ORIGINAL CONTRIBUTION

A Quality-of-Life Comparison of Two Fecal Incontinence Phenotypes: Isolated Fecal Incontinence Versus Concurrent Fecal Incontinence With Constipation

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BACKGROUND: Many patients with fecal incontinence report coexisting constipation. This subset of patients has not been well characterized or understood.

OBJECTIVE: The purpose of this study was to report the frequency of fecal incontinence with concurrent constipation and to compare quality-of-life outcomes of patients with fecal incontinence with and without constipation.

DESIGN: This was a prospective cohort study. Survey data, including Fecal Incontinence Severity Index, Constipation Severity Instrument, Fecal Incontinence Quality of Life survey (categorized as lifestyle, coping, depression, and embarrassment), Pelvic Organ Prolapse Inventory and Urinary Distress Inventory surveys, and anorectal physiology testing were obtained.

SETTINGS: The study was conducted as a single-institution study from January 2007 to January 2017.

PATIENTS: Study patients had fecal incontinence presented to a tertiary pelvic floor center.

MAIN OUTCOME MEASURES: Quality-of-life survey findings were measured.

RESULTS: A total of 946 patients with fecal incontinence were identified, and 656 (69.3%) had coexisting constipation. Patients with fecal incontinence with constipation were less likely to report a history of pregnancy (89.2% vs 91.4%; $p = 0.001$) or complicated delivery, such as requiring instrumentation (9.1% vs 18.1%; $p = 0.005$), when compared with patients with isolated fecal incontinence. Patients with fecal incontinence with constipation had higher rates of coexisting pelvic organ prolapse (Pelvic Organ Prolapse Inventory: 18.4 vs 8.2; $p < 0.01$), higher rates of urinary incontinence (Urinary Distress Inventory: 30.2 vs 23.4; $p = 0.01$), and higher pressure findings on manometry; intussusception on defecography was common. Patients with fecal incontinence with concurrent constipation had less severe incontinence scores at presentation (21.0 vs 23.8; $p < 0.001$) and yet lower overall health satisfaction (28.9% vs 42.5%; $p < 0.001$). Quality-of-life scores declined as constipation severity increased for lifestyle, coping, depression, and embarrassment.

LIMITATIONS: This was a single-institution study, and surgeon preference could bias population and anorectal physiology testing.

CONCLUSIONS: Patients with fecal incontinence with concurrent constipation represent a different disease phenotype and have different clinical and anorectal physiology test findings and worse overall quality of life. Treatment of these patients requires careful consideration of prolapse pathology with coordinated treatment of coexisting disorders. See **Video Abstract** at http://links.lww.com/DCR/A783.

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KEY WORDS: Constipation; Fecal incontinence; Pelvic floor disorders; Prolapse; Quality of life.

Fecal incontinence is a common condition, with a reported prevalence of <50% in elderly patients.[1,2] This loss of control of feces or gas can lead to anxiety and embarrassment, resulting in limitation of one's activities and a deterioration of quality of life (QoL). QoL is very sensitive to even minor changes in the severity of this condition, arguing for treatments that provide even small incremental improvement to the condition.[3] Fecal incontinence has additional social and economic burdens, including the loss of productivity, agoraphobia, and cost of containment garments and diapers.[4] In some patients, fecal incontinence leads to a loss of independence, requiring institutionalization.

Current management of fecal incontinence includes a complex algorithm of interventions, many of them focusing on identification and treatment of sphincter weakness or injury.[5] This form of isolated fecal incontinence attributed to poor sphincter function is fairly well characterized, and its treatments, including sphincteroplasty, injectables, or sphincter reinforcement or replacement, have been evaluated in detail. However, many patients with fecal incontinence do not have this isolated disease phenotype. In these cases, they are labeled as having overflow or idiopathic incontinence.[6] The patients with idiopathic fecal incontinence seem to have strong sphincters, and many have additional coexisting conditions, such as constipation, urinary incontinence, and pelvic organ prolapse. These coexisting conditions could potentially contribute to the patient's overall well-being, and the added impact of each additional condition is poorly understood.

