

Original Article

A study of efficacy of traditional Chinese medicine combined with biofeedback electrical stimulation on postpartum pelvic organ prolapse

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Received August 12, 2020; Accepted September 21, 2020; Epub December 15, 2020; Published December 30, 2020

Abstract: Objective: To investigate the clinical efficacy of traditional Chinese medicine (TCM) combined with biofeedback electrical stimulation (BES) on postpartum pelvic organ prolapse (POP). Methods: From October 2016 to December 2018, a total of 184 patients visiting the postpartum outpatient clinic of our hospital were selected in accordance with the diagnostic criteria of POP-Q stage I and II in Western medicine and uterine prolapse Qi deficiency syndrome in Chinese medicine, and were divided into the BES group (140 cases, biofeedback electrical stimulation therapy) and the TCM combined with BES group (44 cases, oral administration of “decoction for invigorating qi for ascending” combined with BES). The myodynamia, myoelectric potential, vaginal anterior wall prolapse, urinary incontinence and qi deficiency scores in the two groups were observed before and after treatment. Results: After a course of treatment, the myodynamia and myoelectric potential in the two groups increased ($P < 0.05$), the vaginal anterior wall prolapse and urinary incontinence were improved ($P < 0.05$), and the qi deficiency scores decreased ($P < 0.05$). The differences in the vaginal anterior wall prolapse, urinary incontinence, and the qi deficiency scores were more significant in the TCM combined with BES group ($P < 0.05$). Conclusion: TCM combined with BES therapy exhibits an excellent clinical efficacy in the treatment of postpartum POP.

Keywords: Traditional Chinese medicine, biofeedback, electrical stimulation, pelvic organ prolapse

Introduction

Pelvic organ prolapse (POP) [1] happens when the muscles and tissues supporting the pelvic organs (the uterus, bladder, or rectum) become weak or loose. This allows one or more of the pelvic organs to drop or press into or out of the vagina, resulting in abnormal position and function of organs. POP patients primarily experience the protrusion of external pudendal mass accompanied by or not accompanied by urination and defecation disorders, external pudendal bleeding and inflammation, etc., affecting the quality of life of patients to varying degrees. Although POP is not life-threatening, it affects women's quality of life and psychological health through multiple aspects, such as symptoms, physiology, psychology and behaviors [2].

With the aging population and the improvement of people's standard of living and health awareness, the prevalence of POP and the hospital

admittance rate of POP patients are on the rise [3]. Li et al. [4] found that the overall prevalence of POP in urban women in China was 9.67%, and the prevalence of POP in the population aged over 70 years was as high as 26.11%. In United States, the prevalence of POP was 13%, and it is estimated that by 2050, the prevalence of POP in women will reach 50% [1]. Uncomfortable symptoms and high treatment costs bring heavy psychological and economic burdens to POP patients and the society. Clinical observation exhibits that the POP is highly prevalent in early postpartum women.

In TCM, there is no name for POP. According to its clinical manifestations, POP belongs to the category of “Uterine Prolapse”. In TCM, the clinical manifestations and treatment of uterine prolapse have been long recorded. The etiology and pathogenesis of POP are summarized as deficiency of vital qi and parturient injury. This is widely recognized by physicians and basically

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consistent with the understanding of physicians of western medicine. In regard to the characteristics of “strengthening vitality and consolidating astringency and kidney yin”, they remain the guiding principle for treatment of uterine prolapse using TCM. Oral administration of TCM and biofeedback combined with electrical stimulation are commonly adopted to treat POP clinically.

This study was adopted in order to explore the influence of TCM combined with BES on postpartum POP, and to investigate whether the combination of TCM and BES can achieve the efficacies of “1 + 1 > 2”.

