

Article

The Impact of EMG Biofeedback on Evacuation Difficulty Level and Pain Grade During Defecation in Chronically Constipated Elderly Female Patients Due to Dyssynergic Defecation

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Abstract: The purpose of this study was to evaluate the impact of biofeedback therapy on evacuation difficulty level and the pain grade during defecation of elderly female patients with dyssynergic defecation. With this aim, after one month of initial assessment, 16 chronically constipated female patients with dyssynergic defecation were randomized to either a electromyographic biofeedback group ($n = 8$) or to a conventional treatment group ($n = 8$). The results showed a significant decrease in the evacuation difficulty level and pain grade during defecation following behavioral treatment through biofeedback. At the same time, the treatment produced significant improvements in the weekly stool frequency and a decrease in the mean electromyographic (EMG) activity (μV) of the external anal sphincter during straining to defecate. Clinical gains were maintained during the follow-up carried out six months later.

Keywords: dyssynergic defecation; chronic constipation; functional defecation disorders; behavioral treatment; EMG biofeedback

1. Introduction

Dyssynergic defecation is one of the most prevalent forms of chronic constipation [1]. This functional defecation disorder is characterized by incomplete evacuation of fecal material due to either paradoxical anal contraction or inability to relax pelvic floor muscles—particularly the puborectalis muscle and the external anal sphincter—when straining to defecate [2].

In the past, randomized controlled trials conducted in both adults and the elderly have found that biofeedback therapy—particularly electromyographic biofeedback (EMG-BF)—is the most effective treatment for dyssynergic defecation patients [3–7]. Moreover, the efficacy of biofeedback therapy is maintained during long follow-up periods (more than 2 years) [8,9] and has no side effects.

Recent studies carried out by our research group in chronically constipated elderly patients with dyssynergic defecation have shown that these patients present more difficulties in defecating and more pain during defecation than elderly patients who are chronically constipated but without dyssynergic defecation [10]. These results provide empirical evidence of the clinical relevance of these dependent variables as significant bowel symptoms in this functional gastrointestinal disorder. For this reason, these variables could be used as outcome measures to evaluate the effectiveness of the utilized therapeutic procedures.

The aim of this controlled study was to evaluate the impact of behavioral therapy through EMG biofeedback on the evacuation difficulty level and pain grade during defecation in elderly female patients with dyssynergic defecation.

2. Results

A 2×3 mixed-measures MANOVA revealed significant main effects for group (Wilks's $\lambda = 0.05$; $F = 46.86$; $p < 0.01$) and phases (Wilks's $\lambda = 0.03$; $F = 27.67$; $p < 0.01$), as well as for the group \times phases interaction (Wilks's $\lambda = 0.11$; $F = 7.01$; $p < 0.01$). Afterward, the possible differences between EMG-BF and conventional treatment groups during each phase (initial assessment, treatment, and follow-up) were analyzed. In the initial assessment, there were no significant differences between the groups in any of the measured dependent variables (Wilks's $\lambda = 0.41$; $F = 2.17$; $p > 0.05$). Likewise, univariate analysis showed no previous differences between the groups in either age ($F = 3.66$; $p > 0.05$) or mean disease duration ($F = 2.45$; $p > 0.05$). Participant demographic data, clinical symptoms, and EMG activity during straining to defecate in the initial assessment can be seen in Table 1.

Table 1. Demographic data, clinical symptoms, and electromyographic (EMG) activity (μV) during straining to defecate in the initial assessment.

	EMG-BF ($n = 8$)	Conventional ($n = 8$)
Age (years)	77.12 (± 3.18)	73.50 (± 4.31)
Disease duration (years)	9.00 (± 2.14)	11.25 (± 3.45)
Weekly stool frequency	1.87 (± 0.35)	1.50 (± 0.53)
Evacuation difficulty level	6.62 (± 0.92)	7.12 (± 0.35)
Pain grade during defecation	5.25 (± 0.71)	5.62 (± 0.74)
EMG activity (μV) during straining to defecate	10.04 (± 2.15)	11.05 (± 3.16)

Note: data are expressed as mean (\pm standard deviation, SD); EMG-BF: electromyographic biofeedback.

MANOVA for the treatment phase (Wilks's $\lambda = 0.08$; $F = 31.92$; $p < 0.01$) and for the follow-up (Wilks's $\lambda = 0.05$; $F = 53.77$; $p < 0.01$) revealed significant differences between the groups. In both phases, these differences were significant in all variables measured (see Tables 2 and 3).

Table 2. Mean scores (\pm SD) obtained by the electromyographic biofeedback (EMG-BF) and conventional treatment groups in all outcome measures during treatment.

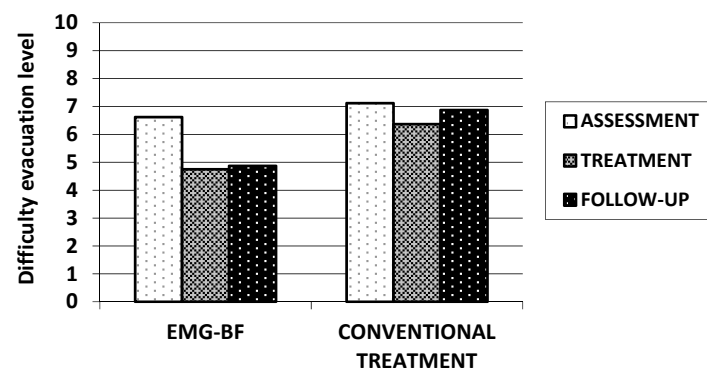
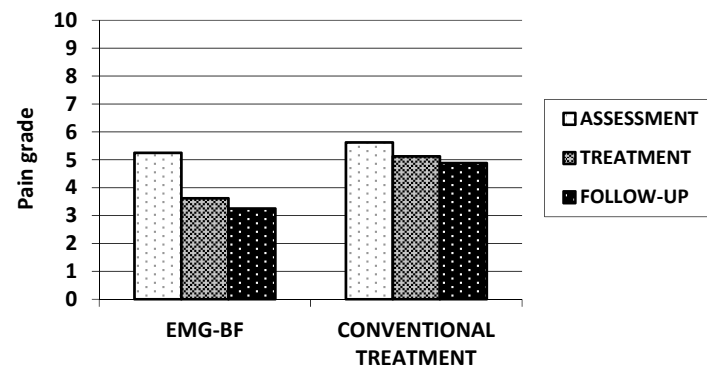
	EMG-BF ($n = 8$)	Conventional ($n = 8$)	F Value *
Weekly stool frequency	3.62 (± 0.52)	1.75 (± 0.46)	58.33
Evacuation difficulty level	4.75 (± 0.89)	6.37 (± 0.52)	20.05
Pain grade during defecation	3.62 (± 0.74)	5.12 (± 0.83)	14.40
EMG activity (μV) during straining to defecate	5.56 (± 1.32)	11.46 (± 2.91)	27.28

* Note: all values are significant ($p < 0.01$).

Graphic representations of the evolution of the evacuation difficulty level and the pain grade during defecation along the study in the EMG-BF and conventional treatment groups are provided in Figures 1 and 2.

Table 3. Mean scores (\pm SD) obtained by the EMG-BF and conventional treatment groups in all outcome measures during follow-up.

	EMG-BF ($n = 8$)	Conventional ($n = 8$)	F Value *
Weekly stool frequency	3.50 (\pm 0.53)	1.62 (\pm 0.52)	50.81
Evacuation difficulty level	4.87 (\pm 0.83)	6.87 (\pm 0.64)	28.90
Pain grade during defecation	3.25 (\pm 0.46)	4.88 (\pm 0.66)	33.80
EMG-activity (μ V) during straining to defecate	4.82 (\pm 0.75)	10.11 (\pm 2.46)	33.97

* Note: all values are significant ($p < 0.01$).**Figure 1.** Evacuation difficulty level along the study in the studied groups.**Figure 2.** Pain grade during defecation along the study in the studied groups.

3. Discussion

The objective of this controlled study was to evaluate the impact of EMG biofeedback therapy on the evacuation difficulty level and pain grade during defecation in chronically constipated elderly female patients due to dyssynergic defecation. The results obtained demonstrate that EMG biofeedback is an effective treatment for dyssynergic defecation, giving place to significant changes in the more relevant and specific bowel symptoms shown by these patients after one month of treatment, maintaining clinical benefits after the follow-up period. Therefore, these results provide firmer evidence about the role of the pain grade during defecation and the evacuation difficulty level as significant symptoms that can be useful in the clinical assessment not only to understand this gastrointestinal disorder [10], but also to be used as a more specific outcome measure to evaluate the effectiveness of therapeutic procedures utilized in the research and the clinical practice. Moreover, weekly stool frequency increased significantly following behavioral treatment with EMG biofeedback, sustaining during follow-up period six months later. Elderly female patients returned to normal values (more than three depositions

weekly). In the same line, there was an important normalization in the anismus index of patients treated with biofeedback, but not in the patients of the conventional treatment group. In the EMG-BF group, the anismus index decreased from 0.53 in the initial assessment to 0.24 and 0.21 during treatment and follow-up, respectively. By contrast, in the conventional treatment group, the anismus index remained above 0.5 in all measurements.

Moreover, although several controlled studies have shown that the biofeedback therapy is effective for the management of dyssynergic defecation [5,9], these trials have been carried out mostly in adults. It is surprising that very few studies have been conducted in elderly people [6] and, even fewer specifically in women [7], despite the fact that the chronic constipation is a gastrointestinal disorder more common in the elderly than in adults, and also more so in women than in men. This controlled trial replicates these findings, singularly obtained by our research group in female elderly patients [7], demonstrating the positive effects of EMG-BF in the treatment of dyssynergic defecation in this group of patients.

