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Efficacy of biofeedback on quality of life in stages I and II pelvic organ prolapse: A Pilot study

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Abstract

Objectives: Pelvic organ prolapse (POP) is a prevalent disorder which seriously affects the sufferer's quality of life. The main goal of this study was to evaluate biofeedback impact on quality of life in women with mild to moderate POP.

Study Design: 40 females in stages I and II POP were allocated into 2 groups. One group received pelvic floor muscle exercise and lifestyle advice in addition to biofeedback twice a week for 4 weeks, while the other received a lifestyle advice sheet and pelvic floor muscle exercise without biofeedback. A valid Persian version of P-QOL questionnaire was applied to assess the patients' quality of life at baseline, 4 weeks and 12 weeks follow up. Pressure biofeedback and Physical examination were also performed in order to determine pelvic floor muscle strength and staging of the prolapse, respectively. Collected data were analyzed by mixed ANOVA test using SPSS 22.

Results: Biofeedback improved the quality of life in seven of nine P-QOL domains. However, it had no significant impact either on pelvic floor muscle strength or on the stage of the prolapse.

Conclusion: Biofeedback could be considered as a non-invasive treatment leading to quality of life promotion in women with stages I and II POP.

Key words: Biofeedback; Muscle strength; Pelvic organ prolapse; Quality of life

Introduction

Pelvic Organ Prolapse (POP) is a prevalent and debilitating condition which seriously affects the sufferer's quality of life and activities of daily living. It is defined as the descent of one or more of the followings: the anterior vaginal wall (cystocele), the posterior vaginal wall (rectocele), apical / uterine and vault /cuff after hysterectomy [1]. The condition may be asymptomatic or lead to urinary, defecatory and sexual dysfunction [2]. Most of the women with POP complain about a feeling of bulge in their vagina or pressure in their pelvis getting worse at the end of the day [3].

Treatment options vary depending on symptoms severity and the prolapse degree. Conservative approaches including pelvic floor muscle exercise, biofeedback, electrical stimulation and lifestyle advice are usually considered for mild to moderate disorder. Several studies have revealed that pelvic floor muscle training (PFMT) can relieve symptoms and improve quality of life specially in women with low degree prolapse [4-8]. PFMT may be performed via biofeedback which has been utilized since 1992 for various conditions [9].

Nowadays, Despite the widespread use of biofeedback in pelvic floor dysfunctions, there is no consensus on preference of biofeedback assisted PFMT over PFMT alone [10]. A Cochrane review of women urinary incontinence in 2011 indicated that biofeedback significantly lead to more cure and improvement in comparison with PFMT alone [11]. However, this finding has not been confirmed by some other studies [12].

Since quality of life is the most important outcome measure of any intervention, the main aim of this study is to assess biofeedback impact on quality of life in women with POP.

Materials and Methods

This research was carried out as a residency thesis by Dr Neda Taghvadoost under guidance of professors from Firoozgar hospital, Iran University of Medical Sciences, Tehran, Iran during May 2015 to November 2015.

It was a single-blind pilot study with an add-on design and balanced randomization (1:1). Forty women with pelvic organ prolapse (stages I and II) were included and simply randomized into two groups of equal size using sealed envelopes. Following the enrollment, a physiatrist (specialist in Physical Medicine and Rehabilitation) performed the first evaluation, exercise training and physical examination and then a physiotherapist put the patients in group A (exercise group) or group B (biofeedback group) considering the letter inside the envelopes they had picked. Inclusion criteria were age 18-75 years, having stages one or two pelvic organ prolapse and not to have followings: stages 3 or 4 prolapse, pelvic surgery or delivery during last 6 months, cancer in pelvic region, previous surgery for prolapse, neurologic disorders, inability to contract pelvic muscles, any low back pain interfering proper position for biofeedback, receiving other treatments for prolapse, planning a pregnancy in following 2 months, untreated UTI and any interruption for more than 2 weeks during intervention period.

Furthermore, not returning for follow up visit and not completing the therapy sessions were considered as exclusion criteria.

One group received home - based pelvic floor muscle exercise program (HBPFMEP) and lifestyle advice in addition to pressure biofeedback in clinic twice a week for 4 weeks, while the other group received a lifestyle advice sheet and HBPFMEP without biofeedback. Both groups performed the home exercise program for 12 weeks. Biofeedback program included eight 30 minute-sessions of pressure biofeedback which were accomplished by Enraf-NONIUS (Mymed632x) device at physical medicine and rehabilitation clinic in Firoozgar hospital. All the patients were visited by the same physiatrist at baseline, 4-5 weeks and 12 weeks follow up.

The HBPFMEP protocol consisted of five sets and each set included 10 repetitions of a 5-second squeeze followed by a 5-second release.

Outcome measures:

Main outcome measure was quality of life which was assessed via a Persian (Farsi) version of P-QOL questionnaire validated by Nojomi et al. [3] This questionnaire consists of 20 items to evaluate quality of life in 9 domains including general health perception, prolapse impact, role limitation, physical limitation, social limitation, personal relation, sleep/energy, emotions and severity measures. There is a 4- point scale for scoring each item. These scores finally turn into a 0 to 100 score in each domain. A lower score represents a better quality of life. This questionnaire was filled in by the patients at baseline, 4-5 weeks and 12 weeks follow up.

The second outcome measure was pelvic floor muscle strength. For this purpose, pressure probe was applied to record the maximum and mean contraction pressures after asking the patients to perform five cycles of strong squeeze and release for 5 and

10 seconds, respectively. Pelvic floor resting pressure was also registered. These 3 parameters were evaluated in baseline and each follow up visit.

The third outcome measure was the stage of the prolapse evaluated by physical exam according to POP-Q system.

Baseline and follow up assessments were done by the same physiatrist who was blind to the group allocation.

Collected data were finally analyzed by mixed ANOVA test using SPSS 22. It is noteworthy that to adjust preexisting statistically difference between the two groups regarding domain scores or pressure amounts at baseline, covariates were introduced in repeated measures ANOVA. Baseline categorical variables in the two groups such as age, stage of prolapse, BMI, education and number of NVDs or cesarean sections were compared using Chi-Square test and the third outcome measure (stage of prolapse) data were analyzed via Friedman's Two-Way Analysis of Variance by Ranks.

This research was in accordance with standards of Ethics Committee of Iran University of Medical Sciences (which requires a written consent given by each participant) and Helsinki Declaration. (Registry No: IRCT2015020620980N1).

Results:

38 out of 40 women completed the trial,19 in each group (figure 1). Statistics revealed that there was no significant difference in terms of age, BMI, education, the number of

NVDs, the number of cesarean sections and prolapse severity between the 2 groups at baseline (table1). Of these women, 42% had stage one and 58% had stage two POP.

As shown in table 2 there was a statistically significant difference between scores of the two groups (time1 versus time3) in domains of P-QOL questionnaire except for general health perception and social limitation domains (P = 0.01, 0.001, 0.01, 0.01, 0.02, 0.0005, 0.02 for prolapse impact, role limitation, physical limitation, personal relation, emotion, sleep/energy and severity measures, respectively). Therefore, prominent improvement was achieved via biofeedback in 7of 9 quality of life aspects in comparison to exercise alone. Developed positive outcomes in all domains persisted following the completion of the intervention until 12 weeks follow up.

On the other hand, within group analysis of the only exercise group represented an enhancement of merely two life quality domains: prolapse impact (P = 0.03) and emotions (P = 0.04).

Despite the significant difference between the two groups in terms of life quality promotion, this difference was not found regarding our second outcome measure including resting, maximum and mean contraction pressures (P>0.05). However, within group analysis in this issue indicated an improvement of maximum and mean contraction pressures in the 4 weeks follow up comparing the baseline in biofeedback group (P =0.005 and P =0.03, respectively). Similarly, in only exercise group, we noted an increase in mean contraction pressure in the second visit compared with the baseline (P =0.02).

Eventually for the third outcome measure, data demonstrated no significant difference in either between groups or within groups analysis (P> 0.05). In the second follow up, only one patient from each group had an improvement of the overall stage of the prolapse.

No complication due to intervention was detected.

Discussion

Quality of life

According to this study, biofeedback outstandingly improved life quality in women with mild to moderate pelvic organ prolapse. This finding is in concordance with data in some other conditions such as results reported by Şahin [13], Araujo [14] and Khalil Ibrahim [10]. They proved that biofeedback can promote quality of life in dyssynergic constipation, stress urinary incontinence and mild to moderate pelvic floor dysfunction, respectively. Furthermore, a Cochrane review of females with urinary incontinence indicated more amelioration in biofeedback recipients compared to women who accomplished pelvic floor muscle exercise alone [11]. In that review, it was suggested that this finding could be due to additional effect of biofeedback or some other factors such as more contact with care givers with which the authors partially agree. Hirakawa (2013) et al. [15] concluded that biofeedback had no apparent additional benefits to pelvic floor muscle training in treating females with stress urinary incontinence, which is in contrast with our findings. On the other hand, another study [16] revealed that pelvic floor muscle exercise alone can significantly improve quality of life in POP. In current study it merely improved the sufferers' emotions and their perception of prolapse impact

