS and ODIQ of the group C compared to the groups A and B ($p < 0.01$), and a significant increase in PPT both spinal sides in the group C compared to the group A ($p < 0.001$), while there was no significant increase in PPT of both spinal sides between the groups B and C ($p > 0.05$) (Table 1).

Also, there was a significant increase in PFM thickness & force and a significant decrease in UDI-6 of the groups B and C compared to the group A ($p < 0.001$), a significant decrease in UDI-6 of the group C compared to that of the group B ($p < 0.01$) (Table 2), but there was no significant difference in PFM thickness & force between the groups B and C ($p > 0.05$). For the modified Oxford scale, there was a significant increase in the score of the groups B and C compared to the group A ($p < 0.001$) while, there was no significant difference between the groups B and C ($p = 0.52$) (Table 3).

4 Discussion

Owing to the biomechanical role that the PFM structure plays in supporting lumbopelvic and postural stability [4, 7], women with incontinence, due to PFM structure weakness, have a significantly higher LBP prevalence than women without that condition. Thus, clinicians should be aware of PFM dysfunction when managing LBP as treating that dysfunction could speed up the LBP recovery time [22]. So, this study aimed to examine the effect of Kegel exercises and TTNS for women with both LBP and SUI.

According to the findings, there was a significant improvement in all measured outcomes post treatment for the groups B and C, with a superior decrease in VAS, ODI and UDI-6 in favor of group C, while the group A showed only a significant improvement in VAS, ODI and PPT.

The improvement noticed in pain outcomes for the groups A& C, who followed standard LBP treatment could be explained by Mahran et al. [23], who reported ultrasound therapy to have a clinical impact in reducing kyphosis and back pain in pre and post-menopausal women, as applying ultrasound could decrease muscle tension and spasm, deactivate trigger points, and relax taut bands [24], improve the circulation, reduce the inflammatory mediators, and restore normal muscle function [25]. Also, Paolucci et al. [26] found that postural rehabilitation, McKenzie exercises, core stability exercises, yoga poses and flexibility training have great effect in reducing pain and related disability in chronic LBP patients.

The results of improved PFM condition and urinary symptoms in the groups applying Kegel exercises were supported by Hwang et al., who found that PFM training reduced urinary leakage, improved female sexual function, and the PFM contraction strength, by facilitating the PFM volitional contraction [27]. For the effects of TTNS on the same parameters, several studies [20, 28-30] reported that form as beneficial in decreasing the incontinence severity in

Table 1: Mean VAS, PPT and ODIQ pre and post treatment of group A, B and C:

	Group A	Group B	Group C	p-value		
	mean ± SD	mean ± SD	mean ± SD	A vs B	A vs C	B vs C
VAS (Score)						
Pre-treatment	7.13 ± 1.3	7.46 ± 1.35	7.33 ± 1.04	0.74	0.89	0.95
Post treatment	6 ± 1.13	4.66 ± 1.23	2.86 ± 1.18	0.01	0.001	0.001
MD (% of change)	1.13 (15.85%)	2.8 (37.53%)	4.47 (60.98%)			
	p = 0.001	***p = 0.001***	***p = 0.001***			
PPT of the right side (kg)						
Pre-treatment	0.61 ± 0.28	0.61 ± 0.21	0.6 ± 0.16	1	0.97	0.99
Post treatment	0.78 ± 0.24	1.08 ± 0.28	1.29 ± 0.37	0.02	0.001	0.16
MD (% of change)	-0.17 (27.87%)	-0.47 (77.05%)	-0.69 (115%)			
	p = 0.03	***p = 0.001***	***p = 0.001***			
PPT of the* left side *(kg)						
Pre-treatment	0.62 ± 0.27	0.60 ± 0.19	0.59 ± 0.15	0.95	0.93	0.99
Post treatment	0.77 ± 0.24	1.09 ± 0.27	1.28 ± 0.35	0.01	0.001	0.18
MD (% of change)	-0.15 (24.19%)	-0.49 (81.67%)	-0.69 (116.95%)			
	p = 0.04	***p = 0.001***	***p = 0.001***			
ODIQ (%)						
Pre-treatment	30.33 ± 6.41	31.73 ± 4.09	32.26 ± 5.73	0.76	0.6	0.96
Post treatment	26.6 ± 5.88	22.13 ± 4.22	17.46 ± 2.92	0.02	0.001	0.01
MD (% of change)	3.73 (12.3%)	9.6 (30.26%)	14.8 (45.88%)			
	p = 0.003	***p = 0.001***	***p = 0.001***			

SD, Standard deviation; p-value, Level of significance

Table 2: *Mean PFM thickness, PFM force and UDIQ-6 pre and post treatment of group A, B and C:*

	Group A	Group B	Group C	p-value		
	mean ± SD	mean ± SD	mean ± SD	A vs B	A vs C	B vs C
PFM thickness (cm)						
Pre-treatment	0.56 ± 0.06	0.59 ± 0.11	0.57 ± 0.09	0.77	0.98	0.86
Post treatment	0.59 ± 0.08	0.79 ± 0.12	0.87 ± 0.14	0.001	0.001	0.12
MD (% of change)	-0.03 (5.36%)	-0.2 (33.9%)	-0.03 (52.63%)			
	p = 0.36	***p = 0.001***	***p = 0.001***			
PFM force (kg)						
Pre-treatment	0.11 ± 0.05	0.1 ± 0.03	0.12 ± 0.04	0.63	0.99	0.55
Post treatment	0.12 ± 0.04	0.18 ± 0.04	0.22 ± 0.05	0.001	0.001	0.15
MD (% of change)	-0.01 (9.09%)	-0.08 (80%)	-0.1 (83.33%)			
	p = 0.41	***p = 0.001***	***p = 0.001***			
UDI-6 (Score)						
Pre-treatment	44 ± 6.84	45.53 ± 4.89	44.73 ± 8.45	0.81	0.95	0.94
Post treatment	42.6 ± 7.34	18.46 ± 4.56	11.8 ± 6.41	0.001	0.001	0.01
MD (% of change)	1.4 (3.18%)	27.07 (59.76%)	32.93 (73.62%)			
	p = 0.33	***p = 0.001***	***p = 0.001***			

SD, Standard deviation; p-value, Level of significance

Table 3: Median values of modified Oxford scale pre and post treatment of group A, B and C.

	Group A	Group B	Group C	p-value		
	Median (IQR)	Median (IQR)	Median (IQR)	A vs B	A vs C	B vs C
Modified Oxford Scale						
Pre-treatment	2 (2-1)	2 (2-1)	2 (2-1)	0.85	0.64	0.73
Post treatment	2 (2-1)	4 (5-4)	4 (5-4)	0.001	0.001	0.52
	p = 0.31	***p = 0.001***	***p = 0.001***			

SD, Standard deviation; p-value, Level of significance

terms of frequency, number of leakage episodes, number of pads used, and overall quality of life. Moreover, TNS was indicated as a treatment for urge and stress incontinence [20]. Multiple theories were suggested, as improving blood flow, and changing neuromechanical balance across neurons [20]. Also, stimulating the PFM through peripheral nerves that represent the same sacral area (S3) as the pudendal nerve is claimed [31].

On the other hand, Gerison et al. stated that neither TTNS nor tradition acupuncture revealed no difference in voiding frequency, mean and maximum voided volume [32]. Also, A study by Wooldridge stated that a retrospective analysis evaluated the application of transcutaneous electrical posterior tibial nerve stimulation in a population of patients failed to achieve adequate control of symptoms of urinary urgency, frequency, and incontinence [33].

Regarding the improved LBP outcomes in the groups B& C, PFM exercises were reported to relieve pain, and decrease disability, when added to abdominal exercises and LBP routine treatment, compared to applying only the routine LBP treatment [34, 35]. Furthermore, PFM could be recommended as a standard program to manage lumbopelvic pain of a mechanical origin [34]. Also, a study done by Sapsford et al. has concluded that activating PFM through stabilization exercises could enhance the LBP symptoms together with SUI in the women complaining from chronic LBP [36]. That effect is attributed to the contribution of PFM to trunk stability, explained by feed forward activation of these muscles in response to trunk perturbation, as a part of the deep stabilizing muscle system [37]. Also, PFM, with the activation of deep stabilizers muscles of the trunk, could decrease lumbar impairment, which suggests a reduction in the lumbar symptoms [38].

The current study has several points of strength, as it approaches a significant problem with a high prevalence among women, with a different point of view. Also, the study used objective tools to measure the outcomes. Though, the study had some limitations, as it lacks a period of follow up to assess the long-term effect of the treatment used.

5 Conclusions

The study has concluded that applying Kegel exercises, with standard LBP treatment and transcutaneous tibial nerve stimulation has a greater effect on reducing LBP as well as improving pelvic floor function in women with SUI, than using each of them alone. Thus, this study may be useful in developing guidelines for treating LBP in patients with SUI.

Acknowledgments: The authors would like to thank all women who took part in the research.

Conflict of interest: The authors stated no conflict of interest.

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