

Physical Therapy Management of Functional Constipation: A 2021 Evidence-Based Clinical Practice Guideline From the American Physical Therapy Association's Academy of Pelvic Health Physical Therapy

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ABSTRACT

Background:

Functional constipation, diagnosed by physicians utilizing the Rome Criteria, is a non-pathologic bowel condition resulting in difficulty with defecation. Adults with functional constipation experience infrequent defecation (<3 per week) and may strain and/or use manual maneuvers to produce a bowel movement. Physical Therapy should be offered as part of conservative intervention. The goals of this clinical practice guideline were to describe the evidence for physical therapy interventions for individuals with functional constipation; and to create a reference document of evidence for physical therapists managing adults with functional constipation symptoms.

Methods:

A systematic search of the literature published between 1990 and 2019 for relevant articles related to physical therapy interventions for adult functional constipation was performed. A summary of details including benefits, risks, harms and costs related to each intervention category is provided to allow consumers of this Clinical Practice Guideline to apply findings to adults with functional constipation.

Results:

Strong evidence suggests that physical therapists should offer biofeedback interventions to their patients with functional constipation, including either Electromyographic; Rectal Balloon Catheter; or Anorectal Manometry biofeedback. Moderate evidence supports the use of manual therapy, a variety of soft tissue mobilization techniques; whereas weak evidence was found to support the use of electrical stimulation to manage functional constipation. Finally, although we were not able to grade the evidence for the use of patient education and therapeutic exercise in the physical therapy management of functional constipation, we did provide a summary of these interventions in the literature.

Discussion/Conclusions:

Our findings suggest that physical therapists can confidently include biofeedback interventions into the plan of care for adults with functional constipation as they are supported by strong evidence. Manual therapy was the only other intervention category that provided a degree of evidence suitable to provide recommendations for its use to manage adults with functional constipation.

Key words: clinical practice guideline, constipation, adult

Disclaimer: These recommendations are intended as a guide for physical therapists to optimize rehabilitation outcomes for adult persons with functional constipation only.

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Summary of Action Statements

Action Statement 1: Electromyographic Biofeedback Training

Clinicians should consider electromyography biofeedback with either an anal sensor or surface electrodes over the external anal sphincter, with variable patient positioning, treatment session duration, and frequency if/when/whenever 18 years of age or older AND diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) AND male or female, but predominantly female AND variable practice settings (laboratory, physician practice/clinic, tertiary care center, unspecified)

Evidence quality: B; Recommendation Strength: Strong

Action Statement 2: Rectal Balloon Catheter Biofeedback Training

Clinicians should consider rectal balloon catheter biofeedback filled with air or water in either right or left lateral side-lying if/when/whenever 18 years of age or older AND diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) AND male or female, but predominantly female AND variable practice settings (laboratory, physician practice/clinic, tertiary care center, unspecified)

Evidence quality: B; Recommendation Strength: Strong

Action Statement 3: Anorectal Manometry Biofeedback Training

Clinicians should consider anorectal manometry biofeedback with both an internal balloon catheter (either air or water-filled) and external surface electrodes over the anal sphincter with the patient positioned in left lateral side lying if/when/whenever 18 years of age or older AND diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) AND male or female, but predominantly female AND variable practice settings (laboratory, physician practice/clinic, tertiary care center, unspecified)

Evidence Quality: A; Recommendation Strength: Strong

Action Statement 4: Manual Therapy

Clinicians should consider manual therapy including a variety of soft tissue mobilization techniques (abdominal massage, perineal self acupressure, reflexology, connective tissue mobilization), joint mobilization, and visceral mobilization for short term effects if/when/whenever 18 years of age or older AND diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) AND male or female, but predominantly female AND secondary or tertiary care centers

Evidence Quality: B; Recommendation Strength: Moderate

Action Statement 5: Electrical Stimulation

Clinicians may consider electric stimulation including: intra-anal (electrogalvanic, unspecified), Transcutaneous Electrical Stimulation, and cranial electrotherapy stimulation if/when/whenever 18 years of age or older AND diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) AND male or female AND secondary or tertiary care centers
Evidence quality: D; Recommendation Strength: Weak

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INTRODUCTION

Aims of the Guidelines

The Academy of Pelvic Health Physical Therapy has an ongoing effort to create evidence-based practice guidelines for women's health physical therapy management of patients with musculoskeletal impairments described in the World Health Organization's International Classification of Functioning, Disability and Health (ICF).¹

The purposes of this clinical practice guideline are to:

- Describe evidence-based physical therapy practice, specifically intervention, for adult functional constipation disorders commonly managed by pelvic health physical therapists.
- Identify interventions supported by current best evidence to address impairments of body function and structure, activity limitations, and participation restrictions associated with adult functional constipation disorders.
- Provide a description to policy makers, using internationally accepted terminology, of the practice of pelvic health physical therapy.
- Provide information for payers and claims reviewers regarding the practice of pelvic health physical therapy for adult functional constipation disorders.
- Create a reference publication for pelvic health physical therapy clinicians, academic instructors, clinical instructors, students, interns, residents, and fellows regarding the best current practice of pelvic health physical therapy for adult functional constipation disorders.

Overview and Justification

Constipation is defined by some healthcare experts as the reduction in stool frequency.² However, this definition is insufficient to describe a condition that affects 63 million people in North America³; and utilizes significant resources per year including 4 million ambulatory medical visits⁴; 1.1 million hospitalizations⁵; 5.3 million prescriptions with a total cost of \$178 million⁶; and, an average of \$2,527 per person to diagnose this condition.⁷ Alternately, the Rome IV Criteria defines functional constipation based on symptoms and anorectal testing.⁸

According to Rome IV criteria, adult functional constipation symptoms must occur for ≥ 6 months before diagnosis, and symptoms should be present during the last 3 months. Symptoms must include 2 or more of the following: straining during more than one-fourth (25%) of defecations; lumpy or hard stools more than one-fourth (25%) of defecations; sensation of incomplete evacuation more than one-fourth (25%) of defecations; sensation of anorectal obstruction/blockage more than one-fourth (25%) of defecations; manual maneuvers to facilitate more than one-fourth (25%) of defecations; fewer than 3 spontaneous bowel movements per week; loose stools are rarely present without the use of laxatives; and there are insufficient criteria for irritable bowel syndrome.⁸ Compared to individuals diagnosed with constipation-predominant irritable bowel syndrome, upper gastrointestinal tract symptoms, anxiety, depression, urinary symptoms, and increased rectal sensation are less common in adults with functional constipation.^{9,10} Yet, 50% of patients having either type of constipation will have a defecatory disorder.⁹

Another constipation classification method utilizes colonic transit and anorectal testing to determine the pathophysiology of the patient's functional constipation. Using this method, the physician can determine if a patient has normal transit constipation; slow transit constipation; or a defecation disorder.¹¹ Defecation disorders are characterized by long toileting time to produce a bowel movement, straining, and the need to use manual assistance to empty the rectum. Because the pathophysiology of normal transit constipation is unclear¹², this clinical practice guideline will not include discussion and recommendations for normal transit constipation.

Slow-transit constipation symptoms include reduction in the urge to defecate, abdominal pain, and abdominal distension.¹³ This condition may occur due to a reduction or loss of postprandial motor activity, impairment in colonic propulsion; delayed emptying of the proximal colon; as well as reduced or absent interstitial cells important to gastrointestinal motility (cells of Cajal).¹² Slowed transit leads to hardened stool as water from stool is lost as it moves through the colon. This hardened stool is slower to reach the anorectal region; and requires greater force to evacuate.¹⁴

For functional defecation to occur, motor coordination between the anal sphincter, levator ani, and abdominal wall muscles must take place. Disordered defecation, or difficulty evacuating stool, may be caused by musculoskeletal and neurologic impairments. Such impairments include anismus (high anal resting pressure), abdomino-pelvic muscle incoordination (dyssynergia); as well as pelvic organ prolapse, reduced anorectal sensation, or a sensation of anal blockage or incomplete emptying).¹⁵⁻¹⁸

Early interventions for many individuals are medical and often include laxatives and dietary recommendations to increase fiber intake.¹⁹ These interventions fail to improve constipation in about 50% of patients to whom they are prescribed; and some patients have concerns including laxative safety, side effects, and cost.²⁰ Further, this approach fails to manage movement impairments that may promote constipation such as pelvic floor motor control, muscle weakness, and muscle spasm.²⁰

Physical therapists possess the knowledge and skills to manage neuromuscular impairments and functional limitations that may contribute to constipation and its impact on an individual's activity, participation, and quality of life.²¹ Currently, physical therapists manage constipation using a multifaceted approach that typically includes neuromuscular re-education (often with the use of biofeedback) to retrain pelvic muscle coordination²², as well as dietary and fluid recommendations²³, proper toileting techniques and timely response to bowel urges²⁴, abdominal massage to improve colonic²⁵, and management of musculoskeletal impairments that may impact bowel health.²⁶ It is important to note that the findings of the cited studies may not be applicable to all subsets of functional constipation.

Randomized control studies support the efficacy of a few physical therapy interventions that address impairments associated with constipation. For example, one trial that included persons with long-standing constipation found participant's symptoms were reduced following 8-weeks of abdominal massage. Results of this study also showed that this intervention resulted in greater symptom improvement in those with more severe constipation.²⁵ Biofeedback as a component of pelvic floor muscle training has also been found to reduce constipation symptoms by 70% as patients learn the proper muscle coordination (relaxing the anorectum) required to expel stool.²⁷ Biofeedback can also be used to assist patients with poor awareness of rectal fullness (utilizing a

rectal balloon catheter), often blunted with constipation.^{28,29} Limited research exists in support of other physical therapy interventions for improving functional constipation. For example, toileting strategies³⁰ and myofascial release techniques³¹.

At the initiation of guideline development, a clinical practice guideline for the physical therapy intervention of adult functional constipation had not been published. To advance current and shape future physical therapy clinical practice, it was determined that a clinical practice guideline was needed to provide physical therapy intervention recommendations based on existing evidence to manage adults with functional constipation. For recommendations on assessment, diagnosis, and diagnostic testing in patients with functional constipation please refer to recently published guidelines and consensus statements.^{32–35}

Epidemiology of Functional Constipation

Economic and Health Care Resource Burden of Constipation

A systematic review which included five studies estimated the annual direct costs of chronic constipation as ranging from \$1,912 to \$7,522 per patient (2012 U.S. dollars).³⁶ Direct costs include inpatient and outpatient care as well as pharmacy, radiology, and diagnostic procedures. These estimates do not include over the counter costs and dietary intervention, not included in medical claims, as it has been estimated that approximately 22% of patients seek care.²

Per OH et al.³⁷, a survey of 4,702 participants with chronic constipation demonstrated that 37.6% had ever discussed their constipation with a healthcare provider. The distribution of the types of consultation with symptoms were reported as follows: primary care providers (87.6%), gastroenterologists (26.0%), and urgent care/ emergency room physicians (7.7%). Despite the high costs, a 2017 US survey of patients with chronic idiopathic constipation notes that 59% of patients were not satisfied with the treatment they received.³⁸

A United Kingdom Bowel Interest Group report in 2019 reported that £91 million (122 million US dollars) were spent in 2017–18 on prescription laxatives. This estimate did not include spending by patients on over-the-counter laxatives.³⁹ In addition to cost of care, constipation has been shown to impart indirect costs (reduced productivity) sustained by impaired persons. Using survey methods of productivity and symptom severity, Neri et al.⁴⁰ estimated a 19.7% mean reduction in productivity in an outpatient Italian sample. This impact was observed to increase with symptom severity, with employment both sick-leave and decreased productivity costs increasing with each quintile of the Patient Assessment of Constipation Symptoms score, with a maximum of over \$13,100 (US dollars) per case at highest symptom severity.

Prevalence of Functional Constipation in Adults

Population-based rates:

The prevalence of constipation worldwide in general populations is reported in a systematic review of cross sectional studies as ranging from 0.4% to 79% with a median of 16%.⁴¹ Similarly, pooled prevalence from a 2011 systematic review and meta-analysis of 45 studies indicated a pooled estimate of 14 % (95 % CI: 12 – 17 %).⁴² Population-based estimates of the prevalence of functional constipation differ by geography, age group, and gender.

Geography:

The estimates reported by Soares and Ford⁴² showed variability by geographic location with lowest rates in studies of Southeast Asian populations (11%, 95% CI 7-15%) and highest rates reported in South American and European populations (16-18%). Variability in rates are seen within geographic locations.

Data from the National Health and Nutrition Study reported rates in U.S. adults across time from 12.8% to 10.2% for women and 4% for men.^{23,43} A range of estimates are reported from studies of international samples. In a multinational survey, Wald et al.⁴⁴ reported rates in adults of 5% (Germany) to 18% (U.S.). Among other European population studies, estimates include an overall pooled European rate of 17.1%⁴⁵ to 19.1% observed in Spain.⁴⁶

A degree of rate variability has been observed in Asian and Middle Eastern adult populations. Based on self-report, adult rates have been estimated at 25.8% in Korea, 28% in Iran, and 24.8% in India.⁴⁷⁻⁴⁹

Inferences regarding the prevalence and impact of functional constipation from published literature are confounded by lack of a consistent definition and outcome measures used. Lower rates have been observed when Rome criteria were applied in prevalence estimate studies. Rates are reported to range from 2.4% in Iran⁵⁰ to 16.2% and 16.8% in Malaysia⁵¹ and India respectively⁴⁸.

Age and Gender Differences:

In population based estimates among U.S. adults over age 50, Andy et al.⁵² have reported higher rates of self-reported constipation in females (11.8%) compared with males, odds ratio 3.0 (2.3-3.8). Prevalence is generally seen to be higher in women (median female-to-male ratio of 1.5:1). Women are also more likely to use laxatives and seek health care for their constipation.⁵³ Bradley et al⁵⁴ have reported rates of self-reported straining for bowel movements (25.0%), and a sense of incomplete bowel movements (34.8%) among older women (mean age 68.7 years).

Risk Factors for Chronic Constipation

A 2011 systematic review including 58 studies illustrated good agreement for the risk factors for constipation. Increasing age, race, female gender, lower socioeconomic status, lower parental education rates, less self-reported physical activity, certain medications, stressful life events, physical and sexual abuse, and depression are associated with constipation.⁴¹ These same risk factors were similarly identified by the Indonesian Society of Gastroenterology in their 2010 Consensus Statement.³⁴ Increasing prevalence is consistently reported in adults greater than 60 years. Many studies suggest higher prevalence of constipation in the non-white population than in the white population.¹¹

Socioeconomic, psychosocial, and behavioral factors such as lower socioeconomic status, stressful life events, low physical activity, depression and history of physical/sexual abuse have been identified as constipation risk factors.^{4,43,44,55-58} It must be also considered that these risk factor associations do not imply causation.

A technical review prepared by the American Gastroenterological association described 14 classes of medications with known associations with constipation.¹¹ Among the more common classes are non-steroidal anti-inflammatory medications, antidepressants, anticholinergics and certain antihypertensives. While a thorough review of medication-induced constipation is beyond the scope of this review, it is clear that a full assessment of medications, comorbid conditions, and multiple body systems is important for the clinician during examination for the patient with constipation.

Cost Effectiveness of Treatment

Given the high prevalence and the reported direct and indirect costs per case of chronic constipation, it is important to consider the cost effectiveness both in financial and quality of life terms. In a 2018 systematic review it was reported that identifying the cost effectiveness of specific interventions from the existing evidence is limited by the heterogeneity of the definition of chronic constipation used to define the population studied, and the outcome measures assessed as sources of costs.⁵⁹

Specifically, evidence supports recommendations to provide dietary and lifestyle modifications in addition to laxatives or an alternative approach to current care. Only abdominal massage (self or professional) has been considered as an alternative intervention. Lamas et al.⁶⁰ compared self-or professional abdominal massage with continued laxative over 16 weeks in a non-blinded, randomized controlled trial of 60 patients with constipation as defined by the Rome II criteria. The cost per quality adjusted life-year of the self-massage intervention compared with laxatives was €75,000 (91,000 US dollars), which included therapist and patient costs. For the professional massage intervention, the cost per quality adjusted life-year compared with laxatives was €60,000 (73,000 US dollars), not including therapist travel and overhead costs. Massage showed a significantly greater quality of life gain over continued laxative use and was considered a potentially cost effective long term management strategy.

There is no source of evidence that includes all intervention in comparison with laxatives. Also lacking is an evaluation that includes all available interventions for patients whose condition has proven unresponsive to management with laxatives.

Additionally there is no evidence evaluating the cost effectiveness of specific biofeedback interventions either in terms of improved quality of life years or reduced economic costs. Furthermore, there appears to be no evidence that considers the cost effectiveness of intervention on work-productivity. A comparison of all available interventions would appear to be research priorities moving forward to illustrate the value in terms of direct/indirect costs and added quality of life.

Statement of Intent

These guidelines are not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every patient, nor should they be construed as

including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made in light of the clinical data presented by the patient; the diagnostic and treatment options available; and the patient's values, expectations, and preferences. However, we suggest that significant departures from accepted guidelines should be documented in the patient's medical records at the time the relevant clinical decision is made.

METHODS

Content experts within the Academy of Pelvic Health Physical Therapy volunteered to participate in the development of a clinical practice guideline for the physical therapy management of adults with functional constipation. To ensure a complete and consistent process, developers of this guideline relied heavily on the updated 2018 and 2020 American Physical Therapy Association (APTA) Manual of Clinical Practice Guideline Development to methodology processes. They additionally followed methods and formatting of previously published APTA clinical practice guidelines⁶¹⁻⁶⁴. These content experts were tasked to identify physical therapy interventions for functional constipation that are supported by current best evidence. Such interventions may address impairments of body function and structure, activity limitations, and participation restriction associated with functional constipation disorders. It was also acknowledged by the Academy of Pelvic Health Physical Therapy content experts that only performing a systematic search and review of the evidence related to diagnostic categories based on International Statistical Classification of Diseases and Related Health Problems (ICD)⁶⁵ terminology would not be sufficient for these ICF-based clinical practice guidelines, as most of the evidence associated with changes in levels of impairment or function in homogeneous populations is not readily searchable using the ICD terminology. Thus, the authors of this guideline independently performed a systematic search of MEDLINE, CINAHL, and the Cochrane Database of Systematic Reviews (1990 through 2017) for any relevant articles related to intervention strategies for functional constipation. Additionally, when relevant articles were identified, their reference lists were hand searched in an attempt to identify other relevant articles. Articles from the searches were compiled and reviewed for accuracy by the authors. Action Statement Profiles were generated utilizing BridgeWiz software (copyright Yale University 2011; developed by Christopher Michael).⁶⁶ This guideline was issued in 2021 based on publications in the scientific literature prior to 2021. This guideline will be considered for review in 2026, or sooner if new evidence becomes available. Any updates to the guideline in the interim period will be noted on the APTA Pelvic Health Physical Therapy website: <https://aptapelvichealth.org/>.

Epidemiologic Methods:

Observational studies that reported primary results from studies of prevalence, risk factors and associated conditions were extracted, summarized and classified as cohort/cross sectional or case control designs. Each study was rated using the National Institutes of Health Quality Assessment⁶⁷ Guidelines by a primary investigator who is a Ph.D. prepared epidemiologist (GM). Each study was similarly scored by a second primary investigator (JL). Both raters judged each study based on scoring as high quality, acceptable quality, or unacceptable/reject. If two raters

differed on quality rating, a third investigator (DBF or SG) provided a consensus on a quality rating.

Literature Search

We searched MEDLINE via PubMed, Embase via Embase.com, CINAHL (Ebsco) and the Cochrane Database of Systematic Reviews (Wiley). The search was developed by a health sciences librarian using a combination of database specific subject headings and keywords. The searches were run on July 20, 2017 and limited to those references published after 1990. The search was updated on January 22, 2021 to include studies from 2018 and 2019. The updated search included an additional filter to exclude pediatric populations (under 18). An example of search terms used in PubMed is illustrated in Table 3, and full search strategies for all databases are available upon request.

TABLE 3. PICO Search Terms for Constipation and Rehabilitation

Patient populations	Constipation	"Constipation"[Mesh] OR "Fecal Impaction"[MeSH] OR "Gastrointestinal Motility"[MeSH] OR anismus[tiab] OR anorectal disease*[tiab] OR anorectal manometry[tiab] OR bowel control[tiab] OR bowel disorder*[tiab] OR bowel dysfunction*[tiab] OR bowel function*[tiab] OR bowel management[tiab] OR bowel symptom*[tiab] OR colonic inertia[tiab] OR colonic transit[tiab] OR constipat*[tiab] OR defaecat*[tiab] OR defecat*[tiab] OR defecograph*[tiab] OR dyschezia[tiab] OR elimination dysfunction*[tiab] OR faecal impaction*[tiab] OR fecal impaction*[tiab] OR hard stool*[tiab] OR rectal evacuation disorder*[tiab]
Intervention	Rehabilitation	"Rehabilitation"[Mesh] OR "rehabilitation"[Subheading] OR ("Acupuncture Therapy"[Mesh:NoExp] OR "Chiropractic"[Mesh] OR "Musculoskeletal Manipulations"[Mesh] OR "Physical Therapy Modalities"[Mesh:NoExp] OR "Reflexotherapy"[Mesh] OR acupressure[tiab] OR acupuncture[tiab] OR applied kinesiology[tiab] OR bodywork*[tiab] OR chiropract*[tiab] OR craniosacral therap*[tiab] OR dry needling[tiab] OR manual therap*[tiab] OR massag*[tiab] OR physical therap*[tiab] OR physiotherap*[tiab] OR positional release therap*[tiab] OR reflexolog*[tiab] OR "Exercise"[MeSH:noexp] OR "Exercise Movement Techniques"[MeSH] OR "Exercise Therapy"[MeSH] OR "Walking"[MeSH:noexp] OR exercise*[tiab] OR physical activit*[tiab] OR physical conditioning[tiab] OR train*[tiab] OR walking[tiab] OR yoga[tiab] OR electrostimulat*[tiab] OR nerve stimulation[tiab] OR neuromodulation[tiab] OR sacral nerve stimulat*[tiab] OR sacral neuromodul*[tiab] OR spinal magnetic stimulation[tiab] OR "Behavior Therapy"[MeSH:noexp] OR "Biofeedback, Psychology"[MeSH] OR "Cognitive Therapy"[MeSH:noexp] OR "Patient education as topic"[MeSH:noexp] OR balloon catheter*[tiab] OR behavioural therap*[tiab] OR biofeedback[tiab] OR bio-feedback[tiab] OR cognitive behavio*[tiab] OR coping[tiab] OR educat*[tiab] OR instruction[tiab] OR reeducation[tiab] OR retrain*[tiab] OR self management[tiab]
Abbreviations: *, truncation symbol; picks up plurals, gerunds, etc; mh, medical subject heading; tiab, the word or phrase anywhere in the title/abstract.		