The goal of this study was to evaluate patients who presented with the complaint of fecal incontinence in the setting of coexisting constipation. We aimed to report the frequency of fecal incontinence with concurrent constipation, compare patients presenting with pure fecal incontinence with those with both fecal incontinence and constipation to understand how this constellation of symptoms effect disease severity and quality-of-life outcomes, and evaluate anorectal physiology testing in patients complaining of both fecal incontinence and concurrent constipation.

PATIENTS AND METHODS

This study was approved by the Partners Institutional Review Board for research purposes. This is a single-institution, prospective cohort study of patients with fecal incontinence who obtained treatment at a tertiary Pelvic Floor Disorders Center from January 2007 to January 2017. All of the patients included in this study presented to the center with a report of fecal incontinence. All of the patients completed a self-reported survey, which included a battery of validated instruments aimed to quantify their fecal incontinence, as well as other coexisting complaints and past medical history information. This study excluded patients who were <18 years old or did not have a primary complaint of fecal incontinence. In addition to survey data, we collected prospective clinical and diagnostic information on each patient, including manometry, ultrasound, and defecography testing, when clinically appropriate.

Survey Tools

Fecal Incontinence Severity Index

All of the patients who reported having fecal incontinence completed the Fecal Incontinence Severity Index (FISI), a previously validated survey tool developed by the American Society of Colon and Rectal Surgeons via a rigorous process that involved patients and clinicians.[7] This index accounts for a variety of forms of fecal incontinence (gas, mucus, liquid, or solid stool) and their frequency (ranging from never to ≥2 times per day). The total score summarizes the item scores from 0 (no incontinence) to 61 (severe incontinence), based on the weight assigned to each occurrence by patients.

Constipation Severity Instrument

Patients who reported symptoms of constipation completed the Constipation Severity Instrument (CSI) survey as well. This is a 16-question, validated survey used to assess constipation severity.[8] The CSI evaluates the frequency, consistency, and ease of evacuation of stools and obtains information about constipation-related symptoms and the need to use defecation aides. Subsets of questions address specific issues of obstructive defecation, colonic inertia, and pain, with scores ranging from 0 to 73. Increasing scores signify increasing severity of constipation.

Fecal Incontinence Quality of Life

Fecal Incontinence Quality of Life (FIQoL) scores were calculated from a previously validated disease-specific questionnaire developed by Rockwood et al.[9] The 29-item FIQoL questions obtain information that measures the impact of fecal incontinence in the 4 domains that appear to be affected most frequently by this condition: lifestyle, coping, depression, and embarrassment (scored from 1 to 5).

Pelvic Organ Prolapse Inventory

This validated instrument was used to collect information about coexisting pelvic organ prolapse. Pelvic Organ Prolapse Inventory (POPIQ-7) is a 31-question instrument that evaluates the degree to which symptoms related to bladder, bowel, and vaginal function affect employment, entertaining, and travel activities. It also evaluates the emotional effects of pelvic floor symptoms, including frustration and embarrassment. The instrument scores responses ranging from *not at all* = 1 to *quite a bit* = 4.[10]

Urinary Distress Inventory

This is a validated instrument that is used to collect information about coexisting urinary complaints. The Urinary Distress Inventory (UDI-6) contains 28 questions to assess the severity of urinary symptoms. Subscales of UDI-6 assess symptoms were associated with obstructive, irritative/discomfort, and stress pathology. It is graded based on severity of symptoms, from *not at all* =1 to *quite a bit* = 4.[11]

Diagnostic Studies

Select patients underwent manometry, defecography, and endorectal ultrasound, as clinically appropriate.

Anorectal Physiology Testing

Anorectal manometry was performed by a physician or nurse practitioner to assess sphincter function. A 4-channel air-charged catheter was positioned just above the anal sphincter, and anal pressures were measured using stationary pull through. (Duet software, Mediwatch USA, West Palm Beach, FL). Anal pressures were calculated using American Society of Colon and Rectal Surgeons definitions.[12,13] *Mean resting pressure* was defined as the mean of the resting pressures recorded within the high-pressure zone. *Maximum resting pressure* was defined as the highest resting pressure recorded in the high-pressure zone. *Maximum voluntary squeeze pressure* was the highest pressure recorded at any level of the anal canal during maximum squeeze by the patient.

