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Biofeedback treatment of fecal incontinence incorporating a mental variable without instrumentation: a prospective pilot study in Hispanic population

Richard A Awad

Summary
The long-established approaches utilized to treat fecal incontinence always require instrumentation with some type of electronic equipment. This equipment is not always available in every institution. In addition, no studied protocol principally used as coordination, sensory, or strength training has reached the level of gold standard. The purpose of this study was to describe a simple biofeedback technique that incorporating a mental variable and not requiring electronic equipment with prior adequate training could be used at any medical institution. Methods: A particular modality of an operant conditioning technique was given once and a home trainer program was established. Forty-eight patients (mean age 37.1 ± 3.7 years) were recruited. Patients had suffered from total incontinence for a period of 55 ± 7.5 months, all used two to three pads per day and suffered 2.4 ± 0.2 episodes of incontinence per day. Patients underwent clinical history recording, laboratory tests, recto-sigmoidoscopy, and double-contrast barium enema. Manometry and rectal sensitivity were performed in 7 and 27 patients, respectively. For physiologic comparisons, 21 healthy volunteers were used. Results: A total of 79.1% of patients became continent in a median period of 3.9 ± 0.5 months. An average of 3.85 ± 0.55 sessions was required. Follow-up continued for 3-11 years. Patients with incontinence showed lower basal mean resting pressure, maximum squeeze pressure and rectal sensitivity (p <0.01) and spontaneous rectoanal inhibitory reflex was absent in 57%.

Conclusions: This biofeedback approach does not employ any type of electronic equipment and can be easily reproduced in any type of medical center. Additionally, this is the first report in which a methodology for biofeedback therapy successfully incorporates a mental variable in addition to sensory and strength training.

Index (palabras claves): Fecal incontinence, biofeedback, recto-anal physiology, visceral sensation.
Introduction

Biofeedback has been well acknowledged as an important alternative for the treatment of fecal incontinence. Treatment protocols as quoted in a recent review of articles dealing with biofeedback for fecal incontinence, published between 1973 and 1999 showed that protocols consisted mainly the following: coordination training (i.e., coordinating pelvic floor muscle contraction with the sensation of rectal filling); sensory training (i.e., improving sensation to diminishing rectal distensions without training pelvic floor muscles contraction); strength training (i.e., pelvic floor muscle contraction); or a combination of these options (i.e., strength training with electromyographic biofeedback and anal canal pressure biofeedback strength training). However, mean success rate of these studies showed no advantage for one treatment strategy over another. Thus, at present we cannot consider at present any particular technique as gold standard. In addition, traditionally the protocol always included an appliance with connection to a transducer monitored voluntary activity in anal sphincter and could provide an audible or visible signal. This strategy implied the use of electronic equipment to a greater or lesser degree. This equipment was not always available at medical institutions. On the other hand, recently reported health care costs for combined fecal and urinary incontinence were estimated at $26 billion dollars (USD) per year in the U.S. Employment of electronic equipment undoubtedly contributes to this cost. Therefore, it would be useful to establish protocols that provide clinical significance and that can be carried out at any hospital, even the most needy. The purpose of this study was to describe a simple biofeedback technique incorporating a mental variable that does not require electronic equipment and could be used at any medical institution with prior adequate training.

Material and Methods

Setting. This study was conducted at the Physiology Section of the Experimental Medicine and Motility Unit at the Ministry of Health's Mexico City General Hospital. Subjects studied were recruited among outpatients with recto-anal disorders consecutively referred to our tertiary-care unit. The study was conducted according to Declaration of Helsinki guidelines (including subsequent revisions) and the local Ethics and Research Committee of the Mexico City General Hospital approved the protocol on March 2, 1987. Signatures were obtained from patients or their parents and treating physicians documented informed consent.

