REVIEW



Biofeedback treatment of chronic constipation: myths and misconceptions

G. Chiarioni^{1,2}

Received: 24 March 2016/Accepted: 27 April 2016/Published online: 22 July 2016 © Springer-Verlag Italia Srl 2016

Abstract Chronic constipation is a prevalent disorder with considerable impact on healthcare costs and quality of life. Most patients would respond to conservative measures in primary care. Patients with refractory constipation are commonly referred to dedicated centers for appropriate investigations and management. After testing, three main subtypes of constipation are commonly identified: normal colon transit, slow transit, and functional defecation disorders. The etiology of functional defecation disorders is consistent with maladaptive behavior, and biofeedback therapy has been considered a valuable treatment option. Being safe and only marginally invasive, retraining has been historically employed to manage all types of refractory constipation. There are a number of strongly held beliefs about biofeedback therapy that are not evidencebased. The aim of this review was to address these beliefs concerning protocols, efficacy, indications, and safety, with a special focus on the relevance of identifying patients with a functional defecation disorder who are ideal candidates for retraining. Randomized controlled trials support the effectiveness of biofeedback therapy for severe, refractory constipation due to functional defecation disorders. Limitations of the treatment are discussed, but biofeedback remains the safest option to successfully manage this hardto-treat subtype of constipation.

Keywords Biofeedback · Constipation · Obstructed defecation · Dyssynergic defecation

Introduction

Chronic constipation is a commonly reported symptom in the general population, affecting 2-30 % of people in Western countries [1]. Population-based epidemiological studies using the Rome criteria to improve symptom definition (Table 1) show a prevalence of up to 15 %, and constipation is about twice as common in women as in men [2]. The prevalence of constipation is reported to increase in the frail elderly where the female prevalence seems to fade away [3]. Constipation is a benign disorder at all ages, except in the elderly where fecal impaction may lead to increased lower urinary infections and to stercoral perforation of the colon [3]. Only a minority of constipated people consult a physician, but constipation is still the fifth most common gastrointestinal complaint for which patients seek physicians' help, with considerable impact on healthcare costs and quality of life [1, 4]. The symptoms of chronic or recurrent constipation may be caused by distinctly different physiological mechanisms. There are two main mechanisms: delayed transit due to decreased peristaltic contractions throughout the colon and outlet obstruction in which the individual has difficulty emptying stool from the rectum [5]. A small group of patients with outlet obstruction have a structural defect such as large rectocele that obstructs rectal emptying [5]. However, outlet obstruction is commonly found to be a functional defecation disorder in which the patient paradoxically contracts or fails to relax the pelvic floor muscles on straining or does not generate adequate intra-abdominal pressure to overcome the resting anal pressure [6]

G. Chiarioni chiarioni@tin.it

¹ Division of Gastroenterology of the University of Verona, AOUI Verona, Gastroenterologia B, V Piano, Ospedale Policlinico GB Rossi, Piazzale LA Scuro 10, 37134 Verona, Italy

² Division of Gastroenterology and Hepatology, Center for Functional GI and Motility Disorders, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Table 1 Rome III criteria for constipation

- 1-Must include two or more of the following:
- a. Straining during at least 25 % of defecations
- b. Lumpy or hard stools in at least 25 % of defecations c. Sensation of incomplete evacuation for at least 25 % of
- defecations
- d. Sensation of an orectal obstruction/blockage for at least 25 % of defecations
- e. Manual maneuvers to facilitate at least 25 % of defecations (e.g., digital evacuation, support of the pelvic floor)
- f. Fewer than 3 defecations per week

2-Loose stools are rarely present without the use of laxatives

3-Insufficient criteria for irritable bowel syndrome

Criteria fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis

Table 2 Rome III criteria for functional defecation disorder

- 1-Must satisfy diagnostic criteria for functional constipation
- 2-During repeated attempts to defecate must have at least two of the following
- a. Evidence of impaired evacuation, based on balloon expulsion test or imaging
- b. Inappropriate contraction of the pelvic floor muscles (i.e., anal sphincter or puborectalis) or <20 % relaxation of basal resting sphincter pressure by manometry, imaging, or electromyography
- c. Inadequate propulsive forces assessed by manometry or imaging

Criteria fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis

(Table 2). Delayed colon transit as measured with radiopaque markers does not distinguish between subtypes, while a simple balloon evacuation test is a reliable screening test [6, 7]. Finally, an additional group of patients have none of these abnormalities and are referred to as having "normal transit constipation." Most constipated patients respond either to fiber-fluid supplementation or to judicious use of laxatives [1]. Among the non-responders, up to 50 % of those referred to tertiary care centers have outlet dysfunction constipation [7, 8]. Functional defecation disorder is commonly considered to a form of maladaptive behavior since no discernible anatomic or neurology abnormality can be found [9]. Restoring altered physiology seems a logical approach to managing symptoms and biofeedback, and behavioral treatment which relies on dedicated machinery to improve defecation effort was proposed as a treatment option soon after the discovery of this constipation su-type [10]. Since the intervention was reported to be effective, noninvasive, and safe, it has been become customary to manage all patients not responsive to standard care with biofeedback and/or bowel retraining techniques [9, 11, 12]. However, a recent Cochrane review concluded that there is insufficient evidence to make conclusions regarding the efficacy and safety of biofeedback for adult patients with chronic constipation [13]. While the Cochrane process is deservedly held in the highest respect, we feel that it is time to address the widespread but incorrect beliefs concerning the effectiveness of behavioral management of chronic constipation in order to illustrate the quality of evidence supporting biofeedback treatment of constipation secondary to functional defecation disorders.

Biofeedback treatment of chronic constipation is performed according to a standardized protocol

Biofeedback is a conditioning treatment in which information about a physiological process is converted into an understandable signal to enable the patient to learn to control a disordered function [14]. Biofeedback is considered appropriate treatment whenever specific mechanism(s) underlying disordered function are defined and the mastering of responses can be learned with the aid of systematic information not usually perceived at a conscious level [14]. The patient attempts some actions and uses feedback from either success or failure to refine the performance. For responses such as relaxation of the pelvic floor muscle on straining, the intrinsic feedback is usually not adequate for successful learning, and amplification of the muscular tension by means of specific devices is relevant to improved performance [15]. Therefore, functional defecation disorders seem to be ideal candidates for biofeedback therapy. Paradoxical increases in anal pressures and electromyographic (EMG) activity on straining are easily detected by dedicated instrumentation. Anal pressure may be measured by means of water perfused catheters and solid state transducers [9]. Anal EMG may be recorded either by intra-anal probes or by perianal EMG skin electrodes to measure the average EMG activity of large number of muscle cells proportional to the contraction of the underlying muscles [9]. No single technique seems superior to the others, and the choice depends on the therapist's training [9]. A standardized treatment would be desirable, but biofeedback training protocols vary among different centers with the terms bowel retraining and biofeedback often used interchangeably [9, 16]. A mainstay of behavioral treatment is to first explain the anorectal dysfunction and to discuss its relevance with the patient before approaching the treatment [15]. This initial approach is likely to be more effective when the patient is shown his/her own data to explain the ineffective straining [8, 13]. Some protocols will then focus on anal manometry or EMG recordings by means of intra-anal plugs or perianal skin electrodes displaying the patient's anal function on straining to teach the patient to relax their pelvic floor through trial and error [11, 17–21]. This objective is first pursued with the visual help of dedicated machinery accompanied by empathic encouragement from the therapist. When the patient is confident about his/her performance, the visual help is gradually withdrawn. This protocol does not seem to be specific for functional defecation disorders as it has been extensively used in uncontrolled trials with similar benefits reported in chronic constipation of diverse etiology [17, 18, 21]. Moreover, this protocol was reportedly no more effective than simple bowel retraining measures, Botox, and surgery of the pelvic floor when it was used in randomized controlled trials (RCTs) [11, 19, 20]. In an attempt to provide a standardized treatment approach to functional defecation disorders, three centers independently developed and validated in RCTs, a biofeedback protocol addressing all aspects of the defecation effort. This protocol is based on a four-step schedule: (1) patient training, (2) straining training, (3) training to relax the pelvic floor muscles on straining, and (4) practice simulated defecation [15]. Patient training is the initial part of treatment focused on explaining the patient's dysfunction and discussing its relevance with him/her. A number of people would find it difficult to believe they unconsciously obstruct defecation and comparing their defective defecation tracing with a normal one is helpful. Patients are then taught to improve the defecation effort by closing the glottis and contracting the abdominal wall muscles to increase the rectal pressure on straining. This task can be accomplished by having the therapists placing their hand on the patient's abdominal wall or recording the abdominal wall EMG activity while straining. To learn to relax the pelvic floor on straining, patients watch recordings of anal canal pressures or averaged EMG and are taught through trial and error to relax the pelvic floor muscles on attempted defecation. This part of the training is best performed with the patient sitting on a commode. A final part of the training is to have the patient defecating a simulated stool. This goal is accomplished by inserting a balloon-tipped catheter into the rectum, filling it with 50 ml of air and having the patient to expel it while the therapist gently pulls the catheter to ease the expulsion. As the patient becomes more proficient, the therapist's help is gradually withdrawn a general biofeedback rule at all stages. Few centers include sensory balloon training to improve rectal defecatory perception, but this does not seem to correlate to an improved outcome [22, 23]. This four-step protocol has been proven to be effective treatment for constipation due to dyssynergic defecation in RCTs, and it should be applied whenever dedicated expertise is available [15]. There is insufficient evidence to provide diverse biofeedback and/or bowel training protocols outside experimental trials. Moreover, in a recent RCT, biofeedback therapy was superior to balloon defecation retraining in 65 obstructed defecation patients with clinical improvement in 79 % of retraining patients compared to only 52 % in the balloon group (p < 0.05) [24]. Some features of uncertainty still persist, namely: (a) the best device for measuring anal activity in the straining training step, (b) the number and duration of therapeutic sessions required, and (c) what professionals should administer treatment. A small RCT suggested that EMG biofeedback was more effective than pressure biofeedback, while a meta-analysis of mostly uncontrolled studies showed that the mean success rate was slightly greater with pressure than with EMG biofeedback (78 vs 70 %) [25, 26]. However, EMG is simpler to administer and better tolerated than other forms of training and is likely to be increasingly employed for retraining in the future. The number and duration of retraining sessions have not been standardized. Some clinics train until the patient reports some benefit [16-18]. However, RCTs have required a minimum number of sessions (most commonly 4-6 sessions) to provide a full treatment protocol [22, 23, 27]. Training sessions are provided on an individual basis and last 30-60 min [22, 23, 27]. Former protocols with fewer sessions showed biofeedback as effective as simpler bowel retraining measures in constipated patients [11]. Therapeutic sessions are demanding, and a highly trained and motivated therapist seems essential to ensure a successful outcome [14]. No study addressed the training required for an individual to administer biofeedback therapy. In a recent study, approximately 50 % of UK biofeedback practitioners consider themselves as selftaught [16]. In addition, it is unclear whether the adequate provider should be either physician (MD), psychologist (PhD), or nurse. However, the low-cost reimbursement provided for behavioral therapy is likely to influence future choices orienting biofeedback to a nurse-based treatment supervised by either PhDs or MDs.

Biofeedback is effective treatment for chronic idiopathic constipation

In 1987, Bleijemberg and Kuijpers first reported the efficacy of EMG biofeedback treatment combined with oatmeal porridge defecation in 10 patients with constipation due to spastic pelvic floor syndrome, later redefined as functional defecation disorder by the Rome criteria (6,9). Treatment was associated with a successful outcome in almost all patients and prompted a number of uncontrolled studies to investigate the efficacy of behavioral therapy in functional defecation disorders (9,14). Therapeutic outcomes were at huge variance with success rates ranging from 18 to 100 % of patients studied [28, 29]. Major drawbacks in assessing this literature were small sample size, lack of any control group, poor standardization in therapeutic protocols, inclusion criteria, and outcome measures [30]. However, the majority of uncontrolled studies in constipated adults reported a favorable outcome in about two thirds of patients without reporting side effects [9, 30]. Anxious patients appeared less likely to improve, but no functional variable able to predict outcome could be safely identified [30, 31]. In addition, a series of studies from the St. Mark's group consistently cast doubts on whether biofeedback has specific value in the treatment of functional defecation disorders [11, 17, 18, 32]. These investigators reported similar efficacy of biofeedback treatment in slow transit constipation and in functional defecation disorders suggesting a potential influence of retraining on the autonomic innervation of the colon [11, 17, 18, 32]. In addition, biofeedback was reportedly no more effective than simpler bowel retraining measures in constipation not responsive to standard care [11]. These studies heralded a practice of providing a nurse-based bowel retraining-biofeedback program as first-choice therapy in all constipated patients not responsive to standard care with successful outcome rates ranging from 62.5 to 71 % of those completing treatment [12, 33]. Biofeedback training was thought to make a specific contribution to the treatment of constipation due to functional defecation disorders that is distinct from education or psychotherapy and led some to consider retraining as a therapeutic option in chronic idiopathic constipation [15]. To address the issue, we studied 52 constipated adults with a history of infrequent defecation and marker-proven slow colon transit. In addition, all patients underwent anorectal physiology testing to investigate comorbid functional defecation disorders. Thirty-four of 52 patients met the Rome criteria for dyssynergic defecation; 12 patients were classified as having slow transit only, and 5 patients partially met the Rome criteria and were classified as a mixed group [2, 34]. The primary aim was to determine whether biofeedback benefits are limited to functional defecation disorders or expanded to all constipated patients irrespectively of etiology. All patients received the four-step biofeedback protocol as outlined above during 5 weekly training sessions. Colon transit, anorectal physiology testing, and clinical parameters were evaluated both before and after behavior therapy. After 6 months, 71 % of patients with both slow transit and functional defecation disorders reported satisfaction with treatment versus 8 % in the slow transit only group. Patients in the mixed group were also improved, but not as much as dyssynergia patients. The results were well maintained at follow-up 2 years later without evidence of side effects [34]. Clinical benefit correlated with improved defecation as demonstrated by successful balloon expulsion and reductions in dyssynergia at manometry. Interestingly, biofeedback training resulted in a significant reduction in the urge threshold, although no specific sensory retraining had been provided. Treatment success was predicted by pelvic floor dyssynergia, milder constipation, and less abdominal pain at baseline [34]. This study allowed us to conclude that biofeedback is specific treatment for dyssynergic defecation and that retraining works through learning to improve the defecation effort. In addition, the finding of delayed colon transit should not preclude behavioral treatment since it can be cured by biofeedback. The poor effectiveness of biofeedback therapy in slow transit constipation not due to dyssynergic defecation has been confirmed by an independent group of researchers. However, biofeedback is costly, labor intensive, and not widely available, while a number of compounds (i.e., laxatives) have been reported to be effective treatment in chronic idiopathic constipation [35]. The need for RCTs investigating the efficacy of biofeedback therapy in chronic constipation secondary to functional defecation disorders has been recently met by three pivotal studies run independently in different referral centers. The first of them compared biofeedback to a commonly prescribed osmotic laxative (polyethylene glycol [PEG] in incremental dosage (14.6–29.2 g/d) in combination with 5 weekly counseling sessions [23]. All patients showed features of normal transit constipation and dyssynergic defecation to be randomized either to the biofeedback (54 patients) or to the laxative group (55 patients). Follow-up assessment extended up to 1 year in the laxative group and to 2 years in the biofeedback group. Satisfaction with treatment, symptoms of constipation, and pelvic floor physiology were regularly assessed throughout follow-up. At 6 months, major clinical improvement was reported by 80 % of patients in the behavior group versus only 20 % in the PEG group [23]. Biofeedback benefits were well sustained for the whole follow-up interval without evidence of side effects. Clinical benefits correlated well with