Balloon Expulsion Testing

This test was performed with a 60-mL air balloon. Failure to expel the balloon was noted if the patient was unable to pass the balloon within 5 minutes of pushing, while alone in the privacy of a bathroom.

Defecography

This test was performed in the radiology suite in patients who did not have an abnormality on anorectal manometry to explain fecal incontinence, as per current guidelines[5] All of the defecography images were reviewed by 2 trained defecography interpreters. Interpreters classified patients into groups based on their prolapse grades according to the Oxford Rectal Prolapse Grade: normal, intrarectal intussusception, intra-anal intussusception, or external rectal prolapse.[12] Additional data were collected on the presence of paradoxical contractions of puborectalis, rectoceles, and cul-de-sac hernias.

Endorectal Ultrasound

This test was performed by trained colorectal surgeons to assess for any evidence of anal sphincter injury in the patients who were considered potential candidates for a sphincter repair.

Statistical Analysis

Data were assessed for missing values and normality. Survey completion was required for entry into the study; therefore, the survey completion rate was 100%. Descriptive statistics are reported as percentages for categorical variables; mean and SD were used to describe continuous variables, except for skewed data. Skewed data are described using median and interquartile range. Univariate analysis using χ^2 and Student *t* tests was performed to determine differences between patients with fecal incontinence with and without coexisting constipation. FISI scores were divided into quartiles for analysis.

After performing the univariate analysis, multivariate regression was used to control for potential confounders. To determine the impact of increasing CSI scores on FIQoL, 4 independent linear regression models were developed for each FIQoL domain. Models were adjusted for FISI score quartile, POPIQ-7, and UDI-6 scores. Finally, manometry and defecography data were reviewed, and fecal incontinence phenotypes with and without constipation were compared. Analysis was performed using SAS 9.4 (SAS Institute, Cary, NC; $\alpha < 0.05$).

RESULTS

Our patient population consisted of 946 patients presenting with fecal incontinence. All of them completed the FISI score (100% survey completion rate) and had moderate-to-severe fecal incontinence (mean FISI score = 21.9). Table 1 describes characteristics of the cohort. A total of 89% of the patients were women, and the median age of the cohort was 60 years. Patients in the cohort had a low burden of comorbid disease, with only 9.0% of patients having a history of smoking and 9.8% of patients having a diagnosis of diabetes mellitus. Irritable bowel syndrome was present in 29% of patients. Several patients had a history of surgery, the most common being hysterectomy at 28.3%. A total of 9.3% of patients had a history of prolapse repair. A majority of patients (85.5%) noted a history of pregnancy, and many of these patients required intervention during delivery with either forceps (18.2%) or episiotomy (34.6%).

A total of 656 patients (69.3%) had coexisting constipation, which was measured by the CSI. These patients were compared with patients who did not have added symptoms of constipation. Table 1 compares characteristics of patients with fecal incontinence with and without constipation. Patients with fecal incontinence with constipation present (FICP) were younger (58.0 vs 63.0 y; $p = 0.03$) and were more likely to have irritable bowel syndrome (34.5% vs 16.6%; <0.001) compared with patients with fecal incontinence with constipation absent (FICA). There was no difference between these groups in surgical history. However, fewer FICP patients reported a history

