Am J Transl Res 2022;14(3):2117-2122
www.ajtr.org /ISSN:1943-8141/AJTR0139656

Original Article

Comprehensive treatment of pelvic floor muscle training plus biofeedback electrical stimulation for stress urinary incontinence: a clinical study

Yinghong Zhu[1], Guifang Li[1], Yingbin Zhu[1], Yanchun Yu[2], Xinling Gong[3]

Departments of [1]Obstetrics and Gynecology, [2]General Surgery, [3]Ultrasound, People's Hospital Affiliated to Shandong First Medical University, Jinan 271199, Shandong Province, China

Received October 8, 2021; Accepted January 17, 2022; Epub March 15, 2022; Published March 30, 2022

Abstract: Objective: To investigate the clinical effect of pelvic floor muscle training (PFMT) plus biofeedback electrical stimulation (BES) on stress urinary incontinence (SUI). Methods: 110 patients with SUI admitted to our hospital in the Department of Obstetrics and Gynecology from November 2018 to November 2019 were selected and divided into control group (n=55) and study group (n=55). The study group received PFMT plus BES while the control group received PFMT alone. Results: Compared with the control group, the incontinence quality of life (I-QOL) score and the international consultation on incontinence questionnaire-urinary incontinence short form (ICI-Q-SF) score in the study group were significantly better (P<0.05), and the patients had better pelvic floor muscle endurance, strength, and coordination (P<0.05). Conclusion: PFMT plus BES could improve the strength, endurance, and coordination of pelvic floor muscles in SUI patients. It can positively influence the improvement of the I-QOL and ICI-Q-SF scores. Clinical trial registration: The name of the registry: Chinese Registry of Clinical Trials. Trial registration number: ChiCTR21000684765. Trial URL: http://www.chictr.org.cn/showproj.aspx?proj=73654424.

Keywords: Pelvic floor muscle training, pelvic floor rehabilitation, electrical stimulation, stress urinary incontinence

Introduction

Stress urinary incontinence (SUI) refers to involuntary leakage of urine from the external urethral orifice when abdominal pressure increases, such as sneezing or coughing [1]. The main causes of SUI include pelvic organ prolapse, obesity and age factors. Urodynamic examination showed involuntary leakage of urine in the absence of detrusor contraction during filling cystography with increased abdominal pressure [2]. Women are prone to SUI because of pelvic floor impairment after childbirth. Specifically, one of the common complications after childbirth is stress urinary incontinence. Pregnancy and childbirth are associated with an increased risk of pelvic floor impairment. The incidence of urinary incontinence in females ranges from 10% to 58%, and it reaches up to 73% with age [3]. The urodynamic examination of SUI showed involuntary urine leakage in the case of increased abdominal pressure without detrusor contraction during filling bladder manometry.

Pelvic floor rehabilitation (PFMT) is the common treatment of stress urinary incontinence. PFMT, also known as Kegel exercise, is the main treatment method for SUI [4]. NICE recommends PFMT for at least 3 months under the guidance of a therapist as first-line treatment for patients with SUI and mixed urinary incontinence predominating in SUI (Grade A evidence). For PFMT to be effective, a sufficient amount of training should be achieved [5]. In addition, pelvic floor BSE has been shown to play a significant role in its treatment. It could improve urinary control by strengthening pelvic floor muscles and increasing urethral closure pressure, but not as a routine treatment for SUI [6]. However, the treatment effect is low when these approaches were applied individually in clinical application.

In this study, we explored whether the combined application of PFMT plus BES could get good clinical results in SUI with significant clinical efficacy.

Materials and methods

Study design

The prospective study was adopted that we selected 110 patients with SUI presenting to Department of Obstetrics and Gynecology in our hospital from November 2018 to November 2019 and randomly divided them into study group and control group. This study was ethically approved by the Ethic Committee of Hainan Medical University (Approved no. 2017-LC 244/21). Patients and their families were willing to receive the treatment and testing.

Inclusion criteria: 1) Patients who met the diagnostic criteria of stress urinary incontinence. 2) Patients with an age over 22 years. 3) Patients who had clear thinking ability and were able to follow oral or written guidance.

Exclusion criteria: 1) Patients with psychological urinary incontinence, impulsive urinary incontinence, neurogenic bladder dysfunction, urethral sphincter closure incompetence, etc. 2) Patients with diabetes, mental disorder, and severe primary diseases of cardiovascular, cerebrovascular, liver, kidney, and hematopoietic system.

