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# Behavioural Treatment of the Dyssynergic Defecation in Chronically Constipated Elderly Patients: A Randomized Controlled Trial

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**Abstract** A randomized controlled trial was carried out with the purpose to determine the effectiveness of EMG-biofeedback in the treatment of chronically constipated elderly patients with dyssynergic defecation as compared to a control condition characterized by information about the bowel functioning and counseling focused on the behavioural mechanisms involved in the defecation. With this purpose, after an initial assessment period (4 weeks), 30 chronically constipated elderly patients with dyssynergic defecation (11 males, 19 females) were randomly assigned to either EMG-biofeedback group ($n = 15$) or control group ($n = 15$). The results shown significant improvements in psychophysiological measures (EMG-activity during straining to defecate and anismus index), as well as in clinical variables (frequency of defecations per week, sensation of incomplete evacuation, difficulty evacuation level and perianal pain at defecation) only in the EMG-biofeedback group. The clinical benefits of this behavioural treatment were maintained at the follow-up period 2 months later.

**Keywords** Dyssynergic defecation · Chronic constipation · Functional defecation disorders · EMG-biofeedback treatment

## Introduction

Chronic constipation is a common problem in elderly subjects, with prevalence ranging from 15 to 20% in the community-dwelling elderly population and up to 50% in some studies of nursing home residents (Bosshard et al. 2004). Because of its high prevalence in the elderly, chronic constipation can have significant morbidity, resulting in tremendous cost in prevention, diagnosis, and treatment. Despite the vast numbers of elderly afflicted with chronic constipation, research has been limited, and there is surprisingly little evidence available on which to base management decisions of this common clinical condition.

Dyssynergic defecation is one of the most common forms of chronic constipation. This functional defecation disorder is characterized by incomplete evacuation of fecal material from the rectum due to paradoxical contraction or failure to relax pelvic floor muscles, particularly the puborectalis muscle and the external anal sphincter, when straining to defecate (Chiarioni et al. 2006a).

Since that Preston and Lennard-Jones (1985) reports this paradoxical response pattern, several investigators have researched this functional defecation disorder, providing greater clarity in your understanding and laying the groundwork for the successful application of behavioural therapy, more concretely, biofeedback techniques. Biofeedback involves the use of pressure measurements (manometry) or averaged electromyographic activity within the canal anal to teach patients how to relax pelvic floor muscles when straining to defecate (Simón and Lara 1996).

However, although biofeedback techniques has been reported to be an effective treatment for dyssynergic defecation in numerous published studies in the last 20 years, several recent reviews have concluded that this behavioural treatment shows high degree of success based mostly on the many uncontrolled studies in this area (Bassotti et al. 2004; Chiarioni et al. 2006a; Palsson et al. 2004). Further,

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most of the research work has been carried out on pediatric population, with few controlled studies on dyssynergic defecation in adults (Koh et al. 2008) and none in elderly patients.

Fortunately, in recent years several randomized controlled trials have been completed in adults. These studies show that biofeedback is more effective than laxatives (Chiarioni et al. 2006b), relaxation training (Rao et al. 2005), pharmacological treatment (diazepam) and placebo (Heymen et al. 2005). Between the different biofeedback modalities (manometric or EMG), EMG-biofeedback has been the most widely utilized (Koh et al. 2008). Based on these results, biofeedback appears to be the treatment of choice for dyssynergic defecation in chronic constipated adults (Chiarioni et al. 2006a).

Although it is encouraging that more controlled studies have been carried out in recent years, these trials were heterogeneous, with varied inclusion criteria, treatment protocols and definitions of success. In fact, a recent systematic review of all randomized controlled trials evaluating the effectiveness of biofeedback in adults with dyssynergic defecation (Koh et al. 2008), suggested that better designed trials are needed to provide a stronger evidence base for the effectiveness of biofeedback in this domain.

Moreover, at the time, it is surprising that controlled studies in elderly patients have been not specifically carried out, despite the fact that the prevalence of chronic constipation has been shown to increase with advancing age (Toner et al. 2006; Wong et al. 1999).

The aim of this randomized controlled trial was to determine the effectiveness of EMG-biofeedback in the treatment of chronically constipated elderly patients with dyssynergic defecation as compared to a control condition characterized by information about the bowel functioning and counseling focused on the behavioural mechanisms involved in the defecation.