TABLE 1. Cohort description and comparison of patients with FICP versus FICA

Characteristics	*All patients (N = 946)*	*FICP patients (N = 656)*	*FICA patients (N = 290)*	*p*
Women, n (%)	844 (89.2)	585 (89.2)	259 (89.3)	0.801
Age, median (IQR)	60.0 (49.0–70.0)	58.0 (48.0–68.0)	63.0 (50.0–73.0)	0.032
Comorbidities, n (%)				
Smoking history	84 (9.1)	59 (9.1)	25 (9.2)	0.956
Diabetes	93 (9.8)	64 (9.8)	29 (10.0)	0.907
Crohn's disease	16 (1.7)	10 (1.5)	6 (2.1)	0.549
Ulcerative colitis	24 (2.5)	16 (2.4)	8 (2.8)	0.773
Irritable bowel syndrome	274 (29.0)	226 (34.5)	48 (16.6)	<0.001
Surgical history, n (%)				
Bowel resection	64 (6.8)	48 (7.3)	16 (5.5)	0.309
Hysterectomy	268 (28.3)	178 (27.1)	90 (31.0)	0.219
Prolapse repair	88 (9.3)	64 (9.8)	24 (8.3)	0.469
Bladder surgery	60 (6.3)	38 (5.8)	22 (7.6)	0.296
Obstetrics history, n (%)				
History of pregnancy	713 (85.5)	479 (82.9)	234 (91.4)	0.001
Required forceps	172 (18.2)	117 (17.8)	55 (19.0)	0.677
Required vacuum assist	51 (5.4)	36 (5.5)	15 (5.2)	0.843
Required episiotomy	327 (34.6)	225 (34.3)	102 (35.2)	0.794
Symptoms, n (%)				
Pelvic pain	256 (31.4)	224 (37.3)	32 (14.9)	<0.001
Bladder pain	158 (19.2)	133 (21.9)	25 (11.5)	<0.001
Abdominal pressure	427 (49.1)	362 (57.0)	65 (27.8)	<0.001

FICA = fecal incontinence with constipation absent; FICP = fecal incontinence with constipation present; IQR = interquartile range.

of pregnancy (89.2% vs 91.4%; $p = 0.001$) when compared with FICA patients.

Patients presenting with fecal incontinence with constipation generally had milder symptoms of fecal incontinence, with lower FISI scores overall when compared with FICA patients (21.0 vs 23.8; $p < 0.001$; see Figure 1). However, this did not translate into an improvement in QoL. In fact, when assessing domains of QoL, FICP patients had lower QoL scores in the domain of depression (2.9 vs 3.1; $p = 0.01$), as seen in Table 2. FICP patients had slightly higher QoL scores for the domain of embarrassment (2.6 vs 2.4; $p = 0.003$). Furthermore, although FICP patients had better FISI scores at presentation, they described lower satisfaction with their overall health (28.9% vs 42.5%; $p < 0.001$).

Evaluation of FICP patients revealed that constipation did not travel in isolation. In addition to constipation, FICP patients also had higher rates of coexisting pelvic organ prolapse (POPIQ-7, 18.4 vs 8.2; $p < 0.001$) and urinary incontinence (UDI-6, 30.2 vs 23.4; $p < 0.001$). FICP patients also reported higher rates of pelvic pain (37.3% vs 14.9%; $p < 0.001$), bladder pain (21.9% vs 11.5%; $p < 0.001$), and abdominal pressure (57.0% vs 27.8%; $p = 0.001$).

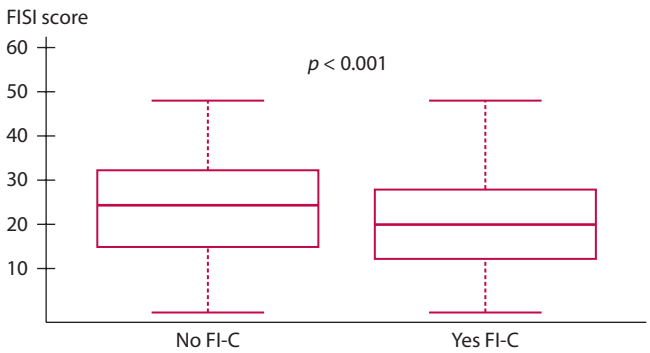

FIGURE 1. Fecal Incontinence Severity Index (FISI) score comparison for fecal incontinence with constipation (FI-C) absent versus FI-C present patients.

These phenotypical differences in patients with and without constipation were also seen in statistically different physiology and defecography results (Table 3). FICP patients had higher mean, maximum, and squeeze pressures, and they were less likely to be able to expel the balloon, which suggested the diagnosis of obstructed defecation syndrome. This diagnosis was also supported by the finding that FICP patients had higher rates of paradoxical EMG. Furthermore, on defecography, FICP patients were far more likely than FICA patients to have intra-anal intussusception and/or rectoceles.

