



Original Article

Biofeedback therapy combined with diet to treating ODS (Anismus): 2 years outcome



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ABSTRACT

Object: The advantages of biofeedback therapy along with diet in patients with constipation are among the issues discussed nowadays. The aim of this study was to evaluate 2 years outcome of biofeedback therapy along with diet in patients with obstructed defecation syndrome (ODS) (Anismus).

Methodology: The focus of this prospective study is a group of 129 patients with ODS constipation, who were referred to two tertiary-care referral academic centers from 2013 to 2016. Patients received biofeedback therapy combined with appropriate diet in cases group and received diet in controls group. Good response was defined as a subject with at least 50 percent improvement from before to after biofeedback therapy on a Cleveland Clinic Florida Constipation Scoring System (CCF). Factors associated with better outcome were analyzed using SPSS 20 software.

Results: Out of the 129 patients, 112 patients (86.8%) were female. The mean age of patients was 42.44 ± 15.05 years. The mean CCF score of the patients before and after biofeedback therapy was 12.41 ± 4.39 and 6.00 ± 3.28 respectively in case group (p -value < 0.001). In addition, the mean CCF score of the patients before and after diet therapy was 12.82 ± 4.85 and 9.43 ± 3.79 respectively in control group (p -value < 0.001). While CCF score in both case and control groups reduced significantly after therapy, the rate of this reduction was higher in case group ($p < 0.001$).

Conclusion: Our findings suggest that biofeedback therapy combined with diet will improve patients outcome in ODS constipation. Prospective clinical trials with larger sample sizes are recommend allowing for causal correlations.

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Terapia por biofeedback combinada com dieta no tratamento da SDO (Anismus): desfecho de 2 anos

R E S U M O

Palavras-chave:

Síndrome da defecação obstruída
Anismus
Terapia por biofeedback
Dieta

Objetivo: As vantagens da terapia por biofeedback, juntamente com a dieta, em pacientes com constipação se situam entre os tópicos atualmente em discussão. O objetivo desse estudo foi avaliar os resultados, após 2 anos, da terapia por biofeedback associada à dieta em pacientes com síndrome da defecação obstruída (SDO) (Anismus).

Metodologia: O enfoque desse estudo prospectivo é um grupo de 129 pacientes com constipação por SDO, encaminhados a dois centros acadêmicos de referência para atendimento terciário entre os anos de 2013 e 2016. Os pacientes receberam terapia por biofeedback em combinação com dieta apropriada no grupo de estudo (casos), e apenas dieta no grupo de controle. Boa resposta foi devida como o paciente com pelo menos 50% de melhora desde antes até após a terapia por biofeedback, com o uso de um Sistema de Pontuação para Constipação do Centro Médico Cleveland Clinic Florida (CCF). Os fatores associados a melhor desfecho foram analisados com o uso do programa SPSS 20.

Resultados: Dos 129 pacientes, 112 (86,8%) eram mulheres. A média de idade dos pacientes era de $4244 \pm 15,05$ years. O escore CCF médio dos pacientes antes e depois da terapia por biofeedback foi $12,41 \pm 4,39$ e $6,00 \pm 3,28$ respectivamente no grupo de casos ($P < 0,001$). Além disso, o escore CCF médio dos pacientes antes e depois da dietoterapia foi $12,82 \pm 4,85$ e $9,43 \pm 3,79$ respectivamente no grupo de controle ($P < 0,001$). Embora o escore CCF tanto no grupo de casos como no grupo de controle tenha apresentado redução significativa após a terapia, o grau dessa redução foi mais elevado no grupo de casos ($P < 0,001$).

Conclusão: Nossos achados sugerem que a terapia por biofeedback em combinação com a dieta melhora o resultado para os pacientes apresentando constipação por SDO. Recomendamos a realização de estudos clínicos prospectivos com amostras mais expressivas, que permitam o estabelecimento de correlações causais.

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Introduction

Constipation is one of the most common digestive problems and it is associated with much cost for its diagnosis and treatment.¹⁻³ It is categorized in primary and secondary forms.⁴ Primary forms of constipation occur due to (1) slow colonic transit, (2) obstructed defecation syndrome, (3) items included both slow transit and ODS, and (4) irritable bowel syndrome constipation. Secondary forms of constipation occur due to peripheral neurogenic causes such as diabetes or autonomic neuropathy, central neurogenic causes such as multiple sclerosis, spinal cord injuries and Parkinson, non-neurological causes such as hypokalemia, hypercalcemia, pregnancy, and anorexia, and eventually medical causes such as opioid, hypertension treatment drugs, tricyclic antidepressants, etc.

