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Neuromodulation effect of laser acupuncture on female stress urinary incontinence: a randomized controlled trial

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ABSTRACT

Although the impact of electroacupuncture or needle acupuncture on stress urinary incontinence (SUI) was previously investigated, there are no previous studies that have investigated the neuromodulatory impact of laser therapy on neurogenic acupoints in women with SUI. The aim of this study was to determine the neuromodulation mechanism of laser therapy on neurogenic acupoints in women with SUI. A prospective, randomized, controlled trial, pre, and post-experimental study was carried out. Thirty women with SUI were equally assigned into two equal groups (control and study groups). The control group received pelvic floor exercises for 6 weeks (n=15), while the study group received the same pelvic floor exercises for 6 weeks in addition to laser acupuncture on neurogenic acupoints (n=15). Before and after rehabilitation, pelvic floor muscle strength (PFMS) was assessed with the XFT-0010 Pelvic Muscle Trainer device, SUI severity was assessed with the Severity Index (SI) for urinary incontinence, and the impact of SUI on quality of life (QOL) was assessed with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF). Comparison between the two groups after treatment showed a significant improvement in PFMS and significant reductions in scores of SI for urinary incontinence and ICIQ-SF ($p<0.05$). The neuromodulatory impact of laser application on neurogenic acupoints significantly increases the strength of pelvic floor muscles and significantly decreases the incontinence level and its impact on QOL in women with SUI.

KEYWORDS

Neuromodulation; Laser therapy; Acupuncture; Neurogenic acupoints; Female Stress Urinary Incontinence

1. INTRODUCTION

Stress urinary incontinence (SUI) includes involuntary leakage of urine due to increased pressure in the abdomen during activities such as coughing and sneezing. It is considered the most well-known form of urinary incontinence in females, as it tends to be caused by an impeded urethral closure mechanism due to pelvic floor weakness, urethral sphincter system damage or urethral hypermobility resulting in ineffective support of the urethral sphincter (Yoshimura & Miyazato, 2012). The SUI risk factors include female population, episiotomy, operative vaginal deliveries, second stage of labor lasting more than one hour, high parity, postmenopause, and pelvic floor muscle weakness (Lindh, Sjöström, Stenlund & Samuelsson, 2016; Arshiya, Noor, Rangaswamy & Sundari, 2015).

The neural regulatory mechanism of micturition that permits the lower urinary tract to eliminate or store the urine, is under the control of the neural circuits that work as an integrated complex of reflexes, as the innervation of lower urinary tract involves both parasympathetic and sympathetic, and also peripheral somatic nerves which include efferent and afferent circuitry from brain and spinal cord (Yoshimura et al., 2014).

The neural active mediated closure of the urethra in case of stress abdominal pressure, like coughing, is considered an important mechanism to prevent SUI, as at first the urethral pressure increases before the transmission of the cough, then the elevated pressure of bladder is exceeded by the urethral pressure elevation during coughing. Blockade of the bilateral pudendal nerves causes a decrease in pressure on the urethral closure during coughing (Yoshimura & Miyazato, 2012).

The neuromodulation technique that is included in lower urinary tract control, considered both the neural circuitry and the neurophysiological process that leads to cross-signaling between postganglionic-parasympathetic nerve terminals and synapses of the sympathetic and parasympathetic nervous system, leading to nerve signals alteration included in the voiding reflex (de Wall & Heesakkers, 2017). The neuromodulation integration of somatic and autonomic nerves to both the urethra and bladder is important in both micturition and incontinence, as stimulation of the sympathetic nervous system originating in the thoracolumbar (T11-L2) spinal cord causes relaxation of the detrusor muscle, while parasympathetic stimulation of the sacral (S2-4) spinal cord region causes contraction, also the external urethral sphincter is controlled by the somatic control (Paik, Han, Kwon, Ahn, Lee & Ahn, 2013).

Therefore, the main aim of neurogenic acupoint therapy is the balanced modulation mechanism of the sympathetic and parasympathetic systems (Al-Bedah et al., 2019). Neurogenic acupoints arise from the activation of somatic afferents of visceral organs in unhealthy conditions with higher electrical conductivity than surrounding tissues (Al-Bedah et al., 2019; Kim et al., 2017). Acupuncture of precise points on both kidney and bladder meridians can prompt qi (the vital substance establishing the human body) enhancement, the improvement of SUI, and the restoration of bladder function (Wang, Zhishun, Peng, Zhao & Liu, 2013). The neurogenic acupoints were selected according to the theory of Korean medicine because their mechanism depends on the somatic and autonomic innervations of the bladder. The common acupoints are BL31, BL32, and BL33, which relate to both the segmental innervation of the bladder by the parasympathetic nervous system and the origin of the somatic fibers of the pudendal nerve which give stimulation to both the sphincter & pelvic floor muscles, so that they can stay in a contraction (Paik, Han, Kwon, Ahn, Lee & Ahn, 2013).