Multivariable modeling was performed to determine the correlation between FISI quartile and FIQoL scores while accounting for the coexisting symptoms of constipation, incontinence, and pelvic organ prolapse, as shown in Table 4. We found that, for each FISI quartile, the disease-specific FIQoL scores increased in the FICP patients as the symptoms of constipation measured by the CSI increased. The most significant change was noted in the QoL domain of depression (–0.022 (95% CI, –0.027 to –0.018); $p < 0.001$). Coexisting pathology, including pelvic organ prolapse and urinary incontinence, worsened FIQoL scores even further.

TABLE 2. Survey findings for the entire cohort and comparison of patients with FICP versus FICA

Survey type	*All patients (N = 946)*	*FICP patients (N = 656)*	*FICA patients (N = 290)*	*p value*
FISI score	21.9 (11.3)	21.0 (11.0)	23.8 (11.6)	<0.001
QoL scores				
Lifestyle	2.9 (1.0)	2.9 (0.9)	3.0 (1.0)	0.26
Coping	2.5 (1.0)	2.5 (1.0)	2.5 (1.0)	0.30
Depression	3.0 (1.0)	2.9 (1.0)	3.1 (0.9)	0.01
Embarrassment	2.5 (1.0)	2.6 (1.0)	2.4 (0.9)	0.003
POPIQ-7 score	15.8 (26.2)	18.4 (27.9)	8.2 (18.3)	<0.001
UDI-6 score	28.4 (25.4)	30.2 (25.6)	23.4 (24.2)	<0.001

FICA = fecal incontinence with constipation absent; FICP = fecal incontinence with constipation present; FISI = Fecal Incontinence Severity Index; QoL = quality of life; POPIQ-7 = Pelvic Organ Prolapse Inventory; UDI-6 = Urinary Distress Inventory.

DISCUSSION

The current literature on fecal incontinence is replete with data on coexisting pelvic floor disorders.[14] Almost 1 in 4 women with urinary incontinence are reported to have concurrent fecal incontinence.[15] In addition, 1 in 5 patients with fecal incontinence are reported to have concurrent urinary incontinence and/or pelvic organ prolapse.[16] As in previous studies, our study notes that these added symptoms are associated with lower QoL scores, which cumulatively drive patients to seek medical advice, although each individual complaint in isolation might not warrant intervention.[14,15,17–19] Our study agrees with these previous observations but also notes that these concurrent disorders represent a specific disease phenotype with consistent findings of fecal incontinence with concurrent constipation. By identifying patients with fecal incontinence and concurrent constipation, the treating clinician can identify this distinct subgroup of patients.

Our observation that patients with pelvic floor disorders are more likely to be present in patients who report constipation is supported by a previous study.[20] A recent review of 439 patients with fecal incontinence observed that patients with normal anal sphincter function were more likely to have coexisting constipation. The authors of that study support identification of these patients as a separate phenotype using anorectal manometry. In contrast, our study suggests that the phenotypic differentiation can be made based on the absence or presence of constipation alone when taking the patient's medical history. With this simple question, the clinician will gather significant information about the possible etiology of the patient's condition.

Fecal incontinence with coexisting constipation has been noted previously by other researchers and clinicians, but it was thought to be rare.[21] Our study suggests that this condition is more common than previously thought. In our cohort, more than two thirds of patients with fecal incontinence reported having concurrent constipation. Interestingly, we found that these patients had different clinical presentations, medical history, and anorectal physiology findings compared with patients with isolated fecal incontinence. Specifically, they had normal or increased sphincter tone on manometry and increased coexisting pelvic organ prolapse, urinary incontinence, and intussusception findings on defecography. Overall, patients with fecal incontinence with concurrent constipation had worse QoL outcomes. These differences support our position that these patients represent a specific phenotype.

