Int J BioMed Public Health. 2020; 3(1):5-9
10.22631/ijbmph.2019.167649.1091

International Journal
of
BioMedicine and Public Health
http://www.ijbmph.com

Original Article

The effect of pelvic floor muscles training using biofeedback on symptoms of pelvic prolapse and quality of life in affected females

Open Access

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ARTICLE INFO

Article History:
Received 13 January 2019
Revised 8 June 2019
Accepted 10 June 2019

Keywords:
Pelvic organ prolapse
Muscle training
Biofeedback

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ABSTRACT

Introduction: Pelvic floor muscle training increases muscle strength and support of pelvic organs. The purpose of this study was to determine the effect of pelvic floor muscles training using biofeedback device on symptoms of urinary incontinence and pelvic organ prolapse in females with anterior and posterior prolapse grades 2 or 3.

Methods: In this interventional study, 20 females with prolapse grades 2 or 3 were examined. Participants were treated with biofeedback 3 sessions/week for 4 weeks. Symptoms of urinary incontinence and prolapses were measured using ICIQ-FLUTS and P-QoL questionnaires, respectively. Prolapse severity was assessed using the POP-Q system and pelvic floor muscle function and strength were evaluated by perineometry.

Results: The results of this study showed that pelvic floor muscle training significantly increases pelvic floor muscle strength and decreases prolapse severity ($P < 0.001$ and $P < 0.01$, respectively). Based on the ICIQ-FLUTS questionnaire, symptoms of filling, voiding, and incontinence improved significantly ($P < 0.05$, $P < 0.01$ and $P < 0.01$, respectively). Our results also showed that the score of quality of life significantly improved based on the ICIQ-FLUTS questionnaire ($P < 0.01$). The results for P-QOL questionnaire indicated that prolapse symptoms in the areas of general health, prolapse impact, physical limitation, social limitation, personal limitation, emotions, sleep, and severity had a significant difference ($P < 0.05$) albeit it did not show any significant differences in the role limitation criteria ($P > 0.05$).

Conclusion: Pelvic floor muscle training using biofeedback improves prolapse symptoms and enhances the quality of life of females with pelvic organ prolapse.

Introduction

The prolapse of pelvic organs is a rectocele or an abnormal protrusion of the bladder and intestines to the walls of the vagina (1). Approximately 60% of females who give birth to children show a degree of prolapse (2). Prolapse causes a variety of bladder, intestinal and sexual symptoms. Bladder symptoms include urinary incontinence, frequent urination, nocturia, and etc. Intestinal symptoms include constipation and the feeling that the bowel is not fully emptied after stool removal. Sexual symptoms include pain as well as vaginal bulge that is placed in the way during intercourse (3). These symptoms are debilitating and affect daily activities as well as the quality of life (4).

Prolapse treatment options include surgical and non-surgical treatments. Non-surgical treatment of prolapse includes: 1) the use of mechanical devices such as pessary 2) life style education to the patients and 3) pelvic floor muscles trainings (3). 58% of females who undergo surgery have reported a recurrence of prolapse (5, 6). This finding highlights the role of pelvic floor exercises for the prevention and treatment of prolapse. Pelvic floor muscle training is one of the non-surgical treatments aimed at increasing the strength and control of the pelvic floor muscles (3). According to the findings of Bo et al., pelvic floor exercises can also be effective in pelvic organ prolapse treatment (8). The results of the literature for this subject are mostly inconsistent. There is a review study consisting of three randomized controlled trials which examined the effect of pelvic floor muscle training on symptoms of prolapse. In these three studies which the intervention group received pelvic floor muscle training and the control group were trained for their lifestyle, examined the effect of pelvic floor training on the severity of prolapse, pelvic floor muscle strength, and urinary incontinence. Although, two of these three selected studies did not show any significant difference between the control and intervention groups but in another one the results showed that the intervention group had a significant improvement in symptoms of incontinence and pelvic floor strength. Therefore, the authors of the review article

concluded that the pieces of evidence for this subject are not enough to make a definitive conclusion (9).
Although pelvic floor exercises are designed to increase pelvic floor muscle strength as well as the perineal area, these types of exercises are highly patient-centered and the outcome of treatment depends on the patient's motivation and their consistency and efforts (10). Because of the nature of these exercises, Aksac, Terlikowski, and Pages have suggested using a biofeedback device which includes a probe that converts pelvic floor muscle contraction into visual and auditory signals to increase effort and motivation (11-13). The aim of this study is to evaluate the effect of pelvic floor muscle training on the symptoms and quality of life in patients suffering from prolapse.

