Sexual Dysfunction in Men With Inflammatory Bowel Disease: A New IBD-Specific Scale

Aoibhlinn O'Toole, MD,^{*,†} Punyanganie S de Silva, MD, MPH,^{*,†} Linda G. Marc, ScD, MPH,[‡] Christine A. Ulysse, BS,[‡] Marcia A. Testa, PhD, MPH,[‡] Amanda Ting,^{‡,§} Alan Moss, MD,^{‡,§} Josh Korzenik, MD,^{*,†} and Sonia Friedman, MD^{*,†,*}

Background: Men with inflammatory bowel disease (IBD) may have increased sexual dysfunction. To measure the prevalence of sexual dysfunction in our male patients, we aimed to develop a new IBD-specific Male Sexual Dysfunction Scale (the IBD-MSDS).

Methods: We used a cross-sectional survey and enrolled male patients (N = 175) ≥18 years old who attended IBD clinics at 2 Boston hospitals. We collected information on sexual functioning via a 15-item scale. General male sexual functioning was measured using the International Index of Erectile Dysfunction (IIEF); the Patient Health Questionnaire (PHQ-9) measured depressive symptoms. Medical history and sociodemographic information were extracted from medical record review. Exploratory factor analyses (EFA) assessed unidimensionality, factor structure, reliability, and criterion and construct validity of the 15-item scale. We used regression models to identify clinical factors associated with sexual dysfunction.

Results: EFA suggested retaining 10-items generating a unidimensional scale with strong internal consistency reliability, $\alpha = 0.90$. Criterion validity assessed using Spearman's coefficient showing that the IBD-MSDS was significantly correlated with all the subscales of the IIEF. The IBD-MSDS was significantly correlated (construct validity) with the PHQ-9 ($P < 0.001$) and the composite score for active IBD cases ($P < 0.05$). Male sexual dysfunction in IBD was significantly associated with the presence of an ileoanal pouch anastomosis ($P = 0.047$), depression ($P < 0.001$), and increased disease activity ($P = 0.021$).

Conclusions: We have developed and validated an IBD-specific scale to assess the psychosexual impact of IBD. This new survey tool may help physicians screen for and identify factors contributing to impaired sexual functioning in their male patients.

Key Words: inflammatory bowel disease, Crohn's disease, sexual dysfunction, ulcerative colitis, men

INTRODUCTION

The inflammatory bowel diseases (IBD) are chronic inflammatory intestinal disorders resulting in significant morbidity and impaired quality of life. Psychosexual function in IBD is particularly relevant given that the peak incidence and prevalence is between the ages of 15–35 years. Crohn's disease (CD) and ulcerative colitis (UC) often require invasive abdominal and pelvic surgery and the use of potent immune modulating and biological therapies. IBD symptoms, disease complications, and treatments influence body image, intimacy, and sexual function.¹ Despite the clear significance of these issues, knowledge of the extent and impact of sexual dysfunction in men with IBD is scarce. Most data have been derived from case reports, small survey-based studies that are not validated in IBD patients, and few meta-analyses.²

To our knowledge, there are no IBD-specific validated questionnaires addressing sexuality issues. Recent studies and surveys have used generic validated questionnaires such as the International Index of Erectile Dysfunction (IIEF), the gold standard for measuring general male sexual function,³ and applied them to the field of IBD.^{4–7} The IIEF assesses erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. However, it is a generic instrument and therefore lacks IBD-specific domains. Historically, the development of the IIEF paralleled the advent of sildenafil

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*Center for Crohn's and Colitis, Brigham and Women's Hospital, Boston, Massachusetts, USA; †Harvard Medical School, Harvard University, Boston, Massachusetts, USA; ‡Harvard School of Public Health, Department of Biostatistics, Boston, Massachusetts, USA; §Center for Inflammatory Bowel Disease, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA.

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Address correspondence to: Sonia Friedman, MD, Center for Crohn's and Colitis, Brigham and Women's Hospital, Boston, Massachusetts, USA; Harvard Medical School, Harvard University, Boston, Massachusetts, USA. E-mail: sfriedman1@partners.org

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and much of the evidence is derived from older patient populations, classically those with diabetes and vascular disease.⁸ There are IBD-specific validated questionnaires that have been used to measure quality of life and disease activity but these look at sexual function only peripherally. For instance, the short and long forms of the Inflammatory Bowel Disease Quality of Life Questionnaire (IBDQ) measure quality of life in IBD and the Crohn's Disease Activity Index (CDAI), Clinical Activity Index, and Colitis Activity Index measure disease activity.⁹⁻¹¹ In addition, patients with active IBD more often report severe depression than patients in remission,^{12,13} and the generic Hospital Anxiety and Depression Scale has been used to explore anxiety and depression in IBD patients.¹⁴ However, this questionnaire does not address specific IBD-related concerns.