Materials and methods

Study subjects

From October 2016 to December 2018, a total of 184 patients visiting the postpartum outpatient clinic of our hospital were selected in accordance with the diagnostic criteria of POP-Q stage I and II in Western medicine and uterine prolapse Qi deficiency syndrome in Chinese medicine, and the patients were divided into the BES group (140 cases, biofeedback electrical stimulation therapy) and the TCM combined with BES group (44 cases, oral administration of “decoction for invigorating qi for ascending” combined with BES). Inclusion criteria: 1. Vaginal delivery of a full term singleton breech fetus without forceps delivery. 2. A time period of 40-60 d after delivery. 3. Fetal birth weight: 2500-4000 g. 4. Mother was aged between 20-0 years. 5. No previous history of pelvic surgery. 6. Voluntary signing of the informed consent and participant consent form. Exclusion criteria: 1. Women who were combined with neuromuscular history, chronic cough and constipation history, and serious cardiac, cerebral, pulmonary, and/or hepatic diseases. 2. Women who were allergic to the drugs used in this study. 3. Women with contraindications of biofeedback electrical stimulation. This study has been approved by the Ethics Committee of Hangzhou Women's Hospital.

Diagnostic criteria

Diagnostic criteria in Western medicine: By reference to the relevant content of *Female Pelvisology* [5] (Zhu L, Jinghe L) and pelvic

organ prolapse quantification (POP-Q) proposed by Bump in 1996 and recognized by the International Continence Society (ICS), American Urogynecologic Society (AUGS), and Society of Gynecologic Surgeons (SGS); the criteria was prepared.

Diagnostic criteria in TCM: By reference to the contents regarding uterine prolapse of *Gynecology of Traditional Chinese Medicine* [6] (Yuzhen Z) and the symptoms and signs of qi deficiency syndrome in the *Guiding Principle of Clinical Research on New Drugs of Traditional Chinese Medicine* issued by the former Ministry of Health, the criteria was prepared: ① The uterus moves down or bulges outside the vaginal opening, the vaginal wall relaxes and swells, intensified by labor. ② The lower abdomen droops, tired and weak spirit, shortness of breath and disinclination to talk, and spontaneous perspiration. ③ Frequent urination, or a large amount of thin and white vaginal discharge. ④ Pale complexion. ⑤ The tongue is light and fat, or has tooth marks and thin fur. ⑥ Slow and weak pulse. The diagnosis can be only conducted if ① and any two of ②-⑥ are possessed.

Treatment options

The patients were divided into the BES group and the TCM combined with BES group (oral administration of “decoction for invigorating qi for ascending” combined with BES). Before treatment, patients in both groups received a detailed explanation of the treatment purpose, precautions and options, so that they understood the treatment process as well as help to increase their enthusiasm for and compliance with treatment. During the treatment, patients received health education, and were instructed to conduct Kegel exercises, so as to assist them in developing a healthy lifestyle.

BES group: The BES group received biofeedback combined with electrical stimulation therapy. PHENIX biological stimulation feedback instrument (U4 type, France) was utilized. The patient was instructed to empty their bladder before treatment. First, the A1 channel was connected to the pelvic floor muscle treatment head, and then the treatment head was put into the patient's vagina after being coated with lubricating conductive paste. Three neutral electrodes of the A2 channel were attached,

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Table 1. Scoring table for qi deficiency symptoms of patients

	Yes (1 Point)	No (0 Point)
The uterus moves down or bulges outside the vaginal opening, the vaginal wall relaxes and swells, intensified by labor		
Lower abdomen falling		
Tired and disinclination to talk		
Pale complexion		
Limb fatigue		
Frequent micturition		
A large amount of thin and white vaginal discharge		

one of which was placed on the epidermis of bony tissue and two of which were placed on the surface of abdominal muscles. Then, the proper biofeedback electrical stimulation therapy was selected, and implemented twice a week for 30 min each time. There were 10 applications in a course of treatment.

TCM combined with BES group: The TCM combined with BES group received BES and oral administration of “decoction for invigorating qi for ascending”. “Decoction for invigorating qi for ascending” consists of 24 g of *Astragalus membranaceus*, 15 g of *codonopsis pilosula*, 15 g of *pseudostellaria heterophylla*, 15 g of *fried atractylodes macrocephala koidz*, 24 g of *rhizoma polygonati*, 20 g of *fructus rubi*, 9 g of *cimicifuga foetida*, 6 g of *platycodon grandiflorum*, 12 g of *fructus aurantii* and 6 g of *liquorice*. The herbs were prepared by the TCM pharmacy of our hospital. Each dose was decocted in 2 bags, and each bag contained 200 ml of herb liquor. A bag of decoction was taken warm both in the morning and evening, and the decoction was taken continuously for 5 weeks. Five weeks was a course of treatment.

