



Evaluation of the effectiveness of biofeedback therapy for functional constipation in children

BOWEL

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ABSTRACT

Background/Aims: Defecation disorders are one of the most common problems in pediatric gastroenterology. Treatment includes changes in the diet, pharmacotherapy, and biofeedback therapy. The aim of the present study was to evaluate the effectiveness of biofeedback therapy as assessed by clinical improvement as well as by changes in manometric parameters in children with constipation and pelvic floor dyssynergia (PFD).

Materials and Methods: A total of 44 children with constipation and PFD hospitalized between 2000 and 2015 were enrolled in this retrospective study. All patients underwent anorectal manometry, and in case of diagnosed PFD, the patient qualified for biofeedback therapy. Amplitudes between extreme and basic pressures during defecation maneuvers in the first and last sessions as well as the difference between them were compared between groups with and without clinical improvement after the last session.

Results: A clinical improvement was achieved in 38 (86%) patients. There were no significant differences found in the amplitudes in the first session (mmHg), 94, 65, 115 vs. 112, 55, 170 (median, first quartile, third quartile, respectively; NS: not significant); last session, 36, 27, 52 vs. 41, -38, 66, respectively; or between them, 71, 11, 124 vs. 81, 17, 109, respectively, in the group with versus the group without clinical improvement, respectively.

Conclusion: Biofeedback therapy has high clinical efficacy, and despite the lack of manometric improvement, it should be used as a treatment method in children in whom dietary and pharmacological procedures do not work, even if we consider the exercises more as a form of psychological training.

Keywords: Biofeedback, children, constipation

INTRODUCTION

Defecation disorders are one of the most common problems in gastroenterology. They often affect adults, but in recent years, children have also been more frequently affected. The most common defecation disorder is constipation. This is defined as bowel movements less than three times a week, with effort and a feeling of incomplete defecation, tough and large volumes of stool-sometimes even causing an obstructed toilet (1,2). According to data in the United States (US), the problem affects 1.5-7.5% of the pediatric population (1). According to the literature, approximately 25% of gastroenterological advice given concerns constipation (2). Constipation may be caused by an organic disease, or more frequently (in 90% of cases), it is a functional problem. From the range of organic causes of constipation,

we can highlight the following: Hirschsprung disease in young children as well as anatomical abnormalities and endocrine, metabolic, or neurological problems (3,4). However, an organic background of constipation is rare, and over 90% of constipation cases are the result of functional disorders, which can be diagnosed in accordance with the Rome III criteria (2,4,5). Treatment includes a high fiber diet, the proper education of patients, pharmacotherapy, and in some cases, biofeedback therapy (2,4,6,7).

Biofeedback is a behavioral therapy that by means of giving a patient feedback, it teaches them proper control over actions of, for example, certain muscles that have a role in defecation. Before scheduling patients for biofeedback therapy, it is necessary to perform all

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diagnostic tests for constipation in order to exclude an organic problem. The theoretical basis of biofeedback is "learning through reinforcement" or "operant conditioning" (3,8,9). Biofeedback training in constipation aims to help a patient achieve control over the muscles of the sphincter apparatus (10-12). The manometric method of anal sphincter exercises in gastroenterology was first used in 1974 for patients with fecal incontinence and then in 1987 for the treatment of constipation due to dyssynergic defecation (8). This is a therapy based on anal sphincter exercises performed using anorectal manometry (8,11-15). Anorectal manometry is used to diagnose, for example, Hirschsprung disease or pelvic floor dyssynergia (PFD). However, in the literature, there are not many studies concerning biofeedback therapy, particularly in the pediatric population (16-20).

The aim of this study was to evaluate the efficacy of biofeedback therapy by assessing the clinical improvement and the changes in manometric parameters and their dependencies in children treated for functional constipation.

MATERIALS AND METHODS

A total of 44 children with functional constipation and PFD (11 girls and 33 boys) hospitalized at the Department of Gastroenterology between 2000 and 2015 were enrolled in the study. Inclusion criteria for the study were diagnosed functional constipation and PFD found during anorectal manometry. Patients younger than 6 years and children with constipation caused by organic disease were not qualified to undergo biofeedback therapy. The diagnostic criteria for functional constipation were those included in the Rome III criteria. According to these criteria, at least two of the following problems had to have been reported: two or fewer defecations per week, at least one episode of fecal incontinence per week (if the child consciously controls their bowel movements), a history of retention of feces, painful bowel movements or tough stools, the presence of large amounts of stools in the rectum, and large volumes of stools that may obstruct the toilet. For children up to 4 years of age, complaints must be present for a month or longer, and for children over 4 years of age, complaints must occur at least once a week for at least two months (2,4,5).