Methods

Studies samples

This interventional study was conducted at the Faculty of Rehabilitation, University of Isfahan, between September 2017 and October 2018. Participants were the females referred to Alzahra, Shahid Beheshti and Sediqeh-Tahereh hospitals in Isfahan. These females were introduced to the study after examination by the specialist and confirmation of grade 1 or 2 prolapse. Prolapse grade was measured by the Pelvic Organ Prolapse Quantification System (POP-Q). 5-6 physicians in the mentioned hospitals referred the eligible patients to the Faculty of Rehabilitation's Clinic, Isfahan University of Medical Sciences. Twenty samples were randomly selected from eligible patients using coin toss (95% CI). Therefore, the sampling was simple random.

Ethical issues

This research was permitted by the Ethics Committee of Isfahan University of Medical Sciences (with code of IR.NUI.REC.1396.3.759) and Iranian Registry of Clinical Trials (with IRCT20180828040898N2 registration number). All patients completed the ethical consent to for participation in the study.

Inclusion and exclusion criteria

Inclusion criteria were females 20-70 years old with grade 2 or 3 prolapse. Exclusion criteria included breastfeeding, history of previous POP surgery (14), radiating back pain, cancer, neurological and mental illness, planning to become pregnant within the next 6 months, and quitting the intervention for more than 4 weeks (15).

Therapeutic intervention

Many patients have trouble on contraction in their pelvic floor muscles, so it is helpful to provide feedback when they are these muscles. We investigated the effect of using a biofeedback device (Bio-feedback Electrotherapy Kit, ReHab Kit) for these patients (12). Patients were treated for 12 sessions (4 weeks, 3 sessions/week and 30 minutes per session). To the exercises, the vaginal probe, which was connected to the device through the interface, was inserted into the patient's vagina. When the patient was contracting the pelvic floor muscles, she could see the feedbacks through a monitor in microvolts. The feedbacks were visual and auditory. When the patient performed stronger contractions of the pelvic floor muscles, the line that indicated the amount of muscle contraction on the monitor was going higher, and the device also made a louder sound. There was a maximum line drawn on the monitor in which in each session, the patients were asked to try to bring their muscle contraction level closer to this line. This procedure could increase the strength of the pelvic floor muscles, gradually which could help the better support of the pelvic organs and as a result, the severity of pelvic organ prolapse stage could decrease over time (16-18).
Urinary incontinence is one of the complications of prolapse caused by the bladder rectocele. Strengthening the pelvic floor muscles using biofeedback strengthens the bladder and prevents it from rectocele, resulting in decreased urinary incontinence (19). According to previous researches, (11-13) in our study, during biofeedback electromyography, the patients were asked to contract their pelvic floor muscles for 10 seconds and then rest for 10 seconds. The degree of prolapse was measured by a Gynecologist using a POP-Q International Classification System.

Research tools

International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS) questionnaire was used to assess urinary incontinence symptoms in the patients (20). This questionnaire has been validated by Abbas Ali Pourmomeny and his colleagues in Iran (21). This questionnaire is designed to assess lower urinary tract symptoms and has 3 domains, including symptoms of urine symptoms of filling, voiding, and incontinence each containing 4, 3 and 5 questions, respectively.
The effect of prolapse on the quality of life of affected females was assessed using the Persian version of the prolapse and quality of life questionnaire (P-QoL) questionnaire. This questionnaire has been validated by Nojomi and colleagues in Iran (22). This questionnaire assesses the symptoms of pelvic organ prolapse and its effect on the individual's quality of life in 9 general health domains, the effect of prolapse, role limitation, physical limitation, social limitation, personal limitation, emotions, sleep, and severity of prolapse.
Perineometer apparatus (Model AV 9300, England) was used to measure pelvic floor muscle strength which its unit is cmH_2O (23). At the end of treatment, all patients again completed P-QoL and ICIQ-FLUTS questionnaires then the pelvic floor muscle strength were assessed using a perineometer by an expert. At the end, the patients were referred to a physician who initially had evaluated the degree of prolapse to reassess the degree of prolapse.