Subjects and study design. From March 1987, 476 outpatients consecutively referred to our tertiary-care unit were examined. All 476 patients and 21 healthy subjects were examined to ascertain whether they suffered from unspecified functional disorders, irritable bowel syndrome, dyspepsia, organic disease, anorectal disease, other disorders, or fecal incontinence. Inclusion criteria were total incontinence (i.e., undifferentiated among gases, liquids, and solids) of at least a 6-month duration, failure of conventional medical treatment, and at least two episodes of incontinence per week. Forty-eight patients (mean age 37.1 ± 3.7 years, range 5-76 years, 26 female) with fecal incontinence were recruited. Factors expected to affect treatment outcome were considered at study initiation. The 48 patients had suffered from incontinence for a period of 55 ± 7.5 months (range: 6 months to 21 years). All used pads and suffered from periods of incontinence of 2.4 ± 0.2 per day (range: 1-7 per day). Causes of incontinence were idiopathic 29.16%, post recto-anal surgery 22.9%, myelomeningocele 10.41%, sphincter injury 6.25%, obstetric 6.25%, congenital malformation 6.25%, post-radiation 10.41%.
4.16%, constipation 4.16%, diverticulum 2.08%, ulcerative colitis 2.08%, infectious diarrhea 2.08%, perianal abscess 2.08%, and Hirschprung 2.08%. Demographic characteristics showed that 47.9% of patients were single, 47.9% married, and 4% widowed; 39.5% were students, 16.6% professionals, 39.5% homemakers, and 4% children without occupation; 6.25% had no education, 29% had an elementary school education, 4% were high school graduates, and 14.5% were college graduates. The study was a longitudinal, prospective, experimental design. All patients underwent clinical history recording, standard laboratory tests (hemoglobin, leukocytes, erythrocyte sedimentation rate, stool cultures, parasite studies, and lactose tolerance test), recto-sigmoidoscopy, double-contrast barium enema, and our biofeedback treatment protocol. Referring physicians had prescribed conventional medical treatment to all patients without success. At the first session, anorectal manometry was performed on seven patients and rectal sensitivity tests were carried out on 27 patients. Full continence was the criterion used to classify biofeedback as successful. Improvement or no change in continence was considered treatment failure.

**Electrical and mechanical recording technique.** Intraluminal pressure was recorded by a probe (Honeywell MP-3 motility probe, Honeywell, Denver, CO, USA), which contains two-miniature pressure transducers within a surgical grade silicone rubber tube 5 mm in diameter, as previously described. One pressure transducer was placed in the internal anal sphincter, while the second transducer was placed in the rectum, at 5 cm from the pressure transducer in the internal anal sphincter. Thirty minutes were allowed for the patient to become accustomed to presence of the probe. The study was performed with the subject in the left lateral position. Pressure waves were recorded on a Hewlett Packard 8-channel polygraph model 4574A (Waltham, MA, USA) with amplifier gain of 12.5 mmHg/cm for motor recordings and paper speed of 0.5 mm/sec. External anal sphincter bipolar contact electrodes measured electrical activity. A reference electrode was fixed to the skin of the right leg with electrode paste. Basal anal pressure, maximum squeeze pressure and presence of spontaneous rectoanal inhibitory reflex were evaluated as mechanical activity. For the evaluation of spontaneous rectoanal inhibitory reflex, a register was carried out over a period of 1 h with the subject in basal state, with static sensors in internal anal sphincter and rectum, registering the presence of rectoanal inhibitory reflex when it appeared spontaneously, as we reported previously.

**Rectal sensitivity.** Assessment of rectal sensitivity was performed following a previously published technique. The procedure was carried out in the laboratory by the same investigator and measured by distending with air a latex balloon 4 cm in length placed in the rectum at 17 cm (distance adjusted in children) from internal anal sphincter with hand-held syringe at a rate of 5 ml/sec-1. The balloon was inflated in a stepwise manner in 10-ml stages every 3 sec. Subjects were requested to report with a click marker (a) when they felt a sensation and (b) when they felt discomfort or pain. The balloon was then deflated. The procedure was repeated three times with an interval of approximately 1 min. Maximum tolerable volume was taken as volume at which a sensation of rectal discomfort was experienced without reaching the level of intense pain.

**Biofeedback technique.** Patients and relatives were instructed on recto-anal anatomy and physiology of defecation with the help of drawings and figures. Emphasis was placed on the established motility pattern of the enteric nervous system to execute recto-anal reflexes. Throughout the procedure, care was taken to assure that patient and relatives understood and used the same medical terminology. Subsequently, we instructed patients to physically identify the affected parts of their anatomy. Next, with the patient in the left lateral position a custom-made device containing a latex balloon 4 cm in length attached to the tip was gently introduced without endoscopy, situating the balloon inside the rectum 17 cm (distance adjusted in small children) from anal margin. The rectal balloon was inflated with air and the patient was asked to describe the sensation caused by the balloon, namely consistency (hard, soft, and not sure), texture sensation (smooth, rough, not sure), and temperature (hot, cold, and not sure). Immediately, patients squeezed the external anal sphincter the moment they felt the balloon. This procedure lasted approximately 30 minutes. After the laboratory procedure ended, the patient was instructed to carry out the following exercise at home three times a day: subjects pointed out with their finger, initiating a trip through their digestive system, simultaneously saying that food entered through the mouth, continued through the esophagus, the stomach, the...
small intestine, the colon, and the rectum. While pointing to the rectum they said, “I feel I have something inside the rectum”, at the same time recalling defecation physiology they learned and the rectal sensation described in the hospital at their first appointment. At that moment, while counting to 10 aloud, they squeezed the external anal sphincter. This procedure was repeated three times at 5 second intervals.

