

**Review article: Pelvic Floor Dysfunction and Biofeedback in the
Pathophysiology and Treatment of Constipation**

Gillian Skardoon, Angela Khera, Anton Emmanuel, Rebecca Burgell

SUMMARY

Background

Constipation is a common symptom with a significant health economic burden. Dyssynergic defaecation secondary to pelvic floor dysfunction is an under-recognised, potentially reversible cause of chronic constipation. Biofeedback therapy to reverse this is available predominantly in specialist centres for the management of chronic constipation.

Aim

To review the evidence pertaining to the pathophysiology of constipation and the importance of identifying and diagnosing pelvic floor dysfunction in this condition. To examine the efficacy of biofeedback in the management of patients with pelvic floor dysfunction.

Methods

Relevant articles addressing the pathogenesis of pelvic floor dysfunction and the use of biofeedback in constipation were identified from a search of Pubmed, MEDLINE Ovid and the Cochrane Library. Seventeen randomised controlled trials were included.

Results

Pelvic floor dysfunction refers to the paradoxical contraction of the pelvic floor muscles, anal sphincter or the generation of inadequate intra-abdominal pressure during attempts at defaecation. Pelvic floor dysfunction is found in 13 – 74% of patient with constipation.

Biofeedback is a treatment free of side-effects which can correct physiological abnormalities and improve symptoms and quality of life. Predictors of a beneficial response to biofeedback are hard stool consistency, short duration of laxative use and the presence of specific

physiological parameters on anorectal manometry including a high anal straining pressure and prolonged balloon expulsion time.

Conclusions

Pelvic floor dyssynergia is a leading cause of chronic constipation and is potentially reversible. Biofeedback is the most successful available treatment for pelvic floor dyssynergia. Further studies of biofeedback employing standardised protocols and patient-centred outcomes are required.

Introduction

Functional bowel disorders result in considerable morbidity and economic burden to individuals and the community.¹ Greater than one third of new referrals to a luminal gastroenterology clinic are ultimately diagnosed with a functional bowel disorder.² The direct and indirect economic burden of functional bowel disorders is likely to be significantly underestimated but is noted in the USA to be upwards of 20.2 billion dollars annually.^{3,4} Patients diagnosed with functional bowel disorders report significantly decreased productivity and reduced mental and physical quality of life.⁵ The recently revised Rome IV Criteria are the standard utilised to diagnose and classify patients with a functional bowel disorder (Table 1).^{6,7}

Constipation is broadly defined as infrequent or difficult bowel emptying, specifically fewer than three bowel movements per week or straining during defaecation greater than 25% of the time.⁸ Constipation is a common condition affecting up to 20% of the population in the developed world, with a higher prevalence in women and the elderly.^{2,3,5} The pathophysiology of constipation is traditionally categorised into primary or secondary causes, the common causes of the latter are summarised in Table 2.⁹ In contrast, primary or functional constipation includes intrinsic disorders of the colon (i.e. slow transit constipation) and disordered defaecation characterised by structural (i.e. rectocele or enterocele) or functional (i.e. pelvic floor dysfunction, inadequate propulsion) abnormalities. The nomenclature used in defining constipation is confusing. To date, pelvic floor dysfunction has been referred to as: anismus,^{10,11} dyssynergic defaecation,¹⁰ functional defaecation disorder, rectal evacuatory dysfunction, “obstipation”, obstructive defaecation^{10,12} and paradoxical anal sphincter or puborectalis contraction¹³. Slow transit constipation is also known as colonic atony, colonic neuropathy and disordered motility.^{8,14} For the purposes of

this review, the terms slow transit constipation, pelvic floor dysfunction and the more specific term, dyssynergic defaecation (see below), will be used.

Historically, slow transit constipation has been considered the archetypal form of constipation. However, there have been significant recent insights regarding the pathophysiology of functional constipation, in part due to the development of new investigative techniques and better appreciation of the role that the pelvic floor plays in symptom generation. Functional constipation affects approximately 8% of patients attending a primary care practice in Australia.¹⁵ Functional subtypes of chronic constipation include: a) isolated functional defaecatory disorder (12%), b) isolated slow transit constipation (42%), c) a combination of slow transit constipation and defaecatory disorder (25%) and, d) constipation predominant irritable bowel syndrome (IBS) (20%) (characterised by abdominal pain and bloating with a normal colonic transit time).¹⁶ The Rome IV criteria further divides functional defaecatory disorders into those secondary to inadequate defaecatory propulsion and dyssynergic defaecation secondary to pelvic floor dysfunction.⁷ Overall the prevalence of pelvic floor dysfunction in patients reporting constipation ranges from 13 – 81%.^{1,17} The epidemiological inaccuracy is in large part relating to controversy regarding diagnostic definition and appropriate investigative techniques.

The relationship between colonic transit and pelvic floor dysfunction also obscures the true prevalence of each condition. Klauser demonstrated that rectal filling caused by voluntary suppression of defaecation resulted in slowed transit through the right colon.¹⁸ In addition, patients with a combination of slow transit constipation and dyssynergic defaecation have been shown to have improvement in colonic transit post correction of evacuatory dysfunction suggesting, in many patients, that the colonic dysmotility may be a secondary process.¹⁹

Normal defaecation is complex. It requires the coordination of increased intra-abdominal pressure in combination with concurrent pelvic floor muscle, anal sphincter relaxation and rectal sensation/perception.²⁰ Dyssynergic defaecation occurs when there is paradoxical contraction or inadequate relaxation of the pelvic floor muscles during attempted defaecation. This impedes the passage of stool leading to incomplete or unsuccessful evacuation.¹¹ Dyssynergia is apparent in 50% of patients with chronic constipation who are refractory to standard medical management.²¹ Symptoms are not reliable predictors of underlying pathophysiology^{22,23}, so the possibility of dyssynergia should be considered in all patients with constipation. Classical symptoms of dyssynergia are excessive straining (84%), a sensation of incomplete evacuation (76%), passage of hard stools (65%), less than 3 bowel movements per week (62%)¹ and digital manual manouvres such as disimpaction or vaginal splinting to relieve symptoms. When these symptoms are clustered in particular patients, the diagnosis should be especially carefully sought. Identifying patients with dyssynergia is important as effective and targeted interventions are available; successful treatment results in improvement in symptoms and quality of life with durable effects.

Biofeedback using electromyography (EMG) intervention was first introduced in 1987 by Bleijenberg and Kuijpers as a treatment for dyssynergic defaecation.²⁴ Since then, biofeedback therapy has demonstrated clinical efficacy in uncontrolled trials and a small number of randomised controlled trials (RCT).²⁵ Biofeedback is based on 'operant conditioning' techniques and uses stimuli such as EMG sensors, balloons or manometry in order to learn to increase intraabdominal pressure effectively and coordinate relaxation of pelvic floor and anal sphincter musculature during defaecation.^{10,26}

This review summarises the current evidence regarding i) the pathophysiology of pelvic floor dysfunction in chronic constipation ii) diagnosis of pelvic floor dysfunction in chronic constipation iii) efficacy of managing dyssynergic defaecation with biofeedback therapy. Our aim is to synthesise and integrate the current evidence addressing the pathophysiology of pelvic floor dysfunction in constipation and the application of biofeedback in its management.

Review Criteria and Methodology

Online databases searched included Pub Med, MEDLINE Ovid and the Cochrane Central Trials Registry. All original research studies, reviews and systematic reviews published in English from January 1950 onwards were considered. The following key words were used alone or in combination; ‘constipation and levator ani,’ ‘constipation and pelvic floor muscle,’ ‘constipation and biofeedback,’ ‘dyssynergic defaecation pathophysiology,’ ‘dyssynergic defaecation and biofeedback,’ ‘pelvic floor muscle and constipation review,’ ‘anismus and biofeedback’, ‘obstructive defaecation and biofeedback’ and dyssynergia and biofeedback.’ Of the articles included, seventeen were randomised controlled trials. Articles were excluded if they incorporated paediatric patients, urinary or obstetric disorders, non-human studies, did not have an abstract available or one that was not published in English.

Normal Defaecation

Prior to examining disordered defaecation, the normal structures and processes involved in defaecation must be understood.

The three muscular components that influence continence are the pelvic floor muscles (levator ani), internal anal sphincter (IAS) and external anal sphincter (EAS) (Figure 2).²⁷

The levator ani is a broad muscular dome comprising of 4 muscles: puborectalis,

iliococcygeus, ischiococcygeus and pubococcygeus which have voluntary and reflexive functions.²⁸ The latter function to provide physical support, acting as a dome shaped ‘diaphragm,’ for the pelvic viscera.²⁸ Whereas, the puborectalis is a U-shaped muscle which forms a sling around the upper anal canal and interdigitates its muscular fibres with the EAS (located caudally) before attaching anteriorly on the pubis.²⁹ Puborectalis contraction acts as a sling by pulling the anorectal junction anteriorly forming the anorectal angle. This angulation of approximately 90° is maintained by tonic activity (postural reflex); creating a mechanical barrier which aids continence (Figure 2).²⁰ The internal and external sphincters also form a physical barrier to defaecation by maintaining a higher anal pressure than rectal pressure.²⁰

If it is a socially acceptable time, an increase in rectal distension mediates the initiation of defaecation whereby a voluntary increase in intraabdominal pressure coupled with puborectalis relaxation widens the anorectal angle and straightens the passage of stool from the rectum to the anus, followed by external anal sphincter relaxation and stool evacuation (Figure 3).²² If timing is not suitable for defaecation the EAS contracts voluntarily (via the pudendal nerve) and the rectum relaxes allowing further accumulation of stool.^{9,28}

Pathophysiology of Pelvic Floor Dysfunction in Chronic Constipation

Dyssynergic defaecation is defined as the presence of functional constipation symptoms plus at least 2 of 3 physiological signs, the most common being paradoxical contraction of puborectalis (on anorectal manometry or surface electromyography) or a delayed balloon expulsion test time (Table 1).³⁰ Dyssynergia occurs when there is paradoxical contraction, or failure to relax the pelvic floor muscles during defaecation. This augments the anorectal angle thereby causing a physical obstruction to defaecation (Figure 3).³¹ Evidence suggests there is a significant bi-directional brain-gut dysfunction in patients with dyssynergic

defaecation when assessed by bidirectional cortical evoked potentials and transcranial magnetic stimulation.³² Inadequate propulsive force may also contribute to dyssynergic defaecation due to an insufficient increase in intrarectal pressure associated with the relaxation of the anal sphincter.³¹

The aetiology of dyssynergic defaecation is unclear and in 2/3rds of patients it is acquired in adulthood.¹⁰ A prospective survey of 100 patients by Rao demonstrated that dyssynergic defaecation began during childhood in 31%, after a physical event such as pregnancy, trauma or back injury in 29% and with no cause identified in 40% of patients.^{1,10}

Diagnosis and Management of Pelvic Floor Dysfunction in Patients with Chronic Constipation

1. History and General Examination

It is paramount on history taking to assess for symptoms of chronic obstructive constipation including incomplete evacuation and straining in addition to the usual stool pattern and consistency.^{33,34} Patients may also have multiple pelvic floor symptoms concomitantly including recurrent urinary tract infections, sexual dysfunction or prolapse which also indicate dyssynergia. In addition, patients with a history of sexual abuse have an increased prevalence of pelvic floor dyssynergia.³⁵

As with all function disorders, a thorough history including detailed questioning regarding alarm symptoms must be undertaken. Alarm symptoms on history include: rectal bleeding, weight loss, anorexia, new onset or significant worsening of constipation symptoms and a family history of colorectal cancer or inflammatory bowel disease.^{36,37} . The presence of alarm symptoms, or if the patient is aged over 50 years, necessitates further investigation, using radiological, biochemical, haematological assessment and/or endoscopy. Unfortunately

however, symptoms of chronic constipation do not reliably predict the subtype of constipation, therefore, it is generally necessary to undertake further diagnostic investigations.³⁸

A general examination may aid in identifying a secondary cause of constipation (Table 2). A digital rectal examination (DRE) is then recommended to further assess for dyssynergia.

2. Focused Examination to Identify Dyssynergia

The simplest and most economical clinical tool available for the diagnosis of pelvic floor conditions is a digital rectal examination (DRE). The performance of a DRE incorporates an assessment for dyssynergia including perineal sensation, ano-cutaneous reflexes, anal resting tone and squeeze pressures, abdominal push effort during simulated defaecation with associated perineal descent, sphincter and puborectalis relaxation.³⁹ When undertaken by an experienced clinician, a DRE has a high sensitivity and positive predictive value for detecting dyssynergia as diagnosed by high resolution anal manometry and balloon expulsion test.⁴⁰ There is controversy as to whether further testing is required to confirm Rome IV criteria of dyssynergic defaecation prior to commencing treatment. However, the poor specificity of DRE (58.7%-87%) allows justification for the Rome criteria to recommend the use of diagnostic modalities for the formal diagnosis of dyssynergia.⁴⁰⁻⁴²

3. Initial Approach

General measures:

Given the scope of this review, the fundamental management of patients with dyssynergic defaecation, rather than constipation as a whole, is discussed. NHMRC guidelines advise a soluble fibre dietary intake of 20g per day in women and 30g in males, this can be supplemented using psyllium or sterculia preparations.⁴³ There is insufficient evidence to

demonstrate that patients with constipation consume less fibre than those with normal bowel habits nor that they will symptomatically improve with an increase in fibre intake.^{32,44,45} In addition, a fluid intake of 2.1L in females and 2.6L in males per day in mild climates has been recommended with additional fluid consumption in hotter regions to prevent dehydration and difficult to evacuate, hard stools.⁴³ The benefit of exercise in the management of chronic constipation has not been supported by the literature.⁴⁶ It is suggested that physical activity may improve quality of life but not symptoms of constipation.⁴⁷⁻⁴⁹

Pharmacological management:

Pharmacological management of dyssynergic defaecation includes the avoidance of exacerbating medications such as iron and calcium supplements, antacids, opioids, calcium-channel antagonists, antipsychotics and antispasmodics. Medications that promote the passage of stool such as stool softeners (sodium and calcium docusate compounds) and osmotic laxatives (preferably polyethylene glycol (PEG) based) are preferred over stimulant laxatives.^{50,51} Suppositories may also be of benefit including the use of a Bisacodyl suppository for patients with soft stools or a Glycerol suppository if the patient describes hard stools.³⁴

4. Second Line Approach

In patients who do not respond to conservative treatment measures, further testing and management using biofeedback therapy may be initiated. The most important outcome of investigations is to predict response to treatment and aid stratification of patients to a specific therapy. Frustratingly, there is no gold standard diagnostic modality for diagnosing dyssynergic defaecation in patients with chronic constipation. There is also evidence of disparity when evaluating between modalities and also with their use in isolation.⁵² This has compromised trial outcomes for the evaluation and management of dyssynergic defaecation.

Despite this, initial identification of dyssynergia by functional testing using two diagnostic modalities including balloon expulsion test, anorectal manometry or electromyography (EMG) allows confirmation of the diagnosis using the Rome IV criteria and justifies the initiation of biofeedback therapy.⁷

Balloon Expulsion Test

The balloon expulsion test is a simple, clinical procedure. A balloon tipped catheter is inserted in to the rectum and inflated with water to 50ml. The patient is asked to evacuate the balloon while timed. A normal test result is the expulsion of the balloon under one to two minutes whereas dyssynergia is suspected if the patient is unable to expel the balloon within three minutes.^{22,53,54} The balloon expulsion test has an 80-90% specificity for dyssynergia but is poorly sensitive (50%)^{10,22,50} There is a high false positive rate if performed in the left lateral position and hence it is recommended the patient be in a seated position to accurately simulate defaecation.

Anorectal Manometry

Anorectal manometry indirectly assesses anorectal function by measuring recto-anal pressures and motor coordination.⁵² It evaluates: i) anal sphincter function ii) recto-anal reflex activity iii) changes in anal and rectal pressures during simulated defaecation. Furthermore the current configuration of catheters allows integrated measurement of rectal sensation, rectal compliance and performance of a balloon expulsion test.⁵⁴ Findings from high resolution anorectal manometry need to be interpreted in context with supporting modalities as used in isolation it has limited application in dyssynergia due to high false positive values.^{52,55}

Electromyography

Electromyography assesses the activity of EAS and puborectalis by detecting paradoxical muscular contraction via recording the number of motor units firing at a certain time point. Surface EMG is most commonly utilised, where electrodes placed on the anal skin over the external anal sphincter is utilized. A sustained increase in surface EMG activity (>50% increase from baseline) on attempted defaecation is defined as inappropriate contraction.^{19,11} EMG has been shown to correlate with balloon expulsion in 82% of patients.^{56,57}

Following confirmation of dyssynergia on diagnostic testing using two modalities, further management using a behavioural therapy such as biofeedback therapy can be commenced.

Biofeedback

Definition of Biofeedback

Biofeedback is a behavioural therapy which incorporates exercise repetition and simulation of defaecation to safely coordinate abdominal and pelvic floor muscle contraction.¹⁰ It is a form of operant (Skinnerian) conditioning utilising consequences as a means of modifying the occurrence or type of behaviour. All patients with confirmed dyssynergic defaecation should be considered for biofeedback therapy.^{26,58} Biofeedback therapy is optimally combined with a holistic behavioural and general pharmacological treatment plan tailored to the individual patient. It includes the use of objective measures of function including EMG, anorectal manometry, ultrasound or digital palpation to “feedback” to the patient what is normal or abnormal with the aim to modify patterns of defaecation. Exercises are repeated and corrected until the patient can perform the correct action independently. This can be coupled with habit training about toileting patterns and psycho-social aspects of toilet use.

Procedure, duration and frequency of training

Fundamental to all behavioural therapies including that of biofeedback therapy is the instruction and training by the therapist who corrects and improves muscle control which translates into actual function. Biofeedback therapy is ideally undertaken in the correct defaecation position (seated, leaning forward at 45 degree angle, legs apart) with the biofeedback instrument *in situ*.³² The key components of a biofeedback session includes instruction on: i) diaphragmatic breathing ii) increase in intraabdominal pressure associated with push effort iii) coordinated pelvic floor relaxation iv) simulated defaecation and may also incorporate v) rectal sensory retraining in patients with altered visceral sensitivity.^{10,32} Biofeedback protocols vary between specialist centers and require instruction by an experienced practitioner (physician, physiotherapist or nurse). A proposed protocol is demonstrated in Figure 5. Biofeedback training optimally requires 5-6 training sessions on a fortnightly basis, each lasting 30-60 minutes but should be individualised based on patient requirements.⁵⁹ Contraindications to biofeedback therapy include; pregnancy, active infection or inflammation, active fissures or acute postoperative period.

Mechanism of action

Dyssynergic defaecation is primarily an acquired condition, therefore, the aim of biofeedback is to relearn a normal pattern of defaecation.³² The mechanism by which biofeedback improves constipation symptoms and bowel function remains incompletely understood. Studies suggest that biofeedback acts locally and improves constipation by removing the mechanical barrier (acute anorectal angle) caused by paradoxical pelvic floor contraction. Relaxation of the pelvic floor muscles allow stool to be propelled forward more readily and may eliminate retrograde peristalsis caused by pelvic floor contraction during defaecation.^{19,60,61} There is also data that suggests biofeedback may play a role in neuromodulation of the gut.¹⁹ Patients with constipation have a reduced rectal mucosal blood

flow which reflects the activity of extrinsic autonomic innervation to the gut.^{19,62} This is seen most obviously in patients with slow transit constipation.¹⁹ It has been demonstrated that such patients, with a positive response to biofeedback therapy, have enhanced gut microcirculation resulting in a decreased stool transit time.¹⁹ The improvement in gut blood flow is due to increased cholinergic and decreased sympathetic inhibition, suggesting biofeedback may modify autonomic pathways.