improved anorectal physiology. Digital facilitation of evacuation prior to treatment predicted poor outcome. Interestingly, consumption of laxatives other than PEG was significantly decreased in the biofeedback group compared to the PEG group, while bowel frequency was significantly increased in both groups compared to baseline. In a second RCT, Heymen et al. [27] randomly assigned 84 constipated subjects with dyssynergic defecation to receive either biofeedback (n = 30), diazepam (n = 30), or placebo pills (n = 24). An important feature of this study was that all subjects were trained to do pelvic floor muscle exercises to correct pelvic floor dyssynergia during 6 biweekly 1-h sessions, but only the biofeedback patients received instrumented (EMG) feedback of pelvic floor physiology. All other patients received pills daily (muscle relaxant or placebo) before attempting defecation. Biofeedback was superior to diazepam by intention-to-treat analysis (70 vs 23 % reported adequate relief of constipation) and also superior to placebo pills (38 % successful). In addition, biofeedback patients reported significantly more spontaneous bowel movements compared to placebo, with a trend favoring biofeedback over diazepam. Biofeedback patients also reduced pelvic floor EMG activity during straining significantly more than diazepam patients [27]. Finally, Rao et al. [22] conducted a short-term (3 months) RCT comparing biofeedback to sham feedback (relaxation therapy) and to standard medical care (diet, exercise, and laxatives) in 77 chronically constipated patients with dyssynergic defecation. At baseline marker study, the vast majority of patients showed features of delayed colon transit. A significantly greater proportion of patients receiving biofeedback (88 %) reported more than a 20 % improvement in global satisfaction and stool frequency expressed as complete spontaneous bowel movements (CSBM) on a visual analog scale compared to subjects receiving sham biofeedback (48 %), but not when compared to standard care (70 %). The authors also reported significant progress in the biofeedback group in normalization of the dyssynergic pattern and improvement of a defecation index, with trends in favor of biofeedback subjects reducing balloon expulsion time and decreasing colonic marker retention compared to alternative treatment groups [22]. However, the results of long-term (12 months) follow-up of this group of patients provided evidence that retraining was associated with sustained improvement of bowel symptoms and anorectal function, whereas standard therapy was largely ineffective [36]. In addition, a large cohort study on 226 patients with dyssynergic defecation showed the effectiveness of biofeedback therapy in improving, in the long term, the validated Eypasch's Gastrointestinal Quality of Life Index (GIQLI) [37]. An improved QOL score in the behavior group was also reported in a smaller RCT comparing biofeedback to laxatives in 88 constipated patients with obstructed defecation [38]. Biofeedback has also been compared to invasive treatments in two small RCTs with negative results. In the first RCT, 48 dyssynergia patients were randomized to receive either biofeedback therapy or an injection of Clostridium botulinum type A (BTX-A) neurotoxin directly into the puborectalis muscle [20]. BTX-A is a neurotoxin that causes reversible paralysis of muscles by presynaptic inhibition of acetylcholine release [39]. At 1-month follow-up, symptomatic improvement was reported by 50 % of biofeedback patients versus 70.8 % of BTX-A patients. Improved anorectal physiology did not correlate with outcome. However, at 1-year follow-up, both treatments lead to disappointing results with relapse of symptoms in the majority of patients of both groups [20]. No side effects were reported. The same group of researchers reported a similar poor outcome of biofeedback management of dyssynergic defecation when compared with partial surgical division of the puborectalis muscle in 60 constipated patients [19]. Surgical treatment was highly effective therapy (95 % at 1 month and 70 % at 1-year follow-up), though with an unacceptable burden of side effects: fecal incontinence, rectal intussusception, and wound infection in 10-15 % of those treated [19]. Moreover, both studies were statistically underpowered, and the biofeedback protocol employed in these two RCTs was simpler than the four-step protocol described above. In addition, a recent RCT reported biofeedback therapy augmented by transanal electrical stimulation as significantly superior to standard care in a series of 81 constipated dyssynergia patients with 46 % of the behavior arm refractory to previous pelvic floor surgery [40]. Concomitant irritable bowel syndrome (IBS) does not seem to influence the outcome of biofeedback therapy for dyssynergic defecation in open-label studies [41]. In conclusion, there is insufficient evidence to support the use of retraining in the management of chronic constipation not responsive to standard care. However, biofeedback is the treatment of choice for a common, hard-to-treat subtype of chronic constipation: functional defecation disorder and it should be employed whenever dedicated expertise is available [9]. Moreover, biofeedback works by improving the defecation effort providing a specific mechanism of action [15]. Patients with refractory constipation should be thoroughly investigated to diagnose a functional defecation disorder as etiology of their symptoms [42]. RCTs have provided consistent evidence that biofeedback is more effective than placebo, standard care, laxatives, and myorelaxant drugs in the management of dyssynergic defecation [43]. Effective management of functional defecation disorders by retraining should not be limited to referral centers [44].

