Psychometric Evaluation of the IBD-Specific Anxiety Scale: A Novel Measure of Disease-Related Anxiety for Adolescents With IBD

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Abstract

Anxiety related to pediatric inflammatory bowel disease (IBD) is a common comorbidity; yet, this construct is understudied because of lack of available valid measurement. **Objective** The present study will report the preliminary validation of the 20-item IBD-Specific Anxiety Scale (IBD-SAS) in a large, geographically diverse sample of adolescents aged 12–18 years with IBD. **Method** A total of 281 adolescents, ages 12–18 ($M = 14.8$, $SD = 1.78$; 51% male), completed the IBD-SAS along with measures of IBD-related quality of life, anxiety, depressive symptoms, and disease activity. Factor structure was assessed using exploratory and confirmatory factor analyses (EFA and CFA). **Results** EFA (Sample 1; $n = 141$) yielded one-, two-, three- and four-factor models. The CFA (Sample 2; $n = 140$) demonstrated that a four-factor model was superior to three- and two-factor model for the amended scale. In total, the IBD-SAS showed excellent internal consistency (Cronbach's $\alpha = .95$) and was most strongly associated with health-related quality of life. Moderate to strong associations were observed between IBD-SAS and general measures of anxiety and depressive symptoms, and IBD disease activity providing additional support that health-specific anxiety is a valid and distinct construct. **Conclusions** Based on the results of this study, the IBD-SAS displayed adequate psychometric properties and can meaningfully contribute to the assessment of IBD-specific anxiety in adolescents diagnosed with IBD, thus filling an empirical and clinical need in this population.

Key words: adolescents; anxiety; assessment; chronic illness; inflammatory bowel disease.

Pediatric inflammatory bowel disease (IBD) is a chronic medical condition with no known cure. The onset of IBD is characterized by an acute phase surrounding the initial diagnosis of the illness, which can require invasive medical procedures (e.g., colonoscopy) and, in some cases, hospitalization. Disease symptoms vary, depending on the severity of inflammation and where it occurs on the gastrointestinal tract, and presence of extra-intestinal symptoms, but the most common symptoms include bowel movement urgency, bloody stool, abdominal pain, and fatigue. Symptoms can range from mild to severe and are characterized by an unpredictable course with periods of active illness followed by periods of remission.

IBD and its treatment present youth and their parents with significant challenges and, for some, is a source of chronic stress that can contribute to emotional and behavioral problems (Mackner, Crandall, & Szigethy, 2006). If undetected or left untreated, these problems can compromise adherence to treatment regimens

(Jackson, Clatworthy, Robinson, & Horne, 2010) as well as impact disease processes (Cohen, Janinicke-Deverts, & Miller, 2007; Segerstrom & Miller, 2004).

To address the emotional burden of this disease, a number of studies have focused on the identification and treatment of comorbid psychiatric conditions such as anxiety and depression as well as general emotional distress (see Graff, Walker, & Bernstein, 2009; Mikocka-Walus, Knowles, Keefer, & Graff, 2016 ; Regueiro, Greer, & Szigethy, 2017 for systematic review). Moreover, a recent practice guideline has also recommended the assessment and treatment of psychosocial health in youth with IBD (Rufo et al., 2012). Yet, there are no current validated measures for assessing IBD-specific anxiety. This is problematic, given that anxiety related to living with and managing a chronic medical condition may not be detected using traditional anxiety inventories (Woodward et al., 2016). Consequently, this lack of measurement likely precludes the full clinical assessment of anxiