

ORIGINAL CONTRIBUTION

Successful Physical Therapy for Constipation Related to Puborectalis Dyssynergia Improves Symptom Severity and Quality of Life

Christina Lewicky-Gaupp, M.D.¹ • Daniel M. Morgan, M.D.¹ • William D. Chey, M.D.² • Philip Muellerleile, B.S.¹ • Dee E. Fenner, M.D.¹

- 1 Division of Gynecology, Michigan Bowel Control Program, Department of Obstetrics and Gynecology, University of Michigan Medical School, Ann Arbor, Michigan
- 2 Division of Gastroenterology, Michigan Bowel Control Program, Department of Internal Medicine, University of Michigan Medical School, Ann Arbor, Michigan

PURPOSE: This study evaluated symptom severity and quality of life in patients with puborectalis dyssynergia before and after physical therapy.

METHODS: Twenty-two patients with puborectalis dyssynergia were prospectively enrolled into a multidisciplinary program for the treatment of pelvic floor and bowel disorders in this case series. All patients had functional constipation and evidence of puborectalis dyssynergia. Physical therapy and behavioral counseling were offered to all. Patients completed the Patient Health Questionnaire, the Patient-Assessment of Constipation Symptom Questionnaire, and the Patient-Assessment of Constipation Quality of Life Questionnaire.

RESULTS: Sixteen patients successfully completed the program. Symptom severity decreased after physical therapy $(2.1\pm0.7\ vs.\ 1.3\pm0.9,\ P=0.007)$. Quality of life also improved significantly $(2.6\pm0.8\ vs.\ 1.5\pm1.0,\ P=0.007)$. Patients reported less physical discomfort, fewer worries/concerns, and indicated satisfaction with treatment. The difference in symptom severity was highly correlated with improvement in quality of life $(r=0.7,\ P=.005)$.

CONCLUSIONS: Successful physical therapy for patients with puborectalis dyssynergia is associated with improvements in constipation-related symptoms and in quality of life.

KEY WORDS: Constipation; Physical therapy; Quality of life.

Constipation is one of the most common digestive complaints among the general population of the

Presented at the American Urogynecologic Society Meeting, West Hollywood, Florida, September 27–29, 2007.

Address of correspondence: Christina Lewicky-Gaupp, M.D., 1500 East Medical Center Drive, Women's Hospital, L4100, Ann Arbor, Michigan 48109-0276. E-mail: clewicky@med.umich.edu

United States. Constipation accounts for over 2.5 million physician visits annually and is well known to have an adverse effect on quality of life. The causes of constipation are variable and include altered metabolic states (hypothyroidism, diabetes, pregnancy), neurologic disorders (multiple sclerosis, Hirschsprung's disease), medications (anticholinergics, narcotics), and others. Constipation can be classified into three categories: normal-transit, slow-transit, and outlet dysfunction. Puborectalis dyssynergia accounts for up to 25 percent of outlet dysfunction-related constipation. Puborectalis dyssynergia is characterized by a paradoxic contraction of the puborectalis muscle and external anal sphincter, leading to the significantly impaired ability to expel stool during attempts to defecate.

The mainstay of therapy for puborectalis dyssynergia is physical therapy with biofeedback. ^{8,9} Improvements in defecation symptoms have been reported by 43 to 89 percent of patients in studies using nonvalidated measures of treatment success. Laxative and enema use and stool frequency were the clinical outcomes measured. ^{10,11} A few studies have addressed how patient-perceived clinical improvement is associated with an impact on quality of life but have also used nonvalidated measures. ^{12,13}

We sought to evaluate patient-perceived symptom severity and quality of life before and after physical therapy for puborectalis dyssynergia using validated instruments and to report any correlations between symptom change, depression, and impact on quality of life.