Observation indexes

General conditions of patients: General conditions of patients were collected using a questionnaire, including age, menarche age, menstrual period, cycle, weight gain during pregnancy, body mass index before delivery, duration of the second stage of labor, fertility, sex of fetus and birth weight of fetus.

Assessment of myodynamia and myoelectric potential: The myodynamia and myoelectric potential of patients were assessed using electromyography (EMG) before treatment and 3 months after treatment, and the pelvic floor

EMG was conducted using the evaluation procedure for pelvic floor function of the PHENIX biological stimulation feedback instrument (U4 type, France), and the myodynamia of Type I muscle was reflected by a continuous contraction value for 6 s. The mean value (rapid contraction value) was obtained by rapid contraction for 5 times to reflect the myodynamia of Type II muscles. The myoelectric potential was recorded using the maximum contraction strength.

POP conditions: Patients with postpartum POP primarily experience vaginal anterior wall prolapse. Therefore, the vaginal anterior wall prolapse of patients was assessed before treatment and 3 months after treatment. The patients were instructed to empty the bladder, keep the lithotomy position, and disinfect the vulva. The vaginal anterior wall prolapse was assessed using POP-Q.

Urinary incontinence: Urinary incontinence was assessed before treatment and 3 months after treatment. Urinary incontinence was divided into urinary incontinence and non-urinary incontinence. According to the degree of urinary incontinence, urinary incontinence was divided into: mild: urinary incontinence occurs under severe pressure, such as coughing and sneezing. Moderate: urinary incontinence occurs under moderate pressure, such as fast walking and going up and down stairs. Severe: urinary incontinence occurs under mild pressure, such as standing, but the discharging of urine can be controlled in a supine position.

Scores for Qi deficiency symptoms: The qi deficiency symptoms were scored before treatment and 3 months after treatment. The scoring basis is shown in **Table 1**.

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Table 2. General conditions of patients in the two groups

Indexes	BES Group	TCM Combined with BES Group	P
Age (years)	30.10±3.59	29.18±3.17	0.131
Menarche age (years)	14 (13-14)	13.5 (13-14)	0.402
Menstrual period (d)	6 (5-7)	5 (5-7)	0.096
Cycle (d)	30 (30-30)	30 (28-30)	0.095
weight gain during pregnancy (kg)	14.28±3.57	14.10±3.21	0.769
BMI before delivery (kg/m ²)	26.08±3.53	25.95±2.40	0.816
Duration of the second stage of labor (min)	35.5 (12.00-71.75)	33.0 (11.25-69.75)	0.902
Fertility	Primiparity	97	29
	Multiparity	43	15
Birth weight (kg)	3.28±0.39	3.31±0.40	0.716
Sex of fetus	M	72	18
	F	68	26

Table 3. Comparison of myodynamia of type I muscle between the two groups before and after treatment (Cases (%))

Group	1 Point	2 Points	3 Points	4 Points	5 Points
BES Group (140 cases)					
Before treatment	83 (59.3)	21 (15.0)	15 (10.7)	14 (10.0)	7 (5.0)
After treatment	2 (1.4)	11 (7.9)	29 (20.7)	36 (25.7)	62 (44.3)
TCM Combined with BES group (44 cases)					
Before treatment	33 (75.0)	3 (6.8)	6 (13.6)	0 (0)	2 (4.5)
After treatment	2 (4.5)	7 (15.9)	12 (27.3)	9 (20.5)	14 (31.8)

Statistical methods

The data were processed using SPSS 22.0. The measurement data conforming to the normal distribution were expressed using ($\bar{x} \pm s$), and the measurement data not conforming to a normal distribution were expressed using Median (IQR). The enumeration data were detected using chi-squared test. The enumeration data not conforming to the chi-squared test conditions were detected using the Fisher exact probability test. $P < 0.05$ indicated a statistically significant difference.