Laser acupuncture (LA) defines a form of acupuncture therapy that depends on the excitation of acupuncture points by using the low-power laser light (Filshie, White & Cummings, 2016). The benefits of LA over other forms of acupuncture mainly depend on its safety, noninvasiveness, and the duration of therapy is relatively short, nearly from 10 seconds to less than 60 seconds per point. The acupoints werestimulated by the laser lightfrom the low-intensity laser (Shin et al., 2015). The impact of electroacupuncture or needle acupuncture on SUI was previously examined (Liuet al., 2017; Shin et al., 2015). However, no previous researches have been studied the neuromodulation impact of laser therapy on neurogenic acupoints in women with SUI. Hence, this examination was the first intending to explore the impact of laser acupuncture on women with SUI. Also, this study might promote the physiotherapy role in woman’s health and neurology.

2. METHODS

2.1. Study design

A prospective, randomized, controlled trial, pre and post-experimental study was carried out. Institutional Ethics Committee of the Faculty of Physical Therapy, Cairo University (No: P.T. REC/012/002930) approved the study and also the ClinicalTrials.gov (NCT04590157).

2.2. Participants and sample size

Thirty married women with a pure SUI diagnose were participated in the study. All participants were randomly selected from the Urology Department, Ahmed Maher Teaching Hospital, Cairo, Egypt. The inclusion criteria for the participants were: Age (30-45) years, body mass index (BMI) less than 30 kg/m^2, parity number (2-4), non-smoking, sedentary lifestyle, and no participation in any exercise training program during this study. The exclusion criteria were other types of urinary incontinence (e.g. urge incontinence and mixed incontinence), urinary tract infections, prolapse of pelvic organs, intrauterine devices, diabetes mellitus, renal disease, pulmonary illness, chronic cough and constipation, any other neurological or musculoskeletal problems of the spine or lower limbs, any acupoint problem such as skin disease, ulcers, or varicose veins, also pregnant or breastfeeding women and the use of any medical or surgical treatment for SUI.

2.3. Randomization

All participants agreed to an informed consent form before the beginning of the study, anonymity and privacy were guaranteed, and all the methods were done consistently with relevant laws and institutional rules. Participants were equally divided into two groups (control and study groups) equally by a computed randomization program. After randomization, no participant withdrawal was detected.

2.4. Interventions

After randomization, procedures were carried out in the outpatient clinic of Physical Therapy for Woman's Health department, Faculty of Physical Therapy, Cairo University. The control group included 15 women who received pelvic floor muscle exercises for 6 weeks, while the study group included 15 women who received the same pelvic floor exercises for 6 weeks in addition to laser acupuncture on neurogenic acupoints for 6 weeks. All procedures of the study are shown in Figure 1.

