

Effect of different electrical stimulation protocols for pelvic floor rehabilitation of postpartum women with extremely weak muscle strength

Randomized control trial

Wenjuan Li, PhD, Qing Hu, BS, Zhujuan Zhang, PhD, Fengxian Shen, PhD, Zhenwei Xie, PhD*

Abstract

Background: Pregnancy is one of the main risk factor of pelvic floor muscle dysfunction. Postpartum women with extremely weak muscle strength have difficulty to do voluntary pelvic floor muscle training. This study aims to evaluate the effects of different protocols of electrical stimulation in the treatment of postpartum women with extremely weak muscle strength.

Methods: A total of 67 women were randomized into 2 groups: group A received transvaginal electrical stimulation (TVES) for 5 times, and group B received TVES for 3 times with electromyogram (EMG)-triggered neuromuscular stimulation twice. Subjects were evaluated before and after treatment. Pelvic muscle strength was measured by both digital vaginal palpation and EMG variables, and quality of life was investigated by 4 kinds of pelvic floor disease-related questionnaires.

Results: According to the intention-to-treat principle, compared with baseline, in group A, EMG of contractile amplitude of endurance phase was significantly elevated ($P = .03$), variation of contractile amplitude in tonic phase was more stable after treatment ($P = .004$), and EMG of mean value of final rest was significantly elevated after treatment ($P = .047$). After 5 times treatments, the incidence of correct pelvic floor muscle contraction in group A was significantly elevated ($P = .045$). No significant difference of muscle strength test by digital vaginal palpation was detected between the 2 groups, so did questionnaires.

Conclusion: For postpartum women with extremely weak muscle strength, TVES for 5 times might be more benefit for control ability of pelvic muscle contractions and elevating muscle strength even in short-time treatment.

Abbreviations: Edu-mean = mean value of 60 seconds sustained contractions, EMG = electromyogram, ES = electrical stimulation, flick-max = max value of fast contractions, IIQ-7 = Incontinence Impact Questionnaire, I-QOL = Incontinence Quality of Life, ITT = intention-to-treat, PFD = pelvic floor muscle dysfunction, PFDI-20 = Pelvic Floor Distress Inventory - short form 20, PFIQ-7 = Pelvic Floor Impact Questionnaire Short Form, PFM = pelvic floor muscle, PFMT = pelvic floor muscle training, PISQ-12 = Prolapse and Incontinence Sexual Function Questionnaire Short Form, POP = pelvic organ prolapse, post-mean = mean value of final rest, PP = per protocol, pre-mean = mean value of initial rest, QOL = quality of life, RCT = randomized controlled trial, SUI = stress urinary incontinence, tonic-mean = mean value of 10 seconds sustained contractions, TVES = transvaginal ES.

Keywords: electromyogram, pelvic floor muscles dysfunction, postpartum women, transvaginal electrical stimulation

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1. Introduction

Dysfunction of pelvic floor muscle (PFM) is associated with stress urinary incontinence (SUI), anal and fecal incontinence, pelvic organ prolapse (POP), and sexual dysfunction, which will negatively affect quality of life (QOL) in women.^[1] It is reported that nearly a quarter of women have moderate to severe symptoms of PFM dysfunction (PFD), especially for women in reproductive age.^[2] The cause of PFD is multifactorial, but pregnancy is one of the main associated risk factor.^[3,4] Pregnancy-induced alterations to the PFM, connective tissues, and reproductive tract are associated to fetal growth and delivery. Decreased collagen content and a signature of collagen fiber dissociation with smooth muscle were detected in pelvic tissue during gestation.^[5] Levatorani muscle complex and the connective tissue attachments of the vagina to the sidewalls provide normal pelvic support. After labor, dysfunction of levatorani has been found irrespective of mode of delivery.^[6] Damages after delivery like nerve injury, avulsion of a muscle, rupture of connective tissue under the skin, and excess levator hiatus area of pelvic floor may result in immediate symptoms. However, when added to deterioration with advancing age, damages can lead to symptoms later in life.^[7] It is reported that postpartum rehabilitation of PFM was effective in reducing the incidence of PFD, and the benefits could present for a long period after delivery.^[8,9] Therefore, postpartum is an ideal time for preventing and treating PFD, especially for those women with extremely weak muscle strength.