Statistical analysis

The normality of the data distribution was analyzed using the Shapiro-Wilk test. According to the normality of the data ($P > 0.05$) they were compared before and after the intervention using a paired t-test. Since, the correlation between the underlying variables with each of the main variables showed that age and menopause were associated with pelvic floor muscle strength therefore the statistical analysis was performed after controlling for the effect of variables.

Results

In this study, females with an average age of 52.95±10.64 years and prolapse grades 2 and 3 were evaluated (n=20). Among these participants, 8 (40%) had anterior prolapse, 3 (15%) had posterior prolapse, 4 (20%) had both anterior and posterior prolapse and 5 (25%) had all three types of prolapse (anterior, posterior and apical). 17 patients (85%) had grade 2 prolapse and 3 patients (15%) had grade 3 prolapse. Table 1 shows the demographic information of the participants (Table 1).
Table 2 shows the descriptive information of the variables. The results of this study showed that the use of biofeedback significantly improved pelvic floor muscle strength and prolapse severity ($P < 0.001$ and $P < 0.01$, respectively).

Seven (35%) patients had 1 degree of improvement in the severity of prolapse as measured by POP-Q and 13 patients (65%) had no improvement in this criteria. The results also showed that the overall score of the ICIQ-FLUTS questionnaire after the intervention was significantly lower than before (P<0.01). Symptoms of filling, voiding, and incontinence showed a significant improvement after the intervention (P < 0.01). Also, the score of quality of life based on the ICIQ-FLUTS questionnaire showed a significant increase (P < 0.01). Prolapse symptoms and their effects on its different domains were measured using the P-QoL questionnaire. This questionnaire included 9 domains which are shown in Table 2 for each domain separately before and after the intervention. The prolapse symptoms in the areas of general health, the prolapse impact, physical limitation, social limitation, personal limitation, emotions, sleep, and severity showed significant differences but there were not any significant differences for role limitation (P> 0.05) (Table 2).

Table 1. Demographic information of participants

Variables		Mean ± SD
Age		10.64± 52.95
Weight		7.99±70.90
Height		46.56±143.63
BMI*		5.10± 28.82
Number of children		2.12±3.20
	Variable category	Frequency (%)
Menopause status	Yes	80(16)
	No	20(4)
Level of Education	High school	60(12)
	High school diploma	30(6)
	Higher education	10(2)

*BMI; Body Mass Index

Table 2. Paired t-test results for comparing SJPS scores of Pre and Post test

		Before intervention	After intervention	ETA	P-value
Prolapse Severity		2.15 ± 0.37	1.80 ± 0.52	0.350	0.008
Pelvic floor muscle strength		16.84 ± 8.10	20.51 ± 8.97	0.827	>0.001
Urinary incontinence score	F score	6.10 ± 3.35	3.90 ± 2.71	0.583	0.001
	V score	3.50 ± 3.50	2.15 ± 2.08	0.354	0.009
	I score	6.05 ± 3.99	4.30 ± 5.39	0.198	0.010
	Overall score	15.65 ± 8.52	10.35 ± 7.53	0.495	0.003
The effect of prolapse on quality of life	Annoyance	50.70 ± 33.84	30.40 ± 20.19	0.516	0.001
	General health	48.7 (25-62.5)	30 (12.5-50)	0.450	0.003
	Prolapse effect	59.6 (33-83)	33.6 (33-49.5)	0.376	0.005
	Role limitation	41.4 (0-66)	28.9 (0-49.7)	0.172	0.092
	Physical limitation	43.9 (0-66)	28.9 (0-57.7)	0.219	0.003
	Social limitation	37.3 (0-66)	18.9 (0-33)	0.335	0.012
	Personal limitation	35.7 (11-66)	17.5 (0-22)	0.384	0.005
	Emotions	46.5 (11-88.7)	31.4 (0-66)	0.513	0.002
	Sleep	33.9 (0-66)	24.8 (0-2.41)	0.158	0.046
	Severity	21.9 (4.1-24.7)	6.13 (0-5.16)	0.384	0.001

Discussion

According to the findings of this study, pelvic floor muscle strength was significantly improved after biofeedback training. According to the evaluation of pelvic floor muscle strength using a perineometer (which shows the muscle strength numerically), it is the objective measurement method that makes the result more valid (23, 24). Increased pelvic floor muscle strength was also confirmed in a study by Lee et al. (25). This study was performed on a group of females in which the pelvic floor muscle strength was measured with the Oxford scale. Oxford scale is a subjective method for measuring pelvic floor muscle strength while in our study perineometry which is an objective method was used. In line with our work, the results of Bræken's (26) study also showed that pelvic floor muscle training increased the strength of pelvic floor muscles in females with prolapse. In the Bræken's study also a perineometer was used to measure the pelvic floor muscle strength.

