Postprint of a Randomized Controlled Trial on the Efficacy of Biofeedback Electrical Stimulation Therapy for Pelvic Floor Function Rehabilitation After Vaginal Delivery

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Abstract

Background: Pregnancy and (vaginal) delivery are significant factors contributing to pelvic floor dysfunction (PFD) in women, manifested as pelvic organ prolapse, stress urinary incontinence, and sexual dysfunction. Postpartum pelvic floor rehabilitation has emerged as a research focus in recent years, aiming to prevent and treat PFD by actively exercising and passively contracting the pelvic floor muscles to enhance detrusor stability and improve levator ani function.

Objective: To investigate the application value of combined biofeedback electrical stimulation and pelvic floor muscle training (PFMT) in pelvic floor functional rehabilitation among postpartum women following vaginal delivery.

Methods: Postpartum women with PFD who delivered at the Department of Obstetrics and Gynecology, Shijitan Hospital, Capital Medical University between January 2020 and January 2022 were enrolled as study subjects. Participants were randomly assigned to either an observation group or a control group using a random number table method. The observation group received biofeedback electrical stimulation combined with PFMT for pelvic floor rehabilitation, while the control group received PFMT alone. The following parameters were recorded before and after treatment: pelvic floor type I and type II muscle fiber strength, stress urinary incontinence (SUI) prevalence, and pelvic organ prolapse (POP) staging; postpartum PFMT training adherence; and scores on the Pelvic Floor Distress Inventory-20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7), and International Consultation on Incontinence Questionnaire-Short Form (ICI-Q-SF) before treatment and at 3 and 6 months post-treatment.

Results: A total of 327 cases were included in the observation group and 343 cases in the control group. After treatment, the recovery of type I and type II muscle fiber strength in the observation group was superior to that in the

control group (P<0.001). The prevalence of SUI in the observation group was lower than that in the control group (P=0.005). No statistically significant difference was observed in POP staging between the two groups (P>0.05). The proportion of participants with PFMT frequency $ $5 times/week at 3 and 6 months post-treatment was higher in the observation group than in the control group (P<0.001). The PFDI-20, PFIQ-7, and ICI-Q-SF scores at 3 and 6 months post-treatment were lower in the observation group compared to the control group (P<0.05).

Conclusion: Compared with PFMT alone, the combination of biofeedback electrical stimulation with PFMT for pelvic floor rehabilitation after vaginal delivery is associated with better recovery of type I and type II muscle fiber strength, lower SUI prevalence, higher compliance with PFMT, and improved quality of life scores.

Full Text

A Clinical Randomized Controlled Study on the Effect of Biofeedback Electrical Stimulation Therapy on Pelvic Floor Function Rehabilitation after Vaginal Delivery

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Abstract

Background
Pregnancy and vaginal delivery are important factors leading to pelvic floor dysfunction (PFD) in women, manifested as pelvic organ prolapse, stress urinary incontinence, and sexual dysfunction. Postpartum pelvic floor function rehabilitation has become a research hotspot in recent years. Stimulating the pelvic floor muscle groups through active exercise and passive contraction can improve detrusor stability and levator ani muscle function to prevent and treat PFD.

Objective
To investigate the clinical value of biofeedback electrical stimulation combined with pelvic floor muscle training (PFMT) therapy in the rehabilitation of pelvic floor function after vaginal delivery through a clinical controlled study.

Methods
Postpartum women with PFD who delivered at the Department of Obstetrics and Gynecology, Beijing Shijitan Hospital Affiliated to Capital Medical University between January 2020 and January 2022 were selected as study subjects and

divided into an observation group and a control group using a random number table method. The observation group received biofeedback electrical stimulation combined with PFMT, while the control group received PFMT alone. The muscle strength of pelvic floor type I and type II muscle fibers, the proportion of SUI, and POP grading were recorded before and after treatment. Postpartum PFMT adherence was documented, and scores from the Pelvic Floor Dysfunction Questionnaire (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7), and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICI-Q-SF) were collected before treatment and at 3 and 6 months post-treatment.

Results
A total of 327 cases were included in the observation group and 343 cases in the control group. After treatment, the strength recovery of type I and II muscle fibers in the observation group was significantly better than in the control group (P<0.001). The proportion of SUI in the observation group was lower than in the control group (P=0.005). There was no significant difference in POP grading between the two groups (P>0.05). The proportion of women in the observation group who performed PFMT $ $5 times/week was higher than in the control group at both 3 months and 6 months post-treatment (P<0.001). The PFDI-20, PFIQ-7, and ICI-Q-SF scores in the observation group were lower than those in the control group at 3 months and 6 months post-treatment (P<0.05).