The PFD can be managed by surgical and conservative therapy. Women with symptomatic PFD who fail or decline conservative therapy are candidates for surgery. Surgical repairs of PFD result in improved prolapse-related symptoms and QOL in most cases.^[10,11] However, surgeries for PFD are usually associated with increased risks of complications, recurrence, and reoperation.^[12] Conservative treatments include lifestyle modifications and PFM training (PFMT) are associated with low risk of adverse events and effective in management of SUI and POP with mild symptoms.^[13,14] Meta-analysis demonstrated women who received PFMT showed a greater subjective improvement in prolapse symptoms and an objective improvement in POP severity, prevent and treat urinary incontinence, and amelioration QOL.^[15-17] Appropriate contraction and relaxation of PFM is important to build a strong and well-functioning pelvic floor. However, the effect of PFMT was limited by the level of initial strength, especially for the postpartum women with extremely weak muscle strength who were unable to do conventional contraction. Electrical stimulation (ES) is an alternative method for enhancing PFM strength, especially in muscles severely compromised. As a passive treatment, transvaginal ESs (TVESs) use electrodes directly stimulate the PFMs. Subtle different from TVES, electromyogram (EMG)-triggered neuromuscular stimulation is a mode of passive stimulation combined with voluntary PFMT. It requires subjects to voluntarily generate sufficient pelvic muscle activity to a target threshold, then assisting ES begins as soon as EMG activity reaches the target threshold.^[18] Studies found ES can cause contractions and relaxation of the pelvic floor, increase the number of muscle fibers with rapid contraction.^[19,20] Based on high-quality evidence, ES is an effective adjuvant treatment to for elevating skeletal muscle strength in adults with advanced disease, even in those patients who have difficulty in engaging training programs.^[21,22] Also, short-term benefit of ES for PFMT has been supported by European

Association of Urology,^[23] and the far superior effect in elevating pelvic muscle strength of ES combined with PFMT had been supported.^[24]

However, the effect of ES on muscle strength of pelvic floor was not settled.^[25,26] Besides, in postpartum women with extremely decreased muscle strength who have difficulty in voluntary PFMT, whether the early onset of involuntary PFMT is required is still need to be discussed. Moreover, optimal protocol for integrating passive ES with active pelvic muscle training has not yet been well established. Hence, we conducted a single-blinded randomized controlled trial (RCT) to evaluate the effect of different protocols in the ES treatment of postpartum women with extremely weak muscle strength. The aim of this single-blinded RCT was to compare the short-term effects of different protocols of ES in postpartum women.

2. Materials and methods

2.1. Population

Sixty-seven postpartum women were successively enrolled at our departments from April 2018 to June 2018. Standardized assessment of extremely weak muscle strength was performed at enrollment. Postpartum women aged 20 to 42 at 7 to 14 weeks after delivery or cesarean section were eligible to participate if they meet the inclusion criteria: postpartum women with weakness of PFM, with or without SUI during pregnancy or after delivery, and POP which is diagnosed according to the International Continence Society and International Urogynecological Association.^[1] Extremely weak muscle strength of pelvic floor in postpartum women refer to muscle strength at level 0 to 1 measured by via vaginal palpation according to modified Oxford scale.^[27] POP is measured using the POP-Q system. Patients voluntarily accepted clinical observation, and signed informed consent; completed the junior high school or higher education; spirit and memory ability are normal; and have complete language expression ability.

Major exclusion factors were patients who have overactive pelvic floor dysfunction: urinary retention, constipation, pelvic pain, vulvar pain, and dyspareunia; POP of stage III and stage IV; chronic diseases of nerve and muscle function (such as multiple sclerosis, Parkinson disease myasthenia gravis, etc); malignant tumor, diabetes, and other serious medical diseases; pelvic radiation rectal surgery, spinal surgery, hysterectomy; pelvic inflammation, urinary tract infection and vaginitis; cardiac pacemaker implantation; pregnancy; cognitive impairment; refuse to accept clinical observation. This research was approved by the Ethics Committee of the Women's Hospital School of Medicine Zhejiang University, Hangzhou, China (ID 20170126), and informed written consent was obtained from all participants. This study had been registered in Chinese Clinical Trial Registry (ID ChiCTR-IOR-17013442).