## Method

### Participants

Thirty patients with dyssynergic defecation unresponsive to dietary corrections and fibre supplements were selected and enclosed in the study on the basis of fulfilled the Rome III criteria for dyssynergic defecation (Wald et al. 2006). Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis. All the patients had constipation, complaining of decreased bowel frequency (fewer than three defecations per week), sensation of incomplete evacuation, lumpy or hard stools at least 25% of defecations, and straining during at least 25% of defecations. Moreover, the paradoxical contraction of the external anal sphincter during straining to defecate was electromyographically evidenced. The mean age was 73.8 years (range, 67–80), and there were 11 mens and 19 womens. Duration of constipation symptoms varied between 6 and 21 years (mean, 12.8). Patients provided informed consent after an explanation of study purpose.

### Measures

Four clinical variables was assessed through self-monitoring, including: frequency of defecations per week, sensation of incomplete evacuation (0 = no sense of incomplete evacuation, 5 = middle sense of incomplete evacuation, 10 = severe sense of incomplete evacuation), difficulty evacuation level (0 = no difficulty, 5 = middle difficulty, 10 = severe difficulty), and perianal pain at defecation (0 = no pain, 5 = middle pain, 10 = severe pain).

Psychophysiological measures was obtained through electromyography (EMG) of the external anal sphincter, including EMG-activity (μV) during resting, squeezing, and straining to defecate. The anismus index was defined how the quotient between EMG-activity during straining to defecate and EMG-activity during squeezing. The EMG was performed using an intra-anal plug electrode (12 mm. diameter and 45 mm. total length) connected to an integrated EMG (model 129/9, Biociber, Spain).

### Design

A matched groups design was used taking the frequency of defecations per week as the yoked or matching variable. After measuring the frequency of defecations per week during the initial assessment phase, patient blocks were formed with the same frequency. The subjects from each block were randomly assigned to the two groups: EMG-biofeedback group ($n = 15$) and control group ($n = 15$). Thus, before the treatment, the groups were matched in frequency of defecations per week (same mean and standard deviation).

### Procedure

The study was carried out following a series of defined phases: clinical and psychophysiological assessment prior to the treatment (initial assessment), treatment and follow-up.

The initial assessment was performed at baseline period along 1 month. In this phase, the subjects filled out self-monitoring of each defecatory episode and were psychophysiologically assessed once a week. The four sessions of psychophysiological assessment were conducted with the patient in left lateral decubitus position with the hips flexed at 90°. After an initial adaptation period (15 min), we

repeatedly assessed the EMG-activity during resting, squeezing (10 exercises), and straining to defecate (10 exercises). These conditions were counterbalanced along each session to avoid a possible order effect. The duration of each session was ~45 min.

After initial assessment, the patients were randomly assigned to the EMG-biofeedback treatment or to the control group.

EMG-biofeedback training consisted of eight sessions, twice a week, carried out during 1 month. The aim of the biofeedback was to eliminate inappropriate contraction of the external anal sphincter during defecation attempts. No bowel preparation was required. The training procedure was conducted with the patient in the same position that in initial assessment. Using the EMG device described above, EMG-activity during straining to defecate were recorded and displayed to the subject in the form of visual and auditory feedback. Each session consisting of 15–20 defecation attempts. The duration of these treatment sessions was 45 min. In this treatment phase the subjects were still completing the self-monitoring.

In the control group, the patients attended eight 45 min counseling sessions (twice a week), equivalent to the contact time for biofeedback patients. The counseling sessions focused on behavioural mechanisms involved in the defecation, with special emphasis on avoiding unnecessary straining, correct defecating posture, and attempting defecation at a routine time each day. Moreover, information about bowel functioning was provided. Each session finished with a psychophysiological assessment of the EMG-activity during straining to defecate. As in the EMG-biofeedback group, during this phase the subjects performed self-monitoring.

Follow-up was carried out 2 months after treatment. In this phase, the patients were assessed in the same way that in initial assessment (self-monitoring of each defecatory episode and four sessions of psychophysiological assessment).

### Data Analysis

Statistical analysis was performed using MANOVA. Since this test assumes multivariate normality, this assumption was tested with Box's $M$, a test very sensitive to violations of normality and specifically designed to test the homogeneity of variances.