on their life. It seems that different exercise protocols and poor compliance of the patients with home-based programs comparing to supervised exercise therapy could lead to these contradictions. In this study, although the participants in biofeedback group had more contact with the physician, this could not totally account for the significant improvement of their life quality comparing the only exercise group. It is apparent that biofeedback training was much more effective than the home exercise program in developing the patients' quality of life. Nevertheless, the findings indicated that HBPFMEP can also partially promote life quality in women with POP by reducing their anxiety and depression (subtypes of emotions domain) and developing a sense of life satisfaction.

Pelvic floor muscle strength

Outcomes in this survey represented HBPFMEP positive impact on mean contraction pressure of pelvic floor muscles in women with mild to moderate POP and biofeedback did not indicate an add-on effect. The promotion was observed in the second but not the third visit, which creates the impression that perhaps increasing visit frequency could help continuity of this progression. Moreover, in this study, biofeedback recipients illustrated an apparent improvement of maximum contraction pressure in 4-week follow-up. However, it was not statistically significant comparing the only exercise group. Neither exercise nor biofeedback improved resting pressure of pelvic floor muscles. According to these findings, it requires further investigation to comment on biofeedback efficacy on pelvic floor muscle strength. Huebner et al. [17] proved that EMG-

biofeedback could improve pelvic voluntary contractions. Biofeedback and pelvic floor muscle exercise had also led to functional improvement of pelvic floor and anal sphincter in some literatures [18,11]. In authors' experience, the utility of a different type of probe in this study (pressure-biofeedback) as well as different measurement protocols and scales may account for this inconsistency. Dumoulin et al. [19] also discussed this issue in a Cochrane review of pelvic floor muscle training for women with stress urinary incontinence.

Stage of prolapse

Neither biofeedback nor exercise affected the stage of pelvic organ prolapse in this survey. Stüpp et al. [20] indicated that significant improvement in prolapses of posterior and anterior vaginal wall could be achieved via pelvic floor muscle training. Previously, Hagen [4] had revealed that 16 weeks of pelvic floor muscle training lead to an improvement of prolapse severity in 5 of 11 females with POP. This improvement was mostly seen in Aa and Ba parameters of POP-Q system. Findings in current study are different from these literatures. It is noteworthy that in this study, we purposed to indicate whether biofeedback could change overall stage of prolapse (distance between the most leading portion of the predominant compartment and vaginal opening) according to POP-Q system, and we did not consider changes in various POP-Q parameters (Aa, Ba, …) which describe descent of different vaginal compartments. Regarding this, our finding is in accordance with the result reported by Brækken et al. [5] in which they suggested that following pelvic floor muscle training, the more the

prolapse degree was, the higher the possibility for improving one stage according to POP-Q system. They also indicated that the chance was 0% ,16.7% and 35.7% for stages I, II and III, respectively. Since only stages I and II were included in our research, it can be concluded that biofeedback could not reduce the stage of prolapse in mild to moderate POP.

The main limitation of this study was lack of a control group due to ethical considerations.

Comments

Pressure biofeedback in this research, significantly improved quality of life in females with mild to moderate POP, although it could not alter the stage of prolapse. It seems that there is not an apparent correlation between the quality of life and pelvic floor muscle strength as well as the prolapse stage in women with POP. Therefore, biofeedback may cause life quality promotion in POP with mechanisms other than affecting pelvic floor anatomy and muscle strength. Enhancing coordination of pelvic floor muscles to contract effectively and timely if necessary, may be considered as one of these mechanisms. More research is needed for better clarification of these findings.

AuthorShip

T Ahadi: Project development, Data collection

N Taghvadoost: Data collection, manuscript writing

S Aminimoghaddam: Data collection

B Forogh: Data collection

R Bazazbehbahani: Data collection

G.R Raissi: Data collection, manuscript editing

Conflict of Interest: The authors declare that they have no conflict of interest.

This research is a residency thesis by Dr Neda Taghvadoost and ethics Committee of Iran university of medical sciences has proved it. (Registry No: IRCT2015020620980N1).