Conclusion
Compared with PFMT alone, biofeedback electrical stimulation combined with PFMT for postpartum women after vaginal delivery resulted in better recovery of type I and II muscle fiber strength, lower SUI rates, higher compliance with PFMT, and better quality of life scores.

Keywords: Pelvic floor disorders; Pelvic floor dysfunction; Biofeedback electrical stimulation; Vaginal delivery; Pelvic floor muscle training; Quality of life; Randomized controlled trial

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1.1 Study Subjects

Postpartum women with PFD who delivered at the Department of Obstetrics and Gynecology, Beijing Shijitan Hospital Affiliated to Capital Medical University between January 2020 and January 2022 were selected as study subjects. Inclusion criteria were: (1) full-term singleton pregnancy; (2) first vaginal delivery with no prior cesarean section history; (3) indications for pelvic floor rehabilitation, including those with high-risk factors for postpartum PFD such as assisted vaginal delivery, levator ani muscle injury, obesity, pregnancy-related urinary incontinence, or those who exhibited PFD symptoms during pregnancy and/or postpartum. Exclusion criteria were: (1) history of mid-pelvic defects, urinary incontinence, or other pelvic floor dysfunction diseases; (2) ongoing lochia, persistent bleeding, poor wound healing, infection, or other conditions

unsuitable for rehabilitation; (3) comorbid malignant tumors, organic urinary system lesions, pacemaker implantation, or other medical conditions preventing treatment; (4) inability to cooperate due to patient-related factors; (5) missing medical records.

All patients were numbered according to delivery order and randomly assigned to either the observation group or control group using a simple randomization method (random number table). The observation group received biofeedback electrical stimulation combined with PFMT for pelvic floor rehabilitation, while the control group received PFMT alone. The planned sample size was 300 cases per group, but considering potential attrition, an additional 60 cases (20%) were enrolled in each group. The observation group initially enrolled 360 cases, of which 27 failed to complete treatment and follow-up as required and 6 were lost to follow-up, resulting in 327 included cases. The control group initially enrolled 360 cases, with 14 failing to complete treatment and follow-up and 3 lost to follow-up, resulting in 343 included cases. There were no statistically significant differences between the two groups in mean age, BMI, gravidity, gestational weight gain, gestational age at delivery, neonatal weight, or neonatal head circumference ($P>0.05$) .

1.2 Methods

1.2.1 Postpartum 42-Day Pelvic Floor Function Assessment The assessment included: (1) recording general information, delivery details, postpartum urinary and bowel function, and conditions related to POP, SUI, and FSD; (2) completing the Pelvic Floor Dysfunction Questionnaire (PFDI-20) [6], Pelvic Floor Impact Questionnaire-7 (PFIQ-7) [7], and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICI-Q-SF) [8]; (3) using a biofeedback electrical stimulation therapy device to record the muscle strength of pelvic floor type I and type II muscle fibers.

1.2.2 Biofeedback Electrical Stimulation Protocol The Nanjing Weisi Biofeedback Stimulation Device (Model: SA9800) was used. Electrical stimulation intensity was adjusted according to each woman' s tolerance and feedback. Reference parameters were: frequency 50 Hz, pulse width 250 s, and current 15-80 mA. Treatment sequentially targeted type I and type II muscle fiber training, with a therapeutic goal of achieving muscle strength grade III or above. Once muscle strength gradually recovered, the biofeedback module was used for training with reference parameters of: frequency 20-80 Hz, pulse width 20-320 s. A comprehensive module was set up based on feedback to adjust training scenarios and consolidate therapeutic effects. Treatment frequency was 2-3 sessions per week.

1.2.3 PFMT Protocol A dedicated instructor guided each woman in performing PFMT using the following steps: contract pelvic floor muscles → hold for 5 seconds → relax muscles → hold for 5 seconds. The routine consisted of

repeating these movements for 10 minutes per session, 3 sessions per day. After becoming familiar with the exercise method, patients could perform training in standing, sitting, or squatting positions. The required training frequency was $ $5 times per week, and patients were asked to record their training using mobile apps, WeChat, training diaries, or other methods.

1.3 Observation Indicators

The study recorded postpartum PFMT training adherence; PFDI-20, PFIQ-7, and ICI-Q-SF scores before treatment and at 3 and 6 months post-treatment; and pelvic floor type I and type II muscle fiber strength, SUI proportion, and POP grading before and after treatment.

