**Objective.** This study was conducted to evaluate the effects of "biofeedback" (BF), electrostimulation (ES), and of the high-fiber diet associated with behavioral therapy in women with obstructed evacuation and paradoxical puborectalis contraction and to compare the results among these three modalities.

**Method.** Thirty-one women were evaluated who fulfilled the Rome III Criteria, and with an electromanometric test positive for the presence of contraction in the evacuation maneuver. These patients were randomized into three groups: group I = conventional treatment of constipation, group II = conventional treatment of constipation associated with biofeedback and group III = conventional treatment of constipation associated with electrostimulation. At the beginning of this study and after six weeks, subjective and objective parameters of the anorectal function were evaluated using the Wexner constipation scoring system, the Bristol scale, an visual analogue scale, and anorectal electromanometry.

**Results.** All patients demonstrated improvement in bowel satisfaction, stool frequency, effort and feeling of incomplete evacuation, stool-type modifications, and improvement in the quality of life. On examination, there was increased mean pressure of voluntary contraction in group III \((p = 0.043)\), decreased sensitivity threshold in group II \((p = 0.025)\) and III \((p = 0.012)\) and decreased maximum rectal capacity in group II \((p = 0.005)\). Only 19.4% \((n = 6)\) had their dynamic defecation normalized, and 80.6% \((n = 25)\) expressed clinical, non-instrumental, improvement.
Introduction

Intestinal constipation (IC) involves aspects related to stool frequency and bowel movement, in association with several symptoms related to stool expulsion. In order to standardize its characterization, the Rome Criteria III were established, defining as constipated patients those subjects with evacuation effort, a sensation of incomplete evacuations, hardened stools or cymbals, less than three bowel movements per week, sensation of exit obstruction, manual maneuvers’ facilitators, with a potential presence of soft stools if in use of laxatives, and with insufficient criteria for irritable bowel syndrome.

According to pathophysiology, IC can be classified into colic and rectal (evacuation obstruction) types, or as an association of these conditions. IC presents a multifactorial etiology, involving dietary, anatomical, functional, psychological, and sociocultural aspects. Evacuation disorders are known to result from anatomical and functional alterations in the posterior compartment, being related to disorders such as rectoceles, intussusception, enterocele, perineal dehiscence, absence of sphincter relaxation, or paradoxical contraction of voluntary sphincter muscles (anismus). These changes promote symptoms such as inability to evacuate the rectal volume, a sensation of a rectum filled with feces, rectal pain, pelvic diaphragm dehiscence, and evacuation effort.

The treatment of this disorder is multifactorial, including a fiber-rich diet, behavioral therapy, laxatives, pelvic perineal kinesiotherapy, biofeedback (BF) and electrostimulation (ES). Some studies report success rates in 40–80% of cases. Although BF is an important resource in the treatment of pelvic floor dysfunctions, there are numerous controversies due to the use of different analytical methods in subgroups of non-homogeneous patients, in addition to non-standardized protocols.

Although the mechanisms of action of these methods are still only partially known, the improvement demonstrated by the patients treated, translated by the modification of the subjective symptoms of constipation and by the impact on their quality of life, encourages their use in the treatment of anorectal dysfunctions. Although there are studies that individually use BF and ES in the treatment of paradoxical contraction of
puborectal musculature accompanied by an obstructed evacuation, further studies with pre-established treatment and evaluation protocols that compare methods of treatment with each other are still necessary, due to their complexity.

Notwithstanding the foregoing, the aim of this study was to verify the immediate effects of BF, ES, and of the high-fiber diet associated with behavioral therapy, in the treatment of women with symptoms of obstructed evacuation and with paradoxical contraction of puborectal muscles through anorectal electromanometry, and also to compare the results of these three modalities.

Materials and methods

This is an analytical, prospective, and randomized study approved by the ethics and research committee of the Hospital Universitário Walter Cantidio (HUWC), Universidade Federal do Ceará (UFC), under protocol no. 088.12.08. Thirty-one women from the UFC HUWC Ambulatory of Coloproctology and from the Center of Coloproctology and Gastroenterology of Ceará were evaluated from August 2010 to July 2012, with a mean age of 52.4 (±10.2) years, fulfilling the Rome III Criteria, and that, on electromanometric examination, had contraction with the evacuation maneuver.

According to the exclusion criteria, women who did not agree to participate due to inability to understand or who did not accept the proposed examinations were excluded, as well as those with absence of relaxation of the sphincter muscles during the evacuation effort, with anorectal malformations, hypothyroidism, metabolic or neurological disease, and those in use of drugs interfering with gastrointestinal function, with mental, visual or auditory deficits, or with acute infectious conditions, cough or other conditions compromising their health status.

The intestinal habit was evaluated according to Roma III Criteria, the Constipation Scoring System of Wexner, the Bristol Stool Form Scale (BSFS), and by the application of a questionnaire of satisfaction for chronic intestinal constipation elaborated by the authors (intensity of symptoms; in need to evacuate, but the patient was unable to; decreased appetite; embarrassment in staying too long in the bathroom when away from home; Have you ever felt irritated, stressed or less self-confident?) and in which patients could mark the following alternatives: (0) – no, (1) a little, (2) moderately, (3) a lot, and (4) always; and by a linear visual analogical scale (VAS) for numerical and facial evaluation.

The classification of Wexner, adopted by the Brazilian Society of Digestive Motility, is based on eight parameters, which are analyzed and scored. The score ranges from 0 to 30, where 0 means a “normal patient” and 30 denotes the maximum degree of constipation. The use of this scoring system allows the quantification of subjective symptoms, in order to adequately compare the groups studied.

BSFS was developed and validated by Kenneth W. Heaton and S. J. Lewis. The aim of these authors was to evaluate, in a descriptive way, the shape of the fecal contents, using graphical methods that represent seven types of feces, according to their shape and consistency. This scale is innovative in that it presents images that illustrate feces, along with accurate descriptions of their shape and consistency, and also makes use of readily recognizable examples. Since the shape of the feces undergoes modification in many intestinal diseases, for example, in chronic intestinal constipation, BFSF was used as an evaluation tool before the beginning of the treatment and after six weeks (final), as a parameter of improvement and worsening of the patients.

For anorectal electromanometry (AE) we used a Dyanmed® hydropneumatic device, consisting of an eight-channel radial catheter. After the infusion system is switched on, we wait for an average of 2–3 min in a continuous perfusion regimen to eliminate air bubbles from inside the catheter. The pressures were calibrated to zero and then the catheter was introduced into the anal canal, with its positioning in the high-pressure zone, at 1.0–2.0 cm from the anal margin. The following parameters were analyzed: maximum and mean resting pressures of the anal canal, maximum and mean voluntary contraction pressures, evacuation maneuver, sensitivity threshold, rectal capacity, and rectoanal inhibitory reflex.

The evacuation maneuver was accomplished by requesting the patient to perform an evacuation effort, which was considered as normal when the reduction in anal canal pressure became evident; on the other hand, the patient was considered with paradoxical contraction in the face of any increase of anal canal pressure over resting pressure. It should be noted that the same findings were repeated in three attempts.

Those patients in whom the anal pressure remained unchanged were characterized as “with no relaxation of the sphincter muscles with an evacuation effort”.

As a standard protocol, participants were oriented regarding the dynamics of defecation, time spent and adequate positioning on the toilet to assist in the evacuation. In addition, the food consisted of a fiber-rich diet, with around 20–30 g of fiber (Fiber plus), intake of 1.5–2.1 of liquids a day, and the use of an emollient laxative (mineral oil) with a daily dose of 30 mL in the evening (the conventional treatment of constipation). Participants were randomly and randomly assigned to three groups: group I – conventional treatment of constipation (CTC); group II – CTC associated with BF (contraction sustained for 40 s, followed by relaxation for 8 s, and by a sustained evacuation and contraction effort for 2 s, with relaxation for 5 s); and group III – CTC associated with ES (frequency of 50 Hz with pulse width = 500 μs, contractions for 5 s, and relaxation intervals for 5 s), with a frequency of once per week, for a total of 10 sessions. At the beginning of the treatment and after six weeks, the subjective and objective parameters of anorectal function were evaluated; for this purpose, the constipation scoring system of Wexner, the Bristol Stool Form Scale, a visual analogical scale, and AE were used.