Critical Appraisal Process and Reliability

Prior to the critical appraisal process, reliability testing was performed to ensure all reviewers were reliable in using the APTA CAT-EI appraisal tool

(<http://apta.adobeconnect.com/p6qi3mk2e2w/>) for reviewing intervention studies. Each reviewer

was assigned 10 intervention study papers to review using the CAT-EI. Across reviewers, inter-agreement for study design and design tally was >70%. Given this result, feedback and review of the grading process was provided to reviewers. Subsequently, all reviewers were tasked to review and grade one additional intervention study. Including data from this final review, the inter-agreement increased to >80%. Articles including causes of bowel dysfunction other than FC or dyssynergic defecation (including but not limited to inflammatory bowel conditions, mechanical obstruction, and neurologic diagnoses) were excluded as they were beyond the scope of this guideline.

Levels of Evidence

Individual clinical research articles were graded according to criteria described by the Centre for Evidence-Based Medicine, Oxford, UK (<http://www.cebm.net>) for diagnostic, prospective, and therapeutic studies (Table 1). If the 2 content experts did not agree on a grade of evidence for a particular article, a third content expert was used to resolve the issue.

Table 1: Levels of Evidence for Studies

I	Evidence obtained from high-quality diagnostic studies, prospective studies, or randomized clinical trials
II	Evidence obtained from lesser-quality diagnostic studies, prospective studies, or randomized clinical trials (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, less than 80% follow-up)
III	Case-control studies or retrospective
IV	Case series
V	Expert opinion

GRADES OF EVIDENCE

The overall strength of the evidence supporting recommendations made in these guidelines was graded according to guidelines described by Guyatt et al,⁶⁸ as modified by MacDermid et al⁶⁹ and adopted by the coordinator and reviewers of this project. This methodology is consistent with the recommendations presented in the APTA Manual of Clinical Practice Guidelines. In this modified system, the typical A, B, C, and D grades of evidence have been modified to include the role of consensus expert opinion and basic science research to demonstrate biological or biomechanical plausibility (table 2).

Table 2: Definitions for Recommendations

A	Strong evidence	A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study
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B	Moderate evidence	A single high-quality randomized clinical trial or a preponderance of level II studies support the recommendation
C	Weak evidence	A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts support the recommendation
D	Conflicting evidence	Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies
E	Theoretical/foundational evidence	A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic science/bench research supports this conclusion
F	Expert Opinion	Best practice based on the clinical experience of the guidelines development team

Expert and Stakeholder Review

An expert advisory stakeholder panel reviewed this guideline prior to public comment. The expert panel consisted of 10 individuals: Michael Kingsley, MD, Clinical Assistant Professor of Medicine Division of Gastroenterology, Hepatology, and Nutrition UPMC Mercy, Pittsburgh, PA; Stephanie Deter Pickett, MD, MS Female Pelvic Medicine and Reconstructive Surgery Mercy Hospital, Edmond, OK; Carina Siracusa PT DPT WCS OncCS OhioHealth, Columbus, OH; Kristin Phillips, PT DPT WCS CLT West Virginia University School of Medicine, Division of Physical Therapy, Morgantown, West Virginia; Lorien Hathaway, PT DPT WCS Baylor Scott and White Institute for Rehabilitation, Plano, TX; J. Adrienne McAuley, PT DPT MEd OCS FAAOMPT Fellow of APTA Education Leadership Institute University of New England, Biddeford, ME; Jennifer Davia, PT DPT WCS Program Director, Physical Therapist Assistant Program Pima Medical Institute, Denver, CO; Laurel Proulx, PT DPT PhD(c) OCS Assistant Professor, Regis University Denver, CO; Karen Snowden, PT DPT WCS Lehigh Valley Health Network Allentown, PA; and Susan Clinton, PT DScPT OCS WCS FAAOMPT Embody Physiotherapy & Wellness, Sewickley, PA. Specific individuals included two physicians (gastroenterologist n=1 and urogynecologist n=1) with extensive practice of treating individuals with constipation; educators and former educators in entry-level doctorate PT programs (n=7), PT assistant programs (n=1), medical education & residency programs (n=1), and pelvic health residency PT programs (n=3), and PT clinician experts in bowel management (n=2). Their individual time in clinical practice ranges from eight to greater than twenty years and they collectively practice across eight states in four regions of the country: Mid-West, South-Central, Northeast, and West. A copy of the clinical practice guideline and an electronic survey were sent to each reviewer. Specific reviewer comments and survey results were reviewed and the clinical practice guideline was revised as appropriate to accommodate reviewer concerns, with responses from the work group available upon request. The reviewed guideline was subsequently posted on the Academy of Pelvic Health Physical Therapy Website for public comment and followed a similar process described previously prior to submission for publication.

Knowledge Translation and Implementation Plan

The authors of this guideline will work with appropriate board and committee members of the APHPT to work on developing specific initiatives for knowledge translation and implementation of recommendations provided in this clinical practice guideline. Limited information is provided in this guideline.

Update and Revision of Guidelines

This guideline will be updated and revised within 5 years of its publication as new evidence emerges. The procedures utilized for updating the guideline will follow those utilized in the writing of this guideline, based on the recommended standards of the APTA and APHPT.

CLINICAL GUIDELINES

Biofeedback

In the studies reviewed, three distinct categories of biofeedback interventions emerged. These categories were reviewed and graded individually and included: electromyography, anorectal balloon catheter, and anorectal manometry. Electromyography utilized surface electrodes with either an intra-anal sensor or peri-anal electrodes connected to a device, usually a computer, which provided visual feedback of pelvic floor muscle performance. Anorectal or rectal balloon catheter utilized a balloon attached to the tip of a catheter inserted into the ano-rectum. Manometry utilized a combination of surface perianal electrodes and a rectal balloon catheter connected to a manometry unit. Two recently published clinical practice guidelines and one position paper on consensus guidelines graded the evidence for biofeedback as an intervention for constipation as grade A level 1b.^{32,33,70} Shin et al.³² advises, “biofeedback therapy may be applied repeatedly and safely, and can reduce the usage of laxatives.” However, these guidelines fail to delineate between categories of biofeedback intervention which limits the clinical applicability of their recommendations. This is in contrast to the findings of five systematic reviews on biofeedback which concluded grade B level II evidence for biofeedback as an intervention for functional constipation⁷¹⁻⁷⁵ and one systematic review on biofeedback which concluded grade C level II-IV evidence.⁷⁶ While minimal evidence was available to delineate patient factors associated with response to biofeedback intervention, Patcharatrakul⁷⁷ reported that lower baseline levels of bowel symptom satisfaction and/or use of digital maneuvers to evacuate stool were associated with a more satisfactory treatment outcomes for individuals with dyssynergic defecation who failed to respond to dietary fiber and laxative intervention.

ACTION STATEMENT 1: Electromyographic Biofeedback Training

Clinicians should consider electromyographic biofeedback with either an anal sensor or surface electrodes over the external anal sphincter, with variable patient positioning, treatment session duration, and frequency when individuals are 18 years of age or older and diagnosed with functional constipation via varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) and male or female, but predominantly female, and variable practice settings (laboratory, physician practice/clinic, tertiary care center, unspecified)

Evidence quality: B; Recommendation strength: strong

Associated ICF impairment, activity, and participation codes: b525, defecation functions; b5250, elimination of feces; b152, emotional function; b28012, pain in the stomach or abdomen and possibly effective for slow transit constipation; b5150, transport of food through stomach and intestines; d5301 regulating defecation; d530, toileting; d230, carrying out daily routine.

Action: Consider electromyographic biofeedback with either an anal sensor or surface electrodes over the external anal sphincter, with variable patient positioning, treatment session duration, and frequency.

Action Statement Profile

Aggregate evidence quality: B

Level II based on 1 level I randomized clinical trial, 6 level II randomized clinical trials, 1 level II outcome study, and 2 level II cohort studies.

Benefits: Non-invasive (if utilizing surface electrodes); ability to be utilized in a variety of positions; promoting internal knowledge of performance to achieve correct pelvic floor muscle coordination: proper activation and relaxation of pelvic floor muscles during the defecatory process; no drug interactions or systemic side effects; Minimal long term risk

Risks, harm, and costs: Cost of equipment including sensory or electrodes and biofeedback unit; Patient incurred costs of in-person intervention; Anorectal tissue irritation; Anorectal bleeding; Psychosocial distress, especially with history of abuse and/or trauma; Cultural sensitivity considerations; Potential variation in therapist interaction; Prolonged use could impede development of an internal reference of correctness, thus impairing long term motor learning; Minimal long term risk

Benefit-harm assessment: Preponderance of Benefit

Value judgment: Electromyographic biofeedback training allows a safe treatment alternative and may be a good option to avoid more invasive medical and surgical interventions.

Intentional Vagueness: None.

Role of patient preferences: Patients may prefer to trial low risk conservative intervention strategies prior to undergoing more invasive medical and surgical interventions.

Exclusions: This aggregate of evidence considered functional constipation and therefore may not be appropriate for patients diagnosed with irritable bowel syndrome- constipation. Other potential exclusions include individuals with cognitive and/or visual impairments for whom this method of learning would not be appropriate.

Policy Level: Third party payers should strongly consider eliminating a trial period of Pelvic Floor Muscle Exercise prior to covering electromyographic biofeedback intervention as this will minimize overall cost and time burden to the patient and payer.

Difference of Opinions: None.