2.2. Treatment and study design

This prospective, single-blinded RCT was conducted in Women's Hospital School of Medicine Zhejiang University. After an initial screening visit, women were randomly assigned to one of the 2 therapy groups on the basis of computer-generated random number. Randomization was performed by concealing the allocations in sequentially numbered, opaque, sealed envelopes. Once enrolled by a physician investigator, eligible volunteers

were randomized in 2 groups using a computer-generated randomization list: group A, TVES for 5 times; group B, TVES for 3 times and EMG-triggered neuromuscular stimulation for twice. Vishee neuromuscle stimulator (MyoTrac Infiniti, model SA9800; Thought Technology Ltd, Montreal, Canada) and surface EMG electrode (type VET-A, produced by Nanjing Vishee Medical Technology Co., Ltd, Nanjing, China) were used for ES. Subjects were positioned supine with 45° of hip and knee relaxed and abducted. Electrode was placed in the vagina of the patients. Intravaginal electrode with 2 independent channels was previously cleaned and inserted. The electric parameters for TVES and EMG-triggered neuromuscular stimulation (constant current generator): biphasic pulse, frequency 50Hz, pulse width was 250 microseconds, time 25 minutes, time on:off 4:8, current intensity: maximal level tolerable.^[28] At each visit, volunteers had 5 minutes Kegel bio-feedback training after ES treatment. Subjects received treatment twice a week, total of 5 sessions. The investigator who responsible for assessing patients' outcomes was not involved in administering any of the interventions and blinded to the group assignments. We did the sample size calculation prior to the study. To calculate sample size, the change of muscle strength after ES was extracted from previous study,^[26] type I error ratio α (2-sided) was 0.05 and the type II error ratio β was 0.1. The sample size calculation was performed using PASS software. Result showed that the sample size was 60; therefore, 67 enrolled patients were enough for this study.

2.3. Measurements

A blinded experienced physiotherapist performed evaluations of pelvic muscle strength via both digital palpation and EMG. Patients were evaluated in the lithotomy position after micturition, with straight knees and leg abducted and instructed to relax the PFM. Muscle strength and questionnaire investigation were given to the subjects before and after the 5 times intervention.

2.4. Digital palpation

Physiotherapists assess PFM strength during vaginal as posed by Laycock and Jerwood.^[27] Physiotherapist introduced the index and middle fingers into the vagina to evaluate muscle strength of PFM. Subjects were asked to perform 3 lift and squeeze movements around the examiner fingers lasting 4 to 5 seconds with the maximum PFM contractions possible with interval of 30 seconds between each. The examiners determined the co-contraction of other muscles (gluteus or abdomen) and whether subjects were breathing normally. The highest contraction was classified according to the modified Oxford scale (0–5 points).

2.5. Surface electromyography

Neuromuscle stimulator and intravaginal electrode for surface EMG evaluation was described as before. Two channels were connected to a disposable intravaginal electrode for recording electrical activity of PFM construction. Other 2 electrodes were placed in region of abdominal rectus muscles (one on the right side and the other on the left side) to monitor crosstalk of contraction of the abdominal muscles. The EMG chart indicated activity of the abdominal muscle compatible with rest (EMG scale between 0 and 5 μ V) is considered as correct PFM contraction. The EMG for pelvic floor evaluation used Glazer protocols following 5-segment assessment sequence: prebaseline for 1

minute rest, muscle electrical signal recorded as mean value of initial rest (pre-mean); 5 rapid contractions with 10 seconds rest between each flicks, recorded as max value of fast contractions (flick-max); five 10 seconds contractions with 10 seconds intervals between each contractions, recorded as mean value of 10 seconds sustained contractions (tonic-mean); endurance, single 1 minute contraction recorded as mean value of 60 seconds sustained contractions (edu-mean); post baseline for 1 minute rest, recorded as mean value of final rest (post-mean).^[29] We also record electrical activity of abdominal muscles by percutaneous electrode during EMG test, if the participation of abdominal muscles was lower than 10% would be recorded as correct PFM contraction.