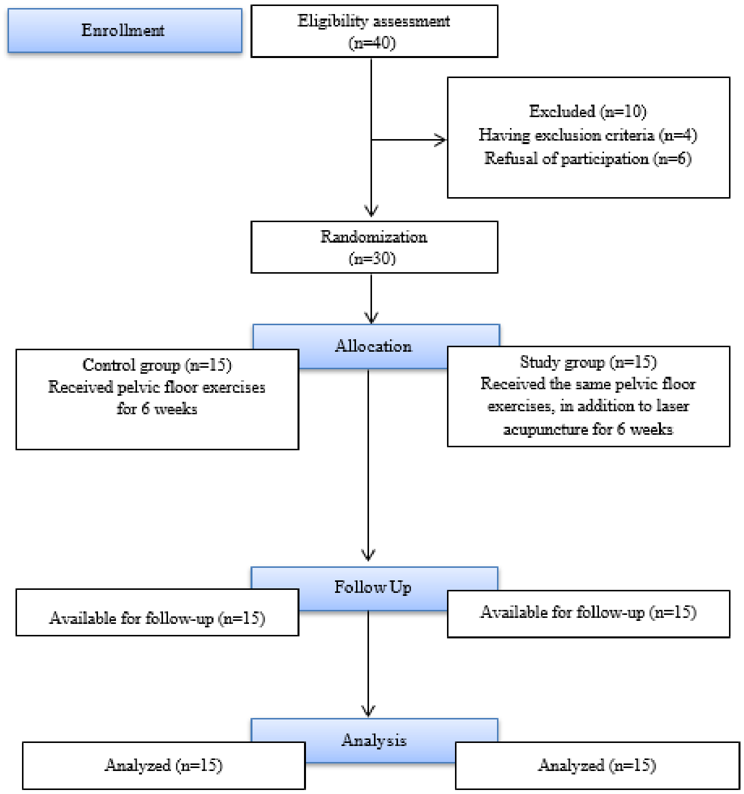

Figure 1. Flow chart demonstrating the procedures of the study.

2.4.1. Pelvic floor exercises

Women in both groups (control and study groups) received 45 minutes of pelvic floor exercises daily for 3 days/week, for 6 weeks. Before the exercises, each woman was instructed to evacuate her bladder and then lie on her back with her knees flexed and hips slightly abducted. The participant was instructed to contract the pelvic floor muscles as hard as possible and hold for 10 seconds; the contraction was repeated 15 times with 10 seconds rest in between. The participant was asked to perform three sets of exercises for 15 minutes per session. Then, the exercises were repeated at home twice per day to reach a total training duration of 45 minutes per day. During the training, the muscles of the abdominal, thigh, and gluteal regions were relaxed to achieve isolated pelvic floor muscle training (Kargar Jahromi, Talebizadeh & Mirzaei, 2014).

2.4.2. Laser acupuncture on neurogenic acupoints

Each woman in the study group received laser acupuncture, through the application of Low-Level Laser Therapy (Gallium-Arsenide diode laser) (Chon, Mallory, Yang, Bublitz, Do & Dorsher, 2019) on neurogenic acupoints, located on Bladder Meridian (BL) and Spleen Meridian (SP) (BL23, BL28, BL32, BL33, BL35, and SP6) (Chang, Lo, Chang, Shiao & Yeh, 2020), three sessions per week, for six weeks. Table (1) explains the clinical importance and the exact location of each neurogenic acupoints (Chang, Lo, Chang, Shiao & Yeh, 2020; Paik, Han, Kwon, Ahn, Lee & Ahn, 2013), as the "cun" is a measurement that was used to detect the location of the acupoint, as a cun described the length of the middle finger between the proximal and distal interphalangeal joints. The laser device parameters were as follows: 904 nm wavelength and a peak power of 15 watts. For the LA treatment procedures, firstly the skin of the treated area was cleaned with alcohol, and the participant was in a prone lying position for the (BL23, BL28, BL32, BL33, and BL35) acupoints, with a pillow under the abdomen. Then, the probe of the laser device was held on the skin, at a right angle, perpendicular to the neurogenic acupoints (Figures 2 & 3), and applied to each acupoint for 60 seconds. Then, the same procedures were repeated on the neurogenic acupoint (SP6) but in the supine position (Paik, Han, Kwon, Ahn, Lee & Ahn, 2013).

Table 1. Locations and neurological clinical importance of neurogenic acupoints.

Point	Location	Neurological Clinical Importance
Bladder (BL) 23	At the level of the 2nd lumbar segment with 1.5 cun external to spinous process lower border.	These two neurogenic acupoints affect the center of micturition and parasympathetic innervation of the urinary system. BL23 is the source point of qi, as its stimulation releases endorphins and serotonin, and facilitates descending pain inhibition
Bladder (BL) 28	At the level of the 2nd posterior sacral foramen, in the middle sacral crest, with 1.5 cun laterally.	
Bladder (BL) 32	At the level of the 2nd sacral foramen, internal and lower to the posterior superior iliac spine.	These points (BL32, BL33, BL35) are related to the parasympathetic segmental innervation nerve supply of the bladder. Furthermore, the BL32 and BL33 areas are related to the somatic fibers origin of the pudendal nerve, which gives excitatory innervation to the pelvic floor muscles and the sphincter, allowing them to remain in a contracted state.
Bladder (BL) 33	On the 3rd posterior sacral foramen in sacral area.	
Bladder (BL) 35	0.5 cun external to coccygeal tip.	
Spleen (SP) 6	Above the medial tip of the malleolus, 3 cun was detected on the tibial posterior border.	SP6 helps with bladder function by invigorating energy.

Figure 2. Model for the application of the laser on the neurogenic acupoint (BL23), which affects the micturition center and the parasympathetic innervation of the urinary system and was located at 1.5 cun external to the inferior border of the 2nd lumbar vertebral spinous process.

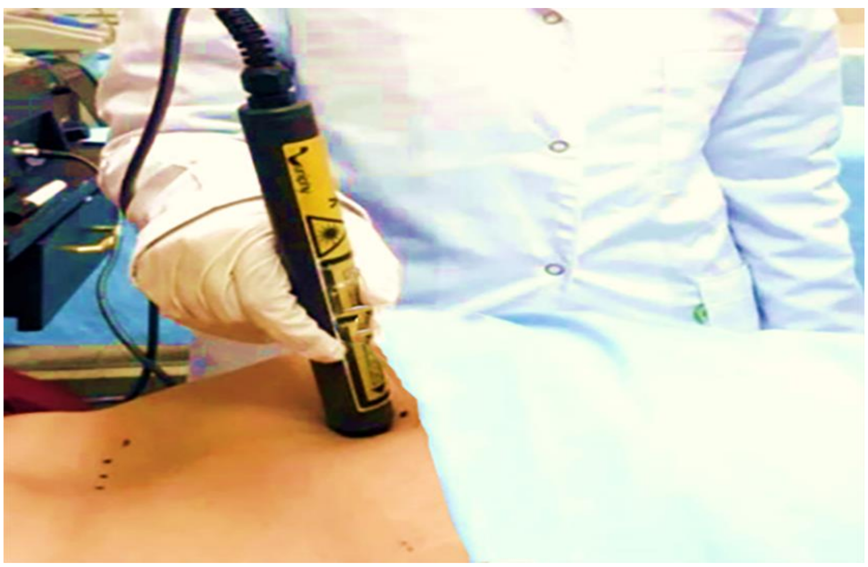

Figure 3. Model for the application of the laser on the neurogenic acupoint (BL33), which corresponds with the origin of the somatic fibers of the pudendal nerve and was located on the 3rd posterior sacral foramen, in the sacral region.

2.5. Outcome measures

2.5.1. Pelvic floor muscle strength (PFMS)

It was assessed pre and post-treatment in all women in the two groups, using the XFT-0010 Pelvic Muscle Trainer device. The device includes a proper size vaginal sensor that was connected by a rubber tube to the main unit. In preparation for the evaluation session, each woman was told to empty her bladder to relax, and all the steps of the assessment were explained to her, and also the exact method of contracting her pelvic floor muscles without the assistance of abdominal or hip muscles. Then, the participant was asked to take a comfortable supine lying position over the plinth, and then perform mental and physical relaxation techniques to achieve complete relaxation prior to PFMS assessment. For mental relaxation, the therapist asked each participant to gently close her eyes and count from 10 to 0 for 5 sets, while for physical relaxation, deep breathing excercises (costal and diaphragmatic breathing) were performed for 3 repetitions; then, a rest period equal to the breathing time was given to avoid hyperventilation. After complete relaxation, the evaluative recording step began using XFT-0010 Pelvic Muscle Trainer. The participant was held in the gynecological position (crock lying position with hip abduction) while a rubber-coated, uninflated sensor covered with a condom and lubricated with KY gel was inserted 2-3 cm into the vaginal introitus, then by pressing a pump button the sensor was inflated and when the air inflation was complete, there was the voice prompt: "pump complete". Once pumping was completed, the voice prompted "please tightly squeeze pelvic muscles as long as you can for 10 seconds, and then relax for another 10 seconds". The test was performed with repetitions of 5 cycles, then the PFMS level was detected by the voice prompt of the device and scored from 1-5 (Artymuk & Khapacheva, 2020).

2.5.2. Urinary incontinence Severity Index (SI)

It was assessed pre-and post-treatment program, in all women in the two groups, using the valid Severity Index (SI) questionnaire for urinary incontinence, which included two questions concerning frequency and amount of urinary loss. The overall score was calculated by multiplying the scores of the two questions as follows: (1 & 2) mild, (3, 4 & 6) moderate, (8 & 9) severe, and (12) very severe (Minassian, Devore, Hagan & Grodstein, 2013).

2.5.3. Stress urinary incontinence (SUI) impact on quality of life (QOL)

It was assessed in all women in the two groups using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF). It contained six questions; related to demographic variables, frequency, amount of leakage, and overall impact on quality of life, as well as unscored item that evaluates the type of incontinence. The higher outcomes presented increased impact with the scores ranging from 0 to 21 (Timmermans, Falez, Mélot & Wespes, 2013).

2.6. Data analysis

The Shapiro-Wilk test was used to test the normality assumption (P>0.05), and Levene's test was used to assess the homogeneity of variance (P>0.05). The data showed normal distribution, and parametric analysis was carried out. The statistical analysis was carried out by using the package program version 25 for Windows (SPSS, Inc., Chicago, IL). For demographic data (age, weight, height, and BMI), PFMS, urinary incontinence SI, and ICIQ-SF variables, all data were presented as mean and standard deviation, while parity was presented as median (interquartile range) and compared between groups by using the Mann-Whitney U test. Within-group comparison between pre-and post-values was done by using the Paired t-test, while between-groups comparison was done by using the unpaired (independent) t-test. For all statistical test, a p-value of ≤ 0.05 was considered statistically significant.

3. RESULTS

Regarding baseline characteristics, there were no statistically significant differences between the two groups before treatment (p>0.05) (Table 2). Statistical analysis within each group showed a significant increase in PFMS (Table 3) after treatment compared to pre-treatment in the control and study groups (p<0.05). In addition, there were significant decreases in urinary incontinence SI and ICIQ-SF after treatment in both groups compared to pre-treatment (p<0.05) (Table 3). Statistical analysis between the two groups showed no significant differences in pre-treatment mean values for PFMS, urinary incontinence SI, and ICIQ-SF (p>0.05) (Table 3). However, after treatment, there were significant differences in the mean values between the control group and the study group as there was a significant increase in PFMS, and significant reductions in both urinary incontinence SI and ICIQ-SF (P<0.05) (Table 3). The results also showed that the percentages improvement were higher in the study group than in the control group for PFMS, urinary incontinence SI, and ICIQ-SF (Table 3).

Table 2. Comparison of mean values of participants' baseline characteristics between both groups.

Variables	Groups (Mean ±SD)		P-value
	Control group	Study group	
Age (Year)	37.79±6.11	38.45±4.69	0.632
Weight (kg)	71.28±9.23	72.26±5.32	0.723
Height (cm)	156.13±6.98	159.07±3.69	0.161
BMI (kg/m^2)	29.24±1.83	28.55±1.27	0.298
	Median (IQR)		
Parity	4.00 (2.00 - 4.00)	4.00 (3.00- 4.00)	0.129

**NOTE: SD (standard deviation); p-value (level of significance); IQR (interquartile range)*

Table 3. Comparison of all measured outcomes variables pre- and post-treatment of the study and control groups.

Variables		Groups (Mean ±SD)		*P*-value
		Control group	Study group	
PFMS	Pre-treatment	1.39 ±0.34	1.87 ±0.26	0.150
	Post-treatment	1.96 ±0.45	3.27 ±0.29	0.0001*
	Change	0.57	1.40	
	Improvement %	41.01%	74.87%	
	P-value	0.002*	0.0001*	
Urinary incontinence SI	Pre-treatment	8.03 ±2.27	8.53 ±1.68	0.494
	Post-treatment	4.09 ±1.30	1.99 ±0.30	0.0001*
	Change	3.94	6.54	
	Improvement %	49.07%	76.67%	
	P-value	0.0001*	0.0001*	
ICIQ-SF	Pre-treatment	14.63 ±1.66	13.48 ±3.70	0.285
	Post-treatment	11.50 ±2.17	4.54 ±1.99	0.0001*
	Change	3.13	8.94	
	Improvement %	21.39%	66.32%	
	P-value	0.0001*	0.0001*	

**NOTE: SD (standard deviation); p-value (level of significance); * (significant (p<0.05)*

4. DISCUSSION

The SUI represents a condition that many women face, and may affect their physical, psychological, and social state. Therefore, the current study demonstrated the neuromodulatory effect of laser acupuncture on neurogenic acupoints in women with SUI for the study group, as there was a significant improvement in PFMS, in addition to significant reductions in urinary incontinence SI and ICIQ-SF. Therefore, the current study findings were consistent with previous studies confirming that acupuncture is an important conservative treatment for women with SUI (Liu et al., 2017; Xu et al., 2016), as it could reduce SUI symptoms through qi reinforcing and promoting recovery of bladder function (Wang, Zhishun, Peng, Zhao & Liu, 2013). Similary, Fistonić et al. (2016) confirmed that laser therapy is a beneficial non-surgical treatment method with minimal invasiveness for women suffering SUI manifestations.

The Female Pelvic Medicine Guidelines and urinary bladder therapy in accordance with the American Urological Association (AUA), begins with diet and behavior lifestyle modification, followed by pharmacotherapy and neuromodulation treatment as a form of third-line therapy (Chang, Lo, Chang, Shiao & Yeh, 2020; Gormley, Lightner, Faraday, Vasavada, American Urological Association & Society of Urodynamics, Female Pelvic Medicine, 2015). The neuromodulatory mechanisms of acupuncture efficacy in SUI include a decline in the activity of the afferent fibers of the bladder wall cells, appropriate energy circulation in channels of meridian, central sensitization reduction, and amelioration of central nervous system (CNS) inhibitory message from descending pathway, as acupuncture controls the parasympathetic system, thereby reducing acetylcholine. The origin of the afferent fibers of the bladder is mainly in the parasympathetic nervous system, as these afferent fibers of the bladder wall, were reduced by the acupuncture mechanism (Paik, Han, Kwon, Ahn, Lee & Ahn, 2013).

The neuromodulation treatment strategy suggests that stimulation of an area of the bladder innervation system may modulate its transmission, as it appears to modify nerve behavior prompting alteration in the function of the bladder through either by stimulating peripheral nerves such as the pudendal nerve, or by stimulating the overlying dermatomes or skin, which is another method of peripheral neuromodulation (de Wall & Heesakkers, 2017; Barroso Jr, Viterbo, Bittencourt, Farias & Lordêlo, 2013).

Manual or electrical stimulation of neurogenic acupoints could be considered as therapy for relevant visceral organ symptoms due to endogenous opioid secretion, with most of neurogenic spots corresponding to the acupoints region (Kim et al., 2016). Abdulaziz et al. (2021) found that the application of cupping therapy to neurogenic acupoints had a significant improving influence on quality of life and decrease in pelvic pain in women with chronic pelvic pain.

Otherwise, laser acupuncture (LA) is considered a neuromodulation method that modulates function and facilitates storage of the urinary bladder, which is in agreement with Chang et al. (2020) study, who found that LA improves quality of life (QOL) and reduces symptoms in women with bladder overactivity. In addition, this previous study confirmed that BL33 and BL34 acupoints, located in the lumbosacral area in the 3rd and 4th sacral foramina, and the pudendal nerve, which supplies the external sphincter of the urethra is formed by the sacral spinal nerves (S2–S4). Jafarpoor et al. (2016) pointed out that the effect of LA therapy in the study group on overactive bladder condition in women was positive and the quantity of nocturia and urinary urgency decreased significantly more than in the control group.

The significant PFMS increase, as well as the significant reductions in urinary incontinence SI and ICIQ-SF scores of the control group, could be supported by Mohamed et al. (2018) who supported the improvement effect in PFMS after six weeks of pelvic floor training, reduction of incontinence manifestations and improving QOL in women with SUI. Therefore, Cavkaytar et al. (2015) confirmed that both PFMS and QOL were significantly improved in women with SUI after home-based pelvic floor muscle training program. Moreover, Bø (2012) also showed that the most important therapeutic exercise for women with SUI included pelvic floor exercises. In the therapy of SUI, pelvic floor muscular exercises are related to two aspects of the pelvic floor muscles, involving pelvic organs support as well as their role in urethral sphincter closure mechanism, as the pelvic floor exercises therapy might be performed to improve power, coordination, and endurance of muscle movements, so the rehabilitation of pelvic floor is commonly the main-line therapy used to treat women with SUI (Kargar Jahromi, Talebizadeh & Mirzaei, 2014).

5. CONCLUSIONS

The neuromodulation effect of laser acupuncture on neurogenic acupoints was effective in treating women with SUI by improving pelvic floor muscle strength (PFMS), decreasing urinary incontinence severity index, and reducing the SUI impact on women QOL. Therefore, it should be included in the treatment program for SUI conditions.

6. LIMITATIONS

The limitation of the current study is that secondary outcomes such as electromyography (EMG), terminal motor latency of the pudendal nerve and sacral reflexes were not evaluated in the current study, which are recommended to be assessed in future research.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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