1.4 Statistical Methods

Data were analyzed using SPSS 22.0 software. Measurement data were expressed as mean ± standard deviation (x±s) and compared between groups using independent samples t-tests. Count data were analyzed using chi-square tests. $P<0.05$ was considered statistically significant.

2.1 Comparison of Type I/II Muscle Fiber Strength, SUI, and POP Before and After Treatment

Before treatment, there were no statistically significant differences between the two groups in type I and II muscle fiber strength, SUI proportion, or POP grading ($P>0.05$). After treatment, the recovery of type I and II muscle fiber strength in the observation group was significantly better than in the control group ($P<0.001$). The proportion of SUI in the observation group was lower than in the control group ($P=0.005$). There was no significant difference in POP grading between the two groups ($P>0.05$) .

2.2 PFMT Frequency During Follow-up and Quality of Life Before and After Treatment

The proportion of women in the observation group who performed PFMT $ $5 times per week was significantly higher than in the control group at both 3 months and 6 months post-treatment ($P<0.001$). There were no significant differences between the two groups in PFDI-20, PFIQ-7, or ICI-Q-SF scores before treatment ($P>0.05$). However, the observation group showed significantly lower scores on all three questionnaires at 3 months and 6 months post-treatment compared to the control group ($P<0.05$) .

3.1 Causes and Current Treatment Status of PFD After Vaginal Delivery

According to the predictive model by DELANCEY et al. [9], long-term presence of risk factors such as lifestyle, smoking, overweight, and chronic increased

intra-abdominal pressure can lead to PFD in women, with clinical symptoms appearing when PFD progresses to a certain degree. However, PFD caused by vaginal delivery often presents symptoms immediately after a single event: 20%-40% of women experience varying degrees of levator ani muscle injury during delivery, and macrosomia, prolonged labor, various assisted delivery procedures, and dystocia from multiple causes can also result in pudendal nerve injury [10-11]. A multicenter study in China showed that 52.5% of postpartum women had impaired type I pelvic floor muscle fiber strength and 56.4% had impaired type II muscle fiber strength, which without effective prevention and rehabilitation measures can lead to postpartum POP, SUI, and FSD [12]. A meta-analysis summarizing 22 studies on PFMT for postpartum rehabilitation demonstrated that PFMT can effectively treat postpartum stress urinary incontinence and symptoms related to levator ani muscle injury [13]. However, other studies have suggested that this therapy does not significantly improve pelvic floor rehabilitation outcomes and noted that patient compliance affects treatment efficacy [14]. Pelvic floor electrical stimulation therapy involves placing electrodes in the vagina or anus (rectum) to passively contract pelvic floor muscles through electrophysiological and biofeedback functions, achieving the goals of muscle strengthening and urinary control. This study employed a randomized controlled trial design to evaluate the efficacy of biofeedback electrical stimulation combined with PFMT on postpartum pelvic floor rehabilitation outcomes and quality of life in women after vaginal delivery, using women who received PFMT alone as controls to explore the clinical value of the combined therapy.

3.2 Efficacy of Biofeedback Electrical Stimulation Therapy for Postpartum PFD

This study demonstrated that the biofeedback electrical stimulation combined with PFMT group showed better recovery of type I and II muscle fiber strength and lower SUI rates. Women in the observation group also demonstrated higher compliance with PFMT (higher proportion achieving $ $5 sessions per week), and better scores on quality of life and urinary incontinence questionnaires (PFDI-20, PFIQ-7, ICI-Q-SF) at 3 and 6 months postpartum. Several factors explain these findings. First, type I fibers (slow-twitch) constitute the pelvic floor support system, while type II fibers (fast-twitch) constitute the pelvic floor motor system. Long-term pregnancy and delivery can cause overstretching and even damage to both fiber types. Postpartum pelvic floor function training actively contracts these muscle fibers, while bioelectrical stimulation promotes muscle activity and functional recovery through passive intervention. A multicenter study across 12 medical institutions in 6 regions of China showed that combined pelvic floor electrical stimulation and biofeedback therapy significantly improved pelvic floor electrophysiological indicators and helped prevent PFD-related diseases [15]. Second, this study used mainstream quality of life assessment scales that can quantify postpartum pelvic floor function status and evaluate the efficacy of both therapies. ARTYMUK et al. [16] conducted a prospective randomized controlled study showing that pelvic floor electrical

stimulation combined with PFMT was more effective than PFMT alone in postpartum pelvic floor rehabilitation, reducing the incidence of POP, urinary incontinence, and fecal incontinence, which aligns with our findings. Third, combined pelvic floor electrical stimulation and biofeedback therapy can improve pelvic floor function through multiple mechanisms. LU et al. [17] reported that this therapy can promote recovery of bladder neck mobility to prevent and treat SUI. The combination of both methods can significantly enhance pelvic floor muscle strength and urethral sphincter contraction force, thereby improving postpartum sexual quality of life including sexual arousal disorder, orgasmic disorder, and dyspareunia [18].