2.6. Questionnaires

Pelvic Floor Impact Questionnaire Short Form (PFIQ-7), Pelvic Floor Distress Inventory-short form 20 (PFDI-20), and Prolapse and Incontinence Sexual Function Questionnaire Short Form (PISQ-12) were investigated by self-administered method. Patients who undergo stress urinary continence during pregnancy or after delivery were required to complete Incontinence Impact Questionnaire (IIQ-7). If there is any omission during the inspection, the patient will be required to replenish. All subjects completed questionnaire investigation and uploaded the pictures of their EMG reported by “Penyikang” app designed by our research group (no 2017016 and no 2017850 of the computer software works of People's Republic of China Copyright Administration).

2.7. Statistical methods

Data were collected by app of “Penyikang.” We analyzed data according to the intention-to-treat (ITT) as well as per protocol (PP) principle. Women who were randomized, but never started or completed treatment were included for the ITT analyses. However, those women were excluded for the PP analysis. All analyses were conducted on an ITT basis for all efficacy variables. Data from the subjects who had a baseline and postbaseline measurement were included. Quantitative data were expressed as the mean \pm standard deviation, including age, body mass index, history of gestation, value of EMG and result of questionnaire, and compared by *t* test for 2 groups. Numeration data were described as percentage, including change of muscle strength by digital palpation and incidence of correct PFM contraction compared by Chi-squared test. Analysis was executed by SPSS V11.0 (SPSS, Chicago, IL). Statistically differences between groups were tested at a 2-sided with significance level of .05.

3. Results

Flowchart of Figure 1 is given showing the disposition of subjects: group A, n = 34; group B, n = 33. Volunteers were included while 25 of whom withdrew from this single-blinded RCT. Most common cause for withdrew is busy baby-care and unwilling for continuing hospital-based treatment. The anthropometric characteristics are described in Table 1, no statistically significant had been detected between group A and group B. *T* test showed no significant differences of EMG and questionnaire result between the 2 groups at the initial of the study (Table 2). One of the patients in group A had a history of twin pregnancy, the others were all singleton. Review of baseline data from these groups of all subjects for whom any of these data were available did not

