

Bio-feedback treatment of fecal incontinence: Where are we, and where are we going?

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Abstract

Fecal incontinence is a disabling disease, often observed in young subjects, that may have devastating psycho-social consequences. In the last years, numerous evidences have been reported on the efficacy of bio-feedback techniques for the treatment of this disorder. Overall, the literature data claim a success rate in more than 70% of cases in the short term. However, recent controlled trials have not confirmed this optimistic view, thus emphasizing the role of standard care. Nonetheless, many authors believe that this should be the first therapeutic approach for fecal incontinence due to the efficacy, lack of side-effects, and scarce invasiveness. Well-designed randomized, controlled trial are eagerly awaited to solve this therapeutic dilemma.

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INTRODUCTION

Fecal incontinence is a common health care problem, with modest physical but important psychosocial consequences that can be distressful and incapacitating, up to complete social isolation^[1]. Fecal incontinence is one of the fields in which bio-feedback techniques are thought to be most

successful, and owing to the fact that bio-feedback procedures have had a strong impact in gastro-enterology, behavioral research in this area has greatly increased in recent years^[2,3]. The term bio-feedback training refers to the use of various devices (mechanical, electrical) that are supposedly able to increase the awareness of a biological response, so that patients can learn, through a process of "trial and error", to improve their voluntary control of this response^[4]. Bio-feedback training sessions are usually supplemented by home practice training (Kegel exercises), with the purpose of enforcing muscle strength through an increase of the number of muscle fibers innervated by existing nerves. It is commonly thought that bio-feedback is not able to repair or generate new neural pathways.

The increase of patient's awareness of somatic sensations, and the improvement of motor skills, which represent the basis of biologic self-regulation, are critical points for bio-feedback training. For instance, a cause of fecal incontinence is the loss of the ability to feel rectal fullness, a major point for contracting the pelvic floor muscles to avoid incontinence^[5]. In these patients, the goal of bio-feedback training is to improve the ability to detect rectal filling through sensory re-training^[6,7].

Types of bio-feedback training for fecal incontinence

Bio-feedback treatment of fecal incontinence was proposed by Engel and coworkers, 30 years ago^[8]. Patients were taught to improve their ability to voluntarily contract the external anal sphincter during rectal filling, either by improving the strength of the sphincter (motor skills training) or by increasing the ability to perceive weak rectal distention (discrimination training) or by combining the previous two mechanisms (training in the coordination of sphincter contractions with rectal sensation). No side effects were reported and the treatment was generally well accepted. Further trials had shown that therapeutic goals can be achieved through training, that employs measurements of pressures (manometry) or electrical activity (electromyography, EMG) in the anal canal^[2,3].

Manometric bio-feedback

Bio-feedback training aimed at increasing the strength of the external anal sphincter has usually been carried out by recording anal canal pressures, coupled to visual/auditory signals proportional to the pressures themselves. Anal pressure may be recorded by balloon probes or by perfused catheters^[4]. During manometric recording, the patient is required to squeeze as to prevent defecation while being given visual feedback and verbal guidance on how to reach

this goal. The patients may also be taught to inhibit wrong responses such as contraction of the abdominal muscles. Asking the patient to squeeze may be obtained in response to balloon distention of the rectum^[9] or without rectal distention^[10]. Some authors have suggested that improving squeeze duration is more important than maximizing anal strength. Therefore, patients are taught to pursue this therapeutic goal as a part of the bio-feedback protocol^[10,11].

EMG bio-feedback

Strengthening the pelvic floor muscle may also be achieved by showing the patient, a recording of the integrated (average) EMG activity from the striated muscles which surround the anal canal^[12]. In EMG training, the patient is asked to squeeze and relax without rectal distention, and home exercises in which the patient is required to repeatedly squeeze the pelvic floor muscles (Kegel exercises) are usually added to the training to further strengthen these muscles. Other methods of EMG recording of the pelvic floor employ an anal plug with surface electrodes^[13], very easy to use and requiring no preparation.

