Peer reviewed article
Systematic Review: The management of constipation using physical therapies including biofeedback

Abstract

Constipation can be a symptom of many diseases and disorders. Functional constipation refers to constipation in the absence of other easily identified diseases or disorders that have a primary or secondary effect on the colon, rectum and anal sphincter. Biofeedback has been suggested as an effective treatment for functional constipation. A systematic review of randomised controlled trials (RCTs) of biofeedback for functional constipation identified five trials. All but one of those trials were of low methodological quality and, although the trials in general supported biofeedback treatment for functional constipation, the level of evidence for this recommendation was Grade C. Further robust research is needed to justify investment in, and use of, biofeedback to treat functional constipation.

Key words: systematic review, constipation, physiotherapy, biofeedback.

Introduction

Constipation is a subjective term used to describe difficulty in defecation involving any or all symptoms such as infrequent passage of stools, passage of small hard stools or straining at defecation. An early definition of constipation stated it to be “straining at stool ≥25% of the time or passing two or fewer stools per week.” Constipation can be a symptom of many diseases and disorders, both physical and psychological, and may also have an underlying congenital or pharmacological cause. Colonic causes of constipation are either structurally or functionally based.

Functional constipation is the term used to describe constipation when none of these factors are present. A recent research definition of functional constipation was provided by the Rome diagnostic criteria; this lists the following five symptoms that must be present for at least 12 weeks (although not necessarily consecutively):

- Bowel frequency less than three times per week.
- A need to strain more than 25% of the time.
- Lumpy or hard stool for more than 25% of bowel movements.
- Sensation of incomplete emptying or blockage for more than 25% of bowel movements.
- A need for manual manoeuvres to facilitate for more than 25% of bowel movements.

Further, two types of functional constipation have been identified – slow transit constipation and obstructive defecation.

Slow transit constipation is diagnosed when there is a delayed transit of faeces through the colon and rectum. While muscular dysfunction is a recognised cause of constipation, sensory dysfunction, for example rectal hyposensitivity, is less well recognised as a contributing factor. Rectal hyposensitivity is an elevation of rectal sensory thresholds beyond normal range and is commonly found in patients with chronic constipation. Slow transit constipation occurs mainly in women and older adults. It may present concurrently with obstructed defecation.

One of the conditions that can cause obstructed defecation is pelvic floor muscle (PFM) dyssynergia; synonymous terms are anismus, paradoxical puborectalis contraction, and pelvic outlet obstruction (OO). The common link between these descriptors is a failure of the puborectalis muscle and anal sphincter mechanism to voluntarily relax in response to rectal distension or contraction. Structural disorders of the pelvic floor such as descending perineum, with or without prolapse, anterior rectal wall prolapse, intussusception and enteric prolapses are also common potential causes. Obstructed defecation is significantly more common in women than men.

In 2000, Chiarelli estimated the prevalence of constipation in younger community dwelling women aged 18-22 years to be 14.1%, while that in mid-aged women 45-49 years, and older women aged 70-74 years was estimated to be 26.6% and 27.7% respectively.

Estimates of the prevalence of subtypes of functional constipation suggest an overall constipation prevalence of 14.7% – 4.6% as functional OO, 4.6% as ‘other’ functional, 2.1% as irritable bowel syndrome (IBS) and 3.4% reported mixed symptoms of IBS and OO. Examination of gender specific subtypes revealed a higher prevalence of OO in women than men. The reasons for a higher prevalence of functional constipation in women compared to men are not known; however, there are hormonal influences, in particular progesterone, and PFM and nerve damage related to pregnancy and childbirth.
Repeted straining at the stool is thought to exacerbate perineal damage, resulting in weakness of the pelvic floor, perineal descent during straining, and secondary anatomic changes that result in anorectal dysfunction and further difficulty in defecation. Normal anorectal function depends in part on the complex synergy between sensory and motor function. Any disturbance to this sensory or motor control can lead to faecal incontinence or constipation. These factors further increase the risk of subsequent faecal incontinence.

Physical therapies for functional constipation aim to target muscular and sensory function of the rectum, anus and pelvic floor. Reported treatments for functional constipation include electrotherapy, verbal instruction training, biofeedback interventions aimed at lowering the threshold of rectal sensation, biofeedback interventions aimed at training for optimal coordination of the PFM during defecation (including such techniques as rectal balloon expulsion), and retraining of defeation techniques.