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CONSORT
TRANSPARENT REPORTING of TRIALS

figure 1- Flowchart of participants

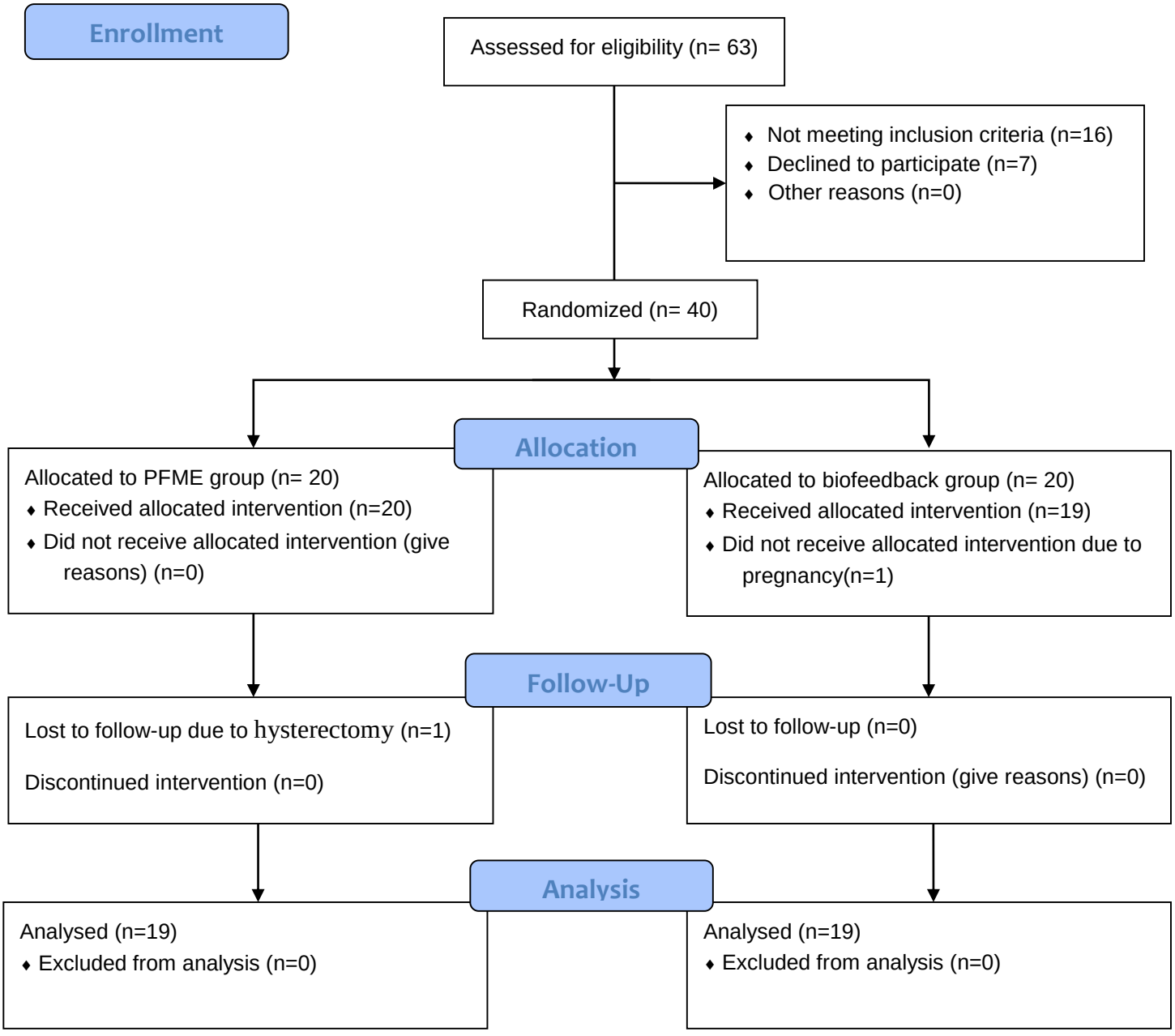

Table 1-The demographic characteristics of the participants in the two groups

		Exercise group (people)	Biofeedback group (people)	Total (people)
Stage of prolapse	Stage I	9	7	16
	Stage II	10	12	22
Age (Mean ± SD)		43.00 ± 10.00	42.00 ± 12.06	38
NVD Number	0	7	8	15
	1	1	2	3
	2	6	6	12
	3	2	2	4
	4	3	0	3
	7	0	1	1
CS Number	0	12	14	26
	1	1	4	5
	2	4	1	5
	3	1	0	1
	4	1	1	2
Education	Illiterate	2	1	3
	School	7	4	11
	Diploma	8	8	16
	BS	0	5	5
	MA/higher	2	1	3
BMI	<20	0	0	0
	20-25	8	10	18
	25-30	7	5	12
	>30	4	4	8

Table 2- time* group interactions of P-QOL questionnaire scores in each domain (between groups comparison)