Among the primary causes of constipation, there is dysfunction in muscles responsible for disposal and anatomical abnormalities of pelvic organs in ODS, so defecation will be difficult.⁵ ODS is the cause of one-third of all cases of constipation.⁵ In this syndrome, the natural feeling of need to defecate occurs with the inability to defecate in the required time. ODS occurs either due to functional causes such as paradoxical contractions of pelvic floor muscles and insufficient contraction of muscles during the defecation or anatomical

causes such as rectocele, intussusception, mucosa prolapse, and perineal descending.

The main functional reason proposed for ODS is anismus. Anismus includes about 15–50 percent of cases of chronic constipation based on diagnostic criteria.⁶ Some of the anismus symptoms include excessive straining, incomplete defecation, difficult and incomplete defecation with great time intervals.⁷

One of the simple diagnostic ways in evaluation of patients with constipation is digital rectal examination. In digital rectal examination, the perineal feeling, anocutaneous reflex, reflex contractions of the external anal sphincter are examined. Looseness, spasm, tenderness, mass, blood, and stool in the rectum are determined. Sphincter tone and puborectal in rest and squeeze are examined. In the straining state, the relaxation of the external sphincter muscle or puborectal along with perineal descent is examined. In digital rectal examination, sensitivity and specialty to diagnose dyssynergy have been reported 87% and 75%, respectively.⁸ One of the effective treatments in patients with anismus is biofeedback with special diet. Some clinical trials studies have shown that biofeedback therapy combined with diet is not only very effective, but also it is preferred over other dyssynergic or anismus treatment options, since it leads to improvement in symptoms caused by underlying pathophysiologic changes.⁹ The goal of biofeedback is modified dyssynergy to

coordinate rectal, anal sphincter anal, and abdominal muscles for complete defecation and to get better sensory perception in patients with reduced rectal sensation. In recent years, studies have found that biofeedback is preferred over diet, exercise, laxatives, polyethylene glycol, diazepam, and treatment by balloon disposal.^{10–13} It is not also followed by bad side effects.

The main objective of this study is to investigate the short-term effects of biofeedback therapy combined with diet in the treatment of dyssynergic dysfunction in pelvic floor muscles as a common cause of constipation.

Methodology

This study was conducted using prospective method. In this study, 129 patients (men and women) referred to clinics of Tehran and Shahid Beheshti University of Medical Sciences due to constipation (according to Rome III criteria) between the years 2013 to 2016 were selected, and they were followed-up for two years. After obtaining careful history and physical examination such as digital rectal exam, they were included in the study by diagnosing paradox contractions of pelvic floor muscles as the main cause of constipation. One of the measures taken before and after treatment was anal EMG assessment. The ethical consent form to participate in the study was taken from patients.

Demographic data including age, gender, weight, and education, history of pregnancy in women, type and number of childbirth were asked from patients. Chief complaint, symptoms such as abdominal pain or rectal bleeding during defecation, previous hysterectomy surgery, and any urinary or anal previous surgery were asked.

In pelvic examination, perineal descending, fissure, hemorrhoids, sphincter tone examination by digital rectal examination, Rectocele, enterocele, and priniocoele, prolapse of rectal mucosa and intussusceptions of mucosa were taken into consideration. Puborectal and anal sphincter muscle status was examined using digital rectal examination.

In the digital examination, we examined the contracting power in which patient contracted his abdominal, gluteal muscles and pelvic floor with his all power (around the examiner's finger). Then, we examined the endurance contraction in which the patient was asked to maintain his pelvic floor status for 10s. We recorded the duration in which patient could maintain his contraction, which it could last from 1 to 10s. This number should approach to 10 gradually during the biofeedback treatment. In examining and treating patients with biofeedback, after putting the probe into the rectum, resting pressure, strength, squeeze amplitude, and resting amplitude of pelvic floor muscles were measured. All of the above examinations were also conducted at the end of biofeedback treatment.

In addition, constipation score was assessed by Cleveland Clinic Constipation Scoring System Questionnaire, which its validity and reliability were already evaluated by Agachan et al.¹⁴ According to this questionnaire, the minimum score is zero and the maximum score is 30.

Inclusion and exclusion criteria of study

Inclusion criteria included a diagnosis of constipation due to pelvic floor muscle disorders (ODS) based on a careful history and digital rectal examination.

Exclusion criteria of study included inflammatory bowel disease, an infection with HIV, neurological disorders, urinary-stress incontinence requiring surgery, urgent incontinence requiring surgery, and fecal incontinence as well as patients who do not perceive biofeedback and patients who are not willing to participate in the study. Patients also underwent colonoscopy to rule out other causes of constipation and to rule out intestinal tumors and malignancies, and colonic slow transit, which all of them were normal. Finally, patients who were followed-up for less than 2 years were excluded from the study.

Finally, patients selected based on the examination and questionnaire were considered candidate for biofeedback treatment and diet, which out of 129 patients, 80 of them were accepted (biofeedback combined with diet). Accordingly, 49 of them were treated through only by diet due to various reasons such inability to pay biofeedback costs, lack of access to skilled physical therapist, long distance from health centers, etc. Accordingly, patients were divided into two groups: case group (biofeedback combined with diet) and control group (only diet).

Diet

In all case and control patients, observing specific diet based on the following protocol was taught to patients and all patients observed this diet:

- Taking 10-8 glasses of fluids daily (except tea) at meals intervals
- Taking dairy products except yogurt
- Using ground wheat bran with milk
- Using vegetables and fruits (especially plums, grapes, figs, kiwi)
- Reduced used of apples and bananas
- Reduced use of starchy foods (rice–potato–pasta)
- Moderated use of medications that cause constipation
- Taking psyllium

Biofeedback performed through this protocol^{15,16}

- a) Open the software program and enter pertinent patient data. Configure a continuous program with the EMG sensitivity based on the patient's muscle testing grade.
- b) Using an internal electrode, provide patient with privacy to self insert or assist as needed. Lubricant was made available.
- c) Establishing a resting baseline of EMG activity for last 2 min.
- d) Ask the patient to perform several contractions and relaxations of the pelvic floor muscles in conjunction with the movement on the visual display.
- e) Ask the patient to perform a series quick flicks of the pelvic floor muscles. The patient is instructed to tighten the pelvic floor quickly, and the quickly relax several times in a row.

- f) Configure a baseline test session in a work/rest mode with work times manual muscle testing endurance score in seconds and rest times equals 10 s use a protocol of 10 total contractions.
- g) Print and file a session summary report, including data such as maximum and minimum EMG muscle activity in microvolts, and visual display of total testing session.
- h) Remove internal electrode.
- i) Clean all electrodes and cables according to clinical setting policy.

We performed biofeedback using an internal electrode in the anal and surface electrode which is located on the thigh's external surface.

Results

Patient characteristics

In this study, 129 patients including 112 females (86.8%) and 17 males (13.2%) were studied. The mean age of patients in this study was 42.44 ± 15.05 at the age range of 15–78 years.

The mean BMI of the patients in this study was 25.63 ± 3.78 . Out of 129 patients, 61 patients (47.3%) had academic education, 62 patients (48.1%) had education up to high school, and six patients (4.7%) were illiterate.

Out of 129 patients, 80 patients were included in the case group based on inclusion and exclusion criteria of study. They received biofeedback along with diet. In addition, 49 patients were included in the control group, who received only diet.

The chief complaint of patients was respectively difficult defecation in 54 patients (41.9%), pain in 45 patients (34.9%), bleeding in 12 patients (9.3%), incontinence in 10 patients (7.8%), and mass in 8 patients (6.2%).

Out of 80 patients in the case group, 28 patients (35.0%) had the history of disease associated with constipation in the past. Additionally, 35 patients (43.8%) had a history of doing anorectal surgery. Out of 80 patient in case group, 20 patients (25.0%) had a history of taking drug related to treatment of constipation or induced constipation in the past.

Out of 112 women participated in the study, 56 patients (50.0%) had the history of NVD and 34 patients (30.3%) had a history of cesarean section (Table 1).

Significant difference was not found between the CCF score before treatment among women (mean CCF score = 12.60) and men (mean CCF score = 12.35) ($p = 0.837$).

Pre-treatment versus post-treatment; EMG

All components of the muscles and anal sphincter tone including strength, squeeze amplitude, resting amplitude and endurance contraction improved after 11.39 ± 4.38 sessions of biofeedback among the 80 patients in group case (Table 2).

Pre-treatment versus post-treatment; physical exam

Before treatment, out of 80 patients in the case group in Digital Rectal Examination (DRE), 39 patients (48.8%) had abnormal resting pressure, 16 patients (20.0%) had abnormal squeeze

Table 1 – Demographic information and general characteristics of patients in case and control groups.