METHODS AND MATERIALS

Since 2004, the Michigan Bowel Control Program, a multidisciplinary program for the treatment of pelvic floor and bowel disorders, has been enrolling patients with chronic constipation into a standardized database. In order to be included in this study, patients had to have functional constipation as defined by the Rome II Foundation. This criteria includes two or more of the

following symptoms for greater than 12 weeks during the preceding 12 months: (a) straining during 25 percent of defecations, (b) lumpy or hard stools in 25 percent of defecations, (c) sensation of anorectal obstruction/blockage during defecations, (d) manual maneuvers to facilitate defecations, and/or (e) fewer than 3 defecations per week, as well as loose stools rarely present without the use of laxatives, and insufficient criteria for irritable bowel syndrome.¹⁴ Patients also had clinical evidence (on physical exam by an experienced attending physician or fellow) or diagnostic testing evidence (anorectal manometry, defecography) of a paradoxic contraction of the puborectalis muscle with straining. All patients had to complete their full course of physical therapy. Patients were excluded if they withdrew from the program and failed to complete physical therapy or had surgical intervention during the study period.

The standard protocol included patient education by a nurse regarding high fiber diets, healthy bowel habits, splinting techniques, and fluid management. If patients were not improved with this management alone, physical therapy was initiated. Physical therapy included biofeedback [manual, electromyogram (EMG), and balloon expulsion], counseling regarding proper defecatory techniques, and abdominal massage. All patients underwent training with some form of biofeedback. Some patients required more than one type of biofeedback in order to learn relaxation of the puborectalis muscle. Similarly, patients were counseled about different defecatory techniques; e.g., placing feet on a stool to raise knees above the pelvic floor or leaning forward and grasping ankles during defecation. The form of biofeedback and defecatory technique used was ultimately determined by the physical therapist and the patient. In this way, weekly sessions were individualized for each patient, as was the ultimate duration of therapy. The ultimate duration of therapy was based on patient-centered goals that were expressed upon enrollment into the program. These goals varied from desire to decrease the amount of time spent daily in the bathroom straining, to the desire to decrease symptoms such as bloating. When the therapist and patient agreed that goals had been met, therapy was considered complete.

Instruments

Upon enrollment into the Michigan Bowel Control Program, patients are asked to complete the Patient-Assessment of Constipation Symptoms Questionnaire (PAC-SYM), the Patient-Assessment of Constipation Quality of Life Questionnaire (PAC-QOL) and the first page of the Patient Health Questionnaire (PHQ). Patients are also asked questions regarding their medical and surgical histories. After completion of physical therapy, participants in this study again completed this same series of questionnaires.

Patient-Assessment of Constipation Symptoms Ouestionnaire

The PAC-SYM was a 12-item instrument that measured severity of self-reported constipation symptoms over the previous 4 weeks. Each item has a 5-point Likert scale and respondents are asked to assess whether a symptom was absent, mild, moderate, severe, or very severe. The instrument has three subscales to differentiate different types of symptoms related to constipation. The subscale for stool symptoms included 5 questions about straining/ squeezing, stool consistency and size, and sensations of incomplete evacuation. The subscale for rectal symptoms included 3 items addressing pain during defecation and rectal bleeding/burning. The subscale for abdominal symptoms included 4 items regarding abdominal discomfort, bloating, and cramping. Higher scores indicate more severe symptoms. Total and subscale scores range from 0 to 4 and are calculated by summing the responses to each question and dividing by the number of completed items. 15

Patient-Assessment of Constipation Quality of Life Questionnaire

The PAC-QOL is a 28-item questionnaire designed to assess the self-reported impact of chronic constipation on a patient's quality of life in the previous 2 weeks. Four subscales exist within the instrument: physical discomfort (4 items), psychosocial discomfort (8 items), worries and concerns (11 items), and satisfaction (5 items). Total and subscale scores range from 0 to 4, where higher scores represent more impact and worse quality of life on a 5-point Likert scale. Patient responses were based on either frequency or severity. ¹⁶

Patient Health Questionnaire

The first page of the PHQ is a 9-item instrument extracted from the comprehensive PHQ, an instrument that addresses a variety of different psychiatric diagnoses including depression, anxiety, and multiple mood disorders. The first page itself is a measure of depression severity. Scores range from 0 to 27 with higher scores reflecting more severe symptoms. The Because questionnaires were mailed to patients and because we had concerns about our ability to offer timely follow-up of all questionnaires, the final question of the first page addressing suicidal ideation was eliminated from the instrument.