**Outcome evaluation and statistics.** Biofeedback was done only at the first session. Patient follow-up took place once per month until they become continent. The purpose of the monthly visit was to verify patient compliance with the mental procedure and to assess success. Success was defined as a patient who recuperated continence. Statistical analysis was performed with 2000 GraphStat statistical software (GraphPad Software, San Diego, CA, USA). Averaged data were compared using nonpaired Student two-tailed t test. Nonparametric Mann-Whitney U test was used to identify predictors of good response to treatment by comparing idiopathic with post-surgery incontinent groups. Data values are presented as mean ± SEM, if otherwise stated. Alpha level of 0.01 was used.

**Results**

**Clinical outcome.** Thirty-eight of 48 patients completed the study; ten withdrew for unknown reasons. However, data from these latter 10 patients were included in the results. Within a period of 3.9 ± 0.5 months (range 10 days to 15 months), the 38 remaining patients (79.17%) had total recovery from incontinence. Frequency of incontinence episodes changed from 2.4 ± 0.2 per day prior to treatment to none after treatment (p < 0.01). Before treatment, all patients used two to three pads per day and after treatment showed total absence of soiled pads or underwear. An average of 3.85 ± 0.55 sessions was required.

**Mechanical and electrical activity.** Basal anal pressure was lower in patients with incontinence (13 ± 2 mmHg) than in healthy subjects (34.9 ± 6.9 mmHg). Spontaneous recto-anal inhibitory reflex, considered a sign of recto-anal mechanical activity and evidence of normal neural pathway between rectum and internal anal sphincter, was absent in 57% of patients studied. External anal electrical activity was present in all patients studied. Maximum squeeze pressure was lower in patients with incontinence (26.8 ± 10 mmHg) than in controls (43 ± 7.5 mmHg).

**Recto-anal sensitivity and response to rectal distension.** Patients with incontinence reported a rectal sensation in a shorter time than normal subjects (4.0 ± 0.4 vs. 6.4 ± 0.5 sec, p < 0.01) and perceived rectal sensation (14.9 ± 1.4 vs. 32.9 ± 2.7 ml, p < 0.01) and discomfort (54.2 ± 6 vs. 87.2 ± 5 ml, p < 0.01) at significantly lower volumes.

**Predictors of successful outcome.** Table 1 shows the comparison of idiopathic to post-surgery incontinent patients at baseline measurements. Severity of fecal incontinence and rectal sensory threshold at baseline were not predictors of response to biofeedback treatment.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Idiopathic</th>
<th>Post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>34.7±28</td>
<td>51±22</td>
</tr>
<tr>
<td>Daily periods of incontinence</td>
<td>2.1±0.8</td>
<td>2.2±1.2</td>
</tr>
<tr>
<td>Rectal sensation threshold (ml)</td>
<td>13.6±8.3</td>
<td>14.2±6.3</td>
</tr>
<tr>
<td>Recovery of continence (months)</td>
<td>3.5±4.1</td>
<td>2.9±1.9</td>
</tr>
</tbody>
</table>

Data are expressed as Mean ± SD

Long-Term Follow-Up. Patients were assessed each month, including patients restored to continence very quickly. Because patients were not recruited at the same time, we were unable to standardize a strict follow up. However, all patients were followed on a personal basis for minimum of 3 years and reported complete satisfaction with treatment. After that individual period, the majority of subjects refused to return to the hospital for a check up or to participate in a telephone interview, arguing that there was no reason to continue in the protocol because they were completely healthy. Only one patient was accessible when we attempted to carry out an 11-year follow-up evaluation. However, during this 11-year period no subject returned to the clinic for continence problems.

**Discussion**

The main contribution of this study was that biofeedback technique without electronic instrumentation resulted successful for treatment of patients with fecal incontinence. Additionally, as far as I know this is the first report in which a methodology
for biofeedback therapy successfully incorporates a mental variable in addition to sensory and strength training.