3.3 Importance of Postpartum Pelvic Floor Function Rehabilitation

As postpartum PFD has become a research focus in recent years, primary healthcare institutions and postpartum women have increasingly recognized the importance of pelvic floor function rehabilitation and quality of life. Based on clinical experience, although most studies suggest that PFMT alone can effectively promote postpartum recovery [19], patient compliance is often poor, which affects outcomes. Combining PFMT with biofeedback electrical stimulation therapy not only guides patients in performing pelvic floor exercises correctly but also improves treatment adherence. Additionally, early postpartum pelvic floor function assessment facilitates screening of women with PFD and enables timely intervention. This study recommends using various quality of life scales to evaluate postpartum pelvic floor function status. ZUCHELO et al. [20] systematically reviewed 359 relevant articles and concluded that these quantitative tools can early identify the degree of postpartum PFD and its impact on quality of life, allowing for effective prevention and treatment. It is important to note that obstetricians should consider the impact on pelvic floor function when making clinical decisions about delivery plans, particularly regarding mode of delivery [21-22]. For high-risk women with obstructed labor or instrumental delivery, cesarean section indications could be broadened. For women with obvious POP, SUI, or fecal incontinence symptoms in previous deliveries who currently have risk factors such as short stature or macrosomia (or relatively large fetal size), cesarean delivery may be recommended to reduce the risk of postpartum pelvic floor dysfunction-related diseases.

Author Contributions: LI Ya, BAI Wenpei, and ZHANG Jin conceived the study and designed the research protocol. LI Ya and ZHANG Rui implemented the study procedures. LI Ya was responsible for data collection, processing, statistical analysis, table preparation, manuscript drafting, final version revision, and takes responsibility for the manuscript.

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Conflict of Interest: The authors declare no conflict of interest.

References

[1] YANG Mingli, WANG Qing, YU Xiaojie, et al. Analysis of pelvic floor function status and influencing factors in 5,143 early postpartum women [J]. Chinese Journal of Obstetrics and Gynecology, 2019, 54(8): 522-526. DOI: 10.3760/cma.j.issn.0529-567x.2019.08.004.

[2] REED M A. Female sexual dysfunction [J]. Clin Plast Surg, 2022, 49(4): 495-504. DOI: 10.1016/j.cps.2022.06.009.

[3] NAPPI R E, TIRANINI L, MARTINI E, et al. Medical treatment of female sexual dysfunction [J]. Urol Clin North Am, 2022, 49(2): 299-307. DOI: 10.1016/j.ucl.2022.02.001.

[4] LAWSON S, SACKS A. Pelvic floor physical therapy and women' s health promotion [J]. J Midwifery Womens Health, 2018, 63(4): 410-417. DOI: 10.1111/jmwh.12736.

[5] SHENG Y, LIU X F, LOW L K, et al. Association of pubovisceral muscle tear with functional capacity of urethral closure: evaluating maternal recovery from labor and delivery [J]. Am J Obstet Gynecol, 2020, 222(6): 598.e1-598.e7. DOI: 10.1016/j.ajog.2019.11.1257.

[6] QUAN Xiaojie, CHANG Xiaoxia, SHEN Wei, et al. Study on the impact of electrical stimulation combined with biofeedback therapy on quality of life in women with stress urinary incontinence [J]. Chinese Journal of Practical Gynecology and Obstetrics, 2021, 37(10): 1066-1069. DOI: 10.19538/j.fk2021100120.

[7] WANG Yingchun, ZHAO Xinrui. Effect of electrical stimulation biofeedback therapy on early postpartum pelvic floor function rehabilitation [J]. China Medical Herald, 2023, 20(17): 107-110. DOI: 10.20047/j.issn1673-7210.2023.17.24.

[8] FU Haihong, WEI Songpu, ZHANG Yong. Effect of bionic electrical stimulation combined with acupoint massage on stress urinary incontinence and its impact on ICI-Q-SF scores and pelvic floor function [J]. Maternal and Child Health Care of China, 2022, 37(21): 3922-3925. DOI: 10.19829/j.zgfybj.issn.1001-4411.2022.21.012.