Sensory discrimination training

This is aimed at increasing the patient's ability to perceive and respond to rectal distention^[14]. After inserting within the rectum a catheter-mounted balloon, the latter is inflated with different air volumes; the patient is then asked to signal when the feeling of distention is perceived, or to contract the pelvic floor muscles in response to the distention. For these purposes, easily perceived distention with large volumes of air is firstly given, the volumes of distention are gradually decreased until the patient is able to perceive them with difficulty. Repeated distention slightly above and below the sensory threshold of the patient, coupled to the investigator's feedback on the accuracy of detection, teach the patient to recognize distention of even weaker intensity^[3,4]. This type of sensory training is often coupled to sphincter strength training, asking the patient always to contract (as strongly as possible) in response to rectal distention and providing feedback on the strength of contraction and accuracy of detection^[3,4]. Several evidences suggest that sensory discrimination training (aimed at reducing the threshold for perception of rectal distention) is very important for an effective bio-feedback procedure^[6-8,15]. We have recently evaluated 24 patients with severe, solid-stool fecal incontinence^[16] by teaching them to squeeze in response to rectal distention; the patients were evaluated 3 mo after bio-feedback training, and were classified as responders (>75% decrease of incontinence episodes) or non-responders. Comparison of the two groups showed that responders displayed significantly lower sensory thresholds after training with respect to non-responders, but squeeze pressures were not significantly different between groups. Sensory thresholds measured before bio-feedback training were good predictors of which patients would respond to it; in fact, patients with more severe sensory impairment had poor response to bio-feedback training^[16]. Sphincter strength and severity of fecal incontinence before bio-feedback training were not useful as predictors of outcome.

METHODS

An internet-based comprehensive search strategy of the Medline and Science Citation Index was performed using the keywords bio-feedback and fecal incontinence, in various combinations with the Boolean operators AND, OR, and NOT. Only articles related to human studies were used, and manual cross-referencing was also performed. Articles published in English between January 1965 and September 2004 were selected; however, a search in non-English languages and in journals was also older than 1965 performed in our library. Letters were excluded, and abstracts were quoted only when the full papers were unavailable.

Usefulness of bio-feedback in fecal incontinence

Most of the available studies concerning the use of bio-feedback to treat fecal incontinence have been carried out by manometric means; however, a clear superiority of pressure *vs* EMG feedback has not surfaced^[17], and only one study aimed at comparing pressure *vs* EMG feedback training showed no significant differences between the two techniques^[18].

Looking at all the studies available in literature regardless of etiology, it is found that about 2/3 of patients display at least a 75% decrease of their episodes of fecal incontinence^[19,20], although only about 50% of them developed complete continence. However, it must be stressed that (1) no uniform criteria for defining improvement or assessing outcome have been adopted; (2) inclusion criteria differed; (3) treatment protocols varied and (4) only few prospective, randomized, parallel-group studies have been published, not enough to draw conclusions on the overall efficacy of bio-feedback training. In addition, recent randomized studies have not confirmed the optimistic outcome of previous open studies. These trials will be examined in detail in the following paragraph.

In a first randomized controlled study, bio-feedback plus behavioral management was compared to behavioral management alone in children with fecal incontinence due to myelomeningocele^[21]; both groups displayed significant improvement, suggesting that bio-feedback has the same effects as behavioral management for most children with myelomeningocele. However, it must be stressed that patients with spinal cord defects show commonly worst responses to bio-feedback than patients with incontinence due to other causes^[22]. In a second controlled study, van der Plas and coworkers studied 71 children with fecal incontinence without constipation and randomized them to standard care and laxatives or standard care and laxatives plus bio-feedback. At 12-18 mo follow-up, approximately 50% of children in both groups showed significant symptoms improvement. A trend toward better outcome was shown in the bio-feedback group, but statistical significance was not reached^[23]. In the first randomized study of bio-feedback in adults with fecal incontinence, a complex cross-over design was employed making interpretation of results quite difficult^[24]. Twenty-five patients were initially randomized to either three sessions, sensory discrimination training without bio-feedback on sphincter strength or equivalent distention without feedback on the accuracy of their

detection of the strength of contractions. Patients in the sensory training group had significant decrease of frequency of episodes of incontinence with respect to controls, but between-group differences did not reach statistical significance (probably due to small sample size). Control patients were then given sensory training, and displayed improvement in continence. Thereafter, all patients were randomized again to sphincter-strengthening exercises without bio-feedback or to squeeze in response to rectal distention with feedback. Overall, the patients had further improvement of continence in this second step of the study, but no significant differences were observed between groups, suggesting that sensory training is important for the treatment of incontinence, although the results are not definitive due to the small size samples. Recently, the St. Mark group reported a large, randomized, controlled study on 171 adults with fecal incontinence^[25]. Patients were randomized into four groups: (1) standard care with advice; (2) standard care with advice plus anal sphincter exercises taught verbally and via digital examinations; (3) same as group 2 plus bio-feedback therapy run at the clinic; (4) same as group 3 plus sphincter exercises guided by a home bio-feedback device. Approximately half of patients in all groups reported improvement of symptoms at one year follow-up. Interestingly, quality of life measurements, bowel symptoms and anal sphincter pressures were improved in similar percentage in all groups. Bio-feedback therapy yielded no greater benefit than did standard care with advice on an intention-to-treat analysis.