Definitions of success and follow-up responses among others important variables to consider in treatment dealing with fecal incontinence. In the present study, full continence was the criterion to classify biofeedback as a success, whereas improvement or no change in continence were considered as failure of treatment. These criteria were different to others adopted by more lenient groups who defined success as >50% decrease in frequency of incontinent episodes. With our parameters that considered patients abandoning treatment as failures, we obtained a 79% rate of success over a follow-up period of 11 years, while with other treatments, such as overlapping anal sphincteroplasty, more than one half of patients are incontinent with liquid or solid stool some years after sphincter repair surgery. The 79% success rate of this study was similar to 71% recently reported elsewhere. Our 11-year follow-up results support other authors who reported a 6-year follow-up and concluded that biofeedback training improved continence not only during treatment and within the subsequent 2 years but also during several years after therapy. On the other hand, it is important to realize that all working groups used some type of instrumentation to carry out biofeedback training. Quoting from a recent review, "sensory training of the rectum utilizes an intrarectal pressure balloon feedback device, strength training may use either anal canal pressure or intra-anal electromyographic feedback of pelvic floor muscles, and coordination training utilizes pressure feedback of intrarectal balloon distention and pelvic floor muscle contractions simultaneously." I believe we should simplify biofeedback treatment protocols by not using any instrumentation. Our study, without using any kind of instrumentation, was able to obtain results resembling those previously described. In addition, the mentioned investigators performed considerably more treatment sessions, including weekly sessions for one group of patients. In our study, we applied one session at the hospital and then a home-trainer program. These observations question the necessity of instrumentation to carry out biofeedback training. Furthermore, the present results support in part recent findings reporting that neither pelvic floor exercises nor biofeedback is superior to standard care supplemented by advice and education.

Objective measurements to assess mechanical activity of rectum, internal anal sphincter and external anal sphincter comprised determination of basal anal pressure, maximum squeeze pressure and spontaneous rectoanal inhibitory reflex. We were unable to obtain consent to perform rectoanal motility studies in all of our incontinent patients. In those in whom the procedure was carried out, basal mean resting pressure of 13 ± 2 mmHg was lower than the pressure in healthy subjects, in agreement with other authors who reported that the majority of patients with incontinence presented low sphincteric pressure. Nonetheless, our data were comparable to 15 mmHg also recently reported in patients with incontinence. Nevertheless, these physiologic data are not accurate because the exact role of internal anal sphincter pressure in patients with incontinence is not well established. Usually, physiologic assessment of internal anal sphincter has been performed when maximum mean resting pressure was measured. However, one third of patients with idiopathic fecal incontinence has maximum mean resting pressures within normal range and other authors suggest that anal canal resting pressure gradient is the measurement to be considered in fecal incontinence. Maximum squeeze pressure was also assessed. However, this is a variable susceptible to artifact and, although in some studies resting and squeeze pressures increased in varying degrees after biofeedback therapy, the magnitude of improvement is relatively small and did not correlate with symptom improvement.

Not all our patients with fecal incontinence showed spontaneous rectoanal inhibitory reflex, coinciding with other reports that observed the reflex in only 6 of 18 patients with incontinence. In this regard, the absence of this reflex could be a negative factor if neural communication between rectum and internal anal sphincter is non-existent. However, it is interesting to note that in our patients presence or absence of the reflex did not influence final outcome.

To assess rectal sensitivity, it is clear that at present the barostat technique must be utilized. Indeed, at our laboratory we have employed barostat procedures for several years. However, the barostat was not easily available for the present study; thus, we used the procedure herein described, which at the time we initiated this study was the most recommendable procedure. In addition, our technique to determine rectal sensation is well standardized in
healthy subjects as well as in patients with irritable bowel syndrome. Using this technique for rectal sensitivity, values in patients with incontinence were lower than in healthy subjects. Our data regarding rectal sensitivity reduction confirm the threshold of rectal sensitivity changes in other reports of patients with incontinence, which additionally suggest that in some patients altered sensory mechanisms may contribute to the pathophysiology of fecal incontinence. Nevertheless, absence or reduction of rectal sensitivity should not limit the use of biofeedback. As observed in our group, reduced sensitivity did not affect outcome.