Biofeedback is effective treatment for obstructed defecation syndrome

Obstructed defecation syndrome (ODS), also called outlet dysfunction constipation, refers to difficulty on emptying the rectum with secondary constipation commonly evidenced by failure to evacuate a rectal balloon [7]. In referral centers, it is diagnosed in approximately 50 % of patients not responding to standard care, but its frequency is likely higher in surgical clinics [7, 8, 45]. The majority of patients with outlet dysfunction constipation will show evidence of a functional defecation disorder [7, 8]. However, in a sizable minority (up to 12 %) of patients with intractable constipation imaging of the pelvic floor will provide evidence of morphological alterations of the pelvic floor potentially obstructing defecation: rectocele, rectal prolapse, enterocele, and excessive descent of the pelvic floor [7] with secondary surgical consultation. While the clinical relevance of the abnormal morphology is a matter of debate, the goal of surgical treatment should be to restore the various pelvic organs to their appropriate anatomical positions in order to regain adequate function [46, 47]. However, there is often a poor correlation between anatomical and functional outcome [47]. This has led to the assumption that biofeedback could be a viable treatment option for ODS potentially due to altered morphology of the pelvic floor [48]. In addition, in an effort to decrease medical litigation, the St. Mark's group first investigated the efficacy of retraining in an open-label trial run in 32 constipated patients with a large rectocele, i.e., a rectocele over 2 cm at defecography [49]. At the end of treatment, few patients (16 %) reported major symptom improvement, while almost half reported partial improvement of symptoms. No information about long-term follow-up was provided. More recently, the efficacy of biofeedback therapy has been investigated in an open-label trial on 90 female patients with ODS thought to be secondary to rectocele and rectoanal intussusception [50]. A successful clinical outcome was reported in 71.1 % of patients with no correlation with improved pelvic floor physiology. However, all patients were prescribed fiber-fluid supplementation as add-on therapy making it difficult to interpret these positive results. In addition, retraining in mixed open-label series of ODS patients including both functional defecation disorder and multiple morphology, alterations of the pelvic floor reported a less favorable outcome (symptoms improved in approximately 50 % of patients) [51]. In a recent RCT, Lehur et al. [52] investigated the efficacy of biofeedback therapy compared to stapled transanal rectal resection (STARR) in 119 women with ODS associated with rectocele and rectal intussusception. STARR is an innovative surgical intervention which is reported to benefit ODS by performing a surgical resection of redundant rectal tissue [48]. The Lehur [52] trial was statistically underpowered for 50 % of retraining patients compared to only 14 % of surgery patients who withdrew early. However, symptom improvement was observed in 44 patients (81.5 %) undergoing STARR compared to only 13 retraining patients (33.3 %) (p < 0.0001) at 1-year follow-up. The QOL and obstructed defecation scores of both groups improved compared to baseline. No biofeedback-related adverse events were reported, while 1 case of serious rectal bleeding was observed in the STARR group. Moreover, an additional open-label trial investigating the efficacy of the STARR procedure reported a high reoperation rate (up to 19 %), 1 death for necrotizing pelvic fasciitis, and worse outcome in patients with concomitant dyssynergic defecation [53]. On the contrary, concomitant pelvic floor abnormalities (i.e., rectocele) did not influence the outcome of retraining in a prospective study of 108 constipated patients with pelvic floor dyssynergia [45]. In terms of comorbidities, even the presence of IBS did not affect the outcome of biofeedback therapy in 50 constipated patients with dyssynergic defecation and 60 % of them experienced symptom improvement [54]. In conclusion, there is insufficient evidence to manage ODS by means of biofeedback therapy in the absence of a functional defecation disorder. The current practice of providing biofeedback therapy in all patients with intractable constipation before proceeding to surgical measures will likely decrease medical litigation, but is poorly supported by the literature [47, 48, 55]. RCTs aiming to improve our understanding of the etiology of ODS in order to provide a tailored management are eagerly awaited.