The following data were retrospectively gathered and analyzed: the number of bowel movements per week, stool consistency, constipation associated with fecal incontinence, and previous pharmacotherapy. All patients underwent anorectal manometry with an evaluation of the function of the external anal sphincter, the sensation of the rectal contents, and tracking of defecation - coordination between the bottom of the pelvic and anal sphincters. In cases of diagnosed PFD (improper coordination between the bottom of the pelvic and anal sphincters, such as paradoxical contraction of the external anal sphincter with a lack of pelvic floor muscle relaxation during defecation), the patient qualified for biofeedback therapy. Informed written consent for the procedure was ob-

tained from the child's parents or guardian before therapy. One to four series of biofeedback were performed, with each series consisting of 2-4 sessions. Each session lasted for approximately 30 min. During the exercises, the patient lay on the couch with their face turned toward the monitor of the manometric equipment. The doctor who performed the exercises explained to the patient to study the record on the monitor, for example, an upward curve on the monitor indicates contraction of the muscles, a downward curve means relaxation of the muscles. Then, the patient was asked to defecate. The task for patients was to attempt defecation during the session with an improvement in the manometric record. The manometric study and biofeedback exercises were performed using the Polygraph equipment (Medtronic; MN, USA). For the manometric exercises, a 4-channel tube was used. To obtain the patient's sensation of their intestinal contents and to provide an impulse for defecation, an anorectal balloon was filled with 20 mL of air. The patients were allowed to choose whether the exercises would be performed in the presence or absence of their parents in order to minimize stress and discomfort during the manometric exercises. Sessions were conducted at intervals of several weeks (the patients were admitted to our clinic for the biofeedback session every 4-8 weeks). During hospitalization and in the intervals between sessions, the patients were recommended to train their bowel movements and to eat a fiber-rich diet. The therapy was terminated when there was clinical improvement. Clinical improvement was defined as an increased frequency of defecation, improved consistency of stools, and reduced number of encopresis episodes. The manometric results were analyzed statistically. The study compared the amplitude of the extreme and basic pressures during the defecation maneuver in the first and last sessions. Moreover, the difference between them (amplitude in the first session - amplitude in the last session) was compared between the group with clinical improvement after the last session versus the group with no clinical improvement.

Data were reported as the mean±standard deviation or as the median and range of continuous variables. The analysis of continuous variables was performed using the Mann-Whitney U test (Statistica for Windows, v5.0; StatSoft; Tulsa, OK, USA). Significance level was assumed at $p < 0.05$.

The protocol of the study was approved by the Local Ethics Committee (190/KBE/2015).

RESULTS

The age of the patients included in the study ranged from 7 to 18 years (mean, 12 years). The age at constipation onset ranged from infancy to 14 years (mean, 4 years). It took from 1 year to 15 years to perform the first biofeedback exercises, with a mean of 7.5 years. The mean time of follow-up after the end of biofeedback therapy was 7.8 years. The clinical characteristics of the patients are presented in Table 1.

During that time, various methods of constipation treatment were used. Each patient was recommended to eat a fiber-rich diet. All of them also received pharmacotherapy for their constipation. In all children except two, the first-line drug was macrogol. The therapy also used lactulose (in 35 patients), MgSO4 (in 26 patients), prokinetics (in 19 patients), sennosides (in 17 patients), paraffin (in 14 patients), enemas (in 12 patients), and fiber preparations (in 9 patients). Consultation with a psychologist was required in 23 patients.

The number of bowel movements per week before biofeedback therapy was 0–20 (mean: 3/week), fecal incontinence 0–28 times per week (mean: 5/week); and 22 patients reported tough stools. After biofeedback therapy, the number of bowel movements per week was 1–21 (mean: 5/week), fecal incontinence 0–14 times a week (mean: 2/week); and eight patients reported tough stools. Clinical improvement was reported in 38 (86%) patients. Six patients (13.6%) did not report clinical improvement. The data are presented in Figure 1.

There were no statistically significant differences in the amplitudes between the extreme and the basic pressure during defecation in the amplitudes in the first session (mmHg), 94, 65, 115 vs. 112, 55, 170 (median, first quartile, third quartile, respectively; NS: not significant); last session, 36, 27, 52 vs. 41, –38, 66, respectively; or between them, 71, 11, 124 vs. 81, 17, 109, respectively, in the group with clinical improvement after the last session versus the group with no clinical improvement, respectively. The results are shown in Table 2.