Our data were analyzed by the statistical program EpiInfo; we adopted as significant a p-value of less than 5% (p < 0.05). The comparison of the means for initial versus final values after the treatment and within each group was performed with the use of the Student’s t-test for paired data, ANOVA when the values obeyed a normal distribution, and Wilcoxon and Kruskal–Wallis test for values that did not present a normal distribution. Finally, for the reversal of paradoxical contraction of puborectal muscles (anismus), the likelihood ratio was used.
### Table 1 – Subjective parameters of anorectal function (Wexner classification) in the three groups studied.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beginning</td>
<td>Final</td>
<td>Beginning</td>
</tr>
<tr>
<td>Total score</td>
<td>14.0 (6.0–21.0)</td>
<td>7.0 (0.0–11.0)a</td>
<td>12.0 (8.0–22.0)</td>
</tr>
<tr>
<td>Intestinal frequency</td>
<td>1.5 (0.0–2.0)</td>
<td>0.0 (0.0–2.0)a</td>
<td>2.0 (0.0–4.0)</td>
</tr>
<tr>
<td>Evaculatory effort</td>
<td>4.0 (1.0–4.0)</td>
<td>0.0 (0.0–3.0)a</td>
<td>3.0 (0.0–4.0)</td>
</tr>
<tr>
<td>Feeling of incomplete evacuation</td>
<td>4.0 (1.0–4.0)</td>
<td>1.5 (0.0–4.0)a</td>
<td>3.0 (1.0–4.0)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>1.0 (0.0–4.0)</td>
<td>0.5 (0.0–2.0)a</td>
<td>0.0 (0.0–4.0)</td>
</tr>
<tr>
<td>Minutes in the toilet</td>
<td>1.0 (0.0–1.0)</td>
<td>1.0 (0.0–1.0)</td>
<td>1.0 (0.0–3.0)</td>
</tr>
<tr>
<td>Type of assistance</td>
<td>1.0 (0.0–2.0)</td>
<td>0.0 (0.0–2.0)</td>
<td>1.0 (0.0–2.0)</td>
</tr>
<tr>
<td>Unsuccessful evacuation attempts</td>
<td>0.5 (0.0–2.0)</td>
<td>0.0 (0.0–1.0)</td>
<td>1.0 (0.0–1.0)</td>
</tr>
</tbody>
</table>

a p < 0.05; Wilcoxon test.

### Results

Intestinal constipation was assessed and classified by the Wexner scoring system for constipation, which has a maximum score of 30 points. It was evidenced that all three groups exhibited moderate constipation at the beginning of treatment; at the end of treatment the groups evidenced only mild constipation; in all three groups, there was a reduction in the points scored.

No statistical difference was found in the points scored between groups at baseline and at the end of treatment. When comparing the medians within each group, a statistical difference was observed for all three groups (group I, p = 0.005, group II, p = 0.003, group III, p = 0.005).

All patients showed improvement in intestinal satisfaction, evacuation frequency, effort and sensation of incomplete evacuation, changes in stool type, and improvement of the quality of life (p < 0.05) (Table 1).

Regarding the duration of the presence of symptoms, 22.6% (n = 7) had constipation for a period of 1–5 years, 29% (n = 9) had a complaint of 5–10 years, 12.9% (n = 4) had a mean time of 10–20 years, and 35.5% (n = 11) of the 31 patients presented symptoms for over 20 years. No statistical difference was found between groups (p = 0.837). The electromanometric examination within each group and between groups showed that, after six weeks of treatment, there was a statistically significant difference only in the mean anal pressure of voluntary contraction in group III (p = 0.043) (Table 2). But as to the sensitivity threshold (first perception), a statistical significance was demonstrated in groups II (p = 0.025) and III (p = 0.012). However, when comparing the analysis of maximum rectal capacity (mL of air), statistical significance was only demonstrated for group II (p = 0.005) (Table 2).