IBD affects men during the peak years of dating, marriage, conception, and child-rearing. Many patients have questions regarding the effect of medical therapy, surgical therapy, and disease activity on sexual function. Therefore, a new tool is needed to assess specific domains measuring the psychosexual impact of IBD in men, including domains measuring psychosexual concerns of patients who have had surgery, perianal fistulae, and symptoms of abdominal pain, diarrhea, and fatigue, all of which are commonly seen in IBD.

In this study, we conducted a psychometric evaluation of a new IBD-specific scale that measures sexual functioning in a population of male patients with IBD (the IBD-Male Sexual Dysfunction Scale or IBD-MSDS). Our goal was to determine the psychometric properties of the IBD-MSDS, the criterion validity of the IBD-MSDS in relation to the IIEF, and the construct validity of the IBD-MSDS in relation to variables in the dataset that measured depression and IBD activity. Using this new scale, we aimed to assess of the prevalence of sexual dysfunction in our patient population and to identify associated factors that may be preventable, reversible, and treatable.

MATERIALS AND METHODS

Item Selection and Content Validity

Our research team followed a three-step process to ensure that a specific set of items measured the content domain, which should be a subset of the universe of appropriate items.¹⁵ First, a literature search of existing questionnaires was conducted to identify relevant domains of sexual functioning in IBD, and a preliminary set of items was created in consultation with an expert in the field of survey development and an endocrinologist specializing in men's health. Second, we reviewed the initial battery of survey items with an expert panel and then piloted these items with a focus group consisting of 10 male IBD patients to refine the wording and content that reflected the underlying construct, IBD-specific male sexual dysfunction. Wording of items was reviewed for appropriateness of content, language level, type and form, sequence, and how information would be sought from the respondents.

Third, based on the outcomes of the first and second steps, an IBD-specific MSDS was developed inclusive of 15-items (Table 1). Each individual item was scored from 0 to 4 points on a Likert-type scale, with the highest score indicating greater severity of sexual dysfunction to facilitate interpretability for use by clinicians (4 = Always or almost always; 3 = Most times (more than half the time); 2 = About half the time; 1 = A few times (less than half the time); and 0 = Never or very rarely). The 15-items measured how CD or UC affected sexual functioning related to: desire, preventing one from having sex, causing problems during sex, feeling guilty about sex, feeling fatigue or lack of energy, abdominal or pelvic pain, increased bowel movements, anal bleeding or discharge, anal pain, discomfort or irritation, joint pain, fear of participating in sexual activity, fear of passing gas, fear of passing stool, fear of experiencing abdominal or pelvic pain, and fear of appliance leaking during sexual activity (Table 1).

Criterion Validity

Criterion validity evaluated whether the new IBD-MSDS had an empirical association with the IIEF, which is considered

TABLE 1. Preliminary IBD-Specific Male Sexual Dysfunction Scale (15 Items)

1. In the last year how frequently has CD or UC affected your desire for sexual activity?
2. In the last year has having CD or UC prevented you from having sex?
3. In the last year has having CD or UC caused problems during sex?
4. In the last year has having CD or UC caused you to feel guilty about intimacy or intercourse?
5. In the last year to what extent has fatigue or lack of energy impacted your sex life?
6. In the last year to what extent has abdominal or pelvic pain affected your sex life?
7. In the last year how much has increased bowel movement frequency affected your sex life?
8. In the last year how much has anal bleeding or discharge affected your satisfaction with your sex life?
9. In the last year how much has anal pain, discomfort, or irritation affected your satisfaction with your sex life?
10. In the last year how much has joint pain affected your satisfaction with your sex life?
11. Are you ever afraid of participating in sexual activity due to your CD or UC?
12. Do you fear passing gas during sexual activity?
13. Do you fear passing stool during sexual activity?
14. Do you fear experiencing abdominal/pelvic pain during sexual activity?
15. Do you fear your appliance leaking (ostomy bag) during sexual activity?

the “gold standard” measure of sexual functioning in males. The IIEF includes a 15-item self-evaluation scale with subscales for: erectile function (score range 0–30), orgasmic function (score range 0–10), sexual desire (score range 0–10), satisfaction in sexual intercourse (score range 0–15), and general satisfaction (score range 0–10).³ The highest score on each subscale indicates no sexual dysfunction; therefore, we hypothesize that the IBD-MSDS will have an inverse correlation with the IIEF.

Construct Validity

Construct validity is concerned with the theoretical relationship of the new scale with other variables in the dataset known to have an association with IBD. Based on the literature review, we hypothesized that sexual dysfunction in male patients with IBD would be positively correlated with depression and increased IBD activity.

Depressive Symptoms

Depressive symptoms were measured using the Patient Health Questionnaire (PHQ-9), which is a brief self-report screening instrument that focuses on the 9 diagnostic criteria for DSM-IV depressive disorders¹⁶: anhedonia, depressed, sleep problems, low energy, appetite problems, low self-esteem, trouble concentrating, psychomotor problem, and suicide ideation. In a meta-analytical review, the PHQ-9 has been deemed acceptable for depression screening in a range of settings, countries, and populations.^{17–33} The PHQ-9 asks whether a symptom has been present more than half the time, over the past 2 weeks. The instrument uses a Likert-type response format ranging from 0 (not at all) to 3 (everyday), and the total score ranges from 0 to 27 with 5 severity categories: minimal (0–4), mild (5–9), moderate (10–14), moderately severe (15–19), and severe (20–27).¹⁶ A higher score indicates greater depressive symptomatology; therefore, we hypothesized that the IBD-MSDS would have a positive correlation with the PHQ-9.

IBD Clinical Activity Indices

We used the Harvey-Bradshaw Index (HBI)³⁴ for patients with CD. A score of 5 or greater is generally considered to represent active clinical disease; therefore, we hypothesized that the IBD-MSDS would have a positive correlation with the HBI. We used the Simple Clinical Colitis Activity Index (SCCAI)¹¹ in patients with UC. A score of 5 or greater is generally considered to represent active clinical disease; therefore, we hypothesized that the IBD-MSDS would have a positive correlation with the HBI and SCCAI. We defined an HBI or SCCAI of 5 or greater as an Active IBD Score.

Study Design, Recruitment and Study Sites

This study used homogenous purposive sampling in a cross-sectional design. Male patients with IBD were recruited and enrolled while attending the adult gastroenterology clinics

at Brigham and Women's Hospital and Beth Israel Deaconess Medical Center in Boston, Massachusetts, between November 1, 2013 and April 30, 2015.

Participants: Inclusion/Exclusion Criteria

Male patients, 18 years of age or older, were invited to complete the survey at or before attendance at the IBD clinic. Most patients filled in the survey during their clinic appointment. If a patient had time constraints, he was given an envelope to mail back the response. Some patients (10%) were sent the survey in the mail before an upcoming clinic appointment. We excluded 1 patient from the study who had impotence following prostatectomy for prostate cancer. The response rate was 40% (225/560), and of 225 surveys returned, 175 were fully completed.

Data Collection

A structured paper questionnaire was administered to study participants capturing information on sexual behaviors and the perceived impact of IBD symptoms, medications, and surgery on sexual function. The IIEF and PHQ-9 were administered simultaneously. A medical record review was performed for each patient, with information extracted including demographics, disease type, medications, surgery, perianal disease, and medical comorbidities. All clinical disease activity index scores were obtained directly from the patient, in person, by the physician at the time of the clinic appointment.

Participant Compensation

The patients were not compensated for participation in the study.

Statistical Analyses

Exploratory factor analysis

Exploratory factor analysis (EFA) was appropriate for this study because the 15 items had not been previously evaluated as a hypothetical scale that measured the underlying construct “Sexual Dysfunction in IBD.” EFA assisted in determining whether the underlying construct was unidimensional, and the Stata default principal factor method was used, which allowed each item to have its own variance, in which each observed item (χ_{i1} – χ_{i15}) had a corresponding unique random error term, ϵ_{i1} – ϵ_{i15} , reflecting there was no shared variance between the 15 items.^{35–37} Goodness of fit was assessed using the Satorra-Bentler Chi-Squared Statistics for the Root Mean Square Error of Approximation (RMSEA) and the Comparative Fit Index (CFI).³⁸ Stata v14³⁹ and Microsoft Excel⁴⁰ were used to analyze the data.

