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POSITION PAPER

ANMS-ESNM position paper and consensus guidelines on biofeedback therapy for anorectal disorders

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Key Messages

This society position paper examined the study performance characteristics and efficacy of biofeedback therapy for anorectal disorders, and provided evidence based recommendations.

Recommendation

Biofeedback therapy is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation (DD). Level I, Grade A.

Recommendation

Biofeedback therapy is recommended for the short-term and long-term treatment of Fecal Incontinence (FI). Level II, Grade B.

Recommendation

Biofeedback therapy may be useful for the short-term treatment of Levator ani syndrome (LAS) with DD (Level II, Grade B) and Solitary rectal ulcer syndrome (SRUS) with DD (Level III, Grade C), but the evidence is fair.

Recommendation

Biofeedback therapy is not recommended for the routine treatment of children with Functional Constipation, with or without overflow FI. Level 1, Grade D.

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Abstract

Background *Anorectal disorders such as dyssynergic defecation, fecal incontinence, levator ani syndrome, and solitary rectal ulcer syndrome are common, and affect both the adult and pediatric populations. Although they are treated with several treatment approaches, over the last two decades, biofeedback therapy using visual and verbal feedback techniques has emerged as an useful option. Because it is safe, it is*

commonly recommended. However, the clinical efficacy of biofeedback therapy in adults and children is not clearly known, and there is a lack of critical appraisal of the techniques used and the outcomes of biofeedback therapy for these disorders. ***Purpose*** *The American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Motility convened a task force to examine the indications, study performance characteristics, methodologies used, and the efficacy of biofeedback therapy, and to provide evidence-based recommendations. Based on the strength of evidence, biofeedback therapy is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation (Level I, Grade A), and for the treatment of fecal incontinence (Level II, Grade B). Biofeedback therapy may be useful in the short-term treatment of Levator Ani Syndrome with dyssynergic defecation (Level II, Grade B), and solitary rectal ulcer syndrome with dyssynergic defecation (Level III, Grade C), but the evidence is fair. Evidence does not support the use of biofeedback for the treatment of childhood constipation (Level 1, Grade D).*

Keywords *biofeedback therapy, constipation, dyssynergic defecation, fecal incontinence, levator ani syndrome.*

INTRODUCTION

Anorectal disorders such as dyssynergic defecation (DD), fecal incontinence (FI), and levator ani syndrome (LAS) are common and affect up to 25% of the adult and pediatric populations. They significantly affect quality of life and pose a major health care burden.[1–3] Although these disorders are treated with several approaches including laxatives, anti-diarrheals, botulinum toxin or dextranomer injections, electrical and sacral nerve stimulations, and surgery,[1,2,4] biofeedback therapy using visual and verbal feedback techniques has emerged as a useful treatment option. However, a critical appraisal of the techniques used and the outcomes of biofeedback therapy are lacking.

The American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Motility convened a task force to examine the indications, study performance characteristics, methodologies used, and the scientific basis, noting especially the results of randomized controlled trials (RCTs) and the impact of biofeedback therapy on patient reported outcomes, objective measurements, and quality of life. These measures were used to provide evidence-based recommendations regarding the clinical utility and efficacy of biofeedback therapy for DD, FI, LAS, solitary rectal ulcer syndrome (SRUS), and childhood constipation.

PubMed, Embase, Medline, and PsychInfo databases from inception to August 2014 were used to identify appropriate studies in adults and children. Inclusion criteria included RCTs, and those that compared biofeedback with standard care, placebo, or no treatment. If unavailable, uncontrolled studies were examined. Treatment recommendations were based on grading recommended by the U.S. Preventive Services Task Force.[5]

BIOFEEDBACK THERAPY FOR DD

Introduction

Neuromuscular dysfunction of the defecation unit can lead to disordered or difficult defecation. Dyssynergic defecation is the most common defecation disorder that affects about 40% of patients with chronic constipation.[6] It is an acquired behavioral disorder where the act of stooling is uncoordinated or dyssynergic.[6] Physiologic testing may demonstrate one or more abnormalities when attempting to defecate: (i) paradoxical anal contraction, (ii) incomplete anal relaxation, (iii) inadequate push effort, or (iv) elevated threshold for the sensation of stooling (rectal hyposensitivity). Whole gut transit time may be delayed in up to two-thirds of these patients, but this is believed to be secondary to the outlet dysfunction rather than a cause of defecatory dysfunction.[6–8]

Indications

Patients with chronic constipation and DD who fulfill the criteria shown in Table 1 are eligible for biofeedback therapy.[6–8] Contraindications include severe neurological disorders, inability to sit on a commode, developmental disability, and visual impairment.

Study performance

Technical aspects The goal of biofeedback training is to improve bowel function by restoring a normal pattern of defecation. Biofeedback therapy is an instrument-based learning process that is based on 'operant conditioning' techniques. The governing principle is that any behavior when reinforced repeatedly can be learned and perfected. In patients with DD, the goal of biofeedback training is threefold[8–10]:

Table 1 Diagnostic criteria for dyssynergic defecation[6,7]

A. Patients must satisfy the diagnostic criteria for functional chronic constipation (Rome III) and
B. Patients must have dyssynergic pattern of defecation (types 1–4), which is defined as paradoxical increase in anal sphincter pressure (anal contraction) or less than 20% relaxation of the resting anal sphincter pressure or inadequate propulsive forces based on manometry,[8] radiologic imaging or EMG
C. Patients must satisfy one or more of the following criteria*:
1. Inability to expel an artificial stool (50 mL water filled balloon) within 1–2 min
2. Inability to evacuate or ≥50% retention of barium during defecography
*3. Some laboratories use a prolonged colonic transit time, i.e. greater than five markers (≥20% marker retention) on a plain abdominal X-ray taken 120 h after ingestion of one radiopaque marker capsule containing 24 radio opaque markers

i To correct the dyssynergia or incoordination of the abdominal, rectal, puborectalis, and anal sphincter muscles in order to achieve a normal and complete evacuation (Fig. 1).
ii To facilitate normal evacuation by simulated defecation training using balloons.
iii To enhance rectal sensory perception in patients with impaired rectal sensation.