Statistical Analysis

Paired *t*-test was used to compare mean scores pretherapy and posttherapy. Pearson's correlation coefficient was used to determine if differences in instrument scores pretherapy and posttherapy were correlated. The study was approved by the University's Institutional Review Board.

RESULTS

Over the course of three years (2004–2007), one hundred and twenty-four patients with constipation were enrolled into the program and agreed to allow their clinical and questionnaire data to be utilized for research purposes. Of these, twenty-two patients (17.7 percent) were identified as having puborectalis dyssynergia. Five patients withdrew from the program prematurely because of extenuating social circumstances and did not complete physical therapy. One patient underwent surgical management of concurrent slow-transit constipation during the time she was receiving physical therapy (subtotal colectomy); these patients were thus excluded. Overall, 16 patients completed physical therapy, resulting in a participation rate of 72 percent. All participants were female. The mean age of participants was 54.5 years (SD,17.8). Mean body-mass index (BMI) was 25.6 kg/m² (SD,6.3) and median parity was 3.0. All patients were noted to have a paradoxic contraction of the puborectalis muscle with straining on physical exam by an experienced attending physician as well as by a physical therapist. Twelve patients underwent further testing to confirm their diagnosis: defecography (6), anorectal manometry (4), and both defecography and manometry (2), which confirmed failure of the anorectal angle to increase or paradoxical pressure increased in the sphincter/muscle complex during straining, respectively. Patients were followed for a mean of 1.1 years (SD,0.5; range, 6 months to 2 years). The mean number of sessions was 4.5 (SD, 2.6; range 1-10).

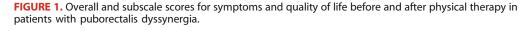
Physical therapy led to decreased symptom severity and improvement in quality of life. An improvement in symptom control was observed in the total PAC-SYM score and in the subscale scores for stool and rectal symptoms, but not abdominal symptoms. Quality of life as measured by the total PAC-QOL score improved, as did all subscales except for the psychosocial (Fig. 1). Symptom improvement, as measured by the PAC-SYM,

was also significantly correlated with the satisfaction subscale of the PAC-QOL (Table 1).

An analysis of the changes in the subscale scores revealed that there were discrete changes in symptoms promoting the improvement in quality of life. The change in stool symptom subscale was highly correlated with multiple subscales of the PAC-OOL. The changes in the abdominal and rectal symptom subscales were correlated with the physical discomfort subscale of the PAC-SYM (Table 2) but not with other areas of quality life such as worries or concerns or satisfaction. Depressive symptoms measured by PHQ scores decreased significantly [baseline 10.7 (SD,7.2) vs. 5.36 (SD, 4.4; P=0.008), but this improvement was not statistically correlated with the change in either the total PAC-SYM (r=0.43, P=0.13) or the total PAC-QOL (r=0.44, P=0.11). A mean score of 10.7 on the PHQ is consistent with moderate depression, while that of patients with major depressive disorder has been reported to be 18.6.¹⁸

DISCUSSION

This study provides evidence that physical therapy for puborectalis dyssynergia is an effective intervention. The response to physical therapy does not appear to be transient, as these findings were among a group of patients with over one-year of follow-up. Patients who can complete physical therapy and comply with behavioral modifications experience less severe symptoms of constipation and improvements in quality of life. Using validated instruments, a consistent pattern between improvement in symptoms, quality of life, and satisfaction with treatment was found. The high correlation of the stool symptom subscale of the PAC-SYM with multiple subscales of the PAC-QOL suggested that patients perceived changes in stool consistency, emptying with defecation, and the need to strain/squeeze to have a



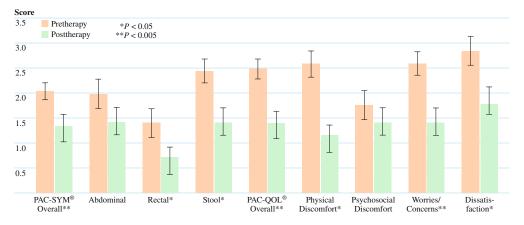


Table 1. Correlation of overall symptom severity and quality of life after physical therapy

		Change in PAC- QOL: Satisfaction
Change in PAC-SYM	r=0.66 P=0.005	r=0.57 P=0.02
Change in PAC-QOL: Symptoms		r = 0.97
		P = 0.0001