Descriptive statistics

Univariate statistics were generated and ceiling/floor effects were considered substantial if $\geq 20\%$ of subjects scored

at the upper-most or bottom-most end on the IBD-MSDS.^{41,42} Internal consistency reliability was assessed using Cronbach's alpha statistic.¹⁵ Criterion and construct validity were assessed using the Spearman's rank correlation coefficient, with significance $P < 0.05$.

We used REDCAP and the STATA program for multivariate regression modeling.

ETHICAL CONSIDERATIONS

Ethical approval was granted by the Partners Health Care Institutional Review Board in October 2014, Protocol Number: 2013P002222.

RESULTS

Participant Characteristics

A total of 225 participated in the study. After data entry, 50 questionnaires were removed from analysis either because of very incomplete data or noneligibility. Of the remaining 175 participants, the mean age was 43.2 years ($SD \pm 13.8$, range 20–84); 62.9% were married and the majority of study participants reported white race (92.0%; $N = 160/174$) (Table 2).

Survey Results

In the past year, 156 patients had sex with women, 9 with men, and 10 did not have sex at all. Eighty-six percent were in a current relationship. Twenty-one percent reported hesitancy starting a new relationship due to IBD and in 14% IBD contributed to a break-up. IBD had a negative effect on libido for 38%, prevented sex in 27%, and caused problems during sex for 18%. Twenty percent of patients reported feeling guilty about sex and 30% feared sex. Symptoms affecting sexual activity included fatigue (35%), abdominal pain (23%), rectal bleeding (20%), and increased bowel movements (25%). Body image was impaired by ileoanal pouch anastomosis surgery (IPAA) (3%), setons (2%), ostomy (9%), perianal fistulae (10%), and scars (12%). Twenty-three percent of patients were using erectile enhancing medications, and 5% were using testosterone to improve sexual function.

Seventy-eight percent of patients reported that they would feel comfortable talking to their doctor about sex, although only 10% reported their IBD provider initiating a conversation about sex. Seventy-two percent had no preference for a male or female provider, and 22% would feel more comfortable talking to a male provider.

Exploratory Factor Analysis

An examination of the 15-item scale showed a factor structure with potentially 2 underlying constructs being measured. Factors 1 and 2 had eigenvalues equal to 6.73 and 1.11,

TABLE 2. Participant Characteristics

Male	175 (100)
Age (years) (Mean $\pm$ Standard Deviation)	43 $\pm$ 13.9
Race/Ethnicity (%)	
White	92
Black	2.9
Hispanic	2.3
Asian	2.9
Marital Status (%)	
Married/Long-term partner	62.9
Single	34.9
Divorced	2.2
IBD (%)	
CD	57
UC	43
Duration of disease (years) (Mean $\pm$ Standard Deviation)	14 $\pm$ 11.7
Disease Activity	
Harvey-Bradshaw Index (% Score ≥ 5 ; $N = 15/94$)	16
SCCAI (% Score ≥ 5 ; $N = 6/73$)	8.2
Surgical Status (%)	
IPAA	7.8
Ostomy	9.3
Perianal disease (%)	15.6
Current medications (%)	
Corticosteroids	7.4
Anti-TNF alpha	42.2
Anti IL12/23	3.4
Immunomodulators	26.7
Narcotics	2.3
Comorbidities (%)	
Endocrine	10.9
Cardiovascular	17.7
Smoking Status (%)	
Current	4.6
Ex-smoker	23
Non-smoker	73.4
IBD-MSDS Scores (Mean $\pm$ Standard Deviation)	4.6 $\pm$ 6.2
IIEF Scores (Mean $\pm$ Standard Deviation)	
Erectile Function	22.9 $\pm$ 9.6
Orgasmic Function	8.3 $\pm$ 2.8
Sexual Desire	7.6 $\pm$ 2.2
Satisfaction in Sexual Intercourse	9.9 $\pm$ 4.8
General Satisfaction	7.1 $\pm$ 2.4
PHQ-9 Score (%)	
Minimal	59.8%
Mild	21.3%
Moderate	10.9%
Moderately Severe	5.2%
Severe	2.9%

respectively. Examining the factor loadings for Factor 2, 3 of the fear items (Items 12, 13, and 14) had positive loadings ≥ 0.30 on both Factors 1 and 2, which was the minimum criteria for an item (Table 3). We performed a promax rotation assuming that Factors 1 and 2 were correlated because “fear of passing gas, stool or experiencing abdominallpelvic pain during sexual activity” was likely to influence sexual functioning. The rotated factor structure showed that all the fear items (Items 12, 13, 14, and 15) had positive loadings ≥ 0.30 on Factors 2 only, as well as Item 10, which asks “how much joint pain affected your satisfaction with your sex life” (Supplementary Table 1). Dropping these 5 items, a rerun of EFA returned a 1-Factor Model, with Factor 1 and 2 having an eigenvalue equal to 5.34 and 0.64, respectively. Factor loadings for the 1-Factor model ranged from 0.58 to 0.82. Our final IBD-MSDS is shown in Table 3.