One limitation of this study could be the technique employed in that because the method, in not agreeing with techniques previously described, could not be compared. Other researchers comparing biofeedback with an educational intervention and with standard care lead to the conclusion that neither pelvic floor exercises nor biofeedback is superior to standard care supplemented by advice and education thus questioning the specific effect of biofeedback. Therefore, if a gold standard does not exist and the present methodology is successful, I think that it is not necessary to make more comparisons with other forms of methodology.

Different authors hypothesize the mechanisms by which biofeedback therapy works from different points of view. Some of these reports support sensory discrimination training, in which subjects are taught to recognize and respond to weak distensions of rectum. Other authors argued that the important point is strengthening external anal sphincter and puborectalis muscles, and others considered that both sensory and strength training must be incorporated, considering them as coordination training. In the present study, sensory and strength training were performed with the addition of a mental variable. This type of methodology came into being following the new possibilities of scientific observations. The idea arose after carrying out numerous recto-anal physiologic experiments in the laboratory, and observing processes of spontaneous inhibitory rectoanal and external anal sphincter reflexes. A crucial point was to take into account the fact that neural vias are no longer considered specific for transmission of a sole hormone or a sole physiologic effect. The idea was that patients suffering from incontinence lost or altered some part of the program previously established for defecation. For this reason, by mentally repeating the manner in which food travels and elicits the rectoanal reflexes, the stimulus could be re-routed and achieve the same end-point, i.e. re-establishing adequate defecation. Mentally reproducing the rectoanal inhibitory reflex, mentally stimulating rectal sensitivity, and performing the anorectal reflex with external anal sphincter contractions achieved this goal. For this reason, a balloon was used during the first session. It was inflated to the volume at which each subject perceived sensation, in an attempt to stimulate rectal receptors and render the stimulus conscious, asking the patient to make an effort to identify the texture and temperature of the balloon. In this context, other researchers have also performed anal sensation test to evaluate the ability of the anal mucosa to discriminate between air and warm water, and others reported that temperature perception is impaired in patients with incontinence in proximal anal canal. Additionally, a goal of biofeedback training is to increase patient ability to perceive distensions of the rectum. This is accomplished in repeated sessions with a device inside the rectum. In our protocol, we used mental imaging that allows subjects to visualize their own rectum with something inside it, instead of this mechanical instrumentation. Given the results obtained, we must ask ourselves if the mental approach indeed triggered a physiologic response. In our study, I feel that successful outcome is due both to a result of increased confidence related to the fact that individuals are attempting to do something about their problem and restoration of the program of anorectal function.

Another limitation could be that the study was repeated as suggested, a controlled trial. However, we must be aware that it is not easy to compare groups with regard to incontinence. First, there is no gold standard to compare the treatment. Second, patients are desperate and do not calmly accept entering into a placebo group. Third, this treatment cannot be compared with other treatments such as surgery or electrical stimulation, with insufficient reported results. On the other hand, randomizing groups leads to obtaining of statistically significant differences, forgetting that obtaining clinical significance is as in this group’s also extremely important. Nevertheless, being very aware of this issue we are conducting at present a randomized, double blind, and placebo-controlled trial with our patient population with incontinence as a part of our university Ph.D. training program.
ning program in gastrointestinal physiology.

With regard to predictors of successful outcome, we were unable to compare patients either with controls or with non-responders due to the lack of a control group and taking into account that all patients included respond favorably to treatment. However, in the intent to obtain some type of predictor we compared the two main incontinent groups, namely idiopathic and post-rectoanal surgery. However, no variable assessed such as severity of fecal incontinence, rectal sensory threshold, etiology of fecal incontinence, and age was able to predict who would respond better or faster to biofeedback treatment. Recently, was suggested that threshold for rectal perception and urge are good predictors of response to feedback treatment. Nonetheless, rectal sensory threshold was not different at baseline in our groups.

In addition, this biofeedback treatment protocol does not use any type of instrumentation and outcome and duration of treatment are similar to those already reported. Moreover, characteristics of the technique render it very simple to use in any institution, thus allowing obtaining of considerable benefits in the quality of life of greater numbers of patients. A very important issue is that the methodology reported in this study recently reproduced successful outcomes, despite recent reports adducing insufficient evidence to support efficacy of biofeedback. Besides, this is the first report in which a methodology for biofeedback therapy successfully incorporates a mental variable in addition to sensory and strength training. For these reasons, the methodology of this pilot study deserves further controlled trials, not only to prove efficacy but also to provide new insights into the pathophysiology of brain-gut interactions in fecal incontinence.

References