 $[\]label{eq:constraints} r = \mbox{Pacron's correlation coefficient} \cdot \mbox{PAC-SYM} = \mbox{Patient-Assessment of Constipation} \\ \mbox{Symptoms Questionnaire} \cdot \mbox{PAC-QOL} = \mbox{Patient-Assessment of Constipation Quality of Life Questionnaire} \\ \mbox{Vector} = \mbox{Patient-Assessment of Constipation} \\ \mbox{Vector} = \mbox{Vector} = \mbox{Patient-Assessment of Constipation} \\ \mbox{Vector} = \mb$

bowel movement led to decreased physical discomfort, fewer worries and concerns, and greater satisfaction with treatment.

The benefits of physical therapy experienced by patients with puborectalis dyssynergia in our study are consistent with previous studies. Wexner reported that physical therapy successfully treated 89 percent of patients in a series of 18 patients over a 9-month follow-up. Patients reported more unassisted bowel movements and a decrease in laxative use. 19 With one year of follow-up in 28 patients, Karlbom reported a success rate of only 43 percent with biofeedback and, similar to Wexner, patients reported increased stool frequency and a reduced laxative use.⁶ The outcome measures we chose do not classify patients as a success or failure, but the improvement in total symptom severity measured by the PAC-SYM and impact on quality of life measured by the PAC-QOL suggest that the therapeutic effect of physical therapy is consistent with these previous studies. The use of validated instruments is a strength of our study, as investigators in future studies may be able to more easily quantify degree of improvement and identify specific types of symptoms that respond best.

While our patients did not document their number of bowel movements or their use of laxatives, the PAC-SYM has shown high correlation not only with patient diaries, ¹⁵ but also with the PAC-QOL, which does specifically address bowel movement frequency. These correlations are consistent with the common finding that clinical improvements are not necessarily correlated with

physiologic testing. For example, multiple studies have reported significant improvements in patient symptoms without changes in anorectal manometry. 20–22

Few studies address quality of life after therapy for puborectalis dyssynergia. In 2007, however, Heyman described biofeedback to be superior to diazepam and placebo in the treatment of constipation secondary to puborectalis dyssynergia in a randomized, controlled trial. In this comprehensive study, patients completed bowel diaries, the PAC-SYM, and the PAC-QOL upon entry into the trial, and again at 3 months posttherapy. The primary outcome was an affirmative or negative response to the question: "Compared to before you started the study, have you experienced adequate relief of constipation?" At three months posttherapy, 70 percent of biofeedback patients responded affirmatively; which was significantly greater than either the diazepam group (P=0.001) or the placebo group (P=0.017). Interestingly, this improvement was not reflected in the PAC-SYM or the PAC-QOL. The authors observed no significant differences in scores from these instruments at 3 months, despite patients who completed physical therapy reporting a significant increase in unassisted bowel movements (P=0.005) and demonstrating significantly lower EMG activity during straining (P=0.001) when compared with those taking diazepam.²

Several differences in our study may explain why we saw correlations between the PAC-SYM and the PAC-QOL. First, our patient sample was a highly motivated group of patients, referred for intractable constipation to this multidisciplinary clinic. The nature of this patient population alone could result in better compliance with dietary recommendations and with practice of techniques learned in physical therapy. Second, upon enrollment in the program, patients reported their goals of therapy. These treatment goals were reviewed and reinforced throughout the duration of physical therapy. Continual emphasis on patient-centered goals is likely reflected in the significant changes in the PAC-SYM and PAC-QOL after physical therapy. Also, while patients in the Heyman study did undergo 4 weeks of education (about defecatory physiology and puborectalis dyssynergia) and medical management (increasing fiber, taking stool softeners),

Table 2. Correlation of instrument subscales								
	Abdominal symptoms	P value	Stool symptoms	P value	Rectal symptoms	P value		
Quality of life subsales	r		r		r			
Overall quality of life	0.44	N.S	0.52	< 0.05	0.03	N.S.		
Physical discomfort	0.50	< 0.05	0.65	< 0.005	0.53	< 0.05		
Psychosocial discomfort	0.41	N.S.	-0.08	N.S.	0.47	N.S.		
Worries/concerns	0.43	N.S.	0.51	< 0.05	0.38	N.S.		
Satisfaction	0.33	N.S.	0.53	< 0.05	0.18	N.S.		