Patient characteristics		
Variable	Cases Number (per- cent)/mean \pm SD	Controls Number (per- cent)/mean \pm SD
Age	43.14 \pm 15.39	41.31 \pm 14.55
Sex		
Female	71 (88.8%)	41 (83.7%)
Male	9 (11.2%)	8 (16.3%)
BMI	25.95 \pm 3.73	25.12 \pm 3.85
Education		
University	35 (43.8%)	26 (53.1%)
Diploma	40 (50.0%)	22 (44.9%)
Illiterate	5 (6.3%)	1 (2.0%)
Chief complaint		
Pain	31 (38.8%)	14 (28.6%)
Difficult defecation	26 (32.5%)	28 (57.1%)
Incontinency	10 (12.5%)	0 (0.0%)
Mass	8 (10.0%)	0 (0.0%)
Bleeding	5 (6.3%)	7 (14.3%)
Past medical history		
Yes	28 (35.0%)	–
No	52 (65.0%)	–
Past surgery history		
Yes	35 (43.8%)	–
No	45 (56.2%)	–
Past drug history		
Yes	20 (25.0%)	–
No	60 (75.0%)	–
Vaginal delivery history		
Yes	37 (52.1%)	19 (38.8%)
No	34 (47.9%)	30 (61.2%)
Cesarean section history		
Yes	19 (26.7%)	15 (30.6%)
No	52 (73.3%)	34 (69.4%)
DRE		
Normal	30 (37.5%)	–
Fissure	20 (25.0%)	–
Hemorrhoid	10 (12.5%)	–
Perineal descending	10 (12.5%)	–
Rectocele	9 (11.3%)	–
Skin tag	1 (1.3%)	–

pressure, and 76 patients (95.0%) had abnormal paradoxical contraction, which it became significantly normal after biofeedback examination of patients ($p < 0.001$) (Table 2).

In addition, out of 80 patients in the case group in DRE, the most common findings in patients were respectively fissure in 20 patients (25.0%), hemorrhoid in 10 patients (12.5%), perineal descending in 10 patients (12.5%), rectocele in 9 patients (11.3%) and skin tag only in 1 patient (1.3%). However, physical examination of 30 patients (37.5%) was normal.

Pre-treatment versus post-treatment; symptoms

CCF score reduced significantly in the case group patients after the biofeedback along with diet ($p < 0.001$). Mean CCF score before treatment in case group was 12.41 ± 4.39 at the range of

Table 2 – Biofeedback therapy along with diet in case group resulted in a significant improvement in all variables measured in patients. In addition to information related to patients’ electromyography, the mean VAS and CCF Score of patients improved significantly after biofeedback therapy along with diet ($p < 0.001$). Effects of biofeedback combined diet therapy on DRE, EMG, VAS & CCF score in patients with ODS.

Variables	Pre-treatment	Post-treatment	p-Value
Resting pressure (n/T) %	(39/80) 48.8%	(79/80) 98.8%	<0.001
Squeeze pressure (n/T) %	(64/80) 80.0%	(80/80) 100%	<0.001
Paradoxical contraction (n/T) %	(4/80) 5.0%	(78/80) 97.5%	<0.001
Strength (mean ± SD)	4.70 ± 1.65	2.61 ± 1.22	<0.001
Squeeze amplitude (mean ± SD)	5.43 ± 3.33	16.88 ± 6.28	<0.001
Resting amplitude (mean ± SD)	3.32 ± 1.95	2.40 ± 0.86	<0.001
Endurance contraction (mean ± SD)	2.70 ± 1.07	6.09 ± 1.00	<0.001
VAS (mean ± SD)	8.96 ± 1.13	3.84 ± 1.99	<0.001
CCF score (mean ± SD)	12.41 ± 4.39	6.00 ± 3.28	<0.001