After six weeks of treatment, normalization of the evacuation dynamics occurred in 19.4% (n = 6) of the participants: five in group II and one in group III. The reversal of the evacuation dynamics presented a different proportion within each group (likelihood ratio = 0.012), being significant for group II.

Regarding stool consistency evaluated by BSF, agreement (in percentage) between definitions and images in stool type relationship was demonstrated in the groups studied. The agreement rate was 58.1% (n = 18) for type 1; 38.7% (n = 12) for type 2, and 3.2% (n = 1) – the lowest rate of agreement – for type 3. The other types were not mentioned. After 6 weeks of treatment, the following percentages were found: 19.35% for type 5 (n = 6), 51.6% for type 4 (n = 16), 9.7% for type 3 (n = 3), and 19.35% for type 2 (n = 6). Thus, in 80.65% (n = 25) of the women showed normalization of consistency, and 19.35% (n = 6) had no modification (Table 3).

In order to improve stool frequency and consistency, CTC patients (group I) had to increase the dose of the laxative and the volume of fluid intake at some point in the treatment versus other groups. However, we could not state the number of times this change was necessary.

When analyzing data obtained from the satisfaction questionnaire and of VAS within groups, we noticed statistical significance in all three groups, which confirmed the impact of the therapies on quality of life (Table 3). When the assessment was performed between groups, statistical difference was observed only at the beginning of the treatment with...
In Constipation

Table 3 - Variation of medians of stool types using BSFS, within and between the groups at baseline and after six weeks of treatment.

<table>
<thead>
<tr>
<th>Group</th>
<th>BSFS</th>
<th></th>
<th></th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Begin</td>
<td>Final</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>1.0</td>
<td>2.5</td>
<td>4.0</td>
<td>.004</td>
</tr>
<tr>
<td>Group II</td>
<td>2.0</td>
<td>4.0</td>
<td>5.0</td>
<td>.003</td>
</tr>
<tr>
<td>Group III</td>
<td>2.0</td>
<td>4.0</td>
<td>4.0</td>
<td>.004</td>
</tr>
<tr>
<td>p&lt;0.05</td>
<td>0.006</td>
<td>0.004</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p, Statistically significantly.

Comparison between groups (Kruskal-Wallis test).

Comparison within groups (Wilcoxon test).

c p < 0.05.

The satisfaction questionnaire (p = 0.046); with VAS the statistical difference was observed only after the end of treatment (p = 0.015) (Table 4).

Discussion

Constipation is a symptom widely reported by patients; in half of the cases, constipation is characterized as an obstructed evacuation. Among the conditions that make up this obstructed evacuation, anismus or paradoxical contraction of puborectal musculature is mentioned by several authors as one of its main causes, being more frequent in female subjects. Studies point to the predominance of constipation in women around the fifth and sixth decades of life. In our study, patients (mean age = 52.4 years) demonstrated similar clinical and electromanometric characteristics.

In the present study, we chose to use Rome III Criteria to define IC because this is the tool recommended by the guidelines of the American Gastroenterology Association, and also thanks to its wide use in international studies. These criteria constitute the tool that best covers the symptoms of low bowel frequency and those related to the difficulty in emptying the rectum. Moreover, because they represent a more uniform criterion, the Rome III Criteria were used as an important tool for the diagnosis of patients.

Some exams are critical for the diagnosis of puborectal paradoxical contraction with obstructed evacuation symptoms, such as AE, defecography, balloon expulsion test, electromyography, proctography, and colon transit markers. For this diagnosis, AE, electromyography, and defecography are the most frequently used tests. Among all investigative methods, AE stands out for its simplicity, ease of execution and availability.

In the initial assessment of our patients’ bowel habits, it was evident that 70.9% had a frequency of less than three times a week, a great difficulty to evacuate, and with a prolonged effort. In addition, participants reported a sensation of incomplete evacuation, even with the use of laxatives, clyster, or digital (anal, vaginal, or perineal) manipulation. Those women who expressed intestinal frequency with a longer interval (29.3%) also referred to these complaints as being predominant. Thus, we do not consider the number of weekly bowel movements as the main factor of this dysfunction; effort and sensation of incomplete evacuation were the two symptoms indicative of a worsening in quality of life.