Supporting Evidence and Clinical Implementation

The most recent level I parallel arm randomized clinical trial⁷⁸ compared office-based manometric biofeedback (initial training session followed by 1 hour biweekly sessions, up to 6 sessions over 3 months) with home-based electromyographic biofeedback (twenty minutes, twice a day for 8 weeks) using an intra-anal sensor with visual feedback in individuals with dyssynergic defecation. Based on both objective and subjective outcomes, the authors concluded that home-based biofeedback was as effective as office-based biofeedback while also less expensive. Given these findings, they recommended that home-based biofeedback should be the preferred intervention for treating dyssynergic defecation. Similar findings and recommendations were reported in a follow-up trial.⁷⁹

A level II randomized clinical trial²⁷ looked at individuals with pelvic floor dyssynergia type constipation. After a 4 week trial of education and medical management, participants who were still constipated were randomized to either biofeedback, diazepam, or placebo intervention. All participants were taught pelvic floor muscle exercises, instructed in toileting strategies, and educated on using diet and stool softeners to improve stool consistency. Regardless of assigned treatment group, participants received six bi-weekly, 50-minute treatment sessions. For the primary outcome, "adequate relief of constipation" at the 3-month follow up, 70% of those in the biofeedback group vs. 23% of the diazepam group and 38% in the placebo group reported adequate relief. Unassisted bowel movements, a secondary outcome, also showed a favorable treatment effect for those in the biofeedback group versus those in the diazepam and placebo groups, respectively. Three additional randomized clinical trials by Simon et al.⁸⁰⁻⁸² investigated the effect of electromyographic biofeedback in elderly individuals with dyssynergic defecation. Based on frequency of defecations per week during the initial assessment phase^{80,82} or psychophysiological assessment^{81,82}, participants were randomized to either the electromyographic biofeedback group or control. In all three studies, biofeedback training and control intervention occurred twice a week for eight sessions for 1 month. Each session consisted of 15 to 20 defecation attempts lasting 45 minutes. The control intervention included counseling on bowel function and defecation. Follow up assessment of self monitored defecation symptoms and electromyographic-activity during defecation attempt at 2 months post-intervention revealed improvement in number of defecations per week and reduction of electromyographic activity during straining in the biofeedback group only⁸⁰, while improvements were present in both groups but favored the biofeedback group in their 2017 study⁸¹. A level II randomized clinical trial assessing younger participants with dyssynergic defecation, compared the effects of biofeedback therapy plus standard care to standard care alone on pelvic floor motion defecography indices, quality of life, and depression.⁸³ Each biofeedback session lasted 60 minutes and was performed twice a week for 12 sessions, followed by once a week for 6 sessions. The patients were instructed to perform the exercises 3 times a day for 10 minutes, within 3 months of the treatment period. Home-training devices for biofeedback training were also used. Both primary study outcomes, change perineal descent (Perineal Descent Index Vertical motion) and the Achgan scale (symptoms) for constipation, demonstrated a greater improvement in the biofeedback group as compared to the standard treatment group.

In a final level II randomized clinical trial, Gong et al.⁸⁴ examined the efficacy of cranial electrotherapy stimulation combined with surface electromyography biofeedback therapy versus biofeedback alone. Biofeedback was performed for 30 minutes per session, 5 times per week, 10 times per course, for a total of 3 courses. During biofeedback training, patients were required to practice when they were at home, using squeezing and relaxing maneuvers for 15- 30 minutes every time, 3-5 times per week. At the end of treatment, outcomes of the Self-Rating Anxiety

Scale and the Self-Rating Depression Scale improved in both groups, however biofeedback plus cranial electrotherapy stimulation demonstrated greater improvement.

Two level II cohort studies and one level II outcomes study also support the use of electromyographic biofeedback as an intervention for functional constipation. Emmanuel, et al.⁸⁵ assessed whether gut transit was improved by biofeedback in patients with idiopathic constipation; whether improved transit was associated with altered level of extrinsic autonomic nerve activity to the gut; and if biofeedback effects were specific to the gut or if there was a more generalized effect on the level of autonomic activity, as measured by cardiorespiratory autonomic tests. Study results included an increase in bowel frequency, as well as a reduction in the mean number of retained markers in both participants with both dyssynergia and, either normal or slow transit constipation. Tang, et al⁸⁶, compared intensive versus non-intensive “adaptive biofeedback training”, which included training to relax the anal sphincter, enhance sensory perception, and improve rectoanal coordination. Each participant received a total of 16, 30-minute training sessions. Those in the intensive therapy group received adaptive biofeedback training once a day or every other day, while those in the non-intensive therapy group received adaptive biofeedback training twice a week. The primary outcome of cure was based on bowel movements changing from severe or mild to normal and effective treatment was based on bowel movements changing from severe to mild. The cure rates of both intervention groups reached 100%. All secondary outcomes including defecation difficulty, hard stools, and straining demonstrated statistically significant improvements in both groups. This suggests that intensive or non-intensive interventions can be effective. Koh, et a.⁸⁷ sought to determine the efficacy of biofeedback in individuals with dyssynergic defecation whose symptoms were resistant to dietary fiber and laxative therapy. Biofeedback consisted of a supervised 4-session program occurring one month or longer, depending on each participant’s performance. Participants were instructed to practice the exercises 40 times per day at home. Patient outcomes included quality of life scores before and after the biofeedback treatment using the Eypasch’s Gastrointestinal Quality of Life Index, a questionnaire with 36 questions that explores disease impact on the patient’s life including gastrointestinal symptoms, emotion, physical function, social function and medication. At one year follow-up, Eypasch’s Gastrointestinal Quality of Life Index scores of gastrointestinal symptoms improved 68.6%.

Research Recommendation 1:

The positive effects of electromyographic biofeedback training are fairly consistent across studies, although variation in treatment parameters warrant further consideration, and the effects of home based electromyography units compared to exercise performance should be further assessed.

ACTION STATEMENT 2: Rectal Balloon Catheter Biofeedback Training

Clinicians should consider rectal balloon catheter biofeedback filled with air or water with the patient in lateral side-lying (right or left). If/when/whenever 18 years of age or older and diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance, defecography, balloon expulsion, physical exam, and colonic transit marker study) and male or female, but predominantly female and variable practice settings (laboratory, physician practice/clinic, tertiary care center, unspecified)

Evidence quality: B; Recommendation strength: strong

Associated ICF impairment, activity, and participation codes: b525, defecation functions; b5250, elimination of feces; b152, emotional function; b28012, pain in the stomach or abdomen), d5301 regulating defecation; d530, toileting; d230- carrying out daily routine.

Action: Consider Rectal balloon catheter biofeedback filled with air or water with the patient in lateral side-lying (right or left).

Action Statement Profile

Aggregate evidence quality: B

Level II based on 4 level II (1 randomized clinical trial, 2 outcome, 1 cohort), 2 level III (cohort), and 1 level IV (case series) studies.

Benefits: Promoting internal knowledge of performance to achieve correct pelvic floor muscle contractions: proper activation and relaxation of pelvic floor muscles during the defecatory process; No drug interactions or systemic side effects; Minimal long term risk; Practice functional activity of stool expulsion; Normalize (rectal hyposensitivity) sensory awareness of rectal fullness

Risks, harm, and costs: Cost of equipment including balloon catheter and syringe; Patient incurred costs of in-person intervention; Anorectal tissue irritation, damage, and/or bleeding; Psychosocial distress, especially with history of abuse and/or trauma or if balloon ruptures; Cultural sensitivity considerations; Prolonged use could impede development of an internal reference of correctness, thus impairing long term motor learning; Minimal long term risk.

Benefit-harm assessment: Preponderance of Benefit

Value judgment: Rectal Balloon Catheter Biofeedback training allows a safe treatment alternative and may be a good option to avoid more invasive medical and surgical interventions.

Intentional vagueness: Patient treatment session duration and frequency were all highly variable across studies, as was patient position during intervention, use of air versus water to fill the balloon, and temperature of water in the balloon if water was utilized.

Role of patient preferences: Patients may prefer to trial low risk conservative intervention strategies prior to undergoing more invasive medical and surgical interventions.

Exclusions: This aggregate of evidence considered functional constipation and therefore may not be appropriate for patients diagnosed with irritable bowel syndrome- constipation. Other potential exclusions include individuals with cognitive and/or visual impairments for whom this method of learning would not be appropriate.

Policy Level: Third party payers should strongly consider eliminating a trial period of pelvic floor muscle exercises prior to covering rectal balloon catheter biofeedback intervention as this will minimize overall cost and time burden to the patient and payer.

Supporting Evidence and Clinical Implementation

Battaglia et al.⁸⁸ examined the long term treatment efficacy of concurrent electromyographic biofeedback and balloon catheter training in individuals unresponsive to conventional treatments with pelvic floor dyssynergia and slow transit constipation. Prior to the intervention, all patients completed a validated symptom questionnaire and anorectal manometry testing. Both measures were repeated at 3 months following the intervention and questionnaire only via telephone at 1 year. The intervention, performed 2 times per week for 4 weeks, included both electromyographic biofeedback with an intra-anal electrode and rectal balloon catheter training. Subjective symptom report on the validated questionnaire at 3 months demonstrated variable levels of improvement between the pelvic floor dysfunction and slow transit groups. At one year, the treatment effect remained in 50% of the pelvic floor dysfunction group and 20% in the slow transit group. Two additional studies (Lewicky-Guapp et al., Pourmomeny et al) looked at individuals with puborectalis dyssynergia and functional constipation who had also failed to improve with a standard intervention.^{21,89} In Lewicky-Guapp et al²¹, participants underwent multi-modal physical therapy including: biofeedback (manual, electromyography, balloon expulsion), counseling regarding defecatory techniques, and abdominal massage. Sessions occurred weekly but total duration varied based on patient centered goals. Symptom severity, measured by the Patient Assessment of Constipation Symptoms, and quality of life, measured by the Patient Assessment of Constipation Quality of Life Questionnaire, improved significantly after completion of physical therapy, with a strong statistically significant correlation between the difference in symptom severity and improvement in quality of life. Depressive symptoms, measured by the Patient Health Questionnaire, also demonstrated significant improvement post-intervention but were not correlated with symptom or quality of life score changes. Pourmomeny, et al.⁸⁹ studied patients with dyssynergic defecation. Routine treatment was provided to all participants. Those who did not respond to routine treatment (fiber diet, increased water intake, exercise, and laxatives) were referred to physical therapy. All participants (n=65, mean age 37 years) received education on anorectal anatomy, physiology of defecation and metabolism of pelvic floor contraction.