This trial appears methodologically sound in most instances with few, relevant limitations mostly related to the lack of details of the bio-feedback protocol used. Type and dosage of anti-diarrheal medications used in all the groups were also not provided. The results of this trial are at variance with a previous open study coming from the same Center, where bio-feedback therapy was reported to improve symptoms in the majority of patients with fecal incontinence^[26]. Moreover, another prospective, randomized, controlled study comparing pelvic floor exercises plus anal exercises taught via digital examination with either manometry or anal ultrasound-guided bio-feedback in 120 adults with fecal incontinence had failed to show any additional benefit of behavior therapy over Kegel exercises in terms of clinical outcome, quality of life measurements, and anal pressures^[27]. In this trial, a clinical benefit was evident in the short term in approximately 70% of all patients. The same group then reported this clinical benefit as substantially preserved in the long term follow-up^[28]. Interestingly, quality of life measurements and subjective perception of "catching up" with incontinence improved even in patients whose incontinence scores worsened. Therefore, intervention "*per se*" seems to improve subjective symptoms perception in fecal incontinence.

Do predictors of outcome exist

Although it is traditionally thought that subgroups of patients (demented, mentally retarded, young children, severely depressed, mobility impaired) are less prone to respond to bio-feedback training, there are few data to support these concepts as guidelines^[29]. The available data may be

summarized as follows: (1) severe mechanical damage of the anal sphincters is generally associated with poor bio-feedback responses^[30,31]; (2) major sensory impairment determines a poor response to bio-feedback training^[16,26,32]; (3) although many studies have not found the response to bio-feedback predictable on the basis of pretreatment findings^[33-35], there are reports showing that a low basal pressure of the internal anal sphincter is associated with poor outcomes^[36]; (4) abnormally prolonged pudendal nerve conduction times are employed to identify subjects with pudendal nerve injuries as a cause of incontinence; these measurements correlate poorly with the response to bio-feedback^[37]; (5) there is no significant association between fecal incontinence and anxiety or depression^[38,39], the latter, however, may decrease the patient's ability to learn and to comply with home practice^[40]; (6) the association of constipation by outlet dysfunction may affect outcome unfavorably^[41].

Associate treatments

There are several reports of miscellaneous combinations of bio-feedback with surgical procedures to treat fecal incontinence. Results described as positive have been reported for high imperforate anus repair^[42], gracilis muscle transposition^[43], and anterior resection of the rectum and total colectomy with ileo-anal anastomosis^[44]; however, all these were uncontrolled studies, and the patient sample's were small. Other studies associated electrical stimulation with pelvic floor bio-feedback in a miscellaneous group of patients (including subjects with fecal incontinence and subjects with constipation due to pelvic floor dysfunction), and claimed that this association was more effective than a single approach^[45]. Real-time ultrasonographic imaging of the pelvic floor muscles has also been employed to teach patients with fecal incontinence to squeeze the external anal sphincter^[46], but the trials with this technique are still ongoing. Loening-Baucke implemented standard medical care with a pressure bio-feedback protocol in a small group of adults with fecal incontinence. No additional benefit could be evidenced compared to standard medical care alone^[47].

Conclusions

Although fecal incontinence is a socially devastating disorder, many physicians are still unaware that it is often amenable to treatment^[48]. Recently, well-designed, randomized trials have shown that standard medical care implemented with simple pelvic floor exercises is effective in a large percentage of patients with fecal incontinence. Attention to diet, scheduled defecations and judicious use of anti-diarrheal medications seem to preserve a relevant role in this "untreatable" disease. Traditionally, bio-feedback techniques have been rated to offer a suitable non-invasive method of approaching the problem superior to conservative simpler therapeutic measurements. This has not been confirmed by randomized, controlled trials. Notwithstanding the reported symptoms improvement in over 2/3 of fecally incontinent patients shown in open trials, and the common belief that behavior therapy is a safe and effective therapeutic option for many patients with fecal incontinence, experimental evidence is giving conflicting results. Properly

designed and carefully analyzed bio-feedback trials are actually needed to prove the effectiveness of this treatment in fecal incontinence. Meanwhile, it is reassuring to know that simple therapeutic measurements may effectively help these individuals affected by such a disabling disorder.

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