**Biofeedback**

Biofeedback is a process by which a person learns to reliably influence body responses, including those not usually under voluntary control such as the internal anal sphincter. Biofeedback can be used to teach patients to sustain, strengthen, direct or eliminate a body action or reaction. The training phase of biofeedback involves sensory input to an individual that is exaggerated and alternative to the usual method of sensation of a normal body function. The ultimate clinical goal of biofeedback is to influence a body response independent of this stimulus.

Recorded electromyographic (EMG) activity within specific muscles, fed back to an individual as an auditory or visual stimulus, is a particular example of this. Other techniques of biofeedback include pressure biofeedback (perineometry), sensory biofeedback (rectal balloons, cones), PFM contraction indicator devices and, more recently, real time ultrasound.

**Biofeedback as a management tool for constipation**

Various types of biofeedback programmes are used to manage constipation. In retraining patients with disordered defecation due to muscular dyssynergia, the aim is to increase abdominal pressure without increasing the anal sphincter pressure. Biofeedback is also used to alter rectal sensitivity.

**Muscle retraining for PFM synergy and strength**

Motor learning is a complicated process of repeated practice in order to acquire new (relatively permanent) motor skills. Feedback during learning is essential if the motor task is to be reproduced smoothly and effortlessly. While repeated, specific practice of new motor skills is of prime importance during skill acquisition, feedback is considered the next most important factor. This feedback can be internal (intrinsic) or external (augmented).

**Biofeedback to improve rectal hyposensitivity**

The aim with this intervention is to increase the patient's awareness of smaller and smaller rectal volumes. Normally, the first sensation of awareness is reported when approximately 15–20cm³ of water is inserted into a rectal balloon and the first sensation of urgency is reported in the presence of a rectal balloon holding about 100cm³ of water. In hyposensitivity retraining, a rectal balloon is filled to slightly above the patient's first sense of awareness. The patient is told the volume within the balloon and asked to concentrate on the feeling. Incrementally, about 5-10cm³ less water is instilled in sequential balloon inflation; the patient is informed of the balloon volume and again asked to concentrate on the sensations at differing volumes. At each smaller volume, the patient is allowed time to concentrate on their sensory awareness of the balloon presence, with rest periods between each inflation aiming to improving rectal sensation at smaller volumes and thus the call to stool.

**Aim**

This paper aims to evaluate the efficacy of biofeedback in the management of functional constipation.

**Method**

A systematic review of the literature was done to locate evidence about the efficacy of biofeedback. To do this, the electronic databases Medline, CINAHL, Embase and the Cochrane Database of systematic reviews were searched using the keywords 'constipation', 'anismus', obstructed/obstructive defaecation', and 'conservative management', 'biofeedback' 'defaecation' and/or 'randomised controlled trials (RCTs'). Only papers available in English were considered. All references that appeared to be studies or reviews of biofeedback in adults were retrieved in hard copy and the reference list of each paper was searched for additional references which in turn were obtained. We aimed to identify systematic reviews and RCTs, although the main focus was to identify RCTs. Two reviewers independently scrutinised identified papers to decide if the paper was eligible to be included in the systematic review.

The quality of the RCTs was evaluated using the PEDro Scale (Figure 1). This scale has been show to be reliable in assessing the quality of RCTs and was developed to evaluate physical therapy interventions. The PEDro Scale provides an effective framework for the evaluation of important study design issues also deemed necessary by the Rome II group. This includes the use of a sample size conferring enough power to show a true treatment effect, a clear definition of exclusion criteria, blind randomisation of patients into groups, a ‘no treatment’ control group, valid and reliable outcome measures, blinded outcome assessment, and careful evaluation of study drop-outs. We feel that studies of functional constipation have been conducted in a rigorous way because a trial of sham intervention aimed at relieving symptoms of obstructed defeation estimates the placebo effect to be higher than 50%.
Figure 1. PEDro scale items for determining methodological quality of an RCT.²⁰

**PEDro scale items**

Each satisfied item (except item 1) contributed one point to the total PEDro scale (range 0-10 points). Total scores are out of 10, with a cut off point at 6 for inclusion in a systematic review.²⁰

- Eligibility criteria were specified.
- Subjects were randomly allocated to groups (in a crossover study subjects were randomly allocated an order in which treatments were received).
- Allocation was concealed.
- The groups were similar at baseline regarding the most important prognostic indicators.
- There was blinding of all subjects.
- There was blinding of all therapists who administered the therapy.
- There was blinding of all assessors who measured at least key outcome.
- Measurements of at least one key outcome were obtained from more than 85% of the subjects initially randomised to groups.
- All subjects for whom outcome measurements were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analysed by ‘intention to treat’.
- The results of between-group statistical comparisons were reported for at least one outcome.
- The study provided both point measures and measurements of variability for at least one key outcome.

The level of evidence found to support biofeedback was rated using the International Consultation on Incontinence (ICI) recommendations²¹:

- **Level 1.** Usually involves one well designed RCT.
- **Level 2.** Includes at least one good quality prospective cohort study.
- **Level 3.** Includes a good quality retrospective case control study.
- **Level 4.** Includes a good quality case series.

These levels of evidence have been used to grade the recommendations emerging from the evidence:

- **Grade A.** Consistent Level 1 evidence.
- **Grade B.** Consistent Level 2 or Level 3 studies.
- **Grade C.** Based on Level 4 studies or majority evidence for Level 2/3 studies.
- **Grade D.** No recommendation possible.

### Results

The databases searched produced 256 unique records. After excluding papers not published in English, those related to pharmaceutical or dietary management, and those studies in children or special clinical subgroups, the abstracts of 167 papers underwent closer scrutiny. Of those, 53 papers appeared to be relevant studies examining the efficacy of conservative physical therapy management of constipation or reviews of this treatment. The reference lists of those 53 papers were searched for additional references; this resulted in the retrieval of nine additional papers, bringing the number of papers that were scrutinised for eligibility to enter the systematic review to 62. While the titles of these papers suggested relevance to the review, on detailed inspection only five papers were of RCTs in adult study subjects. Exclusion criteria for papers are included in Table 1.

### Systematic reviews

The systematic reviews had several flaws. Overall, three of the four reviews made no attempt to validate the quality of their included studies. Validation of included studies was considered in the review undertaken by the American College of Gastroenterology Chronic Constipation Task Force; this review included only studies undertaken in North America.²⁴ The reviewers rigorously explored the evidence available in relation to the epidemiology, diagnosis and therapy of constipation, including bulking agents, stool softeners, a wide range of laxatives and complementary therapies. The task force members concluded that no recommendations could be made about the efficacy or safety of the various

### Table 1. Rationale for excluding papers from this review.

<table>
<thead>
<tr>
<th>Paper topics</th>
<th>No. papers</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Non-randomised outcome studies with various biofeedback methods</td>
<td>20</td>
</tr>
<tr>
<td>- Management or assessment overviews</td>
<td>9</td>
</tr>
<tr>
<td>- Physiological studies</td>
<td>7</td>
</tr>
<tr>
<td>- Randomised uncontrolled group outcome studies</td>
<td>5</td>
</tr>
<tr>
<td>- Systematic reviews</td>
<td>4</td>
</tr>
<tr>
<td>- Treatment method description</td>
<td>3</td>
</tr>
<tr>
<td>- Measures studies</td>
<td>3</td>
</tr>
<tr>
<td>- Retrospective chart analyses</td>
<td>2</td>
</tr>
<tr>
<td>- Letters</td>
<td>2</td>
</tr>
<tr>
<td>- Special client groups</td>
<td>1</td>
</tr>
<tr>
<td>- Prevalence study</td>
<td>1</td>
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<tr>
<td>- Study of placebo effect</td>
<td>1</td>
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<tr>
<td>- Drug or diet study</td>
<td>1</td>
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<tr>
<td>- Case study</td>
<td>1</td>
</tr>
<tr>
<td>- Quasi case control study</td>
<td>1</td>
</tr>
<tr>
<td>- Galvanic stimulation</td>
<td>1</td>
</tr>
</tbody>
</table>
biofeedback management strategies due to the absence of data supported by high quality RCTs.\textsuperscript{24}

The early review by Enck\textsuperscript{21} of the management of constipation by biofeedback included seven studies but set no \textit{a priori} inclusion criteria. Thus the review compared studies with sample sizes as low as n=9, included all age groups, and compared various biofeedback techniques. Enck observed that all studies within his review used a ‘pre/post’ ‘before and after’ approach and commented that, while this approach might detect individual data variance, it is not adequate to truly determine the efficacy of a treatment for chronic constipation\textsuperscript{21}.

Heymen \textit{et al.}\textsuperscript{26} undertook an extensive review of the literature related to biofeedback management of constipation separating the 27 adult studies contained in the review from the 12 studies in children. This review attempted to differentiate between the effects of various types of biofeedback interventions. Their conclusion did not differ from the previous reviews – the RCTs were generally uncontrolled and many studies lacked adequate power. Again, the conclusion was that the lack of scientific rigour in the studies limited the conclusions that could be drawn from the study results.

Palsson \textit{et al.}\textsuperscript{27} included 38 studies within their review of biofeedback trials for functional constipation or PFM dyssynergia, six of which were considered to be RCTs but only one of which was undertaken using an adult sample. While the authors considered the study to be an RCT, on close examination of the single adult study within the review, the control group in fact, received sessions of balloon defecation training, thus invalidating the reported study outcomes.

Table 2. Determining methodological quality of the RCTs using the PEDro scale\textsuperscript{20}.

<table>
<thead>
<tr>
<th></th>
<th>Bleijenbergs &amp; Kuijpers\textsuperscript{22}</th>
<th>Glia \textit{et al.}\textsuperscript{28}</th>
<th>Koutsomanis \textit{et al.}\textsuperscript{13}</th>
<th>Heymen \textit{et al.}\textsuperscript{29}</th>
<th>Chiarioni \textit{et al.}\textsuperscript{30}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility criteria specified: not counted in final score</td>
<td>•</td>
<td>–</td>
<td>–</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Subjects randomly allocated</td>
<td>•</td>
<td>•</td>
<td>•</td>
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<td>•</td>
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<tr>
<td>Allocation concealed</td>
<td>–</td>
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<td>•</td>
<td>–</td>
<td>•</td>
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<tr>
<td>Groups similar at baseline</td>
<td>•</td>
<td>–</td>
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<tr>
<td>Blinding of subjects</td>
<td>–</td>
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<tr>
<td>Blinding of all treating therapists</td>
<td>–</td>
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<tr>
<td>Blinding of outcome assessors</td>
<td>–</td>
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<tr>
<td>Outcome measurements obtained &gt;85% subjects</td>
<td>•</td>
<td>–</td>
<td>•</td>
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<td>•</td>
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<tr>
<td>‘Intention to treat’ analysis</td>
<td>–</td>
<td>–</td>
<td>–</td>
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<tr>
<td>Between-group statistical comparisons</td>
<td>•</td>
<td>–</td>
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<tr>
<td>Point measures and measurements of variability</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
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<tr>
<td>Total</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

While these systematic reviews commented on the need for high quality scientific evidence, none offered alternative qualitative estimations of levels of evidence provided by the existing studies.

**RCTs**

Evaluation of the methodological quality of the RCTs found in the literature review is summarised in Table 2. The PEDro Scale\textsuperscript{20} was used to evaluate the methodological quality of the five studies determined to be RCTs and found those RCTs to be low quality trials\textsuperscript{13, 22, 28-30} (Table 3).

Using the cut-off score suggested by the PEDro Scale\textsuperscript{20}, it can be seen from the table evaluating the quality of the trials that only the study by Chiarioni\textsuperscript{30} fulfilled six criteria related to robust evaluation of treatment efficacy, in that eligibility criteria were all specified, the sample size was determined to provide power for the analysis of findings, groups were similar at baseline and allocation was concealed. However, it should be taken into consideration that study participants were a convenience sample who acted as their own controls during a 30 day run in period. During the run in period, study participants were prescribed 20g/day fibre supplement together with their choice of laxatives, enemas or suppositories. After the run in period (during which participants were considered to be receiving “standard medical care”), participants were randomised into two groups – one to receive biofeedback therapy, the other a course of laxatives.

The studies by Glia\textsuperscript{28} and Heymen\textsuperscript{29} provided no description of participant groups at baseline, while the studies by Bleijenbergs\textsuperscript{22} and Heymen\textsuperscript{29} did not mention concealing the allocation of patients to groups. No studies reported blinding of subjects, therapists or assessors, and none used any ‘intention to treat’ analysis. Only the study by Chiarioni\textsuperscript{30} used any point measures of variability across the study.

**Recommendations**

From the available evidence and using the qualitative levels of evidence suggested by ICI, it would appear that the grade of recommendation for physical therapy interventions in the
Table 3. The methodological quality of the five studies determined to be RCTs.