Those assigned to biofeedback (34 patients) were able to watch electromyographic output as they contracted and relaxed their pelvic floor muscles. They also learned to relax their pelvic floor muscles. Those in the balloon-assisted training (31 patients) group were asked to increase their intra-abdominal pressure, relax their anal sphincter and strain for ≤3 minutes. If they failed to expel the balloon within this time, the volume of water in the balloon was decreased to lessen the task difficulty. Six sessions were performed within one week. While subjective improvement was reported on a non-validated outcome measure in both groups immediately following the one-week intervention, 78% of treated patients reported 'complete' or 'partial' satisfaction, with 18% and 46% in the electromyographic biofeedback group and 19% and 58% for the balloon-assisted group, respectively. Treatment effects were superior in the electromyographic

biofeedback group on both primary outcome measures of incomplete evacuation and the need for manual maneuvers. The change in balloon evacuation time for the electromyographic biofeedback group was a 16 second improvement compared to a one second improvement in the balloon catheter group ($p=0.03$). The volume of the balloon defecated by patients was increased by 18.2mL for the electromyographic biofeedback group and 11.3 mL for the balloon catheter group ($p=0.02$).

Three level II studies assessed patients with idiopathic constipation and/or pelvic floor dyssynergia, one in which patients were previously unresponsive to dietary, drug, and biofeedback treatment. In Chiotakakou-Faliakou et al⁹⁰ biofeedback intervention included 4-5 total sessions at a frequency of every 1-2 weeks. Multiple primary outcomes were assessed, both immediately following intervention and at a mean of 23.4 months after completion. Subjective improvement of constipation and bowel symptoms were significantly improved both immediately and after long term follow up. The use of laxatives were significantly reduced immediately following biofeedback, with maintenance of the observed decrease in use at long term follow up. The most significant reduction was seen in oral laxative use, 66% versus 38%. Wiesel et al.⁹¹ utilized concurrent external electrode electromyography and balloon catheter biofeedback at a frequency of 1x/week for an average of 5-one hour sessions. While anorectal manometry measures were performed before and after treatment, the primary outcome of interest was long term patient satisfaction obtained by telephone interview at a mean of two years following intervention. Seventy-nine percent of patients expressed long term overall satisfaction with biofeedback in the long term, which was similar to the findings immediately following intervention of 85% satisfaction. It is important to note that patient satisfaction did not correlate with objective correction of pelvic floor dyssynergia. Eighty-eight percent of patients who did not report satisfaction demonstrated resolution of dyssynergia on follow up manometric testing. The second study by Emmanuel et al.⁸⁵ assessed symptom change and rectal mucosal blood flow changes following a multimodal intervention, including biofeedback, that was administered for a mean of 5 sessions over the course of a mean of 62 days. Each session lasted 30-60 minutes and included concurrent electromyography and balloon catheter training, education on bowel habits, toileting posture, dietary habits, and gastrointestinal anatomy. Repeat colonic transit studies were completed on average 5 months after treatment completion. This is the only study identified that assessed rectal mucosal blood flow, via laser doppler. Following biofeedback, patients with both slow and normal transit constipation, categorized as responders based on reduced laxative use, demonstrated a statistically significant increase in rectal mucosal blood flow.

Finally a level III cohort study by Papachrysostomou et al.⁹², examined individuals with obstructive defecation with both subjective reports and objective findings of pelvic floor dyssynergia. Biofeedback treatment was multi-modal, occurred for a minimum of 3 in-person treatment sessions, and a minimum of 4 weeks of home performance. During the in-person therapy sessions, a rectal balloon catheter was used to improve recto-anal sensory awareness and muscle control with the catheter expulsion. Education on independent use of the

electromyographic biofeedback device was provided so it could be utilized at home. Primary outcomes of anismus index and rectal sensory threshold demonstrated a moderate to large statistically significant treatment effect following the intervention; however, the treatment effect for defecation rate was small but statistically significant. This can be attributed to the large statistically significant effect of improvement in time for evacuation but very small yet significant, effect in percentage of complete evacuation.

Research recommendation 2: Due to the multimodal intervention approaches utilized in the presented studies, future research should consider the effects of stand alone balloon catheter intervention versus electromyographic biofeedback and/or manometry. Additionally, it may be beneficial to explore identifying a patient profile who would benefit most greatly from rectal balloon catheter training compared to other biofeedback intervention strategies.

ACTION STATEMENT 3: Anorectal Manometry Biofeedback Training

Clinicians should consider anorectal manometry biofeedback with both an internal balloon catheter (either air or water-filled) and external surface electrodes over the anal sphincter with the patient positioned in left lateral side lying if/when/whenever 18 years of age or older and diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) and male or female, but predominantly female and variable practice settings (laboratory, physician practice/clinic, tertiary care center, unspecified)

Evidence Quality: A; Recommendation strength: Strong Recommendation

Associated ICF impairment, activity, and participation codes: b525, defecation functions; b5250, elimination of feces; b152, emotional function; b28012, pain in the stomach or abdomen, d5301 regulating defecation; d530, toileting; d230- carrying out daily routine.

Action: Consider anorectal manometry biofeedback with both an internal balloon catheter (either air or water-filled) and external surface electrodes over the anal sphincter with the patient positioned in left lateral side lying.

Action Statement Profile

Aggregate evidence quality: A

Level I based on 2 level 1 (randomized clinical trials), 8 level II (3 randomized clinical trials, 3 outcome, 2 cohort), 1 level III (cohort), and 1 level IV (case series)

Benefits: Promoting internal knowledge of performance to achieve correct pelvic floor muscle contractions: proper activation and relaxation of pelvic floor muscles during the defecatory process; No drug interactions or systemic side effects; Minimal long term risk; Practice functional activity of stool expulsion; Normalize rectal hyposensitivity (sensory awareness of rectal fullness).

Risks, harm, and costs: Cost of equipment including balloon catheters, electrodes, and manometry unit; Patient incurred costs of in-person intervention; Anorectal tissue irritation and/or bleeding; Psychosocial distress, especially with history of abuse and/or trauma; Cultural sensitivity considerations; Potential variation in therapist interaction; Prolonged use could

impede development of an internal reference of correctness, thus impairing long term motor learning; Minimal long term risk.

Benefit-harm assessment: Preponderance of Benefit

Value judgment: Anorectal manometry biofeedback training allows a safe treatment alternative and may be a good option to avoid more invasive medical and surgical interventions.

Intentional vagueness: None.

Role of patient preferences: Patients may prefer to trial low risk conservative intervention strategies prior to undergoing more invasive medical and surgical interventions.

Exclusions: This aggregate of evidence considered functional constipation and therefore may not be appropriate for patients diagnosed with irritable bowel syndrome- constipation. Other potential exclusions include individuals with cognitive and/or visual impairments for whom this method of learning would not be appropriate.

Policy Level: Third party payers should strongly consider eliminating a trial period of pelvic floor muscle exercises prior to covering anorectal manometry biofeedback intervention as this will minimize overall cost and time burden to the patient and payer.

Differences of Opinion: None.

Supporting Evidence and Clinical Implementation

A level I randomized clinical trial⁹³ compared biofeedback-guided pelvic floor exercise with oral polyethylene glycol. Constipation symptoms, Wexner Scores, and quality of life scores were assessed after 1, 3, and 6 months. Biofeedback sessions occurred weekly for 5 visits, 30 minutes in duration, using manometric (Medtronic Med Ltd)-guided biofeedback. This group was also instructed in pelvic floor muscle exercises for home. In the polyethylene glycol group treatment consisted of oral 17g polyethylene glycol 3x/day for 14 days and a high fiber diet. At the six month follow-up, symptoms in the biofeedback group patients showed significantly greater outcomes compared with the polyethylene glycol group regarding difficult evacuation, hard stools, digitation necessity, laxative dependence, perianal pain at defecation, constipation satisfaction, Wexner Constipation Score, and quality of life score . After a complete course of training, improvements in the clinical symptoms of the biofeedback group were markedly improved and the Wexner Constipation Scores were greatly decreased compared with the oral polyethylene glycol group .

Another level I randomized clinical trial compared biofeedback, Botox, and surgery in adults unresponsive to laxative or enema use.⁹⁴ Outcomes were assessed weekly for the first month, then monthly for the first year. The primary outcome measures included the Agachan Constipation Score (Bowel Symptoms. Secondary outcomes included relaxation of the puborectalis muscle via anal manometry, balloon expulsion, defecography, and electromyography); patient satisfaction (using a visual analogue scale); and were assessed at 6 months and one year. In the biofeedback retraining group, patients received treatment 2 times

per week. Biofeedback was performed using a perfused eight-channel polyvinyl catheter with a compliant balloon at the tip. The patient was asked to relax their pelvic floor muscles and push using abdominal muscles for 30 minutes duration per day. In addition, participants received education on anatomy and physiology of the pelvic floor and a home program after biofeedback, with periodic supervision every 6 months. In the Botox-A group, botox was injected into the paradoxically contracting muscle at 5 and 7 o'clock with .5ml Botox-A as needed based on clinical assessment and manometry into the paradoxically contracting muscle at the position of 5 and 7 o'clock. No more than 2 injections were given if "unsuccessful". In the third group, a bilateral open partial division of the puborectalis was performed. Outcomes at 1 month included a 50% improvement for biofeedback; 75% for Botox-A injection; and 95% for partial division of the puborectalis. At one-year improvement was 30% for biofeedback; 35% for Botox-A injection; and 70% for partial division of the puborectalis. Constipation score of the patients significantly improved post partial division of the puborectalis and Botox-A injection. Manometric relaxation was achieved significantly in the three groups. Farid (2009) also compared biofeedback to botox injections into the puborectalis. The botox group demonstrated statistically significant improvement over biofeedback at 1 month, but at one year visual analogue scale, anorectal manometry, and balloon expulsion groups demonstrated no statistically significant between group changes.

Two randomized clinical trials compared the efficacy of manometric biofeedback plus standard of care (6 sessions over 3 months), standard of care (diet, exercise, laxatives) alone,^{95,96} and sham biofeedback⁹⁵. Rao et al⁹⁵ found significant improvements in the outcomes of defecation index, balloon expulsion time, colonic transit time, frequency of digital maneuver, and number of complete spontaneous bowel movements in the biofeedback group although colonic transit time also improved in the standard of care group. Rao et al.⁹⁶ demonstrated similar findings, with participants in the biofeedback group demonstrating improvement in outcomes of number of spontaneous bowel movements, balloon expulsion time, defecation index, and colonic transit time while no statistically significant change was found on these outcomes in the standard treatment group.

A level II cohort study²⁸ recruited patients all with delayed whole gut transit, 34 with pelvic floor dyssynergia, 12 with slow transit constipation only and 6 with mixed symptoms of both dyssynergia. There was no comparison group. The group underwent five weekly manometric biofeedback sessions.. Questionnaire, symptom diary balloon defecation, and transit study were conducted at 1,6,12 and 24 months while anorectal manometry was tested at 1 and 6 months. At 6 months, 71% of those in the pelvic floor dyssynergia group reported fair to major satisfaction compared to 7% in slow transit group (P= .001). 76% of the pelvic floor dyssynergia group reported ≥ 3 bowel movements per week as compared to 8% in the slow transit group. Improvement was maintained at 24 months of follow-up. Biofeedback eliminated dyssynergia in 91% enabled 85% to expel the balloon, reductions in dyssynergia, and increased rectal pressure during straining. Biofeedback is most helpful in addressing pelvic floor dyssynergia but not slow transit constipation.