Table 1. Clinical characteristics of the patients on biofeedback therapy

Patients enrolled in the study (number, %)	44 (100%)
Girls	11 (25%)
Boys	33 (75%)
Age of the patients, years	12 (7–18)
Age at constipation onset, years	4 (0–14)
Time to biofeedback therapy since constipation onset, years	7.5 (1–15)
Time of follow-up, years	7.8 (1–11)

Table 2. Analyzed manometric results of biofeedback therapy

	Patients without clinical improvement				Patients with clinical improvement				p
	N	Median	Q1	Q3	N	Median	Q1	Q3	
Pressure amplitude in the anal canal during defecation before biofeedback (mmHg)	6	120.5	55	170	38	93.5	65	115	NS
Pressure amplitude in the anal canal during defecation after biofeedback (mmHg)	6	35.5	27	52	37	41	–38	66	NS
Difference between amplitudes (mmHg)	6	81	17	109	37	71	11	124	N

N: number of patients; Q1: first quartile; Q3: third quartile; NS: not significant

During the time of follow-up, PFD relapsed in none of the patients.

DISCUSSION

This study aimed to assess the effects of biofeedback therapy in the treatment of functional constipation in children. The reports show that biofeedback therapy has a highly clinical improvement without significant changes in the anorectal manometry parameters.

In the literature, there are not many studies concerning biofeedback therapy, particularly in the pediatric population (16–20). Heymen et al. (10) described a group of 117 adult patients, Koh et al. (16) a group of 226 adult patients, and Ahn et al. (17) a group of 590 adult patients. Among the pediatric studies, the largest group of patients was described by van der Plas et al. (19) (192 patients), and by Olness et al. (20) (50 patients). Our group of 44 patients is thus one of the largest groups in the literature, and that is why we would like to share our biofeedback therapy experience.

There are several mechanisms of functional constipation; one is the slow movement of feces through the large intestine (slow transit constipation) and slow transit in the sigmoid colon and rectum (outlet obstruction)—caused by abnormal defecation

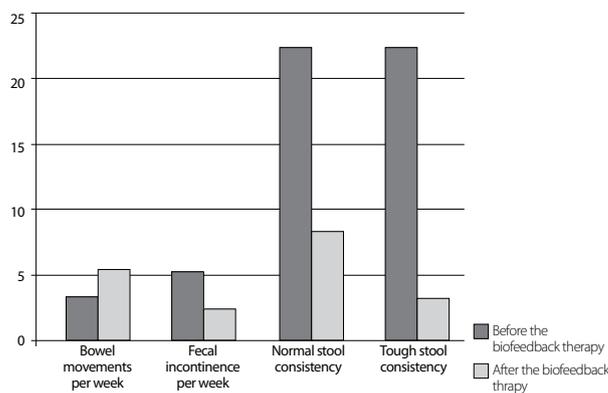


Figure 2. Clinical data collected from taking the history in patients before and after undergoing biofeedback therapy. Results are shown as medians

dynamics, which is a contraction of the external anal sphincter and the absence of pelvic floor muscle relaxation (6,21,22). The second mechanism, called PFD, is responsible for approximately 30–50% of cases of functional constipation (5). We should remember constipation in irritable bowel syndrome (7). In some cases, it is possible to perform biofeedback therapy involving manometric exercises of the external anal sphincter muscles. Biofeedback is a behavioral therapy that uses feedback to teach patients how to properly control some activities, including the proper function of muscles involved in defecation (14). The proper selection of patients is very important. Indications for this therapy are an abnormal tracking of defecation called PFD (paradoxical contraction of the external anal sphincter with a lack of pelvic floor muscle relaxation during defecation) or an abnormal function of the anal sphincter causing incontinence (encopresis) (16,23). The goal of biofeedback therapy in children with PFD is to strengthen the pelvic floor muscles, retrain rectal sensation, and coordinate pelvic floor muscles during evacuation. In this therapy, patients are asked to bear down as if to defecate as usual and to relax the external anal sphincter (14). The basic requirement for the therapy is the patient's willingness to cooperate and their ability to understand the instructions (24). Moreover, it is extremely important to qualify patients of the appropriate age. Data from the literature indicate that the most appropriate age is 5 years (25). In our study, the youngest child was 7 years old. The final qualification is performed by the doctor who will perform the therapy and who will assess the patient's ability to cooperate during the exercises (23). Biofeedback therapy is evaluated very positively in the literature. The reported effectiveness varies between 50% and 90% (2,4,5,15,21,25,26). A wide range of assessments often result from improper patient qualification and the lack of therapy performance standards (2,5,21). Biofeedback therapy is a helpful and effective method for the treatment of functional constipation; biofeedback exercises should be the first-choice method in the treatment of constipation caused by PFD and abnormal function of the anal sphincters confirmed by anorectal manometry. Moreover, it is characterized by high efficiency, a lack of side effects, and low costs. Hart et al. (7) concluded that a high clinical efficacy and the absence of significant statistical differences in the manometric records before and after exercises suggest that the exercises affect the psyche of children and taught them about the regularity of bowel movements and behavioral health practices. We observed the same results in our group of patients. There was no statistically significant difference in the amplitudes between the extreme and basic pressure during defecation in the first and last sessions between the group with clinical improvement after biofeedback therapy and the group with no clinical improvement, despite the good clinical improvement in majority of the trained patients.