Biofeedback is a safe treatment

Historically biofeedback treatment of gastrointestinal disorders has been considered safe and devoid of adverse events [14]. The placement of anorectal devices to provide retraining for dyssynergic defecation has also not been associated with adverse events, while being only marginally invasive [9]. In both open-label and RCTs, there is just one instance of patients (n = 3) dropping out of a study for perceiving biofeedback to treat constipation as psychologically unacceptable [19]. A high dropout rate is reported only in surgical series where biofeedback should not be considered appropriate therapy due to the absence of a functional defecation disorder as relevant etiology in constipation [52]. However, the recent Cochrane review concluded that there was insufficient data to draw definitive conclusions about the safety of biofeedback therapy for constipation. There is always a place for well-designed trials in this field, and safety concerns in the management of a benign, though disabling, disorder are obviously important. However, it is left unclear how large a sample should be to prove the safety of biofeedback therapy for constipation [56]. Moreover, both RCTs and large cohort long-term trials investigating hundreds of adult patients for up to 4 years have failed to report any meaningful side effects related to this marginally invasive therapy for refractory constipation [9, 57-59]. Biofeedback management of constipation has been reported as free of side effects in both pediatric patients and the elderly [3, 45]. In addition, the safety profile of biofeedback treatment of refractory constipation compares favorably with both available drugs and surgical interventions [3, 5, 19, 53]. A number of surgeons would not operate constipated patients provided a trial of biofeedback trial had failed to improve symptoms [48].

Conclusions

The literature supports the safety profile of biofeedback treatment of constipation not responsive to standard care. Retraining is the safest therapy currently available for refractory constipation due to functional defecation disorders.

Compliance with ethical standards

Funding No funding was received for the actual paper.

Conflict of interest Dr Chiarioni has received speaker honorarium from Shire Italia and consulting Board honorarium from Takeda Italia; he is also member of the Anorectal Committee of the Rome Foundation.

Ethical approval All procedures performed in studies involving human participants reported in this article were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was reported from all individual participants included in all of the studies considered in this article.

References

- Lembo A, Camilleri M (2003) Chronic constipation. N Engl J Med 349:1360–1368
- Longstreth GF, Thompson WG, Chey W, Houghton LA, Mearin F, Spiller RC (2006) Functional bowel disorders. In: Drossman DA, Corazziari E, Delvaux M, Spiller RC, Talley NJ, Thompson WG, Whitehead WE (eds) Rome III: the functional gastrointestinal disorders, 3rd edn. Degnon Associates, McLean, pp 487–555
- De Giorgio R, Ruggeri E, Stanghellini V, Eusebi LH, Bazzoli F, Chiarioni G (2015) Chronic constipation in the elderly: a primer for the gastroenterologist. BMC Gastroenterol 15:130
- Sandler RS, Everhart JE, Donowitz M et al (2002) The burden of selected digestive diseases in the United States. Gastroenterology 122:1500–1511
- Wald A (2016) Constipation: advances in diagnosis and treatment. JAMA 315:185–191
- 6. Wald A, Bharucha AE, Enck P, Rao SSC (2006) Functional anorectal disorders. In: Drossman DA, Corazziari E, Delvaux M, Spiller RC, Talley NJ, Thompson WG, Whitehead WE (eds) Rome III: the functional gastrointestinal disorders, 3rd edn. Degnon Associates, McLean, pp 639–685
- Chiarioni G, Kim SM, Vantini I, Whitehead WE (2014) Validation of the balloon evacuation test: reproducibility and agreement with findings from anorectal manometry and electromyography. Clin Gastroenterol Hepatol 12:2049–2054
- Surrenti E, Rath DM, Pemberton JH, Camilleri M (1995) Audit of constipation in a tertiary referral gastroenterology practice. Am J Gastroenterol 90:1471–1475
- Chiarioni G, Heymen S, Whitehead WE (2006) Biofeedback therapy for dyssynergic defecation. World J Gastroenterol 12:7069–7074
- Bleijnberg G, Kuijpers HC (1987) Treatment of the spastic pelvic floor syndrome with biofeedback. Dis Colon Rectum 30:108–111
- Koutsomanis D, Lennard-Jones JE, Roy AJ, Kamm MA (1995) Controlled randomised trial of visual biofeedback versus muscle training without a visual display for intractable constipation. Gut 37:95–99
- Iqbal F, Askari A, Adaba F et al (2015) Factors associated with efficacy of nurse-led bowel training of patients with chronic constipation. Clin Gastroenterol Hepatol 13:1785–1792