Results

General conditions of patients in the two groups

The statistical analysis revealed that there was no statistically significant difference in age, menarche age, menstrual period, cycle, weight gain during pregnancy, body mass index before delivery, duration of the second stage of labor, fertility, birth weight and sex of fetus between the two groups ($P > 0.05$) (Table 2).

Comparison of myodynamia, myoelectric potential, vaginal anterior wall prolapses, urinary incontinence and qi deficiency scores between the two groups before and after treatment

Comparison of myodynamia of type I muscle between the two groups before and after treatment: Before treatment, there was no difference in the comparison of myodynamia of Type I muscle between the two groups ($P > 0.05$). After treatment, the ratios of myodynamia (3-5 points) in the two groups increased ($P < 0.001$), but there was no difference between the two groups ($P > 0.05$) (Table 3).

Comparison of myodynamia of type II muscle between the two groups before and after treatment: Before treatment, there was no difference in the comparison of myodynamia of Type II muscle between the two groups ($P > 0.05$). After treatment, the ratios of myodynamia of Class II muscle in the two groups increased ($P < 0.001$), but there was no difference between the two groups ($P > 0.05$) (Table 4).

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Table 4. Comparison of myodynamia of type II muscle between the two groups before and after treatment (Cases (%))

Group	1 Point	2 Points	3 Points	4 Points	5 Points
BES Group (140 cases)					
Before treatment	72 (51.4)	34 (24.3)	21 (15.0)	8 (5.7)	5 (3.6)
After treatment	5 (3.6)	12 (8.6)	37 (26.4)	53 (37.9)	33 (23.6)
TCM Combined with BES group (44 cases)					
Before treatment	24 (54.5)	7 (15.9)	9 (20.5)	2 (4.5)	2 (4.5)
After treatment	2 (4.5)	6 (13.6)	15 (34.1)	14 (31.8)	7 (15.9)

Table 5. Comparison of myoelectric potentials between the two groups before and after treatment (Median (IQR))

Group	No. of Cases	Myoelectric Potentials (uv)		P
		Before treatment	After treatment	
BES Group	140	4 (3-6)	8 (6-10)	< 0.001
TCM Combined with BES group	44	5 (4-6)	8 (6-10.75)	< 0.001
P		0.087	0.990	

Table 6. Comparison of vaginal anterior wall prolapses between the two groups before and after treatment (Cases (%))

Group	No. of Cases	Before treatment		After treatment		P
		POP-Q Stage I	POP-Q Stage II	POP-Q Stage I	POP-Q Stage II	
BES Group	140	96 (68.6)	44 (31.4)	112 (80.0)	28 (20.0)	0.029
TCM Combined with BES Group	44	30 (68.2)	14 (31.8)	41 (93.2)	3 (6.8)	0.03
P		0.961		0.042		

Comparison of myoelectric potentials between the two groups before and after treatment: Before treatment, there was no difference in the comparison of myoelectric potentials between the two groups ($P > 0.05$). However, the myoelectric potentials of the maximum contraction strength in the two groups increased after treatment ($P < 0.001$), and there was no difference in the comparison of change amplitudes between the two groups ($P > 0.05$) (Table 5).

Comparison of vaginal anterior wall prolapses between the two groups before and after treatment: There was no difference in POP-Q stage of anterior vaginal wall prolapse between the two groups before treatment ($P > 0.05$). The anterior vaginal wall prolapses in the two groups were improved after treatment ($P < 0.05$). The anterior vaginal wall prolapse was more markedly improved in the TCM combined with BES group ($P < 0.05$) (Table 6).

Comparison of urinary incontinence between the two groups before and after treatment: There was no difference in urinary incontinence between the two groups before treatment ($P > 0.05$). However, urinary incontinence in both groups was improved after treatment ($P < 0.05$). Urinary incontinence was more significantly improved in the TCM combined with BES group ($P < 0.05$) (Table 7).

Comparison of qi deficiency scores between the two groups before and after treatment: There was no difference in the comparison of qi deficiency scores between the two groups before treatment ($P > 0.05$). After treatment, the qi deficiency scores in both groups decreased ($P < 0.001$), and the qi deficiency scores in the TCM combined with BES group decreased more obviously ($P < 0.001$) (Table 8).