In pelvic floor dysfunctions, the conservative and functional approach has been a highly relevant alternative, rather than other aggressive and invasive treatments. In recent years, it has become increasingly clear that anorectal rehabilitation, through the modalities proposed in this study, is able to reduce or eliminate functional limitations and inability to relax, thus improving the patients’ quality of life; this is in line with the findings of our study, which showed an increase in the evacuation frequency, which ranged from 29.1% at baseline to 74.2% at the end of treatment, with a significant improvement in subjective symptoms (effort, sensation of incomplete evacuation, and digitation to facilitate defecation).

The women in group I (CTC) showed clinical improvement similar to the observed in the other groups, but the dose of the laxative had to be increased, in comparison with the other groups. In addition, at the beginning of the treatment protocol, all the women, regardless of their group, were instructed and clarified regarding the evacuation dynamics, including about schedules and their adequate positioning in the toilet, as a tool to assist in the evacuation process. The proposed hypothesis is that this initial approach favored a greater relaxation of the pelvic floor musculature and, as a consequence, there was a

Table 4 - Analysis of medians of AVE and of the satisfaction questionnaire within and between the groups at baseline and after six weeks (final) of the treatment.

<table>
<thead>
<tr>
<th>Group</th>
<th>AVE</th>
<th></th>
<th></th>
<th>Satisfaction questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Begin</td>
<td>After six weeks</td>
<td>p</td>
<td>Begin</td>
</tr>
<tr>
<td>Group I</td>
<td>8.0</td>
<td>3.7</td>
<td>.005</td>
<td>9.0</td>
</tr>
<tr>
<td>Group II</td>
<td>9.0</td>
<td>3.0</td>
<td>.003</td>
<td>10.0</td>
</tr>
<tr>
<td>Group III</td>
<td>10.0</td>
<td>3.5</td>
<td>.004</td>
<td>11.5</td>
</tr>
<tr>
<td>p&lt;0.05</td>
<td>0.636</td>
<td>0.015</td>
<td></td>
<td>p&lt;0.05</td>
</tr>
</tbody>
</table>

p, Statistically significantly.

Comparison between groups (Kruskal-Wallis test).

Comparison within groups (Wilcoxon test).

Comparison between groups (ANOVA).

Comparison within groups (Wilcoxon test).

c p < 0.05.
better awareness in the act of evacuating. Based on our sample, we cannot state that this finding in the short term can be maintained for a longer time.

Additionally, Chiarioni et al.25 compared the effects of BF and laxatives in patients with pelvic floor dyssynergia, showing the superiority of long-term BF versus laxatives; but in the laxative group, no guidance was given to evacuation dynamics.

In relation to ES, Boselli et al.26 showed that its use reduced the rectal sensitivity threshold, with a modification in the Wexner incontinence score; but after the treatment, there was no significant change in electromanometric parameters.

In this context, the study by Chiarioni et al.25 revealed a similarity between the physiological mechanisms responsible for the levator ani syndrome (LAS) and dyssynergic defecation or paradoxical contraction of puborectal muscles. Thus, when comparing the effects of BF, ES (galvanic current), and massage, BF was superior versus ES and massage. After treatment with BF and ES, a decrease in maximum volume and in the volume of urgency was found, besides relaxation of the musculature in the effort to evacuate in 94% for BF and in 52% for ES.

The ES studies in cases of constipation with symptoms of obstructed evacuation are still few, although some investigators have reported subjective and objective improvement immediately after therapy. However, the mechanism still needs to be clarified.

After the analysis of the post-treatment electromanometric parameters, it was evidenced that, in group I, no significant difference in anal canal pressures was noted; and, in addition, no patient was able to normalize her evacuation dynamics. In group II, there was a decrease in rectal sensitivity threshold (first perception), a decrease in maximum volume, and normalization of the evacuation dynamics in 45.5% (n = 5); and in group III, there was an increase in mean contraction pressure, a decrease in rectal sensitivity threshold (first perception), and normalization of the evacuation dynamics in 10% (n = 1).