- Woodward S, Norton C, Chiarelli P (2014) Biofeedback for treatment of chronic idiopathic constipation in adults. Cochrane Database Syst Rev 3:CD008486
- Chiarioni G, Whitehead WE (2008) The role of biofeedback in the treatment of gastrointestinal disorders. Nat Clin Pract Gastroenterol Hepatol 5:371–382
- Chiarioni G, Whitehead WE (2011) Biofeedback therapy for constipation. In: Parkman HP, McCallum RW, Rao SSC (eds) GI motility testing: a laboratory and office handbook. Slack Inc, Thorofare, pp 179–187
- Etherson KJ, Horrocks EJ, Scott SM, Knowles CH, Yiannakou Y (2016) A national biofeedback practitioners service evaluation: focus on chronic idiopathic constipation. Frontline Gastroenterol. doi:10.1136/flgastro-2015-100660
- Chiotakakou-Faliakou E, Kamm MA, Roy AJ, Storrie JB, Turner IC (1998) Biofeedback provides long-term benefit for patients with intractable, slow and normal transit constipation. Gut 42:517–521
- Koutsomanis D, Lennard-Jones JE, Kamm MA (1994) Prospective study of biofeedback treatment for patients with slow and normal transit constipation. Eur J Gastroenterol Hepatol 6:131–137
- Faried M, El Nakeeb A, Youssef M, Omar W, El Monem HA (2010) Comparative study between surgical and non-surgical treatment of anismus in patients with symptoms of obstructed defecation: a prospective randomized study. J Gastrointest Surg 14:1235–1243
- Farid M, El Monem HA, Omar W et al (2009) Comparative study between biofeedback retraining and botulinum neurotoxin in the treatment of anismus patients. Int J Colorectal Dis 24:115–120
- Lee BH, Kim N, Kang SB et al (2010) The long-term clinical efficacy of biofeedback therapy for patients with constipation or fecal incontinence. J Neurogastroenterol Motil 16:177–185
- Rao SS, Seaton K, Miller M et al (2007) Randomized controlled trial of biofeedback, sham biofeedback, and standard therapy for dyssynergic defecation. Clin Gastroenterol Hepatol 5:331–338
- Chiarioni G, Whitehead WE, Pezza V, Morelli A, Bassotti G (2006) Biofeedback is superior to laxatives for normal transit constipation due to pelvic floor dyssynergia. Gastroenterology 130:657–664
- Pourmomeny AA, Emami MH, Amooshahi M, Adibi P (2011) Comparing the efficacy of biofeedback and balloon-assisted training in the treatment of dyssynergic defecation. Can J Gastroenterol 25:89–92
- Bleijenberg G, Kuijpers HC (1994) Biofeedback treatment of constipation: a comparison of two methods. Am J Gastroenterol 89:1021–1026
- Heymen S, Jones KR, Scarlett Y, Whitehead WE (2001) Biofeedback treatment of constipation: a critical review. Dis Colon Rectum 44:728–736
- Heymen S, Scarlett Y, Jones K, Ringel Y, Drossman D, Whitehead WE (2007) Randomized controlled trial shows biofeedback to be superior to alternative treatments for patients with pelvic floor dyssynergia-type constipation. Dis Colon Rectum 50:428–441
- Keck JO, Staniunas RJ, Coller JA et al (1994) Biofeedback training is useful in fecal incontinence but disappointing in constipation. Dis Colon Rectum 37:1271–1276
- Fleshman JW, Dreznik Z, Meyer K, Fry RD, Carney R, Kodner IJ (1992) Outpatient protocol for biofeedback therapy of pelvic floor outlet obstruction. Dis Colon Rectum 35:1–7
- Bassotti G, Chistolini F, Sietchiping-Nzepa F, de Roberto G, Morelli A, Chiarioni G (2004) Biofeedback for pelvic floor dysfunction in constipation. BMJ 328:393–396
- Palsson OS, Heymen S, Whitehead WE (2004) Biofeedback treatment for functional anorectal disorders: a comprehensive efficacy review. Appl Psychophysiol Biofeedback 29:153–174