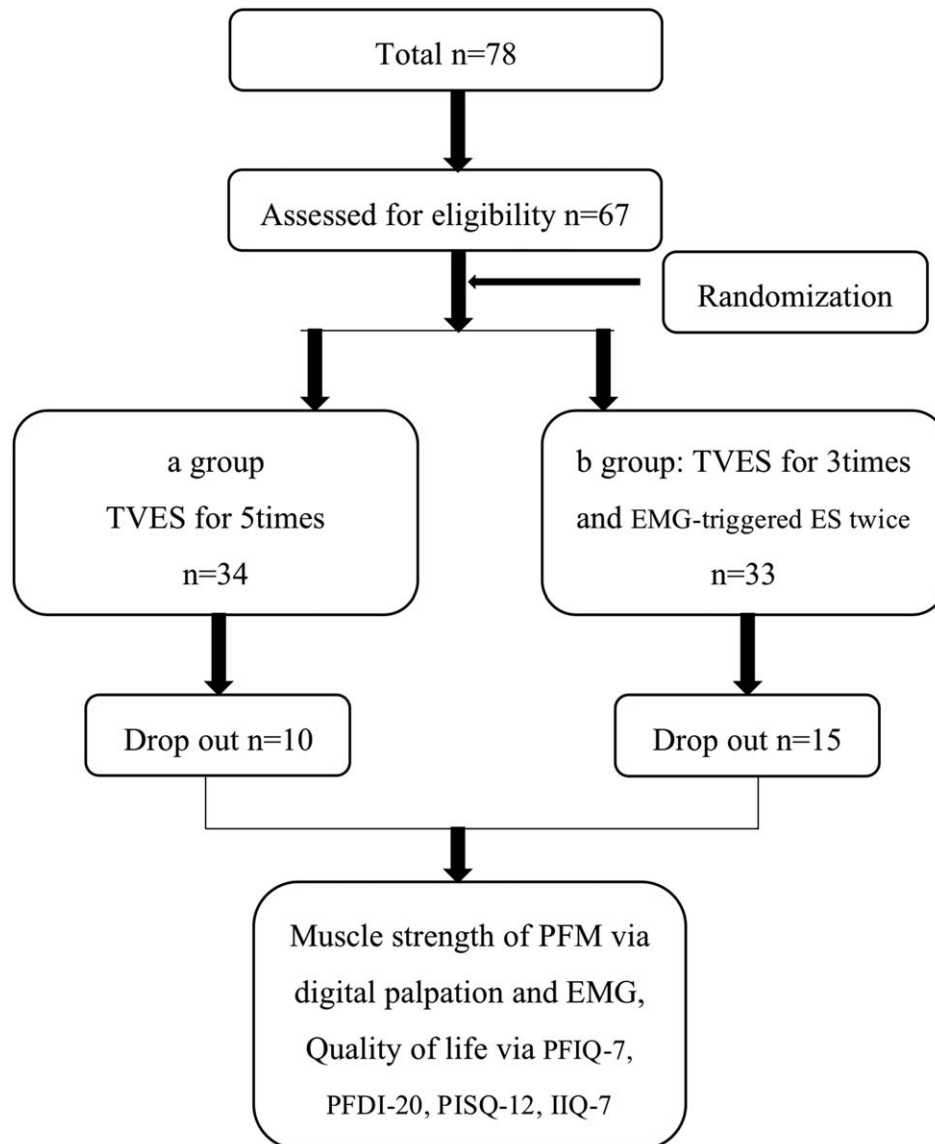


Figure 1. Flowchart of subject disposition in the trial. ES = electric stimulation, TVES = transvaginal electric stimulation, EMG = electromyogram, PFM = pelvic floor muscle, PFIQ-7 = Pelvic Floor Impact Questionnaire Short Form, PFDI-20 = Pelvic Floor Distress Inventory-short form 20, PISQ-12 = Prolapse and Incontinence Sexual Function Questionnaire Short Form, IIQ-7 = Incontinence Impact Questionnaire.

Table 1
Clinical characteristics of subjects.

Items	Group A	Group B	P value
Age, yr	31.12±3.60	30.24±4.23	.36
Height, cm	161.35±6.13	160.64±3.89	.57
Weight, kg	59.19±10.26	57.36±8.65	.43
BMI, kg/m ²	22.76±4.14	22.22±3.19	.55
Cesarean section, % (n)	11.77 (4)	6.06% (2)	.67
Vaginal delivery, % (n)	76.47% (26)	87.88% (29)	.37
Forceps delivery, % (n)	11.77% (4)	3.03% (1)	.37
Highly educated, % (n)	94.12% (32)	90.91% (30)	.67
Multipara, % (n)	38.24% (13)	30.30% (10)	.61
Weight of newborn, >4kg, % (n)	11.77% (4)	30.30% (1)	.39

BMI = body mass index.

disclose evidence of randomization imbalance. After 5 times treatment, questionnaire and muscle strength by both digital palpation and EMG have been tested. All subjects were interviewed about discomfort that had occurred during follow-up, the most common problem was the increase of vaginal discharge which is considered endurable by subjects.

After 5 times treatment, ITT analysis of digital palpation showed 32% of patients in group A and 18% of patients in group B have elevated muscle strength, respectively ($P=.36$). PP analysis also found no significant difference in the change of muscle strength (group A vs group B, 45% vs 33%, $P=.53$).

Table 2 manifests EMG value between the 2 groups during the study. Both groups have elevated EMG valued in flick, tonic, and endurance phase after treatment, but no significant difference had been detected between group A and group B after treatment according to ITT and PP principle. Significant difference of EMG

Table 2**Comparison of EMG for evaluable subjects.**

Data set	Group items	Baseline	After treatment	P value
ITT	Group A (n=34)			
	Pre-mean, μv	3.49 \pm 1.19	4.00 \pm 2.10	.22
	Flick-max, μv	17.83 \pm 8.68	20.12 \pm 9.16	.29
	Tonic-mean, μv	10.68 \pm 4.60	12.31 \pm 6.00	.21
	Variation of tonic-mean	0.27 \pm 0.12	0.22 \pm 0.09	.04*
	Edu-mean, μv	8.56 \pm 3.06	10.87 \pm 5.25	.03*
	Variation of edu-mean	0.22 \pm 0.08	0.19 \pm 0.07	.13
	Post-mean, μv	2.74 \pm 1.33	3.60 \pm 2.11	.05
	Group B (n=33)			
	Pre-mean, μv	3.18 \pm 1.62	3.09 \pm 1.69	.82
	Flick-max, μv	16.42 \pm 8.44	17.60 \pm 10.51	.62
	Tonic-mean, μv	9.91 \pm 5.51	11.48 \pm 7.18	.32
	Variation of tonic-mean	0.26 \pm 0.13	0.23 \pm 0.09	.21
	Edu-mean, μv	8.81 \pm 4.83	9.81 \pm 5.71	.45
Variation of edu-mean	0.20 \pm 0.07	0.19 \pm 0.07	.52	
Post-mean, μv	2.43 \pm 1.21	2.79 \pm 1.68	.32	
PP	Group A (n=24)			
	Pre-mean, μv	3.48 \pm 1.26	4.21 \pm 2.39	.20
	Flick-max, μv	16.96 \pm 8.68	20.20 \pm 9.49	.22
	Tonic-mean, μv	8.65 \pm 3.20	13.16 \pm 6.64	.18
	Variation of tonic-mean	0.26 \pm 0.11	0.19 \pm 0.04	.00*
	Edu-mean, μv	8.65 \pm 3.20	11.92 \pm 5.70	.02*
	Variation of edu-mean	0.22 \pm 0.09	0.18 \pm 0.07	.10*
	Post-mean, μv	2.71 \pm 1.35	3.93 \pm 2.31	.03*
	Group B (n=18)			
	Pre-mean, μv	3.31 \pm 1.71	3.14 \pm 1.83	.77
	Flick-max, μv	17.87 \pm 8.92	20.02 \pm 12.02	.55
	Tonic-mean, μv	20.02 \pm 12.02	12.98 \pm 8.37	.24
	Variation of tonic-mean	0.27 \pm 0.16	0.21 \pm 0.10	.17
	Edu-mean, μv	8.85 \pm 4.80	10.68 \pm 6.23	.33
Variation of edu-mean	0.20 \pm 0.07	0.18 \pm 0.07	.38	
Post-mean, μv	2.60 \pm 1.45	3.254 \pm 2.05	.27	

Edu-mean=mean value of 60 seconds sustained contractions, EMG=electromyogram, flick-max=max value of fast contractions, ITT=intention-to-treat, post-mean=mean value of final rest, PP=per protocol, pre-mean=mean value of initial rest, tonic-mean=mean value of 10 seconds sustained contractions.

*Compared with baseline, $P < .05$.

between baseline and endpoint were seen in group A: mean value of contractile amplitude in endurance phase is significantly elevated (Table 2); the muscle at tonic phase is more stable than baseline (Table 2). Mean value of final rest was significantly elevated after treatment in group A in PP analysis but no in ITT analysis (Table 2). Changes of EMG in group B compared with baseline have no significant difference.

At the end of follow-up, no significant difference of questionnaire had been detected between baseline and after treatment in 2 groups according to both ITT and PP principles (Table 3). After 5 times treatments, the incidence of correct PFM contraction in group A was both significantly elevated (baseline vs after treatment, ITT analysis, 26% vs 50%, $P = .04$; PP analysis, 38% vs 71%, $P = .02$). While in group B, significant difference had only been detected in PP analysis (baseline vs after treatment, ITT analysis, 21% vs 45%, $P = .07$; PP analysis, 39% vs 83%, $P = .01$). Although percentage of incidence of correct PFM contraction was elevated in both groups A and B, no significant difference had been found between these 2 group (group A vs group B, $P = .57$).