Instrument modalities

Instruments used for biofeedback may include a solid state manometry system, electromyography (EMG), rectal balloon, ultrasound (intrarectal, intravaginal, perineal), digital guidance or visual feedback techniques.⁶³⁻⁶⁵

The solid state manometry system includes a probe with microtransducers embedded in it which is connected to a display unit for interpretation of pressure activity and a balloon for simulated defaecation and sensory training. EMG biofeedback systems commonly include a surface electrode attached to a probe or a sensor placed on the surface of the external anal sphincter which is connected to a display unit and provides real time visual and auditory feedback.

Balloon biofeedback may also be undertaken with the patient in the left lateral position or seated on a commode. A catheter with a balloon attached is inserted 10cm into the rectum. Fifty millilitres (mL) of water or air is injected into the balloon to provide sensory awareness, the patient is instructed to generate increased intraabdominal pressure using the diaphragm and abdominal muscles while simultaneously relaxing the pelvic floor and anal sphincter muscles to release the balloon without straining. The therapist holds the end of the balloon catheter to assess balloon movement (propulsion) and may apply gentle traction to the balloon catheter to assist initially.

If the patient is unable to evacuate a 50ml balloon then water or air can be sequentially removed until the patient is able to expel the balloon.⁶⁶ In patients with altered rectal sensitivity, balloon biofeedback can be undertaken by serially inflating a balloon with incrementally smaller or larger volumes; enabling the patient to appreciate rectal filling and to attempt evacuation at an appropriate threshold.

The use of ultrasound imaging for the purpose of biofeedback is a new concept which provides real time information about the direction of pelvic floor movement during pelvic floor muscle contraction and relaxation to assist teaching a patient to relax the muscles during defaecation.

Head-to-head trials between biofeedback treatment techniques are limited and significant disparity between treatment protocols comparing different techniques makes it challenging to identify the most efficacious technique (Table 3).²⁵ Koh *et al.*, undertook a meta-analysis comparing EMG biofeedback with non-EMG biofeedback and found a OR of 6.738 (95% CI, 2.914 to 15.580, $p < 0.001$) favouring EMG.²⁵ A recent Cochrane Review also found that there was a lack of evidence to make a clear conclusion of the most efficacious modality.⁶⁷ EMG biofeedback demonstrated a slightly superior response compared with balloon biofeedback and manometry, however, the findings were not statistically significant.⁶⁷

Efficacy of biofeedback in dyssynergic defaecation

Biofeedback for dyssynergic defaecation has response rates of up to 80% improvement in symptoms with sustained results at 24 months.^{68,69} Ten randomised controlled trials comparing biofeedback with other medical management and numerous uncontrolled trials have formed the foundation for the integration of biofeedback into clinical practice in patients who have failed conservative medical therapy, detailed in Table 4.

Of note are the following landmark studies. Chiarioni *et al.*, randomised 104 patients with dyssynergia to PEG laxatives or EMG biofeedback and assessed their response at 6 and 12 months.⁶⁹ Eighty percent of patients who underwent biofeedback reported a major improvement in symptoms compared with 22% of patients in the laxative treated group ($p < 0.01$); the benefit of biofeedback was sustained at 24 months.⁶⁹ Rao *et al.*, compared anal pressure biofeedback against two control conditions; sham biofeedback and standard care.⁶⁸ Standard care subjects received diet and lifestyle advice, laxatives and scheduled evacuations. At 3 months follow up 79% of patients in the biofeedback group corrected dyssynergia ($p < 0.0001$) compared with 4% receiving sham and 8.3% receiving standard treatment.⁶⁸ Increased complete spontaneous bowel movements and higher global bowel satisfaction was also demonstrated in the biofeedback group compared with sham.⁶⁸ Heymen *et al.*, compared two control conditions, placebo or diazepam against EMG biofeedback.²¹ The trial involved 3 phases including a run in which involved enhanced standard care including diet, lifestyle measures, stool softeners and scheduled evacuations. Of the 117 patients who commenced the trial, 18 reported adequate relief at the end of run in and were excluded.²¹ The remaining 84 patients were randomised to placebo, diazepam and biofeedback. At the 3 month follow up 70% of the biofeedback group reported adequate relief compared with 30% of the diazepam treated ($p < 0.001$) and 38% of placebo treated patients ($p = 0.017$).²¹ A meta-analysis by Koh *et al.*, demonstrated the overall effectiveness of biofeedback with an OR of 5.861 (95% CI, 2.175 to 15.794, $p < 0.001$) in favour of biofeedback compared with non-biofeedback treatment.²⁵

Biofeedback is practitioner dependent and often individualised to a particular patient's needs. This variability makes intra- and inter-centre comparisons challenging and leads to inherent difficulties in designing and interpreting studies. This difficulty was recognised in a recent

Cochrane Review which concluded that the efficacy and safety of biofeedback could not be determined due to inadequacies in study methodology and bias.⁶⁷ Seventeen studies were included in the Cochrane review comprising of a total of 931 participants. Standard medical management was not systematically established between studies. Due to the heterogeneity between study populations, samples, technique methods and outcome measures a meta-analysis was not able to be undertaken. Despite the finding from the Cochrane Review, the randomized controlled trials in Table 4 demonstrate compelling evidence for the utilization of biofeedback therapy for patients with dyssynergic defaecation.

Efficacy of biofeedback in slow transit constipation

Studies of biofeedback therapy in patients with slow transit constipation and dyssynergia have demonstrated a beneficial response rate of 50%.^{70,71} It has been postulated that patients with rectal evacuatory dysfunction and slow transit may have secondary colonic dysmotility as improvement in dyssynergia is associated with improvement with colonic transit.⁷² However, evacuatory dysfunction is not associated with an identifiable specific pattern of transit delay.⁷³

Contention also remains as to whether biofeedback improves whole gut transit in slow transit constipation without dyssynergia.^{19,70} In their prospective study, Emmanuel and Kamm demonstrated that gut directed biofeedback is an effective behavioural treatment for chronic idiopathic constipation, with 59% of patients reporting subjective improvement.¹⁹ In addition, 59% of patients with slow transit constipation normalized their transit time at the end of treatment.¹⁹ There was also evidence of improving transit time in patients with normal transit.¹⁹ In this study, it was also found that patients with constipation, most obviously in those with slow transit, had abnormal cardiovagal cholinergic test scores and reduced rectal blood flow, markers of autonomic function. In patients who demonstrated improvement with

biofeedback there was an increase in rectal mucosal blood flow with no variation of abnormal cardiovascular autonomic reflexes. This suggests that biofeedback results in a gut specific mechanism of action mediated centrally.