Correct dyssynergia and improve rectoanal coordination—The purpose of this training is to produce a coordinated defecatory movement that consists of an abdominal push effort synchronized with relaxation of the pelvic floor (Fig. 1). This is achieved by manometric or electromyographic (EMG)-guided training of the abdominal push effort (diaphragmatic and abdominus rectus muscle training) together with anal relaxation.

The subject should be seated on a commode with the manometry/EMG probe *in situ*. The monitor display of the pressure/EMG changes from the rectum and anal canal provides visual feedback and facilitates learning (Fig. 1). Firstly, their posture and breathing techniques during attempted defecation are corrected. Next, at least 10–15 bearing down maneuvers is performed. Additional bearing down maneuvers may be performed with a 60 cc balloon inflated in the rectum in order to provide a sensation of stooling. After few sessions, the patient is encouraged to perform these maneuvers without visual or verbal feedback (Fig. 2).

Facilitate simulated defecation training—The goal here is to teach the subject to expel a 50 mL water or air-filled balloon using gentle traction to supplement the patient's efforts, preferably in the seated position on a commode.

Sensory training—The objective of this optional training is to improve the thresholds for rectal sensory perception and to promote better awareness for stooling in patients with rectal hyposensitivity.[9,11] This is performed by intermittent inflation of the balloon in the rectum. The goal is to teach the subject to perceive a lower volume of balloon distention but with the same intensity as experienced with a higher volume. Thus, by repeated inflations and deflations newer sensory thresholds can be established.[8,9]

Duration and frequency of training: The number of sessions and frequency of sessions should be customized for each patient. Typically, training sessions are

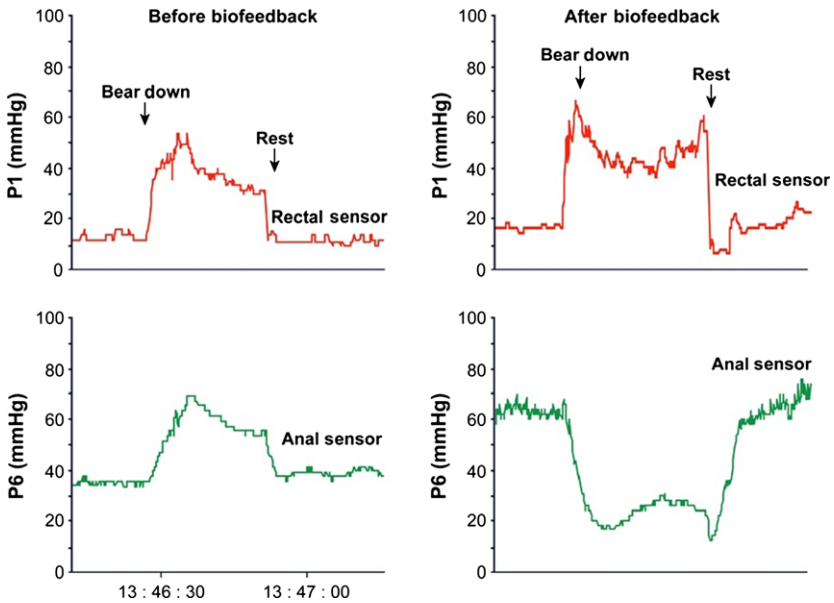

Figure 1 The rectal and anal pressure changes, and manometric patterns in a patient with constipation and dyssynergic defecation, before and after biofeedback showing paradoxical anal contraction at baseline (type 1) that improved and normalized after five sessions of biofeedback therapy.

performed biweekly and each session takes 1 h, and on average, 4–6 training sessions are required; periodic reinforcements at additional intervals may provide benefit,[9,12] but its role has not been examined. Patients are encouraged to practice diaphragmatic breathing and attempted defecation maneuvers at home for at least 15 min, two or three times a day.[11–15] Training is discontinued when patients demonstrate: (i) consistent coordinated pattern of defecation with anal relaxation; (ii) improved stooling habit; and (iii) normal balloon expulsion time.

Devices and techniques for biofeedback: Because biofeedback is an instrument-based learning technique, several devices and methods are available including solid-state manometry systems, catheters with microballoons or perfusion ports, anal EMG probes, and home training devices.[8] A manometry probe with microtransducers located in anal canal and a rectal balloon has the advantage of displaying rectal and anal pressure changes accurately and this may facilitate training of rectal propulsive forces (increases in rectal pressure produced by the diaphragm and abdominal muscle contraction), anal relaxation and sensory training. Electromyographic probes provide information on the striated anal muscles but do not provide information on rectal propulsive forces.

Efficacy of biofeedback therapy and RCTs

Several RCTs have been reported in adults with DD and are summarized in Table 2.[11–15] Although there are methodological differences between the studies including recruitment criteria, end points, and outcome measures, all studies using concealed allocation have concluded that biofeedback therapy is superior to controlled treatment approaches including diet, exercise and laxatives,[11,12] polyethylene glycol,[15] diazepam/placebo tablets,[14] balloon defecation therapy[16], and sham feedback therapy.[11]

Both short-term and 1-year long-term outcome studies have shown that biofeedback is superior to standard therapy alone in patients with DD.[12] A meta-analysis of seven studies involving biofeedback compared to any other treatment suggested that biofeedback conferred a sixfold increase in the odds of treatment success (odds ratio 5.861 [95% CI: 2.2–15.8]).[17] Predictors for successful therapy include harder stool consistency ($p = 0.009$), greater willingness to participate, higher resting anal sphincter pressure, and prolonged balloon expulsion time, with sensitivity and specificity of 0.79–0.81, respectively. A longer duration of laxative use was associated with poor outcome.[18] Dyssynergic defecation is associated with significant impairment in QOL.[19] In a prospective RCT of 100 patients, biofeedback therapy, administered at home or in-office improved most QOL domains in patients with DD.[20]

Strengths and confounding issues

Biofeedback therapy is a labor-intensive approach but has no adverse effects. However, it is only offered in a few centers and is performed by nurse therapists or physiotherapists. In order to treat the vast number of constipated patients in the community, a home based, self-training program is desirable. Uncontrolled studies of home trainers have reported that biofeedback is useful.[21,22] However, there is no standard or approved device. A recent RCT showed that home biofeedback is as useful as office biofeedback therapy in improving symptoms and anorectal function.[23] Click here to enter text.The treatment success also may be best defined by a combination of improvement in bowel function such as ≥1 CSBM/week + correction of dyssynergia pattern, but such measures have not been used in clinical trials.

The mechanism of action of biofeedback therapy is not fully understood. Improvements in defecation appear to be mediated by enhanced rectal propulsive forces and by anal and pelvic floor relaxation and by improved sensory thresholds.[11–15,24] Recent studies using bidirectional cortical evoked potentials and transcranial magnetic stimulations have revealed significant bi-directional brain-gut dysfunction in patients with DD,[25] and biofeedback appears to improve these dysfunctions.[26]

Because biofeedback is an instrument-based treatment, standardization of both equipment and protocols is desirable. At present, both EMG and pressure-based biofeedback therapy protocols have been used, and both appear to be efficacious, but comparative trials are lacking. Electromyographic probes are cheaper, more durable, and usually provide one or two channel display, whereas manometric systems are more expensive, provide multiple channel display, and because they have a balloon and rectal sensor, they can facilitate recto-anal coordination and sensory training. A recent systematic review concluded that there is currently 'insufficient evidence to allow firm conclusions regarding efficacy and safety of biofeedback for treatment of chronic constipation.'[27] However, this review addressed the use of biofeedback in all patients with constipation, for example, it included studies that evaluated biofeedback therapy for conditions that are not always associated with disordered defecation (e.g., rectal prolapse and slow transit con-

Table 2 Summary of randomized controlled trials of biofeedback therapy for Dyssynergic Defecation

	Rao *et al.*[11]	Rao *et al.*[12]	Chiarioni *et al.*[13]	Heymen *et al.*[14]	Chiarioni *et al.*[15]
Trial Design	Biofeedback (manometry pressure) *vs* Standard treatment *vs* Sham biofeedback	Biofeedback (Manometry pressure) *vs* Standard therapy	EMG Biofeedback for slow transit *vs* Dyssynergia	EMG Biofeedback *vs* Diazepam 5 mg *vs* placebo	EMG Biofeedback *vs* PEG 14.6 gm
Subjects and Randomization and Intervention (s)	77 (69 women) 1:1:1 distribution Standard: diet, exercise, laxatives Sham: Progressive muscle relaxation with anorectal probe	52; Short-term therapy 26 = long-term study 12 = biofeedback 13 = standard therapy Standard: diet, exercise, laxatives (titrated)	52 (49 women) 34 dyssynergia 12 slow transit 6 mixed	84 (71 women) 30 biofeedback 30 diazepam 24 placebo	109 (104 women) 54 biofeedback 55 polyethylene glycol
Duration and number of biofeedback sessions	3 months, Biweekly, 1 h, maximum of six sessions over 3 months, performed by biofeedback nurse therapist	One year; six active therapy sessions and three reinforcement sessions at 3 month intervals	5 weekly 30 min training sessions, performed by physician investigator	6 biweekly, 1 h sessions	3 months and 1 year, 5 weekly, 30 min training sessions performed by physician investigator
Primary outcomes	1. Presence of dyssynergia 2. Balloon expulsion time 3. Number of complete spontaneous bowel movements 4. Global satisfaction	Number of complete spontaneous bowel movements Secondary Outcome; Presence of dyssynergia Balloon expulsion time Global satisfaction	Symptom improvement None = 1 Mild = 2 Fair = 3 Major = 4	Global Symptom relief	Global Improvement of symptoms Worse = 0 No improvement = 1 Mild = 2 Fair = 3 Major improvement = 4
Dyssynergia corrected or symptoms improved	Dyssynergia corrected at 3 months in 79% with biofeedback *vs* 4% sham and 6% in Standard group; CSBM = Biofeedback group *vs* Sham or Standard, $p < 0.05$	No of CSBM/week increased significantly in biofeedback ($p < 0.001$) Dyssynergia pattern normalized ($p < 0.0010$) Balloon expulsion improved ($p < 0.001$) Colonic transit normalized ($p < 0.01$)	71% with dyssynergia and 8% with slow transit alone reported fair improvement in symptoms	70% improved with biofeedback compared to 38% with placebo and 30% with diazepam ($p < 0.01$)	79.6% reported major improvement at 6 and 12 months 81.5% reported major improvement at 24 months
Conclusions	Biofeedback was superior to sham feedback and standard therapy	Biofeedback was superior to standard therapy	Biofeedback benefits dyssynergia and not slow transit constipation	Biofeedback was superior to placebo and diazepam	Biofeedback was superior to laxatives

stipation). In fact, biofeedback therapy does not benefit constipated patients without DD.[13] Hence, including patients with these disorders and many other suboptimal and non-randomized older studies in the meta analysis, most likely diluted the benefit of biofeedback therapy, and led to an inappropriate conclusion regarding its use in defecation disorders. Lastly, the review determined that blinding was suboptimal and there was a risk of bias; however, the ability to blind subjects to treatment assignment in behavioral trials is limited and the risk of bias definition used for drug trials cannot be applied to behavioral trials. Hence, these factors should not weigh against the rigorous quality of RCTs for biofeedback therapy. It is essential that only patients who fulfill the criteria for DD be offered this treatment modality.

BIOFEEDBACK THERAPY FOR FI

Introduction

Fecal incontinence affects approximately 8.3% of the population and its treatment remains unsatisfactory. Biofeedback has been shown to be a useful treatment approach.[1,2,4]

Indications

Patients with FI who have not responded to conservative medical treatment measures including a trial of anti-diarrheals or fiber supplements. Patients must have adequate cognitive ability and be motivated to participate in this training program. Contraindications include neurological disorders such as spinal cord injury, severe internal anal sphincter injuries resulting in absence of resting anal canal pressure, dementia, developmental disability, uncontrolled psychotic disorder, age younger than 8 years, and visual impairment.

Study performance

Technical aspects Biofeedback involves the use of electronic or mechanical devices to provide augmented awareness of physiological responses to patients and their therapists to facilitate neuromuscular retraining. The goals are to correct the physiological deficits that contribute to FI by (i) improving the strength coordination and isolation of pelvic floor muscles (Figure 2), (ii) improving the ability to sense small volumes of distentions of the rectum and contract pelvic floor muscles in response to these distentions, and/or (iii) improving the ability to tolerate larger rectal distentions without experiencing uncontrollable urge sensations.[28–34]

Anal and pelvic floor muscle training—Firstly, patients are instructed to isolate the anal sphincter and puborectalis muscles and improve its strength by using modified Kegel exercises in the sitting or lying position with a probe *in situ*. Visual and verbal feedback techniques are used to reinforce the maneuvers, as they are being performed. The anal and rectal pressure changes displayed on the monitor provides visual feedback to the patient. The verbal feedback is provided by the physician/nurse therapist and consists of either complimenting the patient for performing a correct maneuver or rectifying any errors. The patient is instructed to squeeze and to maintain the squeeze for as long as possible. During the maneuver, the patient observes the monitor and is educated about the changes in anal pressure/EMG activity. For comparison, a normal recording is shown.[32] As the sphincter strength improves, the patient is encouraged to maintain a voluntary contraction for at least 30 s. Patients are instructed not to use their abdominal or gluteal muscles to achieve a voluntary squeeze. After a few sessions, the patient is encouraged to perform these maneuvers without visual feedback.[32,33] The patient is also instructed to perform squeeze exercises at home for at least 20 min, two to three times a day, and to perform about 20 squeeze maneuvers per session. Training may be discontinued when patients demonstrate (i) reduction in the number of incontinence episodes; (ii) improvement in anal squeeze pressure and rectoanal coordination when squeezing. Patients also receive sensory-motor coordination training. The objective here is to achieve a maximum voluntary squeeze in less than 1 s after inflation of a rectal balloon and to control the reflex anal relaxation by consciously contracting the sphincter muscles.[28,29,32]

Sensory training—Patients found to have an impaired rectal sensation may benefit from sensory training.[29–31] In brief, a series of progressively smaller balloon inflations are performed, starting with the volume that induced a sensation of urge to defecate, and decreasing by 5–10 mL with each successive distention. The patient is instructed to respond to the rectal distention by squeezing their anal sphincters. When the patient fails to perceive the balloon inflation, this defines the sensory threshold. Sensory discrimination training is used to train the patient to recognize and respond to lower balloon volumes; the balloon is distended with slightly higher, and on other trials, slightly lower volumes than the current threshold. The patient is encouraged to focus on any sensation they feel in their rectum even if it is not the sensation they were expecting, and to squeeze in response to it. They are encouraged to watch for these sensations when they are at home (between training sessions) and to always squeeze when they think they feel something, even if they are not sure. They are told that it does not hurt to squeeze extra times if there is a chance this could prevent an accidental leakage.

Urge resistance training—Patients who have accidents that are preceded by a strong, uncontrollable urge to defecate are desensitized to the sensations of rectal balloon inflation by distending the rectal balloon in a step-wise fashion with progressively larger volumes of air until a strong urge is experienced. Once this strong urge threshold is identified, some air is removed from the balloon and the patient is taught to relax using a deep breathing technique. They are encouraged to use relaxation to counteract the urge sensation while the balloon is gradually inflated again. This process is repeated several times during the training session. The goal is to teach the patient how to use relaxation as a coping mechanism to enable them to tolerate larger volumes of balloon inflation. For home practice, they are taught to use relaxation to counteract urge sensations at home and to 'Walk; don't run' to the toilet when they feel an urge.

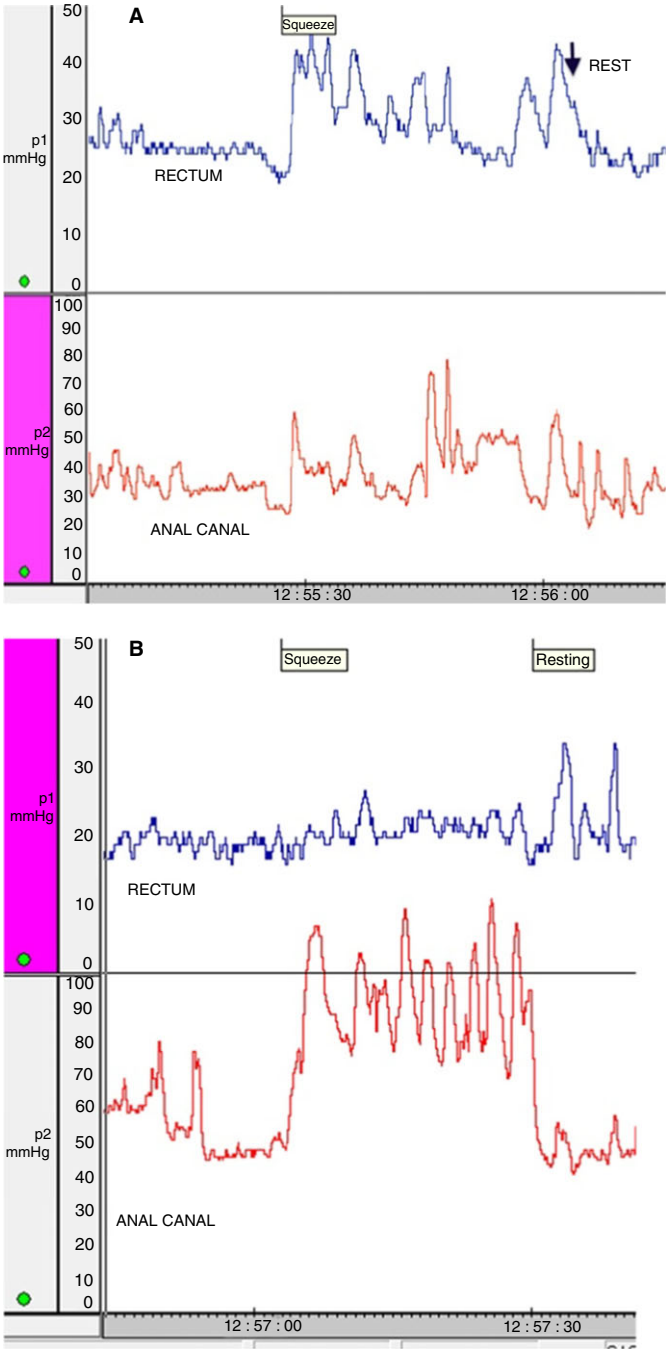

Figure 2 (A) The rectal and anal pressure changes during a squeeze maneuver in a patient with fecal incontinence before biofeedback therapy. The anal resting pressure is weak and when the patient attempts to squeeze, there is a weak anal squeeze response with an abnormal and incordinated increase in the intraabdominal pressure as shown by a rise in intrarectal pressure. (B) The anorectal pressure changes in the same patient after four sessions of biofeedback therapy for fecal incontinence. The patient now demonstrates a coordinated squeeze response with a significant and sustained increase in the anal sphincter pressure, and without any rise in intrarectal pressure.

Duration and frequency of training: Typically, treatment sessions are performed biweekly,[32,35] although different intervals may be used. The number of sessions may be customized for each patient but usually six sessions are performed. Each session takes approximately 1 h.

Devices and techniques for biofeedback: Commonly a manometry system (pressure sensors) or

EMG probe is used,[32,33,35,36] and rarely an anal ultrasound probe[34] or a home training device has been used.[33]

Efficacy of biofeedback therapy and RCTs

Randomized controlled trials of biofeedback for FI have yielded inconsistent results (Table 3).[30–34,37–39] Two earlier studies[33,34] showed no benefit for biofeedback compared to pelvic floor exercises taught by digital rectal exam, while a third study[32] showed a clear superiority for biofeedback compared to pelvic floor exercises taught verbally. In the third study, which had the strongest design, patients with severe FI (at least weekly solid or liquid stool accidents) first underwent a 1-month screening period on

Table 3 Selected randomized controlled trials of biofeedback therapy and/or exercises for fecal incontinence in adults

References	Subjects (F/M)	Baseline FI/ Week	Previous PFM training	Sphincter defects	Treatment	Control	Outcome
Fynes [30]	40/0	NA	NA	All included (obstetric trauma)	BFB Electrical stimulation (weekly, 12 weeks)	Vaginal manometric biofeedback	Augmented group improved symptoms more than control ($p < 0.001$)
Ilnycki [31]	17/8	At least once a week	None	Major defect excluded	Manometric biofeedback Rectal sensory training Coordination training (cross over – weekly, 4 weeks)	Sham training (cross over)	Biofeedback improved symptoms
Heymen [32]	83/25	Mean = 5.2	NA	Surgical candidate excluded	BFB PFMT sensory training (biweekly, 12 weeks)	PFMT	BFB improved symptoms more than PFMT (77% *vs* 41%, $p = 0.001$)
Norton [33]	159/12	Median = 2	Excluded	Major defect excluded	Four groups: 1. Education + advice 2. As group 1 + PFMT 3. As group 2 + manometric biofeedback 4. As group 3 + home BFB (biweekly, 6 sessions and 3 months)	See 4 treatment groups	~54% improved in all groups NSD in symptoms and QOL between groups
Solomon [34]	107/13	'Mild to Moderate'	NA	All excluded	Three groups: 1. PFMT 2. PFMT + anal ultrasound biofeedback 3. PFMT + manometric biofeedback (monthly, 5 sessions)	See groups	NSD in symptoms and QOL and manometry changes between groups
Heymen [37]	60/0	NA	All subjects	All included	BFB (weekly, 12 weeks)	BFB + electrical stimulation	NSD between groups
Naimy [38]	49/0	NA	NA	Major defect excluded	BFB Home exercises	Electrical stimulation	Both groups improved NSD in symptoms and QOL between groups
Schwandner [39]	138/20	NA	NA	All included	Electrical stimulation combined with EMG biofeedback twice daily at least 3 months	EMG Biofeedback twice at home for at least 3 months	Combined Tx produced greater reduction in Cleveland Clinic FI Score (8 *vs* 5 Points) and more patients achieved continence (50% *vs* 26%)

BFB, Biofeedback training using electromyography probe; VAS, Visual analog scale; NSD, Not significantly different; QOL, Quality of life; PFMT, Pelvic floor muscle training; NA, Not available.

conservative management, and patients who achieved adequate relief were excluded from further participation.[32] The remaining 108 patients underwent biofeedback training by an experienced biofeedback therapist during six biweekly sessions and were reassessed at 3 and 12 months follow-up. In the intent to treat analysis, 76% of biofeedback patients *vs* 41% of pelvic floor exercise patients improved at 3 months follow-up ($p < 0.001$) and patients using biofeedback had greater reductions in Fecal Incontinence Severity Index scores. Results were well maintained at 12 months in this and in an independent, uncontrolled study.[36] Anal sphincter exercises (pelvic floor muscle training) and biofeedback therapy have been used alone and in combination for the treatment of FI. Anal sphincter exercises are performed to strengthen the puborectalis and EAS muscles.[32,33,35,36] A single-center, randomized controlled study indicated that a regimen of pelvic floor exercises with biofeedback was nearly twice as effective as pelvic floor exercises alone, with 44% *vs* 21% of patients achieving complete continence at 3 months, respectively ($p = 0.008$).[35] In a more recent randomized study comparing two different pelvic floor exercise regimens, both with biofeedback, 59 of the 69 patients (86%) had improved continence with 20% fully continent, with no statistically significant differences between exercise regimens.[40] A 2012 systematic review of randomized or quasi-RCTs of patients performing anal sphincter exercises and/or receiving biofeedback and/or surface electrical stimulation of the anal sphincter concluded that the addition of biofeedback or electrical stimulation was superior to exercise alone in patients who had previously failed to respond to other conservative treatments, but overall there was insufficient evidence for biofeedback therapy or one method of therapy.[35]

In patients with reduced rectal sensation, there is objective evidence that biofeedback therapy can improve rectal sensation[29,36,41] and shorten the latency between rectal distention and contraction of the external anal sphincter (EAS).[41] While anal resting and squeeze pressure increased after some studies of biofeedback therapy, effects were relatively small.[35] The American College of Gastroenterology[1] and the Rome Foundation[7] recommends biofeedback for the treatment of FI.

Strengths and confounding issues

It is important to recognize some differences in study methodology among the key RCTs of biofeedback therapy that are summarized in Table 3. One study[32] systematically screened patients for 1 month and excluded those who achieved adequate relief with conservative management, and required that patients have at least moderately severe FI (two or more episodes of FI per week) prior to treatment. However, others[33,34] included patients with mild FI and did not exclude those who could benefit from conservative treatment alone. Two studies[31,37] were underpowered, and one[31] used a cross-over design but did not demonstrate return to baseline following the first intervention. Thus, further research is needed to standardize the treatment protocols and the training of biofeedback therapists. Treatment success is best defined by an improvement in bowel function such as 50% reduction in episodes of FI, but this measure has not been used in clinical trials.