4. Discussion

For patients suffered from PFD, loss of muscle strength and its related symptoms bring them declined QOL and cost significant

socioeconomic impact. ES is one of the conservative options which available for managing dysfunction of PFM with mild symptoms.^[13,14] Prior research found that ES could cause contractions and increase the number of muscle fibers, inhibit the parasympathetic motor neurons, and organize collagen of the pelvic floor.^[19,20] Granted, in short term, ES may add benefit to PFMT, but whether the early onset of involuntary PFMT is required in patients with extremely decreased muscle strength who have difficulty in voluntary PFM is still need to be discussed. This study is a single-blinded RCT to assess the efficacy of different protocol of TVES in the management of postpartum women with extremely weak muscle strength.

The TVES is a safe and effective choice for elevated muscle strength, and our study also found the most common adverse effect is the increased vaginal fluid which did not serious disturb subjects. Discussions regarding TVES in PFD treatment have dominated research in recent years. Lack of a clear biologic rationale obstruct reasoned choice of ES parameters might contribute to the difficulty of evaluating potential value and benefits of TVES.^[30] ES parameters, including current, pulse width and duration, stimulus frequency, pulse shape, etc, are vary from study to study. Wide range of parameters, frequencies of 5 to 50Hz, and 200 to 1000 microseconds have been declared effective for PFD.^[28,31] An RCT aimed to compare the effect between medium-frequency current and low-frequency current

Table 3
Comparison of questionnaire for evaluable postpartum women.

Data set	Group items	Baseline	After treatment	P value
ITT	Group A (n=34)			
	PFDI-20	20.20 ± 28.26	20.95 ± 36.73	.93
	PISQ-12	15.83 ± 18.56	15.48 ± 18.88	.94
	PFIQ-7	2.33 ± 5.83	2.07 ± 6.84	.87
	IIQ-7	0.58 ± 1.17	0.50 ± 1.27	.87
	Group B (n=33)			
	PFDI-20	21.57 ± 19.73	18.52 ± 18.11	.55
	PISQ-12	17.00 ± 17.62	16.71 ± 17.76	.95
PP	Group A (n=24)			
	PFDI-20	21.14 ± 29.34	22.33 ± 40.58	.99
	PISQ-12	16.32 ± 18.47	17.00 ± 17.62	.68
	PFIQ-7	2.29 ± 5.46	1.91 ± 6.95	.84
	IIQ-7	0.38 ± 0.52	0.17 ± 0.41	.21
	Group B (n=18)			
	PFDI-20	18.34 ± 19.32	13.57 ± 19.32	.44
	PISQ-12	18.44 ± 17.24	19.00 ± 17.92	.93
	PFIQ-7	1.63 ± 4.80	1.19 ± 2.79	.76
	IIQ-7	0.50 ± 0.55	1.33 ± 1.75	.29

IIQ-7 = Incontinence Impact Questionnaire, ITT = intention-to-treat, PFDI-20 = Pelvic Floor Distress Inventory- short form 20, PFIQ-7 = Pelvic Floor Impact Questionnaire Short Form, PISQ-12 = Prolapse and Incontinence Sexual Function Questionnaire Short Form, PP = per protocol.

protocol of TVES in SUI treatment, they found both were equally effective in increasing perineal pressure.^[32] On the basis of the prior researches, we choose 50Hz for frequency and 250 microseconds for pulse width.

This study demonstrated that short-time treatment of ES could ameliorate weak muscle strength measured by digital palpation in both groups but no significant difference between 2 groups. The effect of ES treatment on pelvic muscle strength from previous studies is uncertain. For patients with SUI, high qualified research analyzed whether the ES was effective than no treatment: Pereira et al conducted a pilot RCT to treat SUI women over 60 years with surface ES for 6 weeks with 2 weekly sessions of 20 minutes each, did not discovered any significance in PFM pressure between ES group and no treatment^[25]; in contrast, another RCT assessed the effect of ES for 12 sessions in women ≥50 years, found significant improvement in PFM strength in TVES group.^[26] However, another study also discovered ES is far superior to no treatment in elevating muscle strength tested by Oxford scale, but PFMT group is more effective than the ES group.^[33] Previous prospective clinical trials have verified result of the effect of TVES. Our study found in postpartum women with extremely weak muscle, both protocol of ES could elevate muscle strength but no significant difference between these 2 protocols. Our study included postpartum women who are in childbearing age and just 7 to 14 weeks after delivery or cesarean section, difference of subject selection might explain the different result from previous study. As digital palpation considered to be subjective and not sufficiently sensitive by some researchers,^[34,35] we introduced surface EMG to measure muscle strength.