- 32. Emmanuel AV, Kamm MA (2001) Response to a behavioural treatment, biofeedback, in constipated patients is associated with improved gut transit and autonomic innervation. Gut 49:214–219
- Yang LS, Khera A, Kamm MA (2014) Outcome of behavioural treatment for idiopathic chronic constipation. Intern Med J 44:858–864
- Chiarioni G, Salandini L, Whitehead WE (2005) Biofeedback benefits only patients with outlet dysfunction, not patients with isolated slow transit constipation. Gastroenterology 129:86–97
- 35. Battaglia E, Serra AM, Buonafede G et al (2004) Long-term study on the effects of visual biofeedback and muscle training as a therapeutic modality in plevic floor dyssynergia and slow transit constipation. Dis Colon Rectum 47:90–95
- Rao SS, Valestin J, Brown CK, Zimmerman B, Schulze K (2010) Long-term efficacy of biofeedback therapy for dyssynergic defecation: randomized controlled trial. Am J Gastroenterol 105:890–896
- 37. Koh D, Lim JF, Quah HM, Tang CL (2012) Biofeedback is an effective treatment for patients with dyssynergic defaecation. Singapore Med J 53:381–384
- Ba-bai-ke-re MA, Wen N, Hu YL et al (2014) Biofeedbackguided pelvic floor exercise therapy for obstructive defecation: an effective alternative. World J Gastroenterol 20:9162–9169
- 39. Joo JS, Agachan F, Wolff B, Nogueras JJ, Wexner SD (1996) Initial North American experience with botulinum toxin Type A for treatment of anismus. Dis Colon Rectum 39:1107–1111
- Cadeddu F, Salis F, De Luca E, Ciangola I, Milito G (2015) Efficacy of biofeedback plus transanal stimulation in the management of pelvic floor dyssynergia. Tech Coloproctol 19:333–338
- 41. Rao SS (2011) What's in a name? Putting patients first: biofeedback for irritable bowel syndrome patients with dyssynergic defecation. J Clin Gastroenterol 45:572–573
- Cremonini F, Chiarioni G, Lembo A (2011) Evolving concepts in chronic constipation in Europe and elsewhere: not worlds apart. Neurogastroenterol Motil 23:693–696
- 43. Rao SS, Benninga MA, Bharucha AE, Chiarioni G, Di Lorenzo C, Whitehead WE (2015) ANMS-ESNM position paper and consensus guidelines on biofeedback therapy for anorectal disorders. Neurogastroenterol Motil 27:594–609
- 44. Chiarioni G, Bassotti G (2015) Biofeedback therapy for constipation due to dyssynergic defecation: ready for prime time. Tech Coloproctol 19:331–332
- 45. Lau CW, Heymen S, Alabaz O, Iroatulam AJ, Wexner SD (2000) Prognostic significance of rectocele, intussusception, and abnormal perineal descent in biofeedback treatment for constipated patients with paradoxical puborectalis contraction. Dis Colon Rectum 43:478–482

- 46. Hicks CW, Weinstein M, Wakamatsu M, Pulliam S, Savitt L, Bordeianou L (2013) Are rectoceles the cause or the result of obstructed defaecation syndrome? A prospective anorectal physiology study. Colorectal Dis 15:993–999
- Ellis CN, Essani R (2012) Treatment of obstructed defecation. Clin Colon Rectal Surg 25:24–33
- Podzemny V, Pescatori LC, Pescatori M (2015) Management of obstructed defecation. World J Gastroenterol 21:1053–1060
- Mimura T, Roy AJ, Storrie JB, Kamm MA (2000) Treatment of impaired defecation associated with rectocele by behavorial retraining (biofeedback). Dis Colon Rectum 43:1267–1272
- Hicks CW, Weinstein M, Wakamatsu M, Savitt L, Pulliam S, Bordeianou L (2014) In patients with rectoceles and obstructed defecation syndrome, surgery should be the option of last resort. Surgery 155:659–667
- Murad-Regadas SM, Regadas FS, Rodrigues LV, Fernandes GO, Buchen G, Kenmoti VT (2012) Management of patients with rectocele, multiple pelvic floor dysfunctions and obstructed defecation syndrome. Arq Gastroenterol 49:135–142
- 52. Lehur PA, Stuto A, Fantoli M, ODS II Study Group et al (2008) Outcomes of stapled transanal rectal resection versus biofeedback for the treatment of outlet obstruction associated with rectal intussusception and rectocele: a multicenter, randomized, controlled trial. Dis Colon Rectum 5:1611–1618
- 53. Gagliardi G, Pescatori M, Altomare DF, Italian Society of Colo-Rectal Surgery (SICCR) et al (2008) Results, outcome predictors, and complications after stapled transanal rectal resection for obstructed defecation. Dis Colon Rectum 51:186–195
- Patcharatrakul T, Gonlachanvit S (2011) Outcome of biofeedback therapy in dyssynergic defecation patients with and without irritable bowel syndrome. J Clin Gastroenterol 45:593–598
- Chaudhry Z, Tarnay C (2016) Descending perineum syndrome: a review of the presentation, diagnosis, and management. Int Urogynecol J 27:1149–1156
- 56. Wald A (2015) Poor quality evidence to support the use of biofeedback for the treatment of functional constipation in adults. Evid Based Nurs 18:55
- Shim LSE, Jones M, Prott GM, Morris LI, Kellow JE, Malcolm A (2011) Predictors of outcome of anorectal biofeedback therapy in patients with constipation. Aliment Pharmacol Ther 33:1245– 1251
- Jodorkovsky D, Dunbar KB, Gearhart SL, Stein EM, Clarke JO (2013) Biofeedback therapy for defecatory dysfunction: "real life" experience. J Clin Gastroenterol 47:252–255
- 59. Lee HJ, Boo SJ, Jung KW et al (2015) Long-term efficacy of biofeedback therapy in patients with dyssynergic defecation: results of a median 44 months follow-up. Neurogastroenterol Motil 27:787–795