The results obtained at the end of the therapeutic protocol showed that 19.4% (n = 6) of the 31 women obtained clinical and electromanometric improvement (relaxation of the normal sphincter in the face of the effort) and that 80.6% (n = 25) reported only clinical improvement, that is, without normalization of the evacuation dynamics. Chiarioni et al.25 studied the long-term effects of ES; these authors observed an increase in maximum resting pressure with a small statistical difference, a significant decrease in the threshold of the first desire to defecate, and that 50% of their patients demonstrated clinical and functional improvement through electromanometry, defecography, and the expulsion test balloon.

Chang et al.27 compared the effects of BF and ES in constipated patients. These authors observed improvement of subjective symptoms and showed no statistical difference in resting pressure, maximum contraction pressure, and volume threshold of rectal sensation for the first perception in the comparison of their groups before and after therapy. Only in the ES group the patients demonstrated a decrease in the volume threshold for the desire to defecate, in the urgency to defecate, and in maximum tolerated volume. It is noteworthy that some factors may have influenced the response to the proposed treatment, for example, the inability to contract and relax the external anal sphincter and to perceive intra-anal balloon distension,28-30 the motivation of the patients,31 and psychological factors.32

In addition, most women expressed fear and shame when performing electromanometry. Duthie and Bartolo33 reported that the anorectal physiology laboratory constitutes an abnormal setting and that patients feel ashamed.

Therefore, some interference may occur in the electromanometric findings, since the physiological improvement does not match the functional improvement found in our study.

In this study, the stool type was also taken into account; it is known that the shape of the stools is a direct consequence of the time of stool contact with the large intestine mucosa: the longer this time, the greater the water absorption. Therefore, when evaluating stool types by BSFS, our patients presented before the treatment a predominance of formats of type 1 and 2, characteristic of constipation. After six weeks, at the end of the treatment, 80.6% (n = 25) of the patients exhibited normalization of stool consistency by BSFS, and 19.3% (n = 6) reported no change, which was considered as an indicator of improved colonic transit time. We can infer that the non-occurrence of puborectal musculature relaxation during the bowel movement may have altered the colonic transit time in these women.

Intestinal constipation, associated with puborectal paradoxical contraction, leads to physical and psychological incapacitation, significantly reducing the quality of life. There are no specific valid instruments for the quantification of this impact on the local environment. In the present study, the authors designed a questionnaire with eight specific questions addressing chronic constipation, in order to evaluate its impact on the quality of life. This questionnaire was applied at baseline and after six weeks (final of treatment).

Another tool used was VAS, which emerged not only as an instrument for assessing the need to measure pain, but also as a way to measure the efficacy of the proposed therapies.32 In this study, we used a linear visual scale for numerical and facial evaluation. On the numerical visual scale, graded from 0 to 10, the assessment is made by the observation of facial expression (from a smile to affliction) for the impact of constipation on the quality of life, at baseline and after six weeks of treatment. In this way, it was possible to measure the effect of the treatment offered to our three groups.

In view of the results found, caution is needed in stating the efficacy of one therapy over another. Apparently, BF is the most effective option for rectoanal coordination; however, ES improved sensory perception, which was probably altered as a result of the sensory failure caused by years of constipation, in addition to the evacuation effort and probable muscle weakness.

This study confirms that BF and ES are valuable therapeutic options that impact on the quality of life. However, the response rate in the reversal of paradoxical contraction may have been underestimated by the inclusion criteria, by the small sample, and by the short period of time of this study. Thus, the comparative evaluation was compromised due to the lack of consensus on the criteria for treatment success and also due to the lack of uniformity of the electromanometric parameters.
Further randomized, controlled, and longer-term studies are recommended to confirm our results. In addition, new studies addressing the association of therapeutic modalities in the treatment of paradoxical puborectal contraction may result in an excellent therapeutic option.

Conclusion

Biofeedback, electrostimulation and high-fiber diet associated with behavioral therapy present a significant subjective improvement of the symptoms due to an obstructed evacuation and also of the quality of life of women with paradoxical contraction of puborectal muscles, evaluated immediately after treatment, regardless of the reversal of the paradoxical contraction of the puborectal muscles, favoring a higher degree of satisfaction.

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Conflicts of interest

The authors declare no conflicts of interest.

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