Alternative/comparative approaches Pelvic floor exercises *alone* are nearly always recommended to patients with FI, but there is little consensus on how they should be taught. There are no known RCTs.[35] In some recent studies, pelvic floor exercises were taught by a health care provider during a digital rectal examination, and reductions in FI from baseline were comparable to those achieved with biofeedback training using electronic devices.[35] Electrical stimulation of the anal mucosa is not effective when used as the sole treatment for FI.[38] However, mucosal electrical stimulation may augment the effects of biofeedback[39] and merits further RCT.

BIOFEEDBACK THERAPY FOR LAS AND SRUS

Introduction

Levator ani syndrome is characterized by chronic or recurrent anorectal pain or aching lasting at least 20 min, without any structural or systemic disease.[7] Its exact prevalence is unknown. It is part of a spectrum of painful anorectal disorders. Levator ani syndrome is associated with tenderness of the levator ani muscle during digital rectal examination,[7] and increased anal canal resting pressures. In a recent study, 85% of patients with LAS showed DD, i.e., paradoxical contraction or failure to relax the pelvic floor muscles when straining to defecate plus inability to evacuate a water-filled rectal balloon.[42]

Solitary Rectal Ulcer Syndrome, is characterized by single or multiple ulcers in the rectum with specific histological inflammatory changes, and is associated with symptoms of excessive straining, chronic or recurring anal or rectal discomfort, use of digital

maneuvers to defecate, and frequent blood and mucus discharge.[43,44] Manometric studies have revealed dyssynergia in up to two-thirds of patients with SRUS,[44,45] and this may develop secondary to painful defecation. It has been suggested that excessive straining over years may lead to rectal mucosal intussusception; repeated trauma of the prolapsing rectal mucosa together with dyssynergia may lead to a stretch injury or ischemic ulceration.[44,45]

Indications

- Levator ani syndrome: (i) Patients unresponsive to standard therapies including anti-spasmodics and muscle relaxants. (ii) Absence of structural or inflammatory causes of chronic anorectal pain and pelvic pain. (iii) Demonstrable tenderness of levator ani muscle on digital rectal exam.
- Solitary rectal ulcer syndrome: (i) Endoscopically and histologically proven SRUS. (ii) SRUS unresponsive to behavioral measures including avoiding excessive straining, laxatives, topical therapies such as sucralfate or 5-ASA.

Study performance and technical aspects

Studies of biofeedback therapy for these disorders have used methods, techniques and protocols similar to those described under the section of biofeedback therapy for DD.[11–14,43,44,46]

Efficacy of biofeedback therapy and RCTs

Reports of biofeedback treatment for chronic functional anorectal pain have shown inconsistent results, and most of these were small and uncontrolled.[46] However, a recent RCT of 157 well-characterized patients with LAS compared three treatments: biofeedback to teach pelvic floor muscle relaxation, electrogalvanic stimulation (EGS) to relax the pelvic floor, and digital massage of the levator muscles.[42] The primary outcome measure was the subjects' report of adequate pain relief. Key to the interpretation of the study was an *a priori* decision to test for tenderness when traction was applied to the levator ani muscles during digital rectal examination, and patients were stratified into the three treatment arms based on the presence or absence of tenderness. Among patients with tenderness on physical examination, adequate relief was reported by 87% with biofeedback, 45% with EGS, and 22% with digital massage. However, none of these three treatments were effective in patients who did not report tenderness on physical examination.[42] The mixed results reported in previous biofeedback studies most likely were a consequence of failure to stratify patients based on the presence or absence of levator ani tenderness.

Biofeedback therapy has also been used to treat SRUS in open, short-term, small-sized (less than 20 patients) studies.[43,44] Inclusion criteria, physiological investigations, and outcome parameters were variable. Biofeedback therapy was associated with symptom improvement in at least two-thirds of patients with some histological improvement.[44] Most notably, the highest successful outcome was reported when SRUS was associated with DD.[44]

Strengths and confounding issues

The biofeedback training protocol that was developed originally to treat DD also appears to be effective for the treatment of LAS in one large RCT, and possibly useful in SRUS based on uncontrolled trials. These observations suggest that DD may be a key pathophysiological dysfunction in both LAS and SRUS, although it is unknown why tense striated pelvic floor muscles cause pain in some patients, bleeding and ulceration with mucosal intussusception in others and only difficulty with defecation in the majority. Further characterization of the underlying pathophysiology of these disorders may shed more insights, and importantly confirmatory RCTs are needed for LAS and SRUS.

BIOFEEDBACK THERAPY FOR PEDIATRIC FUNCTIONAL CONSTIPATION

Introduction

Functional constipation (FC) and overflow FI are commonly encountered in the pediatric population, with a worldwide prevalence of 3%.[47] In most children, the purposeful or subconscious withholding of stool after having experienced the passage of a hard, painful, or frightening bowel movement leads to FC. The retentive child learns to contract the pelvic floor, the anal sphincter, and the gluteal muscles in response to the urge to defecate so as to avoid defecation.[3] The withholding behavior creates a vicious cycle of progressive accumulation of feces and hardening of stool, which when untreated causes stretching of the rectal wall and development of a megarectum. This in turn results in overflow FI, loss of rectal sensation, and eventually loss of normal urge to defecate.[3]

Anorectal manometry can demonstrate abnormal defecation dynamics in 50% of children with FC,[48,49]

and rectal barostat studies show impaired rectal sensation and higher rectal compliance.[50] Conventional treatment consists of educating the parent and the child regarding correct defecation dynamics and behavioral interventions, such as toilet training, laxatives, and/or enemas.[51] Despite these interventions, only half of all children with constipation, followed up for 6–12 months evacuate regular stools without laxatives.[52] Thus, biofeedback therapy may be an option in children with chronic defecation disorders.

Indication

Functional constipation with DD, which is unresponsive to conventional treatment.

Study performance characteristics

Technical aspects The objective is to achieve normal evacuation using visual and verbal biofeedback techniques and correcting the inadequate coordination of pelvic floor muscles and anal sphincter and by improving the awareness for stooling (urge to defecate). Biofeedback teaches children how to relax the EAS with visual reinforcement (anorectal manometry and electromyography) in response to abdominal straining. The equipment used and principles of training including the duration and frequency of therapy sessions are similar to those described above for adult patients undergoing biofeedback therapy for DD. After reliable and consistent relaxation of EAS is accomplished, children are instructed to do the same without visual feedback.

Efficacy of biofeedback therapy and RCTs

Several RCTs have been reported in children and have also been systematically assessed in a recent ESPGHAN/NASPGHAN guideline.[51] There are significant methodological differences among the published studies including recruitment criteria, end points, and outcome measures. These are summarized in Table 4.[48,49,53–57] One single study included children with functional non-retentive fecal incontinence (FNRFI) and one study evaluated children with FI due to a myelomeningocele, and both were excluded from this analysis.

Seven trials compared biofeedback to conventional therapy, including education, toilet training, and laxatives[58] Two studies only used surface EMG to provide biofeedback whereas others used anorectal manometry and EMG. Sample sizes ranged from 21 to 192 subjects, and only children who were older than 5 years were enrolled. Children should be at least 5 year old before starting biofeedback therapy,[48,49,55–57] as attention span and ability to focus and not being intimidated by laboratory environment are important factors that contribute to treatment success. Three studies were conducted in outpatient clinics in USA, two in Europe, one in South America, and one in Australia (Table 4). Four studies included children with chronic constipation and FI and the other three studies enrolled children with constipation associated with FI and pelvic floor dyssynergia. Follow-up varied from 6 to 18 months. As allocation concealment was unclear in five studies and double blinding is not possible due to the nature of performing trials with behavioral interventions, the standard definitions for a risk of bias used in conventional drug studies cannot be directly applied to these studies. One study had a high risk of incomplete outcome data.[51,52] Number of biofeedback sessions depended on how soon the child learned to relax the EAS. Different outcome measures were used across all studies, such as defecation frequency, episodes of FI, use of laxatives, and results of anorectal manometry, but the number of children improved or not cured was used as an outcome measure in all trials.[51,52]

A RCT by Loening-Baucke[48] compared biofeedback with conventional therapy (education, toilet training, and laxatives) in 129 children (5–18 years of age) in USA, in an outpatient setting, with a follow-up period of 4 years. Whether the treatment allocation was concealed was unclear, and because blinding is not possible, meta-analysis adjudged a possible risk of bias. Patients were rated as recovered if they had $\geq$3 bowel movements per week and $\leq$2 FI episodes per month while off laxatives for at least 1 month. Results showed that biofeedback did not improve long-term recovery rates when compared to conventional therapy alone.

Another RCT by Van der Plas *et al.*[49] evaluated the additional effect of biofeedback compared to conventional treatment (education, toilet training, and laxatives) in 192 children with chronic constipation (5–16 years of age) in the Netherlands, in an outpatient tertiary care setting, with a follow-up period of 1 year. Although treatment allocation was concealed, blinding was not possible. Treatment was considered successful if the patients achieved three or more bowel movements per week and had less than two episodes of FI per month while not receiving laxatives for 4 weeks. The results showed that additional biofeedback compared to conventional therapy did not result in higher success rates in chronically constipated children. Furthermore, achievement of normal defecation dynamics was not associated with success.

Table 4 Summary of randomized controlled trials of biofeedback therapy for children with constipation

	Loening-Baucke[48]	Van der Plas *et al.*[49]	Wald *et al.*[53]	Davila *et al.*[54]	Nolan *et al.*[55]	Borowitz *et al.*[56]	Sunic-Omejc *et al.*[57]
Trial design	Conventional treatment (use of laxatives, increase in dietary fiber and scheduled toileting) *vs* Conventional treatment + biofeedback	Conventional treatment (toilet training, dietary advice, use of laxatives) *vs* Conventional treatment + biofeedback	Conventional treatment (toilet training, use of mineral oil as laxative) *vs* Conventional treatment + biofeedback	Conventional treatment (enemas for 3 days + dietary advice + use of laxatives + toilet training) *vs* Conventional treatment + biofeedback	Conventional treatment (laxatives + behavioral modification) *vs* EMG biofeedback training	Intensive medical care including laxatives (IMC) *vs* IMC + enhanced toilet training (EHT) *vs* IMC + ETT + EMG biofeedback	Conventional treatment (toilet training, dietary advice, use of laxatives) *vs* conventional treatment plus biofeedback
Subjects and Randomization and Intervention (s)	41 (31 boys, 5–16 years) 19 conventional treatment 22 biofeedback Sealed envelopes	192 (126 boys, 5–16 years) 94 patients conventional treatment 98 biofeedback Allocation concealment unclear	50 (40 boys, 6–15 years) 26 conventional treatment 24 biofeedback Allocation concealment unclear	21 (14 boys, average age 9 years) 10 patients conventional 11 patients biofeedback block randomization, allocation concealment unclear	29 (24 boys, 4–14 years) 14 conventional treatment 15 biofeedback Stratified blocked schedule by a person not connected with the study. Opaque numbered sealed envelopes stored sequentially	87 (72 boys, 5–13 years) 26 conventional treatment 24 biofeedback Block randomization, Outcome data collected by means of a computerized voice mail data collection system	49 (27 boys, 5–15 years) 24 conventional treatment 25 biofeedback Allocation concealment unclear
Duration and number of biofeedback sessions	Up to six sessions of therapy 7 ± 2 days apart. performed by physician investigator	Up to six sessions of therapy 7 ± 2 days apart. 30 min training sessions performed by physician investigator	Four sessions at week 0, 2, 4 and 8 weeks 30 min training sessions performed by physician investigator	Eight sessions during a 4 week period performed by physician investigator	Up to four sessions of biofeedback training were conducted at weekly intervals	Number of biofeedback sessions unclear 30 min training sessions performed by psychologist investigator	Duration of the study was 12 weeks. Both study groups were followed weekly at the outpatient clinic. Number of biofeedback sessions is unclear. Duration of the session is not mentioned neither the person who gave the instructions
Primary outcomes	Patients were considered to have recovered from chronic constipation and FI if they met the following criteria: >3 bowel movements per week and ≤2 FI episodes per month while not receiving laxatives for 4 weeks	Patients were considered to have recovered from chronic constipation and FI if they met the following criteria: >3 bowel movements per week and ≤2 FI episodes per month while not receiving laxatives for 4 weeks	Number of children cured or improved, number of bowel movements, FI episodes, anorectal manometric assessment	Patients were considered to have recovered from chronic constipation and FI if they met the following criteria: >3 bowel movements per week and ≤2 FI episodes per month	Full remission was defined as no medication and no soiling for at least 4 weeks	No episodes of fecal incontinence during the 2-week assessment, 12 months after initiation of therapy	Patients were considered to have recovered from chronic constipation and FI if they met the following criteria: >3 bowel movements per week and ≤2 FI episodes per month without the use of a laxative