A level II outcomes study compared women symptomatic for constipation and dyssynergic defecation without slow transit and a group of healthy age-matched controls.⁹⁷ All patients underwent bimodal rehabilitation: a single cycle consisted of ten outpatient sessions. Each session lasted 1 hour and took place twice a week. The first step was pelviperineal kinesitherapy using a set progressive exercises to improve proprioceptive awareness of the pelvic muscles. This exercise was then combined with biofeedback training from the 5-10th visits to end the cycle. The rectoanal inhibitory reflex with incomplete relaxation improved significantly by the end of rehabilitation. All patients noted improvement in rectal frequency. Use of laxatives and enemas decreased, and the urge to digitally evacuate the rectum disappeared.

Multiple studies have demonstrated improvement in quality of life measures, including the Short Form-36, Patient Assessment of Constipation Quality of Life, self rating anxiety scale, Zung self-rating depression scale, as well as bowel symptoms following biofeedback intervention. Parameters of intervention frequency and duration, as well as follow up time varied significantly.⁹⁸⁻¹⁰² Lower levels of evidence also demonstrate possible benefit of combining diaphragmatic breathing with biofeedback to augment muscle relaxation.^{103,104} However manometric biofeedback was not shown to affect measures of autonomic nervous function.⁹⁸

Research Recommendation 3: The anorectal manometry units utilized in the presented studies are expensive and impractical for clinical use. Additional research should consider designing reliable, valid, and cost-effective units that require less training to become proficient in use; and determine if these units are valid and reliable compared to traditional anorectal manometry units.

ACTION STATEMENT 4: MANUAL THERAPY

Associated ICF impairment, activity, and participation codes: b525, defecation functions; b5250, elimination of feces; b152, emotional function; b28012, pain in the stomach or abdomen, d5301 regulating defecation; d530, toileting; d230- carrying out daily routine.

Action Statement Profile

Clinicians should consider manual therapy including a variety of soft tissue mobilization techniques (abdominal massage, perineal self acupressure, reflexology, connective tissue mobilization), joint mobilization, and visceral mobilization for short term effects if/when/whenever 18 years of age or older and diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) and male or female, but predominantly female and secondary or tertiary care centers

Evidence Quality: B; Recommendation strength: Moderate

Action: Consider manual therapy including a variety of soft tissue mobilization techniques (abdominal massage, perineal self acupressure, reflexology, connective tissue mobilization), joint mobilization, and visceral mobilization for short term effects

Aggregate evidence quality: B

Level II based on 3 level 1 (randomized clinical trials), 5 level 2 (1 outcomes, 4 randomized clinical trials), 2 level 3 (cohort), and 4 level 4 (3 case series, 1 case report)

Benefits: No drug interactions; minimal long term risk; improved defecation frequency, quality of life, patient satisfaction and stool consistency (Bristol Stool Scale); and improved feeling of incomplete emptying.

Risks, harm, and costs: Patient incurred costs of in-person intervention; tissue irritation, bruising, bleeding, and/or damage; exacerbation of underlying occult secondary condition; cultural sensitivity considerations; autonomic reaction.

Benefit-harm assessment: Preponderance of Benefit

Value judgment: Manual therapy allows for safe short-term treatment effects and may be a good option to avoid more invasive medical and surgical interventions.

Intentional vagueness: Multiple techniques with a variety of parameters were utilized in the aggregate of evidence.

Role of patient preferences: Patients may prefer to trial low risk conservative intervention strategies prior to undergoing more invasive medical and surgical interventions.

Exclusions: This aggregate of evidence considered functional constipation and therefore may not be appropriate for patients diagnosed with irritable bowel syndrome- constipation. Other potential exclusions include: individuals with increased fracture risk due to underlying secondary conditions.

Policy Level: No recommendations.

Differences of Opinion: None.

Supporting Evidence and Clinical Implementation

A level I randomized clinical trial²⁵ and two level II randomized clinical trials^{105,106} assessed the effects of abdominal massage on quality of life, number of spontaneous bowel movements, laxative consumption, and constipation symptom severity in older and elderly adults. Abdominal massage parameters included: performance of the technique for fifteen to thirty minutes, four to eight weeks, thirty to sixty minutes after a meal, for five to seven days per week. Statistically significant improvements in all measures except for laxative consumption were demonstrated with no adverse effects.

A level I randomized clinical trial examined the short-term efficacy of perineal self-acupressure plus standard care treatment.¹⁰⁷ Adults who met Rome III criteria for functional constipation were randomized into the treatment group receiving a 3-5-minute training session on perineal self-acupressure plus standard treatment or the control group which received educational materials about constipation and conventional treatments. Participants completed self-reported measures prior to treatment and at the end of 4 weeks to capture quality of life, bowel function, and health and wellbeing. Patient Assessment of Constipation Quality of Life improved by 0.76 points in the treatment group and by 0.17 points in the control group. The Modified Bowel

Function Index score improved by 18.1 points in the treatment group and by 4.2 points in the control group. The Short Form-12v2 Physical Component Score improved by 2.69 points in the treatment group and 0.36 points in the control group while the Mental Component Score was improved by 3.12 points in the treatment group and by 0.30 points in the control group. For patients with constipation, perineal self-acupressure, in the short term, appears to improve quality of life, bowel function and health and wellbeing as compared to standard constipation treatment alone.

Gursen et al.¹⁰⁸ compared connective tissue mobilization in a sitting position from the lumbosacral region, the lower thoracic, periscapular and cervical regions for 15-20 minute treatment sessions; 5 days/week for 4 weeks; and lifestyle advice to a control group that received lifestyle advice only for constipation. Participants completed self-reported measures prior to treatment and at the end of 4 weeks of treatment with the primary outcome measure, the Constipation Severity Instrument. This outcome demonstrated significant improvement in the intervention group compared to the control across all parameters in Constipation Severity Instrument total score, as well as; the obstructive defecation score, colon inertia score, and pain score. The secondary outcome measure, Patient Assessment of Constipation Quality of Life total score, was higher in the treatment group as well as the physical discomfort, psychosocial discomfort, worries/concerns, and satisfaction Patient Assessment of Constipation Quality of Life sub scores. This study showed that connective tissue mobilization and lifestyle education, in the short term, were superior in reducing symptoms of constipation and increasing quality of life compared with lifestyle education alone for patients with chronic constipation. However, further studies investigating long-term effectiveness of connective tissue mobilization is needed.

Koo 2016¹⁰⁹ compared the effect of Maitland Orthopedic Manual Therapy to dietary fiber. Maitland Orthopedic Manual Therapy was performed at spinal segments T9 to L2, (which correspond to the gastrointestinal tract) for 20 minutes/day, 3 days each week for 8 weeks. Those in the dietary fiber group consumed a total of 20-25g dietary fiber each day for 8 weeks. Statistically significant improvement in both total colonic transit time and rectosigmoid colonic transit time were seen within the intervention and control groups. However, between groups, left colon transit time, rectosigmoid transit time and total transit time were all significantly improved in the Maitland Orthopedic Manual Therapy group with total transit time improving by 18.68 hours as the between group treatment effect $p < .05$. Woodward 2010¹¹⁰ utilized a prospective single-group test-retest design to determine the effects of reflexology on constipation symptoms in females. Reflexology treatment, consisting of pressure applied in a standardized sequence to all the reflex zones on the right foot, using a "hooking" technique with the thumb and fingers then repeated on the left foot, occurred one time per week for six weeks. Ninety-four percent of participants subjectively reported improvement in constipation symptoms. Colonic transit time, anxiety scores, and depression scores all improved as well, however the study was not powered correctly therefore statistically significant improvement could not be determined. Participants in Belvaux 2017¹¹¹ study underwent a weekly course of Osteopathic Manual Treatment for four weeks, consisting of one hour sessions in which the

patient's posture, movement, joint and soft tissue mobility were assessed and treated including: muscle energy, balanced ligamentous tension, myofascial release, and visceral techniques. Patients reported a decrease of abdominal pain, bloating, quality of life score and drug . Two level IV Case Series^{21,112} and two Level IV case reports^{113,114} also support the findings discussed above including abdominal massage, spinal mobilization and manipulation.

Overall these studies demonstrate that manual therapy interventions both soft tissue and joint mobilization may be beneficial in the management of constipation but they lack consistency and long term follow up.

Research recommendation 4: Due to the heterogeneity of manual interventions considered, future research should consider randomized trials directly comparing specific techniques. Additionally, if multimodal intervention is performed, the only difference between groups should be a singular manual technique.

ACTION STATEMENT 5: ELECTRICAL STIMULATION

Associated ICF impairment, activity, and participation codes: b525, defecation functions; b5250, elimination of feces; b152, emotional function; b28012, pain in the stomach or abdomen, d5301 regulating defecation; d530, toileting; d230- carrying out daily routine.

Action Statement Profile

Clinicians may consider electrical stimulation including: intra-anal (electrogalvanic, unspecified), Transcutaneous Electrical Stimulation, and cranial electrotherapy stimulation if/when/whenever 18 years of age or older and diagnosed with functional constipation with varied criteria (ROME II-IV or unspecified) and with variable diagnostic testing (anorectal manometry, magnetic resonance defecography, balloon expulsion, physical exam, and colonic transit marker study) AND male or female AND secondary or tertiary care centers

Evidence quality: D; Recommendation strength: Weak

Action: Consider Electric stimulation including: intra-anal (electrogalvanic, unspecified), Transcutaneous Electrical Stimulation, and cranial electrotherapy stimulation.

Aggregate evidence quality: D

Level D based on 1 level I (randomized clinical trial), 4 level II (3 cohort, 1 randomized clinical trial), and 1 level IV (1 case series)

Benefits: No drug interactions; Minimal long term risk; Improved rectal sensory awareness (hyposensitivity only); Improved anorectal angle on straining; Improved defecation frequency; Improved score on the Constipation Assessment Scale; reduced muscle spasm.

Risks, harm, and costs: Patient incurred costs of in-person intervention; Tissue irritation, bruising, bleeding, and/or damage; Cultural sensitivity considerations; presence of diabetes, hypothyroidism, cancer, and/or psychiatric diagnoses; presence of pacemaker or other implantable cardiac defibrillator; history of previous intestinal surgery or drug abuse

Benefit-harm assessment: Equilibrium due to conflicting evidence.

Value judgment: Electrical stimulation may be considered as an adjunct intervention for individuals with a rectal hyposensitivity impairment.

Intentional vagueness: Electrical stimulation protocol, including mode of delivery which varied widely across studies.