This study has several limitations. First, besides the intra-anal EMG, due to accessibility problems, other objective assessment tests that could be very useful, such as anorectal manometry or defecography, were not performed. Second, the dyssynergic defecation type was not defined. Thus, the results do not identify which dyssynergic defecation sub-type was most impacted by EMG biofeedback. Third, the effect that the improvements in the chronic constipation symptomatology following behavioral treatment through EMG biofeedback had on the quality of life and psychological well-being of these patients was not evaluated. This aspect is very important, because chronically constipated patients have a high psychological morbidity, particularly anxiety and depression [11,12], as well as an impairment in health-related quality of life [13,14]. Future research in a larger sample must be carried out to clarify this important question and, in addition, to accurately determine what factors are associated with the positive results achieved by biofeedback treatment.

4. Materials and Methods

4.1. Subjects

Sixteen elderly female patients with chronic constipation due to dyssynergic defecation were selected and included in the study on the basis of fulfilling the Rome III diagnostic criteria for dyssynergic defecation [15]. Additionally, the paradoxical contraction of the external anal sphincter during straining to defecate was objectified by electromyography (EMG). The mean age of the participants was 75.3 years (range, 69 to 82) and the duration of chronic constipation symptoms varied between 6 and 14 years (mean, 9.81). Patients with secondary causes of constipation, cognitive impairment, or symptoms suggestive of irritable bowel syndrome were excluded. Participants provided their written informed consent after an explanation of the study purpose, conducting the research protocol in accordance with the Declaration of Helsinki and after the approval of the center's ethics committee (code number 1417/2; 14 November 2016).

4.2. Measures

A stool diary was employed for the entire study period to prospectively record each bowel movement as well as the evacuation difficulty level and the pain grade during defecation (both on a visual analog scale from 0 to 10). Moreover, EMG activity (μ V) of the external anal sphincter during straining to defecate was recorded using an intra-anal plug electrode (12 mm diameter and 45 mm total length) connected to an integrated EMG device (model 129/9, Biociber, Barcelona, Spain).

4.3. Procedure

The study was developed along three defined phases: initial assessment, treatment, and follow-up. During the initial assessment, participants completed the stool diary for a month and participated in a session to record the EMG activity (μ V) of the external anal sphincter during straining to

defecate. The approximate duration of this psychophysiological assessment session was 45 min. The psychophysiological record was conducted with the patient in left lateral decubitus position with the hips flexed at 90 degrees. Once this phase was finished, the patients were randomly assigned to the EMG-BF group ($n = 8$) or to the conventional treatment group ($n = 8$).

Female patients in the EMG-BF group received treatment during one month. This behavioral treatment consisted of eight sessions, twice a week, with the purpose of eliminating inappropriate contraction of the external anal sphincter during defecation attempts. To achieve this objective, EMG activity was recorded and displayed to the participants in the form of visual and auditory feedback. At the same time, patients were guided by the therapists across all trials through verbal reinforcement by the gradual learning of the appropriate behavior (sphincter relaxation instead contraction). In each treatment session (approximately 45 min in duration) were carried out 15–20 defecation attempts (simulated defecation). The training procedure was conducted with the patient in the same position as in the initial assessment, and no bowel preparation was required.

In the conventional treatment group, female patients received eight sessions, twice a week, along one month (equivalent to the contact time for the EMG-BF group), focused on the influence of lifestyle in their bowel function. Specifically, adequate fiber and fluid intake as well as regular exercise were advised. At the same time, subjects were instructed to try to evacuate on the toilet at the same time each day (20–30 min after a meal), avoiding unnecessary straining and correcting the posture during defecation if necessary. Additional fiber supplements were not prescribed.

The treatment sessions in both groups were carried out by two clinical psychologist experts in the clinical application of biofeedback techniques (second and third authors), following the same protocol with all the participants. All the patients in both groups continued to fill out the stool diary, and once this phase was finished, they participated in a psychophysiological assessment session to record the EMG activity (μV) of the external anal sphincter during straining to defecate.

Finally, during the follow-up phase, carried out six months later, all female dyssynergic defecation patients were assessed in exactly the same way as in the initial assessment.

4.4. Design

A 2×3 mixed-factorial design was employed, including one between-subjects factor (EMG-BF group, and conventional treatment group) and one within-subjects factor (assessment, treatment, and follow-up phases).

4.5. Data Analysis

The data were analyzed using the package IBM SPSS Statistics 20 for Windows (IBM Corporation, Armonk, NY, USA). Statistical analysis was performed using a repeated-measures multivariate analysis of variance (MANOVA). Later, a series of one-way analyses of variance (one-way ANOVAs) were accomplished to analyze differences between the groups in each of the outcome measures.

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