Factors Associated With Response to Biofeedback Therapy for Dyssynergic Defecation

Tanisa Patcharatrakul,[*,‡] Jessica Valestin,[§] Amanda Schmeltz,[*] Konrad Schulze,[§] and Satish S. C. Rao[*]

*Division of Gastroenterology and Hepatology, Department of Internal Medicine, Augusta University, Augusta, Georgia; ‡Division of Gastroenterology, Department of Medicine, King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand; §Division of Gastroenterology, Department of Internal Medicine, University of Iowa Hospitals and Clinics, Iowa City, Iowa

BACKGROUND & AIMS: **Biofeedback therapy is effective for dyssynergic defecation (DD), but it is not widely available or reimbursed, and is labor intensive. It is therefore important to select the appropriate patients for this treatment. We investigated symptoms and demographic, manometric, and other factors associated with outcomes of biofeedback therapy in patients with DD.**

METHODS: **We performed a post hoc analysis of 2 prospective studies of biofeedback therapy in 127 adult outpatients (18–75 years old, 120 female) with chronic constipation who failed to respond to treatment with dietary fiber or laxatives (>1 year) and were diagnosed with DD based on standard criteria. In each study, patients received 1-hour, biweekly office biofeedback therapy (6 sessions) or home biofeedback therapy with a device. A therapist used visual feedback, postural, and diaphragmatic breathing techniques to teach subjects to improve defecation. Treatment success was defined by a composite of normalization of dyssynergia pattern and increase of 20 mm in baseline bowel satisfaction score. Factors were compared between the treatment success and failure groups. Intention-to-treat analysis was performed.**

RESULTS: **Of the 127 patients enrolled, 77 (61%) had treatment success. Dyssynergia was corrected in 78% of patients and bowel satisfaction improved in 64% of patients. Baseline demographic features, constipation symptoms, manometric and sensory parameters, balloon expulsion time, and colonic transit results were similar between treatment failure and success groups. Patients with lower baseline bowel satisfaction score ($P = .008$) and patients who used digital maneuvers ($P = .04$) were more likely to have successful biofeedback therapy.**

CONCLUSIONS: **Biofeedback therapy is successful in more than 60% of patients with DD. Patients who used digital maneuvers and patients with lower baseline levels of bowel satisfaction were more likely to have treatment success, whereas other factors were not associated with success. Biofeedback therapy should be offered to all patients with DD, irrespective of baseline symptoms or anorectal physiology findings.**

Keywords: Pelvic Floor Disorder; Behavioral Therapy; Clinic Trial; Constipation.

Dyssynergic defecation (DD) is common and affects up to 40% of patients with chronic constipation.[1–3] This acquired behavioral problem is caused by the inability to coordinate the abdominal and pelvic floor muscles to evacuate stools.[4] Recently, randomized controlled trails showed that biofeedback therapy is effective in 70% to 80% of patients with DD. Also, it is more effective than laxatives and other modalities including sham biofeedback and relaxation therapy, both in the short term and long term.[5–8] In addition, the symptomatic improvement correlates well with improvements in the underlying pathophysiology of anorectal dysfunction. Hence, biofeedback therapy is recommended as first-line treatment for DD by the American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Motility.[9] However, this treatment is not widely available, is labor intensive, and its reimbursement, particularly in the United States, remains problematic.

Abbreviations used in this paper: DD, dyssynergic defecation; IBS, irritable bowel syndrome.

1542-3565/$36.00
https://doi.org/10.1016/j.cgh.2017.10.027

Consequently, selecting patients who are most likely to respond is of paramount importance. Few studies have evaluated this, and each study has used a different method of biofeedback training or has examined only selected outcome measures.[3,5] Consequently, there is a lack of information on the individual patient characteristics and factors that could predict the outcome of biofeedback therapy. In this post hoc analysis study of 2 randomized controlled biofeedback trials, we assessed a comprehensive range of baseline demographic, phenotypic, and manometric factors to determine whether these factors can predict the outcome of biofeedback therapy in patients with DD.