Assessing Goodness of Fit

It was assumed that the observed variables were not normally distributed, therefore, the Satorra–Bentler Scaled Chi-Squared test was used because it is robust to nonnormality. Results show that the RMSEA_SB (generated by the Satorra–Bentler command in Stata) was 0.103 on the remaining 10 items, which was higher than the recommended range of 0.05 for a good fit, and less than 0.08 for a reasonably good fit.³⁸ The Comparative Fit Index (CFI_SB) was 0.855, which means that our model does 85.5% better than a null model in which we assume the items are all unrelated to each other; whereas, the recommended cutoff should be either 0.90 or 0.95.³⁸

TABLE 3. Final IBD-Specific Male Sexual Dysfunction Scale (10 Items)

1. In the last year how frequently has CD or UC affected your desire for sexual activity?
2. In the last year has having CD or UC prevented you from having sex?
3. In the last year has having CD or UC caused problems during sex?
4. In the last year has having CD or UC caused you to feel guilty about intimacy or intercourse?
5. In the last year to what extent has fatigue or lack of energy impacted your sex life?
6. In the last year to what extent has abdominal or pelvic pain affected your sex life?
7. In the last year how much has increased bowel movement frequency affected your sex life?
8. In the last year how much has anal bleeding or discharge affected your satisfaction with your sex life?
9. In the last year how much has anal pain, discomfort, or irritation affected your satisfaction with your sex life?
10. Are you ever afraid of participating in sexual activity due to your CD or UC?

Output of Modification Indexes

The output of modification indexes was generated showing error terms for items that should be correlated. The largest modification index (MI) found was between Items 8 and 9, with an MI equal to 66.025, suggesting they were more correlated with each other than with the other 10 items. Both items focus on anal discomfort during sexual activity. By correlating these items, the RMSEA_SB reduced to 0.064 and the CFI-SB increased to 0.946.

Descriptive Statistics and Reliability of the IBD-MSDS

Univariate statistics show a mean IBD-MSDS of ($\bar{x} = 4.6 \pm 6.2$) with a range of 0–27 points, with a higher score indicating greater sexual dysfunction. There were floor effects observed, with 29.1% (N = 51/175) of study participants having a minimum score of 0, suggesting no experiences of sexual dysfunction, yet no ceiling effects were observed in this study population. The Cronbach coefficient alpha is $\alpha = 0.90$, confirming that a large proportion of the scale's total variance is attributed to a common source. Figure 1 shows the distribution of the IBD-MSDS scores.

A stratified analysis across educational level and age groups was performed. Reliability across educational level was consistent at $\alpha = 0.90$ for individuals with high school, some postsecondary education, and participants who graduated with a postsecondary education. Reliability across ages groups (18–29, 30–45, 46–59, and 60–86) showed that participants in the youngest age group have a lower scale reliability (18–29: $\alpha = 0.83$, 30–45: $\alpha = 0.92$, 46–59: $\alpha = 0.88$, 60–86: $\alpha = 0.92$) compared with the older participants, which might suggest greater discomfort (or uneasiness) to respond to questions about sexual dysfunction in IBD.

Criterion and Construct Validity

Using the Spearman's rank correlation coefficient, the 10-item IBD-MSDS was highly significant, and inversely correlated with all the subscales of the IIEF: erectile function (N = 173; $r = -0.2730$, $P < 0.05$), orgasmic function (N = 173; $r = -0.2594$, $P < 0.05$), sexual desire (N = 173; $r = -0.3074$, $P < 0.001$), satisfaction in sexual intercourse (N = 172; $r = -0.1819$, $P < 0.05$), and general satisfaction (N = 172; $r = -0.2654$, $P < 0.05$). Supplementary Figure 1 shows these distributions, which establishes strong criterion validity. Similarly, the IBD-MSDS was highly significant and positively correlated with the summary score for the PHQ-9 (N = 174; $r = 0.4431$, $P < 0.001$) and with the Active IBD Score (N = 167; $r = 0.2883$, $P < 0.05$). Supplementary Figure 2 shows these distributions, which establishes strong construct validity.