The Glazer protocol is an electrical physiologic approach integrated with EMG amplitude and standard deviation of pelvic muscle for each contraction and relaxation period for measuring. It had been proven to be reliable and consistently predictive tool in detection and prophylactic intervention for PFD.^[36] Results of our study demonstrated contractile amplitude of endurance

contraction is significantly elevated and the stability of contractile amplitude at tonic phase is significantly elevated in group A compared with baseline. Levatorani muscle, main support tissue of pelvic floor, has 3 patterns of fiber type: type I fiber (slow switch, oxidative) is function for antigravity and endurances activities, type IIA (fast switch, oxidative) and type IIB (fast switch, glycolytic) are equipped for more rapid, physical activity of shorter duration. By biopsy, cluster size of type I fiber can take up to 90% while type II fiber below 8% and never above 10% in levatorani muscle. EMG value of elevated contractile amplitude of endurance phase and stability of tonic phase in group A manifested TVES might be benefit for elevating slow constriction fiber of PFD even in short follow-up. For postpartum women with PFD, another multicenter, single-blinded, randomized trial had been carried out to evaluate ES treatment in pelvic floor rehabilitation in postpartum, they also found TVES could obviously improve pelvic floor electrical physiologic index compared with PFMT group in postpartum 6 and 12 months.^[9] Our results of EMG indicated that TVES for 5 times treatment benefit for the stability of PFM for slow contraction.

In patients with vulvar vestibulitis syndrome, biofeedback could release vulvar vestibular pain and decreased resting tension levels of EMG.^[29] In our study, post-mean of EMG was significantly elevated compared with baseline in group A, but none of these women reported vulvar vestibular pain. Hence, we suggest longer time of Kegel bio-feedback training after TVES treatment according to previous study.

In clinical trials, QOL has become an important outcome measure. We investigated subjects by 4 kinds of questionnaire before and after ES treatment, and did not discover any significance after treatment. Although applied different investigation tool from our study, previous RCTs both derived that compared with no active treatment, ES could significant improvement QOL in SUI patients.^[25,26,33] Besides, Terlikowski et al detected TVES with biofeedback group had higher score of

QOL questionnaire than biofeedback group in premenopausal women with SUI.^[24] While compared with PFMT, Castro et al evidenced that the effect of ES on the QOL investigated by Incontinence Quality of Life (I-QOL) was equal to PFMT in SUI patients; nevertheless, Sun et al found no significant difference in QOL tested by PFIQ-7 and PISQ-12 in postpartum women with dysfunction of PFM.^[9,33] In our study, we designed different protocols for treatment, also detect no statistical significant in ameliorating QOL after treatment which is accordance with the result in postpartum women who had been investigated by the same questionnaires. PFD is a chronic disease with long treatment time. Take SUI for example, the guide recommends PFMT for at least 12 weeks.^[17] While our study focused on the improvement of muscle strength in patients with very weak muscle strength after short-term treatment. The short observation time may be the reason why there no significant difference in the QOL.

In postpartum women with SUI, pelvic-floor rehabilitation is recommended.^[37] Actually, in women with PFD, 70% of them were unable to perform correct voluntary PFM contraction.^[38] After treatments, the incidence of “correct PFM contraction” was both significantly elevated in our study. Pelvic floor rehabilitation is an effective short-term treatment to elevated pelvic muscle strength, but should be supervised by a physiotherapist.^[39]

In conclusion, this study demonstrates that for postpartum women with extremely weak muscle strength receive ES treatment, TVES for 5 times might be more benefit for control ability of pelvic muscle contractions and elevating muscle strength even in short-time treatment. More RCTs with sufficient sample sizes and long-term follow-up are still needed for further study.

Author contributions

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Formal analysis: Fengxian Shen.

Funding acquisition: Zhenwei Xie.

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