Patients with fecal incontinence with concurrent constipation deserve a separate algorithm of care from patients with isolated fecal incontinence, which we propose with Figure 2. In this study, patients with pure fecal incontinence tended to have low manometry pressures and would generally benefit from having endorectal ultrasound testing early in their care.[22] Based on our findings, these patients are more likely to have sphincter injuries, which might benefit from sphincter repairs, sphincter augmentation, and injectables. In contrast, endoanal ultrasound is unlikely to benefit patients with

TABLE 3. Anorectal physiology testing/defecography findings

Anorectal physiology test	*All patients (N = 946)*	*FICP (N = 656)*	*FICA (N = 290)*	*p value*
Mean resting pressure ± SD	52.9 ± 24.3	56.8 ± 25.2	44.9 ± 20.4	<0.001
Maximum resting pressure ± SD	74.8 ± 29.6	78.8 ± 30.3	66.6 ± 26.2	<0.001
Maximum squeeze pressure ± SD	132.4 ± 54.7	138.1 ± 55.4	120.3 ± 51.1	<0.001
Inability to expel balloon, n (%)	140 (22.4)	117 (27.7)	23 (11.4)	<0.001
Paradoxical EMG, n (%)	161 (28.0)	147 (37.5)	14 (7.7)	<0.001
Intussusception/intrarectal, n (%)	34 (45.9)	26 (40.0)	8 (88.9)	0.005
Intussusception/intra-anal, n (%)	40 (54.1)	39 (60.0)	1 (11.0)	0.005
Intussusception/rectocele, n (%)	83 (59.3)	75 (61.5)	8 (44.4)	0.15

FICA = fecal incontinence with constipation absent; FICP = fecal incontinence with constipation present.

TABLE 4. Multivariable models evaluating the effect of POPIQ-7, UDI-6, and CSI on FISI quality-of-life outcomes

Quality-of-life theme	*1 unit increase in POPIQ-7*	*1 unit increase in UDI-6*	*1 unit increase in CSI (FICP patients only)*
Lifestyle	−0.011 (−0.013 to −0.008) $p < 0.001$	−0.001 (−0.004 to 0.0014) $p = 0.36$	−0.013 (−0.018 to −0.009) $p < 0.001$
Coping	−0.008 (−0.010 to −0.005) $p < 0.001$	−0.003 (−0.010 to −0.005) $p = 0.028$	−0.012 (−0.017 to −0.007) $p < 0.001$
Depression	−0.011 (−0.013 to −0.008) $p < 0.001$	−0.003 (−0.005 to −0.001) $p = 0.036$	−0.022 (−0.027 to −0.018) $p < 0.001$
Embarrassment	−0.003 (−0.006 to −0.001) $p = 0.017$	−0.002 (−0.005 to 0.0004) $p = 0.108$	−0.007 (−0.012 to −0.002) $p = 0.004$

FICP = fecal incontinence with constipation present; FISI = Fecal Incontinence Severity Index; POPIQ-7 = Pelvic Organ Prolapse Inventory; UDI-6 = Urinary Distress Inventory; CSI = Constipation Severity Instrument.

fecal incontinence and concurrent constipation. In this patient phenotype, the sphincter pressures were found to be normal or high, and many patients were found to have prolapse or intussusception on defecography. This is consistent with the findings of Wijffels et al,[23] who evaluated 88 patients with internal prolapse and found that most of these patients experienced this phenotype of fecal incontinence with coexisting constipation. These patients are more likely to benefit from routine defecography early in their care for consideration of possible ventral rectopexy if biofeedback is unsuccessful.[24] A recent study of 919 consecutive patients who underwent laparoscopic ventral rectopexy noted that the procedure seemed to improve symptoms of both fecal incontinence and obstructed defecation, presumably targeting the patients with this mixed incontinence/constipation phenotype.[24] Identifying these phenotypes based on their reported symptoms could prospectively minimize unnecessary testing and improve identification of the right patient for the right operation (ie, ventral rectopexy in intussuscepting FICP patients versus sphincteroplasty in FICA patients with damaged sphincters).

Identification of this specific phenotype of fecal incontinence is important to expand our understanding of associated conditions (eg, IBD), diagnostic algorithms, or performance of comparative efficacy studies. For example, we suspect that biofeedback may require re-evaluation in patients with this specific FICP phenotype, because it is less successful in patients with isolated incontinence. Similarly, sacral nerve stimulation (SNS) should be evaluated in this subtype. Previous studies support our hypothesis that SNS treatment is less effective in patients with fecal incontinence and concurrent constipation compared with those with pure incontinence.[25–27] Our hypothesis is further supported by randomized control trial data, which find that SNS does not improve QoL in constipated patients.[28]

Our findings are descriptive and relevant because of the current lack of clarity regarding fecal incontinence subtypes. Our findings should be evaluated considering

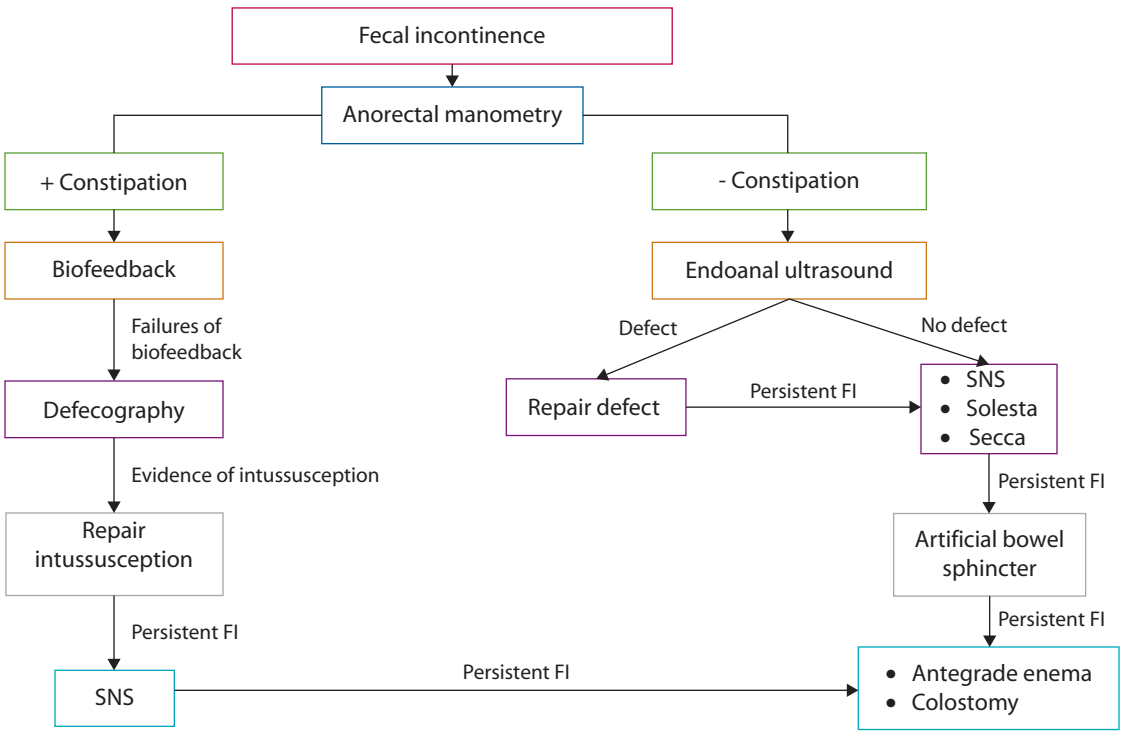

FIGURE 2. Fecal incontinence (FI) care algorithm. SNS = sacral nerve stimulation.

some important limitations. The survey tools were previously validated individually; however, the tools were never validated as a combined survey. These data were obtained from a single institution over a decade, which could introduce bias based on patient referral patterns. In addition, defecography and manometry testing was performed at the discretion of the surgeon; this testing was not performed on every patient in the cohort, and the patients tested could have been biased by provider preferences. Medication history was not obtained in this study.

CONCLUSION

Patients with fecal incontinence with concurrent constipation represent a different disease phenotype from patients with isolated fecal incontinence. They have a different constellation of symptoms, different medical and family histories, and worse overall QoL. Their manometric and defecography findings support our hypothesis that these patients will benefit from different treatment algorithms than patients with isolated fecal incontinence. Treatment of FICP patients requires careful consideration of prolapse pathology with coordinated treatment of coexisting disorders to ensure the best outcome for these patients.

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