Role of patient preferences: Patients with rectal hyposensitivity may prefer to trial low risk conservative intervention strategies prior to undergoing more invasive medical and surgical interventions.

Exclusions: This aggregate of evidence considered functional constipation and therefore may not be appropriate for patients diagnosed with irritable bowel syndrome- constipation. See risk, harm, costs for additional exclusion considerations.

Difference of Opinions: Evidence for the use of electrical stimulation is conflicting. One clinical practice guideline³³ as well as three systematic reviews^{71,74,75} failed to include a recommendation or considerations for the use of electrical stimulation in the management of functional constipation. One clinical practice guideline³² recommended that electrical stimulation may be considered as an adjunct therapy for patients with rectal hyposensitivity or for those who failed biofeedback intervention.

Policy Level: No recommendations.

Supporting Evidence and Clinical Implementation

Three level II cohort studies examined electrical stimulation therapy utilizing an intra-anal plug electrode to deliver the stimulation.¹¹⁵⁻¹¹⁷ Chang et al,¹¹⁵ compared biofeedback to electrical stimulation in patients with functional constipation and impaired rectal sensation. Electrical stimulation was performed using variant stimulation according to patient tolerance. While participants in both groups subjectively improved, electrical stimulation appeared to affect only frequency of sense of desiring to defecate and rectal sensory threshold values, while only biofeedback improved anal residual pressure during attempted defecation. These findings support the recommendation by Shin et al.³² that electrical stimulation may serve as a good adjunct modality if a rectal sensation impairment exists. Chiarioni et al,¹¹⁶ looked specifically at the longer term effects (1 year) of electrogalvonic electrical stimulation in people diagnosed with functional constipation and pelvic floor dyssynergia. Voltage, similar to Chang et al.¹¹⁵, was determined by patient tolerance. At one year follow up, there was no change in colonic transit time for participants with normal or slow transit, slight improvement in maximum basal pressure of the internal anal sphincter, significant decrease in defecatory sensory threshold, significant increase in anorectal angle on straining, and significant improvement on all clinical variables. As there was no comparison group in this study, no conclusions could be made regarding the superiority of this intervention to other interventions. Chiarioni et al.¹¹⁶ noted important limitations in this study including possible placebo effects and the reduced use of laxatives. Jung et al.¹¹⁷ compared the effects of intra-anal electrical stimulation therapy in patients with a functional defecatory disorder as classified by the Rome II criteria, with or without rectal hyposensitivity confirmed on anorectal manometry and failure of balloon expulsion test, who had

failed a trial of medication and biofeedback. Subjective outcomes on a likert-scale were assessed immediately following each intervention cycle, with some participants completing more than one cycle. Patients in the responder group did report increased overall satisfaction compared to non-responders. However, there were no treatment effects observed between responders and non-responders in those with or without rectal hyposensitivity, with no significant differences found between responders and non-responders on follow up anorectal manometry testing or colonic transit time. It is also important to note that two participants experienced oozing rectal bleeding as an adverse event upon removal of anal plug.

A level II randomized clinical trial compared the effects of biofeedback to biofeedback with cranial electrotherapy stimulation in patients with functional constipation.¹¹⁸ There were no between group differences found on anorectal manometry testing but measures of anxiety, depression, and bowel symptom scores via the Wexner Constipation Score decreased in both groups with improvement in the group receiving biofeedback and electrical stimulation statistically greater than biofeedback alone. Participants' ability to evacuate a rectal balloon filled with 50 milliliters of water within 5 minutes improved in both groups, again with greater improvement in the biofeedback plus electrical stimulation group.

Finally a level IV case series assessed the effects of low-frequency current applied using transcutaneous electrical nerve stimulation through four electrodes placed over the buttocks on S2 and S3 dermatomes in individuals with idiopathic slow transit constipation.¹¹⁹ Participants underwent treatment for 20 minutes, 3 times per week for 6 weeks with the following parameters: frequency of 50 Hz and burst intervals of 3 and 6 seconds. While a statistically significant improvement was found on all three outcomes measures of interest (number of bowel movements per day, number of bowel movements per week, and score on the Constipation Assessment Scale), this study had a very small number of participants. Statistically significant improvement in stool frequency following transcutaneous electrical nerve stimulation intervention was reported in a recent systematic review and meta-analysis on non-pharmacologic interventions for chronic functional constipation, however these results must be interpreted with caution as only two of the included studies utilized transcutaneous electrical nerve stimulation.¹²⁰ One of the studies compared transcutaneous electrical nerve stimulation to sham transcutaneous electrical nerve stimulation (n=39), while the other compared transcutaneous electrical nerve stimulation to acupuncture (n=64).

Research recommendation 5: Electrical stimulation appears to offer greatest benefit to patients with rectal hyposensitivity. Additional studies should examine the most efficacious type and parameters of electrical stimulation for this sub-group of patients diagnosed with functional constipation.

Additional Intervention Considerations: Patient Education and Therapeutic Exercise

Associated ICF impairment, activity, and participation codes: b525, defecation functions; b5250, elimination of feces; b152, emotional function; b28012, pain in the stomach or abdomen, d5301 regulating defecation; d530, toileting; d230- carrying out daily routine.

Patient Education

Patient education is a common physical therapy intervention; however, two clinical practice guidelines^{32,33} and six systematic reviews^{71-75,121} failed to discuss the role of patient education or existing evidence in the management of constipation. Although some did address specific recommendations for fiber and laxative use^{32,33,71,74,75,121}, these recommendations were not specific to patient education. While patient education was described in multiple studies reviewed for this guideline as part of a multi-modal physical therapy intervention, it was only the primary intervention in one high quality level I study.¹²² This made it impossible to provide an action profile or grade of recommendation for patient education interventions. However, since it has not been previously addressed as it relates to the management of constipation to the authors' knowledge, a summary of existing educational interventions in the literature are found below.

Supporting Evidence and Clinical Implementation

Patient education in the management of constipation fell within ten domains across the studies included in this clinical practice guideline: Dietary education (including fiber intake), fluid intake, abdominal massage, toileting strategies and mechanics/reflexes of defecation, laxative use, posture, physical activity, pelvic floor anatomy and physiology, role of biofeedback, and lifestyle/psychosocial education. Multiple studies included dietary education as part of a multi-modal intervention program.

Dietary and fluid intake education, including the role of fiber, were the most frequently reported educational interventions. A three-arm cluster randomized trial with economic evaluation did compare laxative use; standardised, non-personalised dietary and lifestyle advice; and personalised dietary and lifestyle advice, with reinforcement.¹²³ They found similar treatment effects in all groups but did find healthcare cost savings in the education groups. The study had multiple limitations, however, including small sample size and low self-reported rates of constipation.¹²³ Dietary education largely focused on increasing daily fiber intake with high-fiber foods but also included education on avoiding dietary irritants¹¹³ and consultation with a dietician.^{21,27,83,95,96,102,108,110,114,124-129} Fluid intake education varied from general encouragement to increase fluid intake to 1.5-2 liters of water intake per day; however, there is no consistent supporting evidence regarding specific fluid intake recommendations.^{21,27,83,95,96,102,108,110,114,125-127}

Education on the role of abdominal massage as well as instruction in self performance occurred in multiple studies.^{21,84,113,114}

Education in toileting mechanics and strategies always accompanied abdominal massage education but was also included in additional study interventions.^{27,81,83,85,90,95,96,98-100,102,108,124-128,130} The most common recommendations were to avoid straining, avoid delaying defecation once an urge was felt, and sitting on the toilet with feet raised (on a step) and anterior trunk lean to increase anorectal angle and promote ease of defecation.

Laxative use education was discussed in multiple studies^{83,95,96,99,102,125,126}; however, the guideline authors recommend extreme caution with this education as medication recommendations are outside the scope of physical therapy practice and should be directed by the patient's physician(s). There are clinical practice guidelines and systematic reviews that discuss laxative use further if additional information is desired.^{32,33,71,74,75,121}

Postural education, including purpose and retraining, was discussed in a level IV case report.¹¹⁴

Physical activity education emphasized the importance of physical activity and exercise on both bowel and overall health.^{27,83,95,96,108,114,124–126,130} Specificity of recommendations varied from generalized increased physical activity to walking 20 minutes, three-seven days per week^{83,126}.

Education of pelvic floor anatomy and physiology was performed with images and models, sometimes including that patient's own images and test results.^{27,84,94,102,113} In one study, the emphasis of education was on basic gut specific anatomy and function.⁸⁵

Biofeedback education, which was performed prior to biofeedback intervention, included an explanation of the objectives of biofeedback training to correct a dyssynergic pattern of defecation.^{83,84,98,102}

Finally, lifestyle and psychosocial education emphasized breathing techniques for relaxation^{83,97} and self-management strategies¹²⁴ including visualization of pelvic floor muscle relaxation while utilizing a vibrator vaginally over the levator ani muscles and dilator rectally¹¹⁴.

Therapeutic Exercise

Therapeutic exercise is also a hallmark physical therapy intervention. A recent systematic review and meta-analysis assessed the effects of exercise on constipation symptoms but these exercises were not specific to physical therapy.¹³¹ Exercise included both aerobic and anaerobic activities. While general physical activity was discussed in one previously published clinical practice guideline³² and systematic review⁷⁵, neither described specific exercises recommended in the treatment of functional constipation. Shin et al³², stated that low levels of physical activity are associated with chronic constipation and suggested that physical activity may improve symptoms of constipation, particularly in the elderly population, as well as quality of life and other health measures. However, the potential benefit of physical activity or therapeutic exercise on constipation symptoms may be negated in this age group due to the fact that individuals in this age group are likely to be on multiple medications. The benefits of physical activity were supported with a low level of evidence. Muller-Lissner and Wald⁷⁵ reported similar findings and differentiated the effect of exercise on the various Rome II criterion symptoms, including bowel frequency, straining, number of hard stools, and number of people fulfilling the Rome II criteria. They also found low to very low level evidence to support this recommendation. It is worth noting that no adverse effects of exercise were found by either group.

Supporting Evidence and Clinical Implementation

Due to the heterogeneity of within study interventions included in this guideline discussing physical activity or exercise, a formal recommendation cannot be made. However, many of the studies included did describe specific exercise interventions utilized in conjunction with the primary intervention studied. This descriptive specificity has not been previously examined and may provide clinical utility in the physical therapy management of individuals with functional constipation. Recommended therapeutic exercise interventions fell within six domains identified by the authors of this guideline: pelvic floor muscle training (strengthening, relaxation, and coordination), muscle training (not pelvic floor), functional training (including balance), cardiovascular & aerobic exercise, breathing exercises, and stretching.