## Results

Once secured compliance with the relevant requirements (Box $M = 37.84$; $p > 0.05$), a $2 \times 3$ mixed-measures MANOVA revealed significant main effects for group (Wilks's lambda $= 0.138$; $F = 19.56$; $p < 0.01$), and phases (Wilks's lambda $= 0.042$; $F = 27.34$; $p < 0.01$), as well as a significant group by phases interaction (Wilks's lambda $= 0.049$; $F = 25.16$; $p < 0.01$). Subsequently, were analyzed the differences between the groups during the initial assessment, treatment and follow-up. MANOVA for the initial assessment phase revealed no significant differences between the groups in any of the variables (Wilks's lambda $= 0.936$; $F = 0.21$; $p > 0.05$). On the contrary, in both phases of treatment (Wilks's lambda $= 0.106$; $F = 26.55$; $p < 0.01$) and follow-up (Wilks's lambda $= 0.085$; $F = 33.59$; $p < 0.01$), highly significant differences are evident between the groups.

Frequency of defecations per week, mean EMG-activity during straining to defecate, and anismus index along the study in both groups can be seen in the Figs. 1, 2, and 3.

In view of these results, the differences between the groups in the treatment phase and in follow-up for each dependent variable were analyzed through ANOVA. The

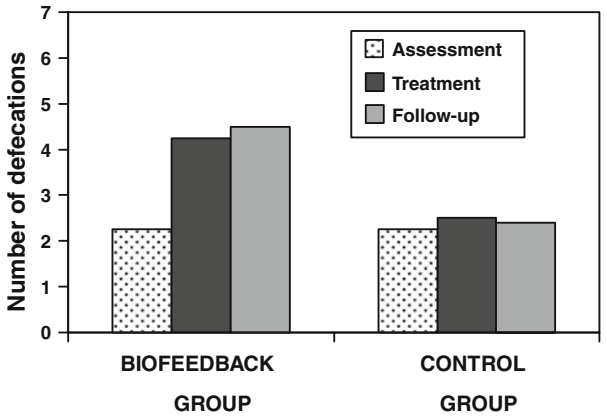


**Fig. 1** Frequency of defecations per week along the study in both groups

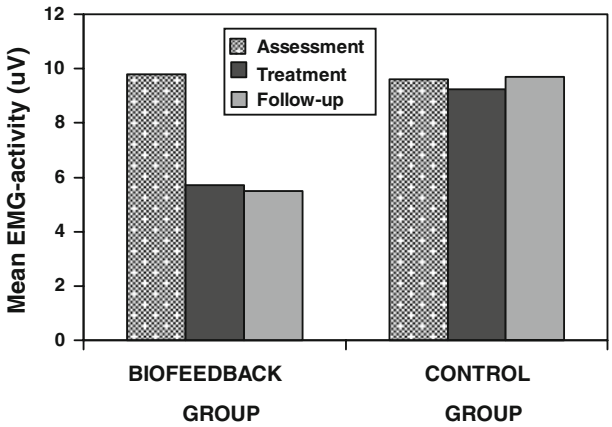


**Fig. 2** Mean EMG-activity during straining to defecate along the study in both groups

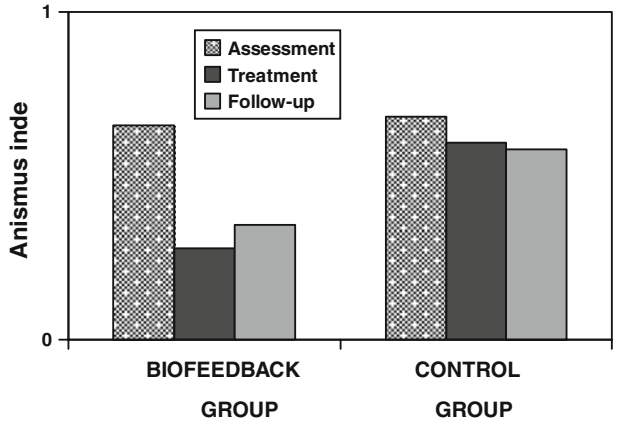


**Fig. 3** Anismus index along the study in both groups

**Table 1** Results of the ANOVA carried out for each dependent variable at treatment and follow-up

| Variable | *F* value (treatment) | *F* value (follow-up) |
|---|---|---|
| Frequency of defecations per week | 187.97 | 175.49 |
| Sensation of incomplete evacuation | 27.7 | 29.19 |
| Difficulty evacuation level | 11.32 | 16.47 |
| Perianal pain at defecation | 16.71 | 15.01 |
| EMG-activity during straining to defecate | 24.03 | 27.71 |
| Anismus index | 37.48 | 43.52 |

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

results of these analysis shown that the differences between the groups were statistically significant in all the variables. These results are shown in Table 1.