Domain	Time	Group	Mean Score	SD	P-value
General health perception	Baseline visit	Biofeedback	36.84	19.30	1.00
		Exercise	39.47	24.03	
	Follow Up 1	Biofeedback	36.84	21.02	
		Exercise	38.15	25.50	
	Follow Up 2	Biofeedback	30.26	19.68	
		Exercise	32.89	22.13	
Prolapse Impact	Baseline visit	Biofeedback	73.17	30.00	0.01
		Exercise	49.56	40.65	
	Follow Up 1	Biofeedback	49.21	34.43	
		Exercise	35.75	39.71	
	Follow Up 2	Biofeedback	33.12	33.49	
		Exercise	31.68	35.21	
Follow up 1: 4-5 weeks from baseline Follow up 2: 12 weeks from baseline					

Role Limitation	Baseline visit	Biofeedback Exercise	53.50 24.55	37.09 33.03	0.001
	Follow Up 1	Biofeedback Exercise	31.57 20.17	29.34 29.17	
	Follow Up 2	Biofeedback Exercise	25.43 22.80	28.52 28.44	
Physical Limitation	Baseline visit	Biofeedback Exercise	52.62 26.31	37.37 25.64	0.01
	Follow Up 1	Biofeedback Exercise	29.82 20.17	27.54 23.29	
	Follow Up 2	Biofeedback Exercise	22.80 19.29	26.76 21.70	
Social Limitation	Baseline visit	Biofeedback Exercise	25.72 7.60	29.40 18.90	0.17
	Follow Up 1	Biofeedback Exercise	15.49 3.50	21.15 15.29	
	Follow Up 2	Biofeedback Exercise	12.86 2.33	22.60 10.19	
Follow up 1: 4-5 weeks from baseline Follow up 2: 12 weeks from baseline					

Personal Relation	Baseline visit	Biofeedback	23.95	35.46	0.01
		Exercise	15.78	27.48	
	Follow Up 1	Biofeedback	15.62	26.15	
		Exercise	16.66	30.42	
	Follow Up 2	Biofeedback	9.37	14.86	
		Exercise	14.91	25.39	
Emotions	Baseline visit	Biofeedback	49.70	32.99	0.02
		Exercise	23.39	29.13	
	Follow Up 1	Biofeedback	33.91	15.07	
		Exercise	8.77	23.86	
	Follow Up 2	Biofeedback	21.63	24.97	
		Exercise	17.54	26.53	

Follow up 1: 4-5 weeks from baseline

Follow up 2: 12 weeks from baseline

Sleep/energy	Baseline visit	Biofeedback	42.10	26.27	0.0005
		Exercise	16.66	20.03	
	Follow Up 1	Biofeedback	26.31	28.49	
		Exercise	11.40	14.75	
	Follow Up 2	Biofeedback	14.03	19.45	
		Exercise	13.15	16.27	
Severity measures	Baseline visit	Biofeedback	21.92	23.27	0.02
		Exercise	10.52	8.71	
	Follow Up 1	Biofeedback	13.59	19.87	
		Exercise	7.01	7.98	
	Follow Up 2	Biofeedback	11.84	21.21	
		Exercise	8.33	8.78	

Follow up 1: 4-5 weeks from baseline

Follow up 2: 12 weeks from baseline

Table 3 - time* group interactions of pelvic floor muscle strength

(between groups comparison)

Variable	Time	Group	Mean Pressure (hectopascal)	SD	P-value
Maximum Contraction Pressure	Baseline visit	Biofeedback	176.01	46.80	0.48
		Exercise	132.95	45.71	
	Follow Up 1	Biofeedback	213.06	60.27	
		Exercise	157.62	68.17	
	Follow Up 2	Biofeedback	209.34	65.82	
		Exercise	152.28	55.71	
Mean Contraction Pressure	Baseline visit	Biofeedback	153.17	35.68	0.89
		Exercise	118.74	46.08	
	Follow Up 1	Biofeedback	178.22	48.07	
		Exercise	145.93	65.90	
	Follow Up 2	Biofeedback	176.70	48.42	
		Exercise	139.97	54.59	
Resting Pressure	Baseline visit	Biofeedback	142.87	41.96	0.24
		Exercise	104.86	46.02	
	Follow Up 1	Biofeedback	138.65	45.58	
		Exercise	125.84	64.24	
	Follow Up 2	Biofeedback	133.22	50.34	

		Exercise	118.12	53.95	
Follow up 1: 4-5 weeks from baseline Follow up 2: 12 weeks from baseline					