[9] DELANCEY J O, KANE LOW L, MILLER J M, et al. Graphic integration of causal factors of pelvic floor disorders: an integrated life span model [J]. Am J Obstet Gynecol, 2008, 199(6): 610.e1-610.e5. DOI: 10.1016/j.ajog.2008.04.001.

[10] URBANKOVA I, GROHREGIN K, HANACEK J, et al. The effect of the first vaginal birth on pelvic floor anatomy and dysfunction [J]. Int Urogynecol J, 2019, 30(10): 1689-1696. DOI: 10.1007/s00192-019-04044-2.

[11] ZHANG Xiaohong. Impact of different delivery modes on pelvic floor function and rehabilitation treatment [J]. Chinese Journal of Practical Gynecology and Obstetrics, 2015, 31(2): 169-173. DOI: 10.7504/fk2015010117.

[12] SUN Zhijing, ZHU Lan, LANG Jinghe, et al. A national multicenter cross-sectional study of pelvic floor electrophysiological indicators and pelvic organ prolapse grading in primiparous women at 6 weeks postpartum [J]. Chinese Journal of Practical Gynecology and Obstetrics, 2015, 31(5): 433-439. DOI: 10.7504/fk2015040114.

[13] BOYLE R, HAY-SMITH E J, CODY J D, et al. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women [J]. Cochrane Database Syst Rev, 2012, 10: CD007471. DOI: 10.1002/14651858.CD007471.pub2.

[14] HILDE G, STAER-JENSEN J, SIAFARIKAS F, et al. Postpartum pelvic floor muscle training and urinary incontinence: a randomized controlled trial [J]. Obstet Gynecol, 2013, 122(6): 1231-1238. DOI: 10.1097/AOG.0000000000000012.

[15] SUN Zhijing, ZHU Lan, LANG Jinghe, et al. Preventive effect of postpartum pelvic floor rehabilitation exercises on female pelvic floor dysfunction diseases [J]. Chinese Journal of Obstetrics and Gynecology, 2015(6): 420-427. DOI: 10.3760/cma.j.issn.0529-567x.2015.06.005.

[16] ARTYMUK N V, KHAPACHEVA S Y. Device-assisted pelvic floor muscle postpartum exercise programme for the management of pelvic floor dysfunction after delivery [J]. J Matern Fetal Neonatal Med, 2022, 35(3): 481-485. DOI: 10.1080/14767058.2020.1723541.

[17] LU Hui, YU Shijia, SHI Tiemei. Ultrasound evaluation of urethral mobility at different segments in female stress urinary incontinence patients [J]. Chinese Journal of Medical Imaging Technology, 2012, 28(10): 1874-1877. DOI: 10.13929/j.1003-3289.2012.10.012.

[18] ROOS A M, SPEKSNIJDER L, STEENSMA A B. Postpartum sexual function; the importance of the levator ani muscle [J]. Int Urogynecol J, 2020, 31(11): 2261-2267. DOI: 10.1007/s00192-020-04250-3.

[19] HADIZADEH-TALASAZ Z, SADEGHI R, KHADIVZADEH T. Effect of pelvic floor muscle training on postpartum sexual function and quality of life: a systematic review and meta-analysis of clinical trials [J]. J Obstet Gynecol, 2019, 58(6): 737-747. DOI: 10.1016/j.tjog.2019.09.003.

[20] ZUCHELO L T S, BEZERRA I M P, DA SILVA A T M, et al. Questionnaires to evaluate pelvic floor dysfunction in the postpartum period: a systematic review [J]. Int J Womens Health, 2018, 10: 409-424. DOI: 10.2147/IJWH.S164266.

[21] HOU Lin, SHANG Min. Research progress on postpartum pelvic floor dysfunction diseases [J]. Chinese Journal of Medicine, 2022, 57(2): 145-148. DOI: 10.3969/j.issn.1008-1070.2022.02.008.

[22] ZOU Yanqi, ZHANG Guangzheng, AN Li, et al. Effect of pelvic floor neuromuscular electrical stimulation and sling training on postpartum diastasis recti

abdominis [J]. Chinese Journal of Rehabilitation Theory and Practice, 2020, 26(11): 1353-1357. DOI: 10.3969/j.issn.1006-9771.2020.11.019.

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Note: Figure translations are in progress. See original paper for figures.