The evolution of the sensation of incomplete evacuation, difficulty evacuation level, and perianal pain at defecation along the study in both groups, EMG-biofeedback group and control group, can be seen in the Figs. 4 and 5.

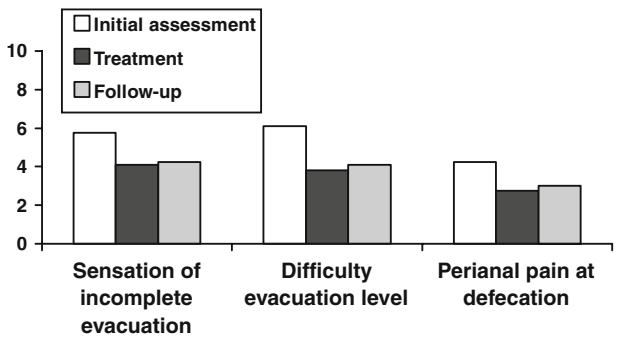


**Fig. 4** Evolution of the sensation of incomplete evacuation, difficulty evacuation level, and perianal pain at defecation in the EMG-biofeedback group

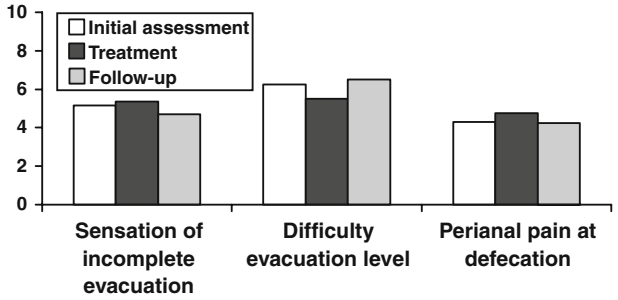


**Fig. 5** Evolution of the sensation of incomplete evacuation, difficulty evacuation level, and perianal pain at defecation in the control group

Respect to the differences between phases, MANOVA revealed significant differences between initial assessment and treatment (Wilks's lambda = 0.061; $F = 22.57$; $p < 0.01$), and between initial assessment and follow-up (Wilks's lambda = 0.051; $F = 24.80$; $p < 0.01$), but not between treatment and follow-up (Wilks's lambda = 0.853; $F = 1.17$; $p > 0.05$).

## Discussion

The results obtained in this controlled study shown that dyssynergic defecation in chronically constipated elderly patients can be treated effectively with EMG-biofeedback training. Through EMG-biofeedback, the patients learned to relax external anal sphincter during straining to defecate, decreasing significantly the anismus index. As result of this learning process, the subjects reduce obstructive symptoms, with a significant increase in the frequency of defecations per week as well as a significant decrease in sensation of incomplete evacuation, difficulty evacuation level and perianal pain at defecation. Treatment's outcomes were sustained at the follow-up period 2 months later.

Despite the subjective nature of some outcome variables, the improvement was supported by an increase in bowel frequency and a reduction in the EMG-activity of the external anal sphincter during straining to defecate. Our high success rate may be due to the fact that all of our patients ended the treatment. Motivation of elderly patients to complete the treatment and other psychological factors are important variables in therapeutic success. In fact, several previous studies showed that after biofeedback therapy, the psychological state was significantly improved (Wang et al. 2003; Wiesel et al. 2001).

In conclusion, this randomized controlled trial shows that EMG-biofeedback is an effective behavioural treatment for chronic constipation in elderly patients with dyssynergic defecation. As mentioned at the beginning of this work, so far there have been no controlled clinical

studies specifically designed to evaluate the effectiveness of EMG-biofeedback in the treatment of dyssynergic defecation in elderly patients. Therefore, the results obtained in this work are a first empirical evidence that supports the application of behavioural procedures in this context. This fact is very important both because of the prevalence and clinical significance of this variety of chronic constipation in the elderly, such as by the lack of effectiveness of the treatments traditionally used for its management. Nevertheless, future controlled clinical trials are needed to provide a stronger evidence base for the effectiveness of biofeedback in the treatment of elderly patients with dyssynergic defecation. These trials must carried out using accurate experimental designs, larger numbers of participants, clearly defined outcome measures and long term follow-up.

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