Materials and Methods

Patients

Adult outpatients, 18 to 75 years old with chronic constipation, who failed to respond to dietary fiber and laxatives (>1 year), and with a diagnosis of dyssynergic defecation based on standard[10] and previously published criteria[7] were assessed in this study. All subjects underwent a colonic transit study, anorectal manometry, and a balloon expulsion test at baseline and at the end of the study, and some selected patients underwent defecography. They recorded their bowel symptoms and stool frequency in prospective diaries. DD was defined as follows: (1) patients must fulfill the diagnostic criteria for functional constipation (ROME II) and/or irritable bowel syndrome with constipation (ROME II), (2) patients must show a dyssynergic pattern (types I–IV) during repeated attempts to defecate, and (3) patients must satisfy 1 or more of the following criteria: (a) inability to expel an artificial stool (50-mL water-filled balloon) within 1 minute, (b) inability to evacuate or more than 50% retention of barium during defecography, and (c) 20% or more retention of radiopaque markers on colonic transit studies.[7]

Exclusion criteria included severe cardiac or renal disease; previous gastrointestinal, spinal, or pelvic surgery except cholecystectomy, hysterectomy, or appendectomy; neurologic diseases such as multiple sclerosis, stroke, or spinal injury; impaired cognizance (Mini-Mental State score < 15); legal blindness; pregnancy; rectal prolapse; anal fissure; and alternating constipation and diarrhea. Patients who fulfilled the aforementioned inclusion and exclusion criteria were enrolled in 2 prospective biofeedback therapy trials.[7,11] This study was a post hoc analysis of the biofeedback arm of these 2 clinical trials. One trial was a randomized controlled trial comparing biofeedback with sham feedback and standard therapy[7] and 27 patients from the biofeedback arm were included in this study.[7] The other randomized trial compared 50 patients who had home biofeedback with 50 patients who had office-based biofeedback therapy.[11]

Biofeedback Therapy Protocol

Details of our biofeedback therapy protocol have been published previously.[7,11] In brief, patients were provided advice regarding bowel habits, exercise, laxatives, dietary fiber and fluid intake, and timed toilet training. The nurse therapist taught subjects how to improve their push effort by using postural and diaphragmatic breathing techniques[4,12] and instructed them to practice these maneuvers at home for 15 minutes, 2 to 3 times a day. During attempted defecation, they were instructed to push at a level of 50% to 70% of their maximum straining effort, and spend no more than 5 minutes. All subjects were advised to discontinue digital maneuvers, and its use was recorded. A rescue laxative Q10 regimen was provided. The office biofeedback therapy to correct dyssynergia consisted of biweekly training sessions (maximum, 6 sessions), and each 1-hour session consisted of improving rectoanal coordination during defecation followed by simulated defecation training. The goal of rectoanal coordination was to produce an adequate abdominal push effort, as reflected by an increase in intra-abdominal/intrarectal pressure, that was synchronized with anal relaxation, as reflected by a decrease in the anal sphincter pressure.[4,12] The goal of simulated defecation was to train subjects to expel a 50-mL water-filled balloon within 1 minute. If the subject was unable to expel the balloon, gentle traction was applied to the balloon to supplement the patient's effort. Regarding the home biofeedback therapy, patients were instructed to insert a disposable 2-sensor probe into the rectum, attached to a hand-held pressure monitor with color illuminations that displayed the patient's response (Anatoner; Protech, Hyderabad, India). Thus, by observing the changes in the liquid crystal display, the patient received instant feedback of their anal and rectal pressure changes. The patient was asked to sit on a commode and attempt 10 to 15 push maneuvers, 2 to 3 times a day, and record their attempts in a daily log. The Q11 patient returned for follow-up assessments at 4 and 8 weeks. Based on their progress, newer targets were set by adjusting the sensitivity of the device. After completion of 3 months of training, subjects underwent a colonic transit study, anorectal manometry, a balloon expulsion study, and symptom(s) assessment.

Data Analysis and Outcome Measurement

Four constipation symptoms that described difficulty with defecation including straining, sensation of incomplete evacuation, sensation of anorectal blockage, and manual maneuvers to facilitate defecation with at least 25% of defecations were analyzed at baseline and after treatment. Although a diagnosis of DD involves both bowel symptoms and a dyssynergia pattern on either anorectal manometry or electromyography,[7–9] previous studies have used either an improvement in global bowel