In contrast, Chiarioni *et al.*, in their study of 52 patients demonstrated that 71% of patients with combined slow transit constipation and pelvic floor dyssynergia improved following biofeedback training compared with 8% in the slow transit only group.⁷⁰ This study suggested that biofeedback resource allocation should be directed at those patients with pelvic floor dyssynergia with or without coexisting slow transit.⁷⁰ Further research is warranted to determine those likely to benefit most from biofeedback.

Clinical predictors of success

Biofeedback is a labour intensive therapy predominantly performed in specialised tertiary centers which limits patient access.⁷⁴ The majority of biofeedback studies specifically selected patients with a functional defaecation disorder although a smaller number of studies have shown possible benefit in all patients with constipation.^{19,75} Clinical predictors of success for biofeedback therapy may aid in resource allocation. Clinical predictors that have demonstrated an increased likelihood of beneficial effect include: harder stool consistency, shorter duration of laxative use and willingness to comply with treatment protocols.⁷⁴ Physiological parameters on anorectal manometry that correlate with clinical improvement with biofeedback are a high straining rectal pressure and a prolonged balloon expulsion time.⁷⁴ Risk factors for a poor response to biofeedback include a long history of constipation, an eating disorder or poor compliance. Manometric findings of anal canal hypertonia, a long anal canal, increased rectal maximum tolerable volume, poor pre-treatment defaecation index and paradoxical contraction specifically in those patients with severe defaecatory dysfunction due to anatomical or physiological impairment may also predict a poor response.^{76,77,78,79} However, despite negative

predictors patients may have a reasonable response to therapy.⁸⁰ Symptom improvement in patients with good compliance can be demonstrated within one to six months.

To date the vast majority of biofeedback trials have only included patients diagnosed with a functional defaecation disorder by anorectal manometry or balloon expulsion. Hence, it seems reasonable to use similar criteria to select patient for biofeedback therapy.

Symptomatic improvement is also known to correlate with correction of anorectal manometric abnormalities and at least one trial has shown poor response of biofeedback in patients without dyssynergic defaecation.⁷⁰ There remains significant controversy as to the clinical utility of tests of anorectal function and the role of biofeedback in patients without dyssynergic defaecation as there is evidence that there may be a role for a behavioural therapy such as biofeedback therapy in all constipated patients.^{19,75}

5. Specialist Testing

Defaecating proctography

Defaecating proctography involves the insertion of barium paste into the rectum followed by videofluoroscopy at rest and during rectal evacuation.^{10,81,82} Defaecating proctography is a cost-effective procedure which mimics normal defaecation. A lack of perineal descent and an evacuation time longer than 30 seconds is highly predictive of dyssynergia.^{83,84}

Unfortunately, defaecating proctography is often poorly tolerated, can be difficult to access outside of tertiary centers and involves exposure to low-dose ionising radiation (average dose 4.9 mSv).⁸⁵

Magnetic Resonance Imaging (MRI)

MRI is a highly validated modality with negligible radiation which allows a global assessment of pelvic floor muscles (in particular of sphincter defects) and their function.

Interestingly, it has a diagnostic sensitivity of 70% compared to that of defecating proctography despite improved image resolution.⁸¹ Unfortunately, it is expensive and there are few functional MRI facilities, in particular those with an open magnet enabling patients to be seated during the evacuation phase.

Ultrasound

Ultrasound is a portable and inexpensive imaging modality which avoids radiation and is effective in assessing both anatomy and function of the pelvic floor. Two-dimensional (2D) and three-dimensional (3D) ultrasound is readily available and emerging techniques using four-dimensional (4D) including echo defaecography and endoanal ultrasound technology is available in selected centers. Echo defecography (3D dynamic anorectal US) is utilised at few centers and has been shown to correlate well with defecography and was validated in a prospective multicentre study.^{86,87} Overall, ultrasound is a well-tolerated, reliable modality but is operator dependant and has a limited field of view.

Colonic transit studies

There is an apparent relationship between colonic transit and evacuatory outlet obstruction caused by dyssynergia, whereby evacuation impairment may result in slowed transit.⁸⁸ If there is a suspicion of slow transit constipation or overlap with pelvic floor dyssynergia a colonic transit study may be requested to assess whole gut transit as there are discernible treatment implications.

Radio –opaque marker study

The most accessible investigation is a radio-opaque marker (Sitzmark or Kolomark) study. The patient consumes a capsule containing radio-opaque markers and subsequent abdominal radiographs are taken to assess the progression of markers through the colon. Colonic transit

studies separate results into normal or slow transit times based on the number of markers retained on x-ray after ingestion. It is a simple, reliable and reproducible test. However, it exposes patients to radiation and does not measure the transit of a physiological meal.⁸⁹

Scintigraphic studies

Scintigraphic studies measure total gut transit and regional colonic transit via the ingestion of a radiolabelled meal (for gastric and small bowel transit) or coated capsule with radiopaque markers dispersed in the ileocaecal region.⁹⁰ Scintigraphy provides accurate information about transit through individual colonic regions, however, it exposes the patient to radiation.⁹¹

Wireless Motility Capsule

Wireless motility capsule is an emerging imaging modality that can identify normal, slow and rapid colonic transit time without radiation. There are a number of contraindications to its use including swallowing difficulties, however it is generally well tolerated. It is expensive and has a retention rate of 0.33%.⁹²

6. Additional management

Botulinum toxin injection

Botulinum toxin injection into non-relaxing puborectalis has shown temporary improvement in patients with dyssynergic defaecation but is not widely utilised.^{93,94,95} Based on small uncontrolled studies, Botulinum toxin has demonstrated an inconsistent improvement in symptoms and its effect decreases within three months post injection. A recent AGA technical review on constipation has noted that Botulinum toxin injection is not superior to biofeedback as first line therapy in patients with dyssynergic defaecation.^{26,59,96}

Surgery

In patients without dyssynergia or in refractory cases of dyssynergic defaecation, surgery should be considered only if there is a significant effect on quality of life and after nonsurgical measures have failed. Partial surgical division of the puborectalis muscle has demonstrated to be effective, however, it has an unacceptable risk of faecal incontinence and overall poor results.⁹⁷ A number of studies have demonstrated that the stapled transanal rectal resection (STARR) procedure to be superior to behavioural therapy using biofeedback, however, the outcomes of biofeedback demonstrated in these surgical studies were strikingly poor and the complications (pelvic sepsis, fistula, peritonitis, bowel perforation, pain, and bleeding) in addition to long term results were suboptimal.^{98,99,100} Given this, surgery is no longer recommended for the management of dyssynergic defaecation.

7. Further areas of interest

The management of pelvic floor dyssynergia has also been investigated in patients with inflammatory bowel disease.¹⁰¹ It has been found that a significant number of these patients with evacuatory dysfunction have concomitant pelvic floor dyssynergia. Biofeedback therapy in this cohort has demonstrated encouraging results with 80% reporting improvement in symptoms.¹⁰²

Biofeedback has also been utilised in patients with spinal cord and neurogenic bowel dysfunction. A recent study by Mazor et al., demonstrated that patients with incomplete motor spinal cord injury responded as well as matched controls to anorectal biofeedback.¹⁰³ Improvement in anorectal sensorimotor function and balloon expulsion was also demonstrated in these patients.¹⁰³ Biofeedback has also been used with success in patients with multiple sclerosis who have constipation.¹⁰⁴

For practical purposes, home biofeedback may enable patients in rural or regional settings to access this treatment. Home based training devices predominantly use an EMG home trainer or silicone probe device where pressure or electrical activity can be simply displayed. The few studies that have examined home biofeedback have demonstrated encouraging results.¹⁰⁵

Despite an increase in evidence based research into pelvic floor dyssynergia in chronic constipation and its management, there are a number of areas which require further research. Biofeedback modality head-to-head trials need to be undertaken to determine a gold standard diagnostic modality. Studies evaluating the economic benefit and impact of biofeedback therapy on reducing primary care visits may allow an increase in funding to this treatment technique. Further studies exploring new biofeedback techniques and home biofeedback would be beneficial.

Conclusion

Chronic constipation is a common clinical presentation that adversely affects quality of life for many patients. Dyssynergic defaecation is an under-recognised, potentially reversible cause for chronic constipation. There is no gold standard diagnostic modality for dyssynergic defaecation and further research is required in this area. In patients diagnosed with a functional defaecation disorder, biofeedback therapy is the most efficacious treatment available. There is also emerging evidence that biofeedback may be beneficial in other conditions (i.e. slow transit constipation, irritable bowel syndrome or inflammatory bowel disease). Further research into biofeedback therapy with standardised protocols and patient centered outcomes is required to expand its utility in clinical practice.

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Table 1: Rome IV Criteria for Functional Constipation, Functional Defaecation disorder including Dyssynergic Defaecation

Functional Constipation⁶

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

1. Must include 2 or more of the following
 - a. Straining during more than one-fourth (25%) of defaecations
 - b. Lumpy or hard stools (BSFS 1-2) more than one-fourth (25%) of defaecations
 - c. Sensation of incomplete evacuation more than one-fourth (25%) of defaecations
 - d. Sensation of anorectal obstruction/blockage more than one-fourth (25%) of defaecations
 - e. Manual maneuvers to facilitate more than one-fourth (25%) of defaecations (eg. Digital evacuation, support of the pelvic floor)
 - f. Fewer than 3 spontaneous bowel movements per week

Functional Defaecation Disorder⁷

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

1. The patient must satisfy diagnostic criteria for functional constipation and/or irritable bowel syndrome with constipation
2. During repeated attempts to defecate, there must be features of impaired evacuation as demonstrated by 2 of the following 3 tests:
 - a) Abnormal balloon expulsion test
 - b) Abnormal anorectal evacuation pattern with manometry or anal surface EMG
 - c) Impaired rectal evacuation by imaging

Dyssynergic Defaecation⁷

Inappropriate contraction of the pelvic floor as measured with anal surface EMG or manometry with adequate propulsive forces during attempted defaecation

Table 2: Causes of Chronic Constipation

Constipation Causes

Primary	normal transit slow transit evacuation disorder: <ol style="list-style-type: none">(i) structural (rectocoele, enterocoele)
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(ii) functional (Dyssynergic defaecation, IBS-C, slow transit constipation with dyssynergia)

Secondary

- 8. Medications (narcotics)
- 9. Metabolic (hypothyroidism, hypercalcemia)
- 10. Neurologic disorders (Parkinson’s disease, multiple sclerosis)
- 11. Obstructing colorectal cancers
- 12. Systemic (scleroderma, amyloidosis)
- 13. Psychiatric (depression)

Table 3: Comparison between biofeedback modalities

Study authors	Study publication year	Study details	Primary outcome	Overall result	Limitation/ Bias
Bleijenberg and Kuijpers ¹⁰⁶	1994	RCT 11 patients: EMG biofeedback 9 patients: balloon biofeedback	Standard EMG, constipation score, standard diary	Change score significant improvement with EMG (8/11) vs. balloon (2/9)	Blinding
Koutsomanis <i>et al.</i> ¹⁰⁷	1995	RCT 60 patients unresponsive to standard treatment n=47: pelvic floor dyssynergia n=17 slow transit. Visual biofeedback vs muscle training no visual display 2-3 month follow up	Patient symptom diary, whole gut transit, surface EMG, simulated defaecation.	14/31 visual biofeedback improved symptoms vs 12 of 28 in muscle training group, changes in bowel frequency, duration of abdominal pain and improvement in anismus index were similar in both groups	Blinding
Glia <i>et al.</i> ¹⁰⁸	1997	RCT 26 patients n=10: anal manometry, n=10: EMG 6 month followup	Balloon expulsion test, anorectal manometry and EMG, bowel symptom diary, global rating of treatment	15/26 (58%) patients improved anorectal function and symptoms. Of those that completed therapy 15/20 (75%) improved symptom with persistence at 6 month follow up. No difference in	Blinding, attrition bias Low power

Pourmomeny <i>et al.</i> ¹⁰⁹	2010	RCT Follow up 1 week post treatment 65 patients n=34 EMG biofeedback, n=31 balloon assisted training	Satisfaction (low, moderate, high), change in Rome criteria, ability to expel a balloon	efficacy of feedback modes. Reduction in constipation in both groups, improved balloon evacuation, patient satisfaction 52% in balloon training and 79% in biofeedback.	Selection, blinding, reporting bias
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Table 4: Comparison between Randomised Controlled Trials of Biofeedback vs. Non-

Biofeedback modalities

	Chang <i>et al.</i> ¹¹⁰	Chiarioni <i>et al.</i> ⁶⁹	Rao <i>et al.</i> ⁶⁸	Heymen <i>et al.</i> ²¹	Rao <i>et al.</i> ¹¹¹
Study publication year	2003	2006	2007	2007	2010
Study design	RCT Electrical stimulation therapy (EST) versus EMG biofeedback	RCT Biofeedback versus polyethylene glycol (PEG) 14.6g	RCT Biofeedback versus sham versus sham biofeedback	RCT Biofeedback versus diazepam versus placebo	RCT Biofeedback versus conventional medical therapy Followed up for 12 months
Detail	Electrical stimulation using anal plug versus EMG biofeedback with visual display. Total study duration 10-12 days.	Patients with chronic severe PFD were treated with fibre plus enemas or suppositories up to twice weekly. Nonresponders were randomised to biofeedback or PEG plus counselling sessions.	Anal pressure biofeedback compared to two control conditions, sham biofeedback and standard care. Standard: diet and lifestyle advice, laxatives and scheduled evacuations versus Biofeedback versus Sham biofeedback	RCT involving 3 phase run in, treatment, follow up. Patients were assigned to biofeedback, diazepam or placebo. Partially blinded trial.	RCT involving short term therapy followed by those who completed biofeedback therapy were asked to continue for long term study
Subjects	22 total 12 electrical stimulation 10 EMG biofeedback	104 total 55 PEG plus counselling 54 biofeedback	77 total 24 standard therapy 28 biofeedback 25 sham biofeedback	84 total 24 placebo 30 diazepam 30 biofeedback	52 total randomized 44 completed short term therapy 13 completed long term study with biofeedback
Type of biofeedback and duration	10-14 sessions lasting 60-90 minutes EMG biofeedback with visual display	5 x weekly 30min training sessions Intraanal EMG probe Balloon defaecation test	2 x per week 1 hour biofeedback session. Up to 6 sessions within 3 months. Anal pressure biofeedback using manometry probe	2 x per week 50 min session 6 sessions within 3 months EMG with anal plug	Short term phase: 2x per week 1 hour biofeedback. Up to 6 sessions within 3 months. Long term study: 3 follow up visits at 3 monthly intervals. Last review at 12 months. Intraanal manometric probe.

Primary outcomes	Symptom questionnaire, anorectal manometry before and after, balloon distension	Global Improvement of Symptoms Physiological variables: change in anal canal pressure, pelvic floor EMG when straining and balloon expulsion	Presence of dyssynergia Balloon expulsion time Number of complete spontaneous bowel movements Global satisfaction	Global symptom relief	Primary outcome: number of complete spontaneous bowel movements (CSBM)/week. Secondary outcomes: global bowel satisfaction, stool frequency, stool consistency, straining effort, digital assistance and laxative consumption score per week. Sustained improvement in results at 12 months.
Response rates	Global improvement in symptoms in both groups (48.3% bowel satisfaction in electrical stimulation group and 59% in biofeedback patients)	80% major improvement at 6 months in biofeedback group. Laxative treated had 22% improvement in symptoms. Biofeedback benefit sustained at 24 months.	Dyssynergia correction at 3 months: Biofeedback- 79% Sham- 4% Standard 6% At 3 months follow up the biofeedback group reported more complete spontaneous bowel movements, defaecation improvement and higher satisfaction than the sham treated group.	Improved symptoms: Biofeedback- 70% Diazepam – 30% Placebo- 38%	Significant increased CSBM/week ($p < 0.001$), significant improvement in normalisation of dyssynergic muscle pattern ($p < 0.0010$), significant improvement in normalisation of colonic transit ($p < 0.01$) and improvement in balloon expulsion ($p < 0.001$)
Overall result	EST comparable to biofeedback therapy in patients with impaired rectal sensation. EST can be considered as an adjunctive therapeutic modality EST	Biofeedback superior to laxatives	Biofeedback was superior to standard therapy and sham biofeedback	Biofeedback is superior to diazepam and placebo	Sustained response to biofeedback therapy. Biofeedback is superior to conventional medical therapy
Limitations/ Bias	Performance and detection bias	Performance and detection bias	Performance and detection bias	Performance and detection bias	Performance and detection bias
	Jung <i>et al.</i>¹¹² (abstract only)	Simon and Bueno¹¹³	Hart <i>et al.</i>¹¹⁴	Ba-bai-ke-re <i>et al.</i>¹¹⁵	Cadeddu <i>et al.</i>¹¹⁶
Study publication year	2007	2009	2012	2014	2015
Study design	RCT	RCT Follow up for 2 months post-treatment	RCT 12 weeks duration with no follow up	RCT Follow up 1, 3, 6 months post treatment	RCT Follow up at 6 months post treatment

Detail	Randomised cross-over design 5 week duration. Electrical stimulation therapy (EST) for 2 weeks then biofeedback for 5 weeks versus biofeedback for 5 weeks then EST for 2 weeks	EMG biofeedback vs. 8 counselling sessions with EMG assessment during straining to defecate in chronically constipated elderly patients	EMG (rectal probe) biofeedback plus coaching for pelvic floor relaxation vs. muscle relaxation techniques, emg with sham surface electrode placement	Anorectal manometry vs. Polyethylene glycol (PEG) 17g, 3 times daily with high fibre diet.	Intra-anal EMG biofeedback plus electrical stimulation vs. standard care (counselling, fibre diet, lifestyle, enemas)
Subjects	40 patients with pelvic floor dyssynergia n=20: electrical stimulation, n=20: biofeedback therapy	30 patients with dyssynergic defaecation n=15 EMG biofeedback n=15 Control	21 patients with pelvic floor dyssynergia, failed lifestyle modification and other medical intervention. n=10 biofeedback, n=11 control	88 patients confirmed dyssynergic defaecation n= 44 anorectal manometry biofeedback, n=44 oral PEG	81 patients n=40 intra-anal EMG biofeedback plus transanal electrostimulation, n=41 control patients
Type of biofeedback and duration	Unspecified modality	EMG biofeedback, 8 sessions over 1 month with visual and auditory feedback	8EMG biofeedback 6x1hour sessions plus home practice	Anorectal manometry 30mins x5 weeks, home practice encouraged	6x 20 minute weekly sessions Intra-anal EMG biofeedback and 6x20 minute transanal stimulation
Primary outcomes	Symptom assessment, patients opinion, anorectal manometry, balloon expulsion, substance P expression within rectal mucosa	Self reported bowel frequency, sensation of incomplete evacuation, and perianal pain on defaecation, Latter 3 symptoms rated on a scale, EMG activity and anismus index	Constipation severity instrument, irritable bowel quality of life scale, SF-36, trauma history questionnaire	Constipation symptoms, Wexner score, Quality of life score	PAC-QOL, anorectal manometry and balloon expulsion test at baseline, Wexner score and obstructed defaecation score end of treatment and 6 months after treatment
Response rates	Overall satisfaction improved significantly in both groups, after 2 nd treatment the success was 80% in both groups. Objective parameters such as resting anal sphincter pressure decreased in biofeedback predominant group.	Significant difference (p<0.01) in frequency of defaecations, sensation of incomplete evacuation, perianal pain, difficulty of evacuation, EMG activity during straining and anismus index in EMG biofeedback group only. Significant difference	Biofeedback group constipation scores decreased by 35.5% comared with 15.3% in control and obstructive defaecation symptom scores decreased by 37.9% compared with 19.7%. Improvement in IBS-QOL. SF-36 improved 28% compared with control which worsened 12.7%	After completing the course of biofeedback treatment improvement in clinical symptoms and Wexner Constipation Score were decreased compared with oral PEG group (p<0.05). Significant improvement at 6 months in difficult evacuation, perianal pain, hard stools, laxative dependence, Wexner Constipation	Significant decrease in Wexner score and obstructed defaecation score (p<0.0102, p<0.0001 respectively). No significant change in control group. PAC-QOL improved significantly (p<0.0001) in EMG biofeedback group otherwise

		(p<0.01)between initial assessment and treatment but not between treatment and follow up(p>0.05)		score and Quality of life score (p<0.05)	PAC-QOL did not change in control group.
Overall result	EST efficacy comparable to biofeedback. EST has a beneficial effect in addition to biofeedback therapy.	EMG biofeedback superior to control. Benefits maintained at 2 months post.	Biofeedback superior to control	Manometric biofeedback superior to oral PEG with sustained response at 6 months	Biofeedback plus transanal electrostimulation provided sustained improvement. Standard therapy was large ineffective.
Limitations/Bias	Abstract only	Blinding	Under powered, blinding, attrition bias	Blinding	Blinding

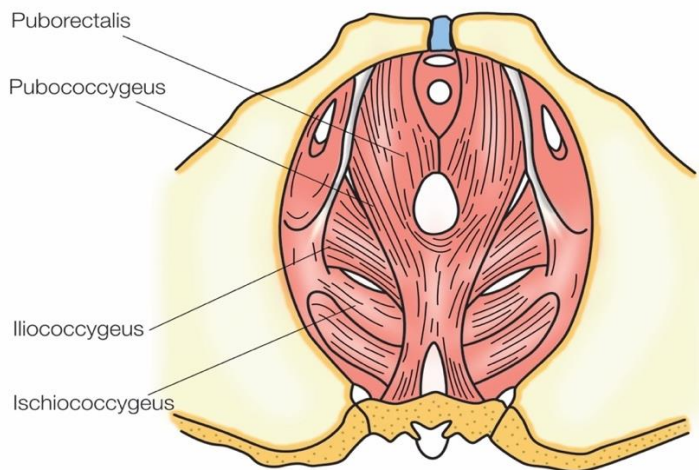
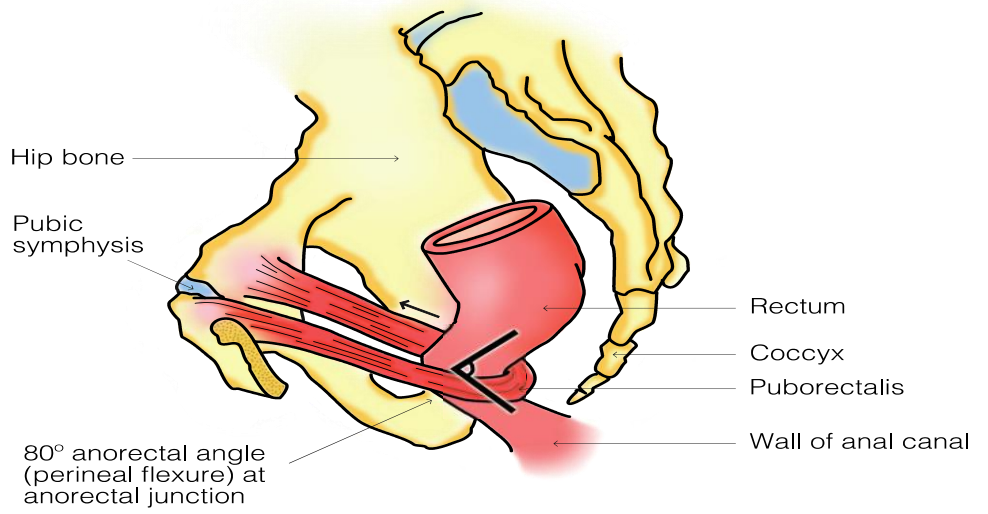


Figure 2: Levator Ani musculature

A. Contracted



B. Relaxed

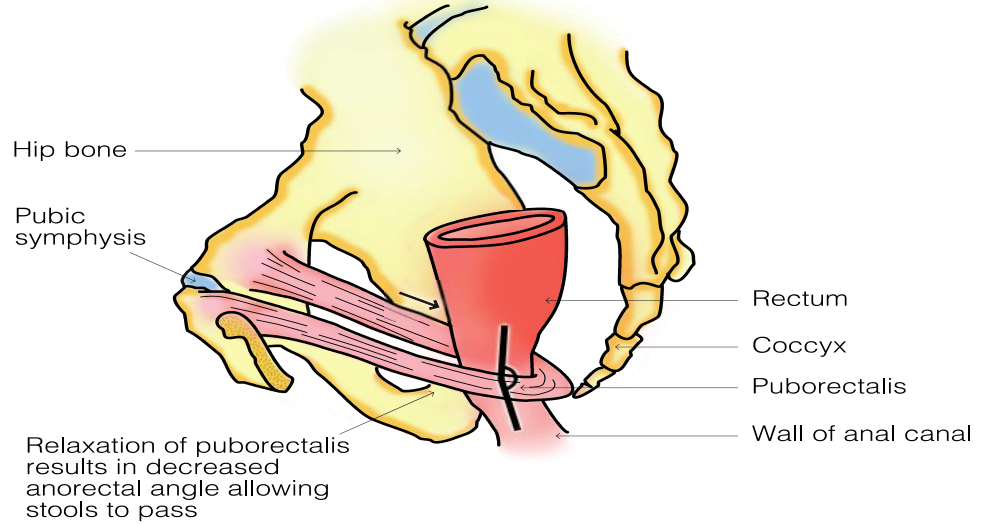


Figure 3: Comparison of the anorectal angle during puborectalis contraction and relaxation.

KEY POINTS

- Dyssynergic defaecation attributes to 50% of patients with chronic constipation who don't respond to standard medical therapy
- Diagnosis starts with history (straining, incomplete evacuation), DRE to assess for paradoxical contraction of puborectalis. Balloon expulsion, anorectal manometry or surface EMG can confirm.
- Biofeedback therapy is first line management (up to 70% of patients demonstrate improved symptoms) for dyssynergic defecation