Table 4 Continued

	Loening-Baucke[48]	Van der Plas *et al.*[49]	Wald *et al.*[53]	Davila *et al.*[54]	Nolan *et al.*[55]	Borowitz *et al.*[56]	Sunic-Omejc *et al.*[57]
Success	Dyssynergia corrected at 7 months in 77% with biofeedback *vs* 13% in conventional group. At 7 and 12 months 5% and 16% in the conventional treatment recovered and 55% and 50% in the biofeedback-treated patients ($p < 0.01$ and $p < 0.05$)	Dyssynergia corrected at 6 weeks increased in the conventional group from 41% to 52% (not significant) and in the biofeedback group from 38% to 86% ($p = 0.001$). At 1 year, 59% in the conventional group recovered and 50% in biofeedback group ($p = 0.24$)	55% success rates were reported in both groups at 3 months. No significant differences were found between the groups at 6 and 12 months; 62% *vs* 50% and 60% *vs* 50% respectively	Dyssynergia corrected at 4 weeks increased from 79.6 ± 10 to 97.9% ± 6% ($p < 0.001$) in the biofeedback group *vs* 84 ± 7 to 93% ± 6% (ns) in the conventional group. At 4 weeks 90.8% recovered in the biofeedback. While it is unclear how many in the conventional group recovered	Dyssynergia corrected in all but one child. At 6 months' follow-up, laxative free remission was sustained in 2/14 patients in the biofeedback group and in 2/15 controls (95% confidence interval (CI) difference, −24% to 26%)	At 12 months, the cure rates for each group were: IMC – 36%, ETT – 48%, and BF – 39%, respectively (ns)	Correction of dyssynergia at 6 weeks increased in the conventional group from 50% to 58% (ns) and in the biofeedback group from 56% to 92% ($p < 0.001$). At 12 weeks, 63% in the conventional group and 84% in biofeedback group recovered ($p < 0.05$)
Conclusions	Biofeedback treatment is complementary to a good conventional therapeutic regimen in patients with constipation and abnormal defecation dynamics	Additional biofeedback training compared to conventional therapy did not result in higher success rates in chronically constipated children. Furthermore, achievement of normal defecation dynamics was not associated with success	Biofeedback was not superior to conventional treatment	Biofeedback seems useful in the treatment of the child with constipation and FI	No evidence of a lasting benefit in clinical outcome for biofeedback training in children who had treatment resistant or treatment dependent FI associated with abnormal defecation dynamics	Enhanced toilet training is more effective in treating childhood FI than either intensive medical therapy or anal sphincter biofeedback therapy	No clear evidence for long-term benefit of biofeedback therapy, despite recovery of abnormal anorectal dynamics and manometric parameters

After pooling the data and excluding the trials that either enrolled children with FNRFI or children with FI due to organic causes, there were no significant differences between biofeedback plus conventional treatment when compared to conventional treatment alone after 12 months for the number of children designated as cured or improved (OR: 1.13; 95% CI: 0.77–1.66) and 18 months (OR: 1.42; 95% CI: 0.79–2.53).

Strengths and confounding issues

In these different RCTs, neither adverse effects nor cost-effectiveness analysis were reported, although risk is very small. Studies in constipated children have shown that abnormal defecation dynamics can begin at any age in childhood.[58] Thus, it is possible that in the majority of these patients, withholding behavior due to painful defecation could be avoided by early and adequate therapeutic intervention with laxatives and reassurance alone.[59] Because many children are diagnosed late and fail to respond to laxative therapy, alternative therapies are often sought either by caregivers or medical providers. Although several pediatric studies show that biofeedback therapy results in an improvement of defecation dynamics and other parameters like maximal defecation pressure,[49,55] it appears that the long-term treatment success does not differ between most children who have received biofeedback *vs* those who have received conventional therapy.

The results of biofeedback therapy in children are at odds with those in the adult literature. As discussed earlier in this article, several RCTs in adult patients have demonstrated that biofeedback therapy is effective in improving bowel symptoms and in correcting DD. It is unclear why biofeedback therapy in children is less successful. The absence of clinical improvement after correction of abnormal defecation dynamics, could suggest that DD plays a less crucial role in the pathophysiology of pediatric constipation or the nature of illness and its natural history is different in children. For example, children may learn to stop withholding more easily or the cognitive skills required for biofeedback to succeed might be more complex and challenging making clinical outcomes less favorable. Thus, based on published evidence, although biofeedback therapy is useful, it does not provide additional benefit over conventional treatment of constipation in most children, either with or without FI.[51]

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Dr Rao reports no conflict of interest in the context of this report but has served as a consultant for Forest Laboratories, Ironwood Pharmaceuticals, Takeda Pharmaceuticals, Salix Pharmaceuticals and Given Imaging. Dr Benninga reports no conflict of interest in the context of this report, but he serves as a consultant for Shire, Sucampo and Johnson and Johnson Pharmaceuticals. Dr Bharucha served as a consultant for Uroplasty Inc, Gicare Pharma, and Furiex Pharmaceuticals. Dr Chiarioni served as a speaker for Shire Italia S.P.A. Dr Di Lorenzo reports no conflict of in interest in the context of this report, but he is consultant for QOL, Sucampo Pharmaceuticals and Ironwood Pharmaceuticals. Dr Whitehead received a grant from Salix Pharmaceuticals, and he is a member of the board of the Rome Foundation.

AUTHOR CONTRIBUTION

All authors were equally involved in the design, preparation of the manuscript, critical appraisal, and final approval. Specifically, SR and AEB critically reviewed and summarized the literature on biofeedback therapy for dyssynergic defecation. WEW and GC reviewed and summarized the literature on fecal incontinence; MAB and CDL on pediatric functional constipation and fecal incontinence and GC and SSCR on levator ani syndrome and solitary rectal ulcer syndrome.

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