<table>
<thead>
<tr>
<th>Study</th>
<th>n &amp; ♀</th>
<th>Diagnosis</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| Chiarioni et al. 30    | n=109 | Rome II criteria: chronic constipation | *Group 1: Retraining of straining pattern with correct breathing* and EMG biofeedback PFM, followed by balloon expulsion training  
*Group 2: Laxatives/PEG* | A. Self-report of improvement in symptoms. Scale:  
0) Worse 1) No improve 2) Mild 3) Fair 4) Major  
Major change reported: 80% intervention / 22% control p=0.01  
B. ↑ anal canal pressure during defecation.  
17% intervention / 96% control  
C. PFM EMG during defecation  
*Authors’ conclusion*: Biofeedback better than laxatives |
| Heymen et al. 26       | n=36  | Fulfilling criteria for paradoxical puborectalis contraction (PPC)  
Chronic problem  
Using laxatives, enemas, digitation or combinations thereof (cathartics) | *Group 1: Out-patient anal sphincter EMG*  
*Group 2: As above plus balloon distension hyposensitivity testing*  
*Group 3: As group 1 plus EMG home training unit*  
*Group 4: All of the above* | A. Bowel diary.  
Significant increase in unassisted bowel movements  
Groups 1, 2, 4 p=<0.05  
B. Significant decrease use of cathartics in groups 1, 2, 3  
p=<0.05  
*Authors’ conclusion*: Neither home trainer or intrarectal balloon training added benefit |
| Gia et al. 28          | n=26  | Functional constipation and EMG determined paradoxical puborectalis contraction (PPC) during defaecation attempts | *Group 1: Out-patient anal manometric biofeedback*  
*Group 2: Surface EMG* | Bowel diary. Stool frequency significantly improved in both groups p=0.05. PPC improved both groups  
Improvement sustained at 6 months  
*Authors’ conclusion*: No difference between anal manometric or surface EMG biofeedback |
| Koutsomanis et al. 13  | n=60  | Complaints of bowel frequency >3 x weekly or excessive straining, or both | *Group 1: MCT: verbal muscular coordination training with rectal balloon*  
*Group 2: EMG biofeedback augmented coordination training plus rectal balloon coordination training. Patients began randomised Rx. If no change after 2 visits, they swapped treatments* | A: EMG during straining. Both groups improved p=<.001  
B: Self report improved over 7 consecutive days  
14/31 EMG biofeedback , 12/28 verbal feedback  
C: Gut transit – no difference  
D: Able pass balloon. No significant difference  
*Authors’ conclusion*: Verbal instruction in muscular coordination training was as effective as EMG biofeedback |
| Bleijenbergs & Kuijpers 22 | n=21  | Spastic pelvic floor on defaecography | *Group 1: EMG during defaecation*  
*Group 2: Balloon withdrawal to relax EAS plus balloon defaecation* | A: Change in EMG ↑ EAS during defaecation.  
I/V: p=0.01 Control: nil  
B: Diary checklist. I/V: p=0.01 Control: nil  
C: Constipation score change. I/V p= 0.01 Control: nil  
*Authors’ conclusion*: EMG more effective than balloon expulsion as biofeedback |
management of functional constipation is at Level C. While a number of interventions to improve constipation have been promoted, there is scant evidence related to patient acceptability of these interventions.

There is need for a scientifically robust study of the interventions mentioned in this paper that were aimed at improving constipation – PFM/anal sphincter synergistic retraining with verbal, manometric or EMG biofeedback, rectal balloon expulsion training and rectal balloon training to improve rectal hyposensitivity.

If sufferers of functional constipation are to be offered the most effective interventions, there is need for scientifically robust RCTs to determine the efficacy of the various physical interventions currently being employed. Such a study should:

- Compare interventions against a control group that receives no management intervention at all.
- Involve both male and female participants of measurably similar characteristics at baseline.
- Include enough subjects to provide the power required for sensitive data analysis within and across groups.
- Use scientifically acceptable randomisation protocols.
- Ensure patients, therapists and outcome assessors are all blinded to patient randomisation.
- Make valid, reliable measures a number of times across the time span of the study.
- Undertake an intention to treat analysis to provide at least some evidence of patient acceptability.

Until such scientifically robust evidence is available, no best practice guidelines can be provided to help clinicians make confident, well informed treatment choices for patients seeking help for functional constipation.

References