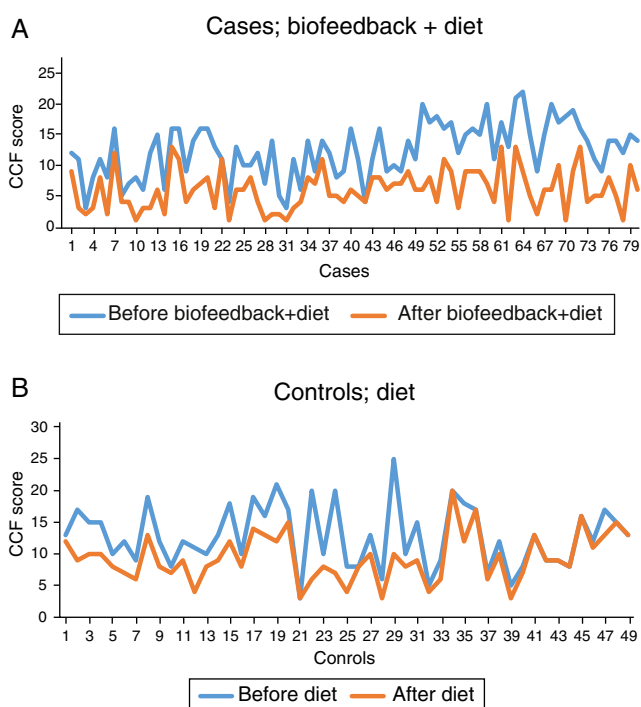


Fig. 1 – (A) Significant reduction of the CCF score in case group patients after biofeedback along with diet ($p < 0.001$); (B) significant reduction of the CCF score in control group patients after the biofeedback along with diet ($p < 0.001$), while in both case and control groups, CCF score after treatment significantly reduced, but rate of this reduction is more in case group ($p < 0.001$).

3–22, which it reduced after the treatment to 6.00 ± 3.28 at the range of 1–13 (Table 2). However, mean CCF score in the control group before treatment was 12.82 ± 4.85 at the range of 3–25, which it reduced to 9.43 ± 3.79 at the range of 3–20 after treatment ($p < 0.001$). While CCF score significantly decreased after treatment in both case and control groups, the rate of reduction in the case group was significantly higher ($p < 0.001$) (Fig. 1).

The mean VAS score of case group before the start of biofeedback was 8.96 ± 1.13 that it became 3.84 ± 1.99 after the treatment, which was significantly (on average, about 5 points) reduced ($p < 0.001$) (Table 2).

Out of 80 patients in the case group, 44 patients (55.0%) had good satisfactory response (over 50% reduction in CCF score) and the rest of the patients (45.0%) had not enough satisfaction despite improvement in EMG components. However, out of 49 patients in control group, only four patients (8.2%) had good satisfactory response and 45 patients (91.8%) had not enough satisfaction with results of treatment (only diet).

Satisfactory versus unsatisfactory response

Significant difference was not found between the male and female gender in terms of satisfactory response after treatment in the case group ($p = 0.628$), while significant difference was found between patients older than 40 years and patients aged 40 and under 40 years in terms of satisfactory response after treatment in case group ($p = 0.010$) (Table 3).

Additionally, significant correlation was found between the BMI of patients and satisfactory response ($p = 0.05$), so that patients who had a BMI less than 25 had a better response to treatment, compared with patients who had a BMI equal or 25 or over 25 (Table 3).

The relationship between a history of C/S and the satisfactory response was also significant ($p = 0.004$), so that patients who had no history of C/S had much more satisfactory response compared to patients with a history of C/S (Table 3).

Additionally, out of patients in case group who underwent C/S, 26.3% had a good outcome, but out of patients who were under the NVD, 56.8% of them had a good outcome. However, it could be concluded that patients underwent NVD gave better response to biofeedback along with diet compared to patients underwent C/S.

Mean endurance contraction before treatment has significant correlation with satisfactory response of patients after treatment with biofeedback and diet ($p = 0.002$), so that patients who had lower mean endurance contraction before treatment provided much more satisfactory response after the course of treatment with biofeedback along with diet.

Finally, a significant relationship was found between the mean VAS score of patients before treatment and satisfactory response after treatment in case group ($p = 0.011$). Thus, patients who had more VAS score before treatment provided better satisfactory response to treatment after the treatment.

However, there was no correlation between satisfactory response of patients and other variables.

Table 3 – In the case group patients 40 ≥ years, BMI < 25 years and finally patients without cesarean had much more satisfaction with than biofeedback therapy along with diet, while these relationships were not significant in control group. Correlations between satisfactory response and variables:.