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Table 7. Comparison of urinary incontinence between the two groups before and after treatment (Cases (%))

Group	No. of Cases	Before treatment		After treatment		P
		Non-urinary Incontinence	Urinary Incontinence	Non-urinary Incontinence	Urinary Incontinence	
BES Group	140	77 (55.0)	63 (45.0)	100 (71.4)	40 (28.6)	0.004
TCM Combined with BES Group	44	20 (45.5)	24 (54.5)	40 (90.9)	4 (9.1)	< 0.001
P		0.269		0.008		

Table 8. Comparison of qi deficiency scores between the two groups before and after treatment (Median (IQR))

Group	No. of Cases	Qi Deficiency Scores (Points)		P
		Before treatment	After treatment	
BES Group	140	4 (3-5)	3 (2-4)	< 0.001
TCM Combined with BES Group	44	4 (3-5)	2 (1-2.75)	< 0.001
P		0.389	< 0.001	

Discussion

Early treatment of postpartum POP

Studies reveal that there are multiple environmental factors affecting POP, such as estrogen level, age, weight, constipation, long-term smoking, a history of pelvic surgery, fetal weight, delivery mode, multiple parities, prolonged second stage of labor, etc. [7-11]. Among them, vaginal delivery is recognized as a risk factor closely related to POP [12]. Vaginal delivery can cause extreme traction of pelvic floor nerves and muscles, tear or injury of pubocervical fascia, and directly or indirectly destroy the supporting structure and vaginal wall of pelvic floor fascia. These are the pathogenesis of postpartum POP. Clinical findings suggest that there are many female patients with POP in the early postpartum period. Lin et al. [11] reported that the incidence of POP in women was 75.2% at 42-60 days after delivery. Postpartum pelvic floor rehabilitation plays a crucial role in the prevention and treatment of PFD, and lays a solid basis for women's lifelong plan for prevention and treatment of PFD [13]. Pelvic floor muscle training and biofeedback therapy remain the common options to treat postpartum POP in modern medicine.

The goals of postpartum POP treatment are to restore the anatomy, relieve symptoms, avoid complications and achieve the treatment expectations of patients [14]. Currently, behavioral guidance (improvement of patients' life-

style) and non-surgical therapy remain the primary treatment options for early postpartum POP. The non-surgical therapy includes pelvic floor rehabilitation therapy and TCM therapy. Pelvic floor rehabilitation therapy includes pelvic floor muscle training and biofeedback electrical stimulation. Among them, pelvic floor muscle training, namely, Kegel exercise, is simple and effective, and patients can exercise by themselves without being at hospital, but the compliance is relatively poor. Clinical findings reveal that very few patients can stick to Kegel exercises, and most patients cannot master the correct essentials of Kegel exercises. Therefore, the scientific education and guidance regarding Kegel exercises should be promoted clinically. BES therapy includes biofeedback and electrical stimulation therapy. Electrical stimulation is adopted to stimulate pelvic floor muscles and nerves using current stimulation with different frequencies under the guidance of therapists, so as to increase the excitability, strength and contractility of pelvic floor muscles [15]. Currently, BES therapy has been extensively implemented in China. Studies suggest that BES therapy can effectively improve the pelvic floor myodynamia, POP, and the incidence of urinary incontinence of postpartum women.

TCM is an effective option to treat postpartum POP

Patients who are in POP-Q stage II or below and have indications of surgery but are unable to

receive surgery due to age or general conditions can be treated with TCM (oral administration of TCM, TCM washout or acupuncture, etc.). In the early postpartum period, these patients may reveal repeated lochia, physical weakness and other symptoms. Regarding the treatment of these patients, TCM has its unique advantages compared with other therapies.

In TCM, there is no name for POP. The presence of life activities is based on the ascending and descending of qi. According to TCM, uterine prolapse can be caused by weak body, deficiency of middle qi, childbirth injury, unconsolidation of chong and conception channels, belt channel dysfunction, or postpartum labor and qi consumption and injuries of diaphragm and internal organs. This may be due to qi deficiency and weakness and ascending and descending disorder. Modern epidemiological investigation exhibits that qi deficiency syndrome is common in patients with uterine prolapse. Li et al. [16] found that all POP patients experienced qi deficiency and qi depression, and among 222 clinical cases, 100% of cases were diagnosed with qi deficiency and 94.59% of cases were diagnosed with qi depression.