In some countries, there are devices available for anorectal manometry that can be used at home (24). They are usually rented to the patient by the hospital. It is possible to more

easily plan the treatment for a patient at home. The record from the device is then sent directly to a specialist, who will interpret and communicate the result to the patient and will provide further recommendations (27). According to preliminary data, clinical improvement usually occurs after several weeks of home exercises (18,24,28,29). Most likely, the exercises play a role in psychological therapy. Toilet training, which can bring about good results, is also very important. During therapy, patients are taught to isolate the pelvic muscles and perform maximal voluntary contractions, focusing on both their amplitude and duration. Moreover, repeated contractions and relaxations are recommended at the beginning and end of home exercises. Habit training is recommended for all patients with constipation and with symptoms of incomplete or difficult evacuation. Patients are encouraged to devote 10 to 15 min at approximately the same time each day for unhurried attempts to evacuate. Other attempts during the day are also acceptable. Training should take place after a meal, which will stimulate bowel movements. A proper position is also very important. Flexion of the hips stretches the anal canal in the anteroposterior direction and tends to open the anorectal angle, which facilitates rectal emptying (11). In the literature, there are not many studies of this therapy on the pediatric population. Heymen et al. (30) conducted an analysis of 11 pediatric studies, with five of them being uncontrolled, six parallel, and three randomized. All six controlled studies compared biofeedback with traditional methods of constipation healing - diet and pharmacotherapy. In the three randomized studies, there was no statistically significant difference in the results between the use of biofeedback therapy and conventional treatment. Among these, van der Plas et al. (31) enrolled an adequate number of patients and compared electromyographic biofeedback (EMG biofeedback) with conventional medical therapy in 71 patients. The study showed no statistically significant difference between the groups, although the authors did not specify how the results of the treatment were evaluated. Moreover, in only 24 patients, PFD was the reason for constipation. In the second randomized study conducted by Wald et al. (32), children were qualified with various etiologies of constipation. In patients with PFD, better results were observed for biofeedback therapy than for mineral oil administration. However, for the whole group, there was no statistical difference. The third randomized trial was conducted by Nolan et al. (33) and included only patients with an abnormal defecation track, with the results showing no significant advantage of EMG biofeedback over conventional methods. However, the studies conducted by Wald et al. (32) and Nolan et al. (33) did not include a sufficient number of patients for statistical analysis. Moreover, there were different causes of constipation in the groups. Nevertheless, the authors considered biofeedback therapy as a promising method and expressed a need for further randomized trials. In another study, van der Plas et al. (19) evaluated the effect of adding biofeedback to conventional therapy in children with constipation with or without anismus. They randomized

94 patients to undergo conventional therapy and 98 patients to undergo conventional therapy plus biofeedback. After 6 weeks of follow-up, in the group subjected to biofeedback, patients showed normal defecation dynamics, but after 1 year, there was no difference between both groups. Heymen et al. (10) conducted an interesting study in a group of adult patients. The study assessed whether the efficacy of biofeedback therapy was higher than that with the use of diazepam or placebo. The study involved 117 adult patients. The first phase of the study included education and pharmacological treatment. The second phase qualified 84 patients who did not feel an improvement after the first phase. They were randomized into three study groups: 30 patients were assigned to undergo biofeedback therapy, 30 received diazepam, and 24 received a placebo. All patients performed pelvic floor exercises. Before treatment, patients from all groups did not differ with regard to age (50 years on average), physiological or psychological symptoms, constipation severity, and expectations toward therapy. The authors demonstrated a higher efficacy of biofeedback therapy than that with the use of diazepam or a placebo.

The most important limitation of our study was that it was a retrospective analysis based on medical histories. Observational studies are less valuable than clinical trials. In order to determine the advisability of biofeedback therapy and to establish guidelines for biofeedback therapy in functional constipation, randomized, multicenter studies on large groups of patients are required, because our study was conducted on only 44 patients using conventional, and not high-resolution, manometry. On the other hand, our clinic is a center with the highest degree of referentiality and one of the few where biofeedback therapy prevails. For this reason, this study has great value because it shows the scale of the problem among a population of Polish children. Moreover, compared with the above-mentioned studies, mostly conducted among adults, our population comprised 44 pediatric patients with PFD.

In conclusion, our results are comparable with those of other pediatric studies. In our opinion, biofeedback therapy with the proper selection of patients (manometric parameters and age) and in the absence of any complications (safe method), despite the lack of manometric improvement, should be used as a treatment method in children in whom dietary and pharmacological procedures do not work, even if we consider the exercises more as a form of psychological training.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of The Children's Memorial Health Institute in Warsaw, Poland (nr 190/KBE/2015).

Informed Consent: Written informed consent was obtained from the parents of the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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