Variables	Cases			Controls		
	Satisfied	Unsatisfied	p-Value	Satisfied	Unsatisfied	p-Value
Total patients	55.0%	45.0%	–	8.1%	91.9%	–
Women	54.9%	45.1%	0.628	4.8%	95.2%	0.120
Men	55.5%	44.5%		25.0%	75.0%	
Age > 40 yr	41.8%	58.2%	0.010	4.3%	95.7%	0.353
Age ≤ 40 yr	70.2%	29.8%		11.5%	88.5%	
BMI ≥ 25	46.9%	53.1%	0.055	3.8%	96.2%	0.259
BMI < 25	67.7%	32.3%		13.0%	87.0%	
High educated	60.0%	40.0%	0.286	11.5%	88.5%	0.353
Low educated	51.1%	48.9%		4.3%	95.7%	
C/S; Yes	26.3%	73.7%	0.004	13.3%	86.7%	0.357
C/S; No	63.9%	36.1%		5.8%	94.2%	
NVD; Yes	56.7%	43.3%	0.473	0.0%	100.0%	0.129
NVD; No	53.4%	46.6%		13.3%	86.7%	

Multivariate analysis

In the multivariate analysis based on Cox regression model, variables that had satisfactory response of patients in single-variable analysis as well as variables that were seemingly correlated with satisfactory response of patients including gender, age, BMI, VAS before treatment and C/S history were included in model. Finally, it was found that age, C/S history and the VAS score prior to initiation of treatment were effective in prognosis of case group patients ($p < 0.05$).

Discussion

This study proved that biofeedback therapy has significant impact in improvement of patients with ODS. It became clear when we found that out of 80 patients treated with biofeedback along with diet, 55.0 of them experienced CCF score reduction over 50% after the course of treatment and they were satisfied with the treatment. However, out of 49 patients treated only with diet, 8.1% of them experienced relative improvement.

The impact of treatment with biofeedback has been proven in various studies. In a study conducted by Murad Regadas et al. in 2016 on 116 patients with anismus to examine the impact of biofeedback along with diet on recovery of patients, it was found that 59% of patients were satisfied with results of the treatment.⁶ Other similar studies confirm these results.^{17–21} Following improvement in CCF score, VAS score of patients also improved significantly after biofeedback and diet in case group, indicating the impact of biofeedback on the recovery of patients.

In this study, the effect of biofeedback on EMG, muscle tone, and pelvic sphincters was higher than its effect on patients' satisfaction with treatment. This means that EMG indices of pelvic muscles of almost all patients after treatment improved compared to before treatment. Many studies had found results different from results of our study. In these studies, despite clinical improvement of patients, significant improvement was not seen in EMG of patients after biofeedback.^{6,17,22–24}

In our study, despite the general improvement in resting pressure, squeeze pressure, paradoxical contraction, strength, squeeze amplitude, resting amplitude, and endurance contraction, satisfactory response of patients was not complete after biofeedback therapy along with diet. It may be due to other reasons, except for pelvic muscle dysfunction, including anatomic disorders such as Rectocele, enterocele, and perineal descending as well as other primary and secondary causes of constipation such as neuropathies and even psychological causes.

The main weakness of this study was short duration of follow up of patients. Some studies have followed-up the positive impact of biofeedback long times after the treatment (up to 5 years after treatment),^{25–27} but the weakness of studies conducted in this regard is prolonged follow-up of the patients.

In this study, we continue the follow-up of patients and we release the long-term effect of biofeedback treatment on patients with ODS, while we could prove the positive impact of biofeedback therapy under the light of comparing the case group with control group in this study. Another important point in this study was the impact of patients' age on response to biofeedback therapy along with diet, so that significant difference was found among patients older than 40 years and 40 years old and younger patients in terms of satisfactory response after the treatment in the control group ($p = 0.010$). It was found that 40 years old and younger patients provided better response to treatment compared to older than 40 years patients.

This issue was not found in our similar previous studies. It is due to better response of muscles and sphincters of young patients received biofeedback therapy along with diet compared to muscles and sphincters of older people and the direct impact of the phenomenon of aging in muscle cells in response to treatment. However, the better cooperation of younger patients, especially during EMG and eye examination, should not be overlooked.

Another important result found in this study was the impact of C/S history in response to treatment. Patients who had no C/S history had much more satisfactory response compared to patients who had no C/S history. In a study conducted

by Murad Regadas et al. in 2009, significant difference was not found between distribution of pelvic disease in women and type of childbirth among them.²⁸

Other disadvantage of this study was lack of studying and treatment of patients with other types of constipation. It is recommended that further study to be conducted on patients with other types of constipation.

Conclusion

The study showed that biofeedback therapy along with diet could be an effective and acceptable option for patients with ODS, although it seems that more studies are required in this area, especially with larger sample sizes and longer follow up.

Conflicts of interest

The authors declare no conflicts of interest.

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