Astragalus membranaceus is selected as the sovereign drug. *Astragalus membranaceus*, which is sweet and mild, can condition, replenish, and invigorate the spleen and stomach, and raise up spleen Qi and yang. It is said in *Integrating Chinese and Western Medicine* that “*Astragalus membranaceus* can invigorate and ascend up qi, and treat qi depression in the chest”. Modern pharmacological studies demonstrate that *Astragalus membranaceus* can exert significant positive inotropic effects to dilate peripheral blood vessels, improve microcirculation and protect cells from ischemia and hypoxia [17]. *Astragalus membranaceus* has bidirectional regulation effects on collagen metabolism [18] and can improve sex hormone levels [19]. These may be due to the mechanism of prescription of *Astragalus membranaceus* for the improvement of POP. *Codonopsis pilosula*, *Pseudostellaria heterophylla*, *Atractylodes macrocephala* Koidz, *Rhizoma polygonati* and *fructus rubi* are selected as ministerial drugs. Among them, *Codonopsis pilosula* and *Pseudostellaria heterophylla* can strengthen the spleen and replenish the lung to enrich the source of qi. *Atractylodes macrocephala* can enrich qi and nourish the spleen, and replenish the middle burner (housing the spleen and

stomach), thus resulting a constant supply of qi. *Rhizoma polygonati* can replenish the spleen, lung and kidney. *Fructus rubi* can nourish the kidney. All the herbs are combined, so that the lung and kidney are full of qi, the temper is strong, and the ascending is strong. Besides, *Rhizoma polygonati* and *fructus rubi* can nourish true yin, and yin and yang are rooted in each other. Full of yin promotes a supply of qi, which greatly helps sovereign drugs to invigorate qi. *Rhizoma cimicifugae*, *Platycodon grandiflorum* and *fructus aurantia* are selected as adjuvant drugs, which can elevate clear qi to lower turbid qi and invigorate the middle-qi. Licorice is used to blend the herbs. This prescription is composed of multiple ingredients combined to form a treatment that can nourish yin and tonify qi. It is used clinically to treat yin stagnation due to qi deficiency, which can obviously relieve patients' discomfort, such as lower abdomen sagging, tired and weak spirit, shortness of breath and disinclination to talk, and spontaneous perspiration.

Comparison of modern medicine and TCM in treating POP

In this study, it is found that the myodynamia and myoelectric potential of type I and type II muscles in the BES group and the TCM combined with BES group increase after treatment ($P < 0.001$), but there is no statistically significant difference between the two groups ($P > 0.05$). After treatment, vaginal anterior wall prolapse and urinary incontinence are improved more remarkably ($P < 0.05$), and qi deficiency symptoms are relieved more significantly ($P < 0.001$). This exhibits that TCM combined with BES therapy is superior in treating postpartum POP patients. The TCM combined with BES therapy can not only improve the electrophysiological indexes of pelvic floor of POP patients, but also effectively relieve the discomfort, such as lower abdomen falling, tired and weak spirit, shortness of breath and disinclination to talk, and spontaneous perspiration, etc. This makes up for the deficiency of BES therapy and improves the quality of life of patients. Therefore, TCM combined with BES therapy is worthy of clinical promotion.

Prospects

POP is a common social concern. Currently, the pathogenesis of POP remains unclear, but most scholars believe it is a multifactorial disease

[20]. TCM has long been adopted to treat POP, and the clinical efficacy is remarkable. It remains the focus of the future studies to explore the mechanism of TCM in treating POP and interpret the mechanism of action of TCM on POP based on the study methods in TCM and modern medicine.

Acknowledgements

Traditional Chinese Medicine Science and Technology Project, Zhejiang (Grant No. 2017-ZB077) Project Title: the clinical effect of Buqi Shengti Tang combined with biofeedback electrical stimulation therapy in Postpartum Pelvic Organ Prolapse.

Disclosure of conflict of interest

None.

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