Regression Analysis

Male sexual dysfunction as measured by the IBD-MSDS is significantly associated with the presence of an IPAA ($P = 0.047$), mild, moderate, or severe depression ($P < 0.001$),

FIGURE 1. Distribution of IBD-MSDS Scores.

active IBD ($P = 0.021$), previous history of smoking ($P = 0.021$); and marginally associated with the presence of an ostomy ($P = 0.103$), endocrine-related comorbidities (0.098), and cardiac-related comorbidities ($P = 0.063$) (Table 4).

DISCUSSION

The IBD-MSDS is a novel tool to assess sexual functioning in male patients with IBD. Impairments in psychosexual functioning remain underdiagnosed, which reflects the lack of an IBD-specific screening tool, poor physician awareness, and a reluctance to discuss issues of an intimate nature with one's IBD provider. A striking finding reproduced in numerous studies is that disease activity relates strongly to impaired psychological function, and the most consistently reported risk factor for sexual problems in IBD patients are coexisting mood disorders.^{43,44} Disease activity appears to have a significant impact on libido, sexual attractiveness, level of sexual activity, and enjoyment of sex.⁵

We found that male sexual dysfunction in IBD is significantly associated with the presence of an IPAA, mild, moderate or severe depression, and active IBD. We hypothesized that the presence of an ostomy would impair sexual function; this was marginally but not statistically significant. Only 15 patients had an ostomy, therefore, we may not have had sufficient cases to show a significant association. Similarly, steroid and narcotic use have been shown to decrease testosterone levels. Twelve of our patients were using steroids and 4 were using narcotics and these small numbers may not have been sufficient to demonstrate significant associations.

Psychometric evaluation of the final 10-item instrument was assessed in 3 major ways: (1) reliability, (2) criterion validity, and (3) construct validity. Overall, the 10-item IBD-MSDS has strong internal consistency reliability. Using Spearman's correlation coefficient, strong criterion validity was noted with all the subscales of the IIEF; and positive

TABLE 4. Regression Analysis of Factors Contributing to Sexual Dysfunction as Measured by the IBD-MSDS

Variable	Beta Coefficient	Standard error	P Value
Ostomy	3.4	2.1	0.103
IPAA	3.8	1.9	0.047
PHQ > 5	52	0.09	0.000
IBD Activity (HBI/SCCAI ≥ 5)	3.4	1.5	0.021
Previous smoker	-3.2	1.3	0.021
Endocrine-related comorbidities	3.0	1.8	0.098
Cardiac-related comorbidities	2.5	1.4	0.063

statistically significant associations (construct validity) were shown with the measure for depression and the composite score for active IBD cases.

A limitation to this study is that both for initial validation and subsequent screening, a cross-sectional observational cohort was utilized. Since the validation is in a single city setting, bias may be increased along with limitations of generalizability. However, we hope to counter this by ensuring that a wide spectrum of patients was offered participation in the study. Possible recall bias may be present; to limit this, medical records were reviewed to verify clinical information and a longitudinal assessment of each patient's medical history. In addition, an evaluation of clinical disease activity (either the HBI or the SCCAI) was ascertained by the physician from the patient at the time of the clinic appointment. Methodologically, test-retest repeatability in a longitudinal design is more desirable to assess scale reliability, along with the evaluation of responsiveness when study participants are enrolled in a pre/post treatment design. Unfortunately, we do not have endoscopic data here, but we suggest that future studies might include endoscopic and biochemical endpoints. Furthermore, this new tool

warrants further evaluation and should be used as an adjunct to, rather than a substitute for, a detailed history of sexual dysfunction in men with IBD.

In conclusion, we have developed and validated a novel tool to assess the specific psychosexual impact of IBD. We hope that it can be used for clinical and research purposes to diagnose sexual dysfunction in male patients with IBD. We propose that IBD physicians assume a proactive role in screening for and identifying factors contributing to impaired sexual function in our IBD patients. Specifically, we should strive for disease remission and screen for underlying depression in our patients.

SUPPLEMENTARY DATA

Supplementary data are available at *Inflammatory Bowel Diseases* online.

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