 $r = Pearson's \ correlation \ coefficient \bullet N.S. = not \ significant$

patients in the current study received regular, concomitant reinforcement of dietary changes and fluid intake from our nurses via phone contact. This personalized reinforcement may have increased patient compliance with treatment as well as may be reflected by the fact that one patient who participated in only one physical therapy session reported improvement. Last, our therapists not only used EMG biofeedback, but also incorporated balloon and manual biofeedback as necessary. This customized protocol likely contributed to the decrease in symptoms and improvement in quality of life as measured by the PAC-SYM and PAC-QOL. The high correlation between overall scores on the PAC-SYM and PAC-QOL seen in our study establishes a strong correlation between symptom severity and its impact on quality of life. When patients reported an improvement in their stool-related symptoms, they experienced less physical discomfort, fewer worries and concerns, and were much more satisfied with their treatment of constipation.

The limitations of this study stem from the observational design of a clinical practice. Initially, all patients received behavioral treatments and nursing interventions (fiber therapy, adequate hydration, etc.); if these alone did not improve their symptoms, physical therapy was initiated. Only five patients with puborectalis dyssynergia enrolled in the program did not continue on to physical therapy. Because of extenuating social circumstances (including losing a home, spousal abuse, caring for a sick parent, and the death of a parent), these patients withdrew from the program and could not be contacted. Thus, selection bias is inherent in this group of highly motivated patients enrolled in this multispecialty clinical program. The physical therapy protocol was also individualized for each patient and included various combinations of abdominal/colonic massage, biofeedback (manual, EMG, and balloon) and training in defecatory techniques. While not ideal from a perspective of research, customized physical therapy and biofeedback more closely mimics the real world clinical setting than a standardized physical therapy and biofeedback protocol. Customized therapy has also been shown to be beneficial in patients with other bowel disorders.²⁴ In the future, our goal is to have a standardized physical therapy protocol that can be customized. Our less stringent diagnostic criteria for puborectalis dyssynergia may have influenced our results. Because of the nature of this program with practitioners from urogynecology, gastroenterology and colorectal surgery, the diagnosis of puborectalis dyssynergia was made using different modalities. All patients had dyssynergia on physical exam, and generally, we did not extensively test patients when paradoxic contraction of the puborectalis during straining was easily appreciated on physical exam. Patients that did require further evaluation had defecography, anal manometry, or both performed. In the future, it will be

important to standardize our diagnostic practice. We also included patients with coexisting conditions such as rectoceles or perineal descent. We did so because it has been shown that the outcome of biofeedback is not adversely affected by these posterior vaginal wall and perineal body variants.²⁵ In the future, we hope to also be able to increase our follow-up time and reexamine our patients after successful physical therapy to determine how their exam has changed.

While PHQ scores significantly improved after physical therapy, this improvement did not correlate with changes in the PAC-SYM or the PAC-QOL. Depressive scores may have decreased because of other factors during the study period. For example, patients may have felt less depressed because they were able to discuss their constipation and related quality of life issues with the nurses and physicians within the program. This improvement in their well-being may have been independent of their physical symptoms. Also, because changes in the PHQ were not one of our primary outcomes, we did not perform an *a priori* power calculation for this variable. Thus, it is likely that we did not have enough power to detect a correlation between the changes in the PHQ and the PAC-SYM and PAC-OOL.

CONCLUSION

This study substantiates that physical therapy with biofeed-back is effective in the treatment of constipation secondary to puborectalis dyssynergia. Using validated measures, we have shown that when patients reach their goals with physical therapy, they report improvement not only in their symptoms, but also in their quality of life. These improvements are highly correlated with patient satisfaction.

ACKNOWLEDGMENTS

The authors thank Anne McLeod, R.N., B.S.N., and Raylene Marcum, R.N. of the Michigan Bowel Control Program, and the Department of Physical Therapy at the University of Michigan Hospital for their participation and support of this project.

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