Our results showed a significant decrease in the severity of prolapse. This considerable increase in pelvic floor muscle strength protects pelvic organs and decreases prolapse severity. In a study conducted by Stüpp et al. (27) to assess the impact of pelvic floor exercise training, pelvic floor muscle training reduced the severity of prolapse which is in line with our study.

Although our results showed that the prolapse symptoms in the areas of general health, prolapse impact, physical limitation, social limitation, personal limitation, emotions, sleep, and severity have not any significant difference in role limitation. The study conducted by Stüpp et al., (27) using the P-QoL questionnaire showed a significant improvement in four domains of role limitation, social limitation, physical restraint and severity of prolapse.

According to Bai's study, one of the most common symptoms of prolapse is urinary incontinence that about 62.6% of patients suffering from prolapse also showed symptoms of urinary incontinence (19). In this study, the score of the ICIQ-FLUTS questionnaire showed a significant decrease. Three different sections of this questionnaire including symptoms of filling, voiding, and incontinence had a significant improvement after the intervention. It is also demonstrated that the quality of life of patients had a significant increase based on the ICIQ-FLUTS questionnaire. There are several

studies on the effect of biofeedback on symptoms of urinary incontinence. Hirakawa et al. (24) investigated the effect of pelvic floor muscle training with or without biofeedback on symptoms of females with urinary incontinence. They assessed the impact of urinary incontinence on quality of life using the Kings Health Questionnaire (KHQ) questionnaire. The results of the Hirakawa study showed that there was a significant difference between the two groups in the two domains of personal relationships and social limitation. The ICIQ-SF questionnaire was also used in this study to assess the subjective symptoms and quality of life of females with urinary incontinence. There was not any significant difference between the two groups in the scores of the domains based on the results of this questionnaire. The results of the Hirakawa study were consistent with ours which states that biofeedback significantly reduces the score of the ICIQ-FLUTS questionnaire. Also, Hirakawa et al. showed a significant difference between the intervention and control groups based on their pelvic floor muscle strength measurements with perineometry, albeit there was no significant difference between the scores of these two groups.

Our literature review showed that several researchers investigated the effect of pelvic floor muscle training without using biofeedback method on pelvic prolapse symptoms (9, 14, 15, 20, and 21). To our knowledge, there is only one study that evaluated the effectiveness of pelvic floor muscle training using biofeedback which is on symptoms of anal prolapse (28). In the mentioned study, fecal incontinence improved in both control and intervention groups, but the improvement in the biofeedback group was higher. Unlike the study by Hämäläinen and Maran (28) which did not examine the severity of prolapse and its effect on the quality of life. In our study the severity of pelvic prolapse was measured and its effect on the quality of life was also evaluated.

An important advantage of this study is its novelty. We evaluated the effect of biofeedback on prolapse symptoms, which can pave the way for future studies. The major limitation of this study is the lack of a control group due to patients' unwillingness to attend 12 sessions of physiotherapy, which limits the acceptance of positive results.

Conclusion

This method is one of the most novel approaches for the treatment of patients with pelvic organ prolapse which, due to few studies in this field, can be a good subject for future researches. Since the lack of control group in this intervention, further studies are recommended to evaluate the effect of biofeedback on prolapse symptoms in the control and intervention groups.

Ethical disclosure

This study was approved by IRCT and Ethical Committee of Isfahan University of Medical Sciences. Before performing this study, it was explained to the patients and an informed consent was obtained from all patients.

Acknowledgements

Thanks to the financial support of the Vice-Chancellor for Research of Isfahan University of Medical Sciences who provided the funding for the present study under IR.NUI.REC.1396.3.759 project number.

Author contributions

All authors contributed equally in this study.

Conflict of interest

There is no conflict of interest in this study.

Funding/Support

This study is supported financially by the Isfahan University of Medical Sciences.

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