Research methods

Treatment of the control group: The control group received PFMT [7] with the specific method as follows. The patient continued to contract the pelvic floor muscles (namely anal contraction exercise) for no less than 3 seconds, followed by relaxation and rest for 2 to 6 seconds, which were practiced for 15 to 30 minutes continuously, and repeated 3 times a day for 3 months.

Treatment of the study group: On the basis of PFMT, the study group adopted BES [8] as follows. The patients lay in semi-supine position after defecation and urination. Biofeedback electrical stimulation probe was put into the vagina of parturient women, and the instrument parameters were adjusted to 8-32 Hz, pulse width 320-740 μs for parturient women with type I muscle fiber contraction, and perform electrical stimulation. For patients who were exercising to strengthen class II muscle fiber, the frequency should be set to 20-80 Hz and the pulse width of 20-320 μs. The operation time was set to 10-20 min, twice a week for continuous 5 weeks.

Research outcomes

ICI-Q-SF questionnaire: International consultation on incontinence questionnaire-urinary incontinence short form (ICI-Q-SF) [9] includes 4 items: frequency or urinary incontinence, amount of leakage, overall impact of urinary incontinence, and self-diagnostic item. The total score ranged from 0 to 21 with lower score indicating better condition.

I-QOL questionnaire: Incontinence Quality of Life Scale (I-QOL) [10] includes psychosocial influences, self-distress, escape, restrictive behaviors, etc., with a total of 24 questions and 1-5 points for each. The lower the score, the worse the quality of life.

Pelvic floor muscle strength and endurance: Patients were in a supine position with legs flexed and slightly apart. A guiding sensor with the condom on was inserted into patient's vagina and it was measured when the score was 0. Then patients were instructed to tighten the pelvic floor muscles with her full effort, keep for a long time, which was conducted for 3 times. The pelvic floor muscle strength is defined as the mean score of contraction strength, and the score is proportional to the pelvic floor muscle strength.

Coordination ability: Patient was in a supine position with her legs flexed and slightly apart. A doctor put his/her fingers into the vagina, and the patient tried to tighten the pelvic floor muscles and then relax for 5 times. In the meantime, the doctor observed her coordination on pelvic floor contraction and relaxation, with 1 point equal to incoordination, 2 points to slow coordination, and 3 points to ideal coordination.

Clinical efficacy: It was considered as markedly effective if the comprehensive strength of the pelvic floor returned to normal and the patient's symptoms disappeared completely after treatment, with the average urine flow rate ≥25 ml/s. And the patient didn't experience leaks of urine when coughing, sneezing, position changes, etc. It was considered as effective if the symptoms and the comprehensive strength of the pelvic floor muscle had

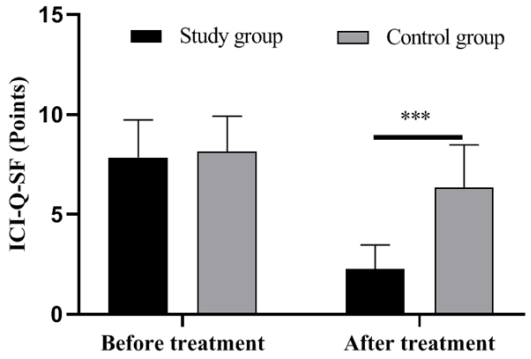

Figure 1. Comparison of ICI-Q-SF score. Note: The X-axis represents groups before and after treatment, and the Y-axis represents the ICI-Q-SF score. The scores of patients in the study group before treatment and after treatment were 6.51±2.67 points and 1.39±1.72 points, respectively. The scores of patients in the control group before and after treatment were 6.89±2.51 points and 4.84±3.02 points, respectively. ***P<0.001 between control group and study group by two independent samples t test.