Pelvic floor muscle exercise parameters varied widely across the thirteen studies specifying this as an intervention independent of or in addition to biofeedback, including combinations of strengthening, relaxation, and coordination training.^{27,84,87,88,94,97,99,113,114,127,128,132,133} Two of those studies specifically mentioned pelvic floor muscle exercises were performed as part of the participants' home program.^{87,132} Eleven studies included abdominal muscle training and bracing^{27,83,84,86,87,90,91,94,113,132}, one of which performed this with electromyography on the abdomen²⁷, while two studies included strength training of other muscles not specified^{97,114}. Chin et al.⁵⁵ included lower extremity strengthening and balance training as part of their intervention but found that they did not have an effect on constipation symptoms or laxative use. A case series¹³⁴ looked at the effect of 4 weeks of cardiovascular activity, monitored by a pedometer, in eight individuals with a mild to moderate active lifestyle and found no correlation between constipation index scores and physical activity scores. They suggested that higher levels (increased frequency and duration) of exercise may have yielded different results. Diaphragmatic breathing was utilized in eight studies^{83,96,97,100,109,114}) with a likely goal to improve intra-abdominal force production required to effectively eliminate stool¹³⁵. Only two studies included stretching as part of their intervention^{97,114}, one of which included perianal and perivaginal stretching as part of a pelviperineal kinesiotherapy program⁹⁷. The other study included stretching of hip flexors, hamstrings, gluteals, and piriformis.¹¹⁴

DISCUSSION

Given the lack of constipation symptom reporting by adult patients to their healthcare provider³⁷, an increase of constipation awareness by all physical therapists, regardless of their specialization, is needed. This clinical practice guideline summarizes the epidemiology of and risk factors for functional constipation; and the comparative efficacy of physical therapy interventions to improve adult constipation.

For patients diagnosed with functional constipation and under the care of a pelvic health physical therapist, physical therapy interventions that we strongly recommended based on data reviewed include: 1) electromyography biofeedback, a non-invasive intervention that carries minimal long-term risk to improve pelvic floor muscle contractions; and can be performed in positions that eliminate and/or modulate the use of gravity to progressively train the muscles; 2) Rectal Balloon Catheter Biofeedback, an invasive intervention to promote pelvic floor muscle contractions; and proper activation and relaxation of pelvic floor muscles during defecation that is costly and carries higher risk compared to electromyography biofeedback, yet long term risk is minimal; and 3) Anorectal Manometry Biofeedback, an invasive intervention to promote motor learning of correct pelvic floor muscle activation and relaxation during the act of defecation, as well as improving sensory awareness of stool in the rectum (rectal fullness).

Despite the strong recommendation for biofeedback interventions, the physical therapist should consider feedback scheduling and its impact on skill retention, in other words, motor learning. Based on motor learning research, a less frequent, or a fading schedule of feedback has been shown to lead to better retention (learning) of a motor task.¹³⁶ In addition, the therapist must consider potential risks, harm, and costs incurred to the patient if this intervention is to be included into the patient's plan of care. Although long term risks are minimal, some short-term risks may interfere with patient acceptance (in the case of individuals that have a history of abuse or trauma; or cultural beliefs that may interfere with this intervention).

An intervention that may be considered based on lower level (moderate) evidence quality is manual therapy. Consumers of this clinical practice guideline should strongly take into account that this intervention category includes a diversity of intervention techniques (perineal self-acupuncture, connective tissue mobilization, reflexology, joint mobilization and visceral mobilization) not only within but between studies assessed for this clinical practice guideline. Thus, replication and translation of the presented evidence for manual therapy interventions to actual clinical practice presents a significant challenge to the physical therapist. Precautions should be considered with the application of manual therapies targeted at articular structures in patients at risk for fracture.

Another intervention, electrical stimulation, which would appear to be useful in the management of functional constipation, received a weak recommendation based on the reviewed evidence. This clinical practice guideline included intra-anal (electrogalvanic, unspecified), transcutaneous electrical stimulation, and cranial electrotherapy stimulation in this intervention category. Similar to manual therapy, electrical stimulation protocols varied widely across studies; and some were vague.

Perhaps most important, electrical stimulation appears to provide the best benefit only to individuals with rectal hyposensitivity. Thus, the cost of this intervention to a physical therapy practice could be a barrier to its utility depending on the preponderance of patients upon which this intervention would be relevant. In addition, risks associated with this intervention must be strongly considered. Tissue irritation, bruising, bleeding and/or damage can occur. Additionally, this intervention may carry risks for patients with diabetes, hypothyroidism, cancer, psychiatric diagnoses, previous intestinal surgery, surgically implanted pacemaker or cardiac defibrillator, or drug abuse. Finally, our recommendation was not based on single studies. Instead, the evidence was obtained from one published clinical practice guideline and three systematic reviews.

Patient education and therapeutic exercise are gold standard interventions provided by physical therapists regardless of diagnosis. Despite our extensive literature search, we did not unveil studies that focused their aims toward determining the evidence for individual patient education and therapeutic exercise interventions. Although a limitation of such investigations, it is understandable given patient education rarely includes single intervention recommendations. However, this clinical practice guideline does summarize educational intervention recommendations including dietary and fluid intake; abdominal massage; toileting strategies; defecation mechanics, laxative use and toileting mechanics as provided in the reviewed literature.

CLINICAL IMPLICATIONS

The recommendations from this clinical practice guideline were developed to assist pelvic health physical therapists to select and implement evidence-based physical therapy interventions for adults with functional constipation. However, this clinical practice guideline is relevant to all physical therapists that manage adult clients. Specifically, this guideline may enhance non-pelvic health physical therapists understanding of the importance of screening adult patients for constipation risk factors; and in some cases, may be able to recommend behavioral advice for functional constipation risk factor reduction. In others that require more extensive intervention,

this clinical practice guideline may provide non-pelvic health physical therapists greater recognition to refer such patients to a pelvic health physical therapist.

STUDY LIMITATIONS

The recommendations provided in this clinical practice guideline are intended for patients with functional constipation only. In addition, our recommendations are based on the review of the literature from 1997 to 2020. Thus, results of additional studies published beyond this timeline are not included in this guideline. Another limitation of these guideline recommendations is that we did not provide specific details regarding intervention length (frequency and number of intervention sessions) due to the heterogeneity of intervention protocols utilizing within and across studies.

CONCLUSIONS AND FUTURE RECOMMENDATIONS

As the role of physical therapy expands, clinical practice guidelines are critical to guide both physical therapist specialists, as well as those involved in general practice. This clinical practice guideline provides intervention recommendations based on published evidence from 1997 to 2020. As evidence evolves, there will be a future need to update this clinical practice guideline to further advance the physical therapy profession; and ultimately improve patient outcomes.

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TABLE 4. Components of Functional Constipation Are Listed and Categorized According to the International Classification of Functioning, Disability and Health (ICF) Model

ICF Category	Description
Body Function	
<i>Sensory Functions and Pain</i>	
b28012	pain in the stomach or abdomen
<i>Functions of the Digestive, Metabolic, and Endocrine Systems</i>	
b5150	transport of food through stomach and intestines
b525	defecation functions
b5250	elimination of feces
b5251	faecal consistency
b5253	faecal continence
b5254	flatulence
b5258	defecation functions, other specified
b5259	defecation functions, unspecified
b5301	regulation defecation

b535	sensations associated with the digestive system
b5351	feeling bloated
<i>Neuromusculoskeletal and Movement-Related Functions</i>	
b735	muscle tone functions
Body Structure	
<i>Structures Related to the Genitourinary and Reproductive Systems</i>	
s620	structure of the pelvic floor
<i>Structures Related to Movement</i>	
s740	structure of the pelvic region
s7402	muscles of the pelvic region
s7408	structure of the pelvis, other specified
s7409	structure of the pelvis, unspecified
s7403	ligaments and fascia of pelvic region
Activities and Participation	
<i>General Tasks and Demands</i>	
d2100	undertaking a simple task

<i>Self-Care</i>	
d530	toileting
d5301	regulating defecation
d5308	toileting, other specified
d5309	toileting unspecified
Environmental Factors	
<i>Products and Technology</i>	
e115	products and technology for personal use in daily living
<i>Support and Relationships</i>	
e310	immediate family
e355	health professionals
<i>Attitudes</i>	
e450	individual attitudes of health professionals
e460	societal attitudes
e465	Social norms, practices and ideologies
<i>Services, Systems and Policies</i>	
e580	health services, systems, and policies

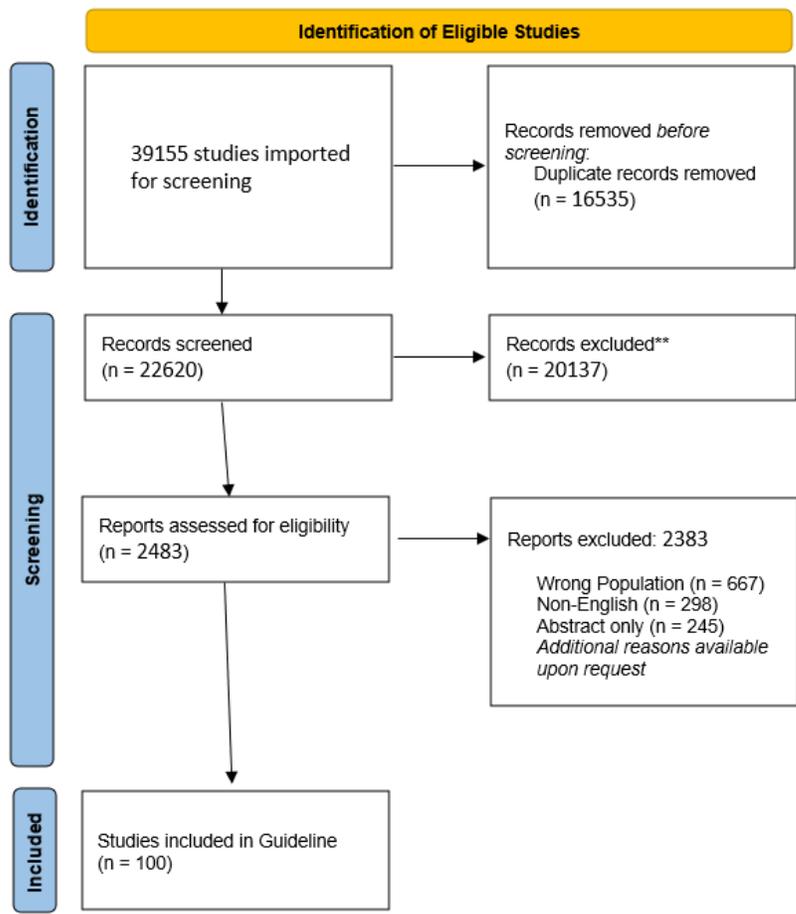
Abbreviation: ICF, International Classification of Functioning, Disability and Health.

Categories are denoted as follows: b for body functions, s for body structures, d for activities and participation, and e for environmental factors. The numbers refer to the World Health Organization's coding system for the specific domains.

Adapted from Grill et al³⁶ with permission from IOS Press.

DRAFT

Figure 1: PRISMA Table¹³⁷



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