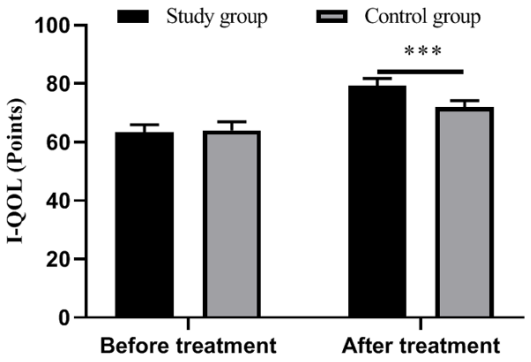

Figure 2. Comparison of I-QOL scores. Note: The X-axis represents groups before and after treatment, and the Y-axis represents I-QOL score. The scores of patients in the study group before and after treatment were 61.38±3.76 points and 77.56±3.49 points respectively. The scores of patients in the control group before treatment and after treatment were 61.99±4.13 points and 70.41±3.14 points respectively. ***P<0.001 between control group and study group by two independent samples t test.

improved. Still, the patient experienced occasional leaks of urine when coughing, sneezing, position changes, etc. It was considered as ineffective if there was no improvement in symptoms and comprehensive strength of the pelvic floor muscle or even the patient got worse and experienced leaks of urine when coughing, sneezing, position changes, etc. The average urine flow rate was recorded and calculated by urograph recorder.

Statistical analysis

GraphPad Prism version 8.0 (GraphPad Software) and SPSS Statistics version 21 (SPSS 21.0; SPSS Inc.) were adopted. The measurement data were represented by ($\bar{x}$±sd), and pair-sample t test was used for intra-group comparison while two independent samples t test was adopted for inter-group comparison. The enumeration data were expressed as % and analyzed using the χ^2 test; counting grade data were expressed as % and tested with rank sum tests. P<0.05 indicated statistically significant difference.

Results

General data

In the study group, there were 55 patients aged 22 to 35 years, with a mean age of 28.4±3.69 years, and in the control group there were 55 patients aged 23 to 39 years, with a mean age of 27.66±3.5 years. No significant difference in the clinical data of the two groups was seen, and they were comparable (P>0.05).

ICI-Q-SF scores

Before treatment, the ICI-Q-SF scores of study group and the control group were 6.51±2.67 and 6.89±2.51, with no significant difference (P>0.05). After treatment, the ICI-Q-SF scores were decreased to 1.39±1.72 and 4.84±3.02 respectively, and the score in experiment group was significantly lower than that in the control group (all P<0.05). See **Figure 1**.

I-QOL scores

Before treatment, the I-QOL scores of study group and the control group were 61.38±3.76 and 61.99±4.13, with no significant difference (P>0.05). After treatment, the I-QOL scores were increased to 77.56±3.49 and 70.41±3.14 respectively, and the score in experiment group was significantly higher than that in the control group (all P<0.05). See **Figure 2**.

Pelvic floor muscle strength

Before treatment, the pelvic floor muscle strength of the two groups was similar (P>0.05). After treatment, the two groups had better pelvic floor muscle strength, and the study

Table 1. Comparison of pelvic floor muscle strength [n, (%)]

		1 point	2 points	3 points	4 points	5 points	Mean
Control group (n=55)	Before	5 (9.09)	25 (45.45)	22 (40.00)	3 (5.45)	0	33.19
	After	0	19 (34.55)	20 (36.36)	11 (20.00)	5 (9.09)	34.56
Study group (n=55)	Before	5 (9.09)	31 (56.36)	12 (21.82)	7 (12.73)	0	30.56
	After	0	19 (34.55)	20 (36.36)	11 (20.00)	5 (9.09)	34.56

Table 2. Comparison of pelvic floor muscle endurance [n, (%)]

		1 point	2 points	3 points	4 points	5 points	Mean
Control group (n=55)	Before	11 (20.00)	16 (29.09)	17 (30.91)	8 (14.55)	3 (5.45)	30.13
	After	0	11 (20.00)	22 (40.00)	16 (29.09)	6 (10.91)	35.21
Study group (n=55)	Before	10 (18.18)	17 (30.91)	16 (29.09)	7 (12.73)	5 (9.09)	30.78
	After	8 (14.55)	15 (27.27)	18 (32.73)	8 (14.55)	6 (10.91)	12.67

Table 3. Comparison of coordination [n, (%)]

		1 point	2 points	3 points	Mean
Control group (n=55)	Before	23 (41.82)	26 (47.27)	6 (10.91)	29.14
	After	12 (21.82)	32 (58.18)	11 (20.00)	35.78
Study group (n 55)	Before	22 (40.00)	25 (45.45)	8 (14.55)	30.64
	After	17 (30.91)	29 (52.73)	9 (16.36)	31.97

Table 4. Comparison of efficacy [n, (%)]

Group	Marked effective	Effective	Ineffective	Total effective
Control group (n=55)	39 (70.91)	13 (23.64)	3 (5.45)	52 (94.55)
Study group (n=55)	30 (54.55)	9 (16.36)	16 (29.09)	39 (70.91)
χ^2				10.752
P				<0.001

group had better pelvic floor muscle strength than that in the control group (all P<0.05). See **Table 1**.

Pelvic floor muscle endurance

Before treatment, the pelvic floor muscle endurance of the two groups was similar (P>0.05). After treatment, the two groups had better pelvic floor muscle endurance, and the study group had better pelvic floor muscle endurance than that in the control group (all P<0.05). See **Table 2**.

Coordination ability

Before treatment, the coordination ability of the two groups was similar (P>0.05). After treatment, the two groups had better coordination ability, and the study group had better coordination ability than that in the control group (all P<0.05). See **Table 3**.

Efficacy

Total effective rate of the study group and the reference were 94.55% and 70.91%, respectively. The study group possessed significantly higher overall effectiveness rate compared to that in the control group (P<0.05). See **Table 4**.

Discussion

SUI is common with a high incidence in the department of obstetrics and gynecology. During pregnancy and childbirth, the muscles, fascia, etc., in the pelvic cavity are excessively pulled, which damages the tissues in the pelvic floor and the urethra and may result in dysfunction of the bladder and urethra [11]. The bladder's pressure is usually higher than that in the urethra when the abdominal pressure increases, which leads to the uncontrolled outflow of urine in SUI patients [12, 13]. The common manifestations are bladder neck dysfunction, urethral sphincter dysfunction, excessive lowering of the proximal urethra, pelvic floor relaxation, etc. Patients might experience SUI when sneezing, laughing, coughing, or even changing their positions, etc. [14, 15]. Medical professionals generally recommend PFMT for prevention of SUI during pregnancy or postpar-

tum, but its efficacy remains controversial. A meta-analysis of 46 trials involving 10,832 women showed that there was no evidence that PFMT could reduce the risk of SUI the third trimester or one year postpartum. And there is little data on the impact of PFMT on the quality of life of incontinent women [16]. However, the result showed that PFMT could reduce the ICI-Q-SF scores of patients while increasing the I-QOL scores. This difference may be related to the population included. In this study, all the participants were young puerpera (age 22 to 35 years), who had better compliance and could ensure the training effect. In addition, this study evaluated the effect at 3 months after the intervention and could not predict the long-term efficacy.

Compared to those in the control group, the pelvic floor muscle strength, endurance, and coordination of the study group after treatment were significantly better. We carried out combined rehabilitation for their SUI through pelvic floor muscle training. Then we employed the low-frequency electrical stimulation to enhance the neuromuscular excitability, and successfully activated a part of the depressed neuromuscular cells and improved the recovery of nerve cells. After electrical stimulation, the pelvic floor muscle strength and endurance of patients in the two groups were significantly improved, and patients in the study group had better treatment effects than patients in the control group. For those with pelvic floor dysfunction, biofeedback can relieve pelvic floor muscle spasm and pain [17]. Biofeedback can help patients have scientific pelvic floor muscle training to achieve and increase the contraction and relaxation of the pelvic floor muscles and promote blood circulation [18]. For this reason, the complications can be prevented to a certain extent. In this study, patients in the study group possessed a higher overall effectiveness rate than the control group, which was consistent with the results of Lasak et al. [19], wherein the authors pointed out that after pelvic floor muscle training, patients in the study group had higher effectiveness rate as compared to patients in the control group (97% vs. 78%), suggesting that pelvic floor muscle training could effectively improve the pelvic floor strength, endurance, and coordination, and reduce the incidence of SUI [20].

However, this study still has some limitations. There was no way to blind the enrollments or health care professionals on whether they had exercised or not. In addition, more attention should be paid to long-term outcomes and this study only looked at outcomes after 3 months.

Together, our findings suggest that pelvic floor muscle training plus biofeedback electrical stimulation is a preferable option for treating SUI due to its merits in repeatability and high cure rate, safety, and effectiveness.

Disclosure of conflict of interest

None.

Address correspondence to: Xinling Gong, Department of Gynecology, Department of Ultrasound, People's Hospital Affiliated to Shandong First Medical University, Jinan 271199, Shandong Province, China. Tel: +86-18976367766; E-mail: chenmanling76@163.com

References

[1] Lasak AM, Jean-Michel M, Le PU, Durgam R and Harroche J. The role of pelvic floor muscle training in the conservative and surgical management of female stress urinary incontinence: does the strength of the pelvic floor muscles matter? PM R 2018; 10: 1198-1210.

[2] Ladi Seyedian SS, Sharifi-Rad L, Ebadi M and Kajbafzadeh AM. Combined functional pelvic floor muscle exercises with Swiss ball and urotherapy for management of dysfunctional voiding in children: a randomized clinical trial. Eur J Pediatr 2014; 173: 1347-1353.

[3] Chiu AF, Hsieh CM, Chu SF and Yang T. Effectiveness of two types of incontinence rehabilitation exercises: a pilot study. Int J Urol Nurs 2018; 12: 2-3.

[4] Kalejaiye O, Vij M and Drake MJ. Classification of stress urinary incontinence. World J Urol 2015; 33: 1215-20.

[5] Karahan N, Arslan H and Çam Ç. The behaviour of pelvic floor muscles during uterine contractions in spontaneous and oxytocin-induced labour. J Obstet Gynaecol 2018; 38: 629-634.

[6] Thomaz RP, Colla C, Darski C and Paiva LL. Influence of pelvic floor muscle fatigue on stress urinary incontinence: a systematic review. Int Urogynecol J 2018; 29: 197-204.

[7] Nilsen I, Rebolledo G, Acharya G and Leivseth G. Mechanical oscillations superimposed on the pelvic floor muscles during Kegel exercises reduce urine leakage in women suffering from stress urinary incontinence: a prospective co-

hort study with a 2-year follow up. Acta Obstet Gynecol Scand 2018; 97: 1185-1191.
[8] Nyström E, Asklund I, Sjöström M, Stenlund H and Samuelsson E. Treatment of stress urinary incontinence with a mobile app: factors associated with success. Int Urogynecol J 2018; 29: 1325-1333.
[9] Rodrigues MP, Paiva LL, Ramos JGL and Ferla L. Vibratory perineal stimulation for the treatment of female stress urinary incontinence: a systematic review. Int Urogynecol J 2018; 29: 555-562.
[10] Hagovska M, Švihra J, Buková A, Dračková D and Švihrová V. Prevalence and risk of sport types to stress urinary incontinence in sportswomen: a cross-sectional study. Neurourol Urodyn 2018; 37: 1957-1964.
[11] ICS 2018 Philadelphia Scientific Programme. Neurourol Urodyn 2018; 37 Suppl 5: 1-430.
[12] Ben Ami N and Dar G. What is the most effective verbal instruction for correctly contracting the pelvic floor muscles? Neurourol Urodyn 2018; 37: 2904-2910.
[13] Kruger J, Budgett D, Goodman J and Bø K. Can you train the pelvic floor muscles by contracting other related muscles? Neurourol Urodyn 2019; 38: 677-683.
[14] Barzegari M, Vahidi B, Safarinejad MR and Ebad M. A computational analysis of the effect of supporting organs on predicted vesical pressure in stress urinary incontinence. Med Biol Eng Comput 2020; 58: 1079-1089.
[15] Sapsford RR, Clarke B and Hodges PW. The effect of abdominal and pelvic floor muscle activation patterns on urethral pressure. World J Urol 2013; 31: 639-44.
[16] Woodley SJ, Lawrenson P, Boyle R, Cody JD, Mørkved S, Kernohan A and Hay-Smith EJC. Pelvic floor muscle training for preventing and treating urinary and faecal incontinence in antenatal and postnatal women. Cochrane Database Syst Rev 2020; 5: CD007471.
[17] Giutronich S, Scalabre A, Blanc T, Borzi P, Aigrain Y, O'Brien M, Mouriquand PD and Heloury Y. Spontaneous bladder rupture in non-augmented bladder exstrophy. J Pediatr Urol 2016; 12: 400.e1-400.e5.
[18] Bø K, Ellstrøm Engh M and Hilde G. Regular exercisers have stronger pelvic floor muscles than nonregular exercisers at midpregnancy. Am J Obstet Gynecol 2018; 218: 427.e1-427.e5.
[19] Hall LM, Aljuraifani R and Hodges PW. Design of programs to train pelvic floor muscles in men with urinary dysfunction: systematic review. Neurourol Urodyn 2018; 37: 2053-2087.
[20] Wakaiki T, Tanaka T, Shimatani K, Kurita Y and Iida T. Individualization of musculoskeletal model for analyzing pelvic floor muscles activity based on gait motion features. J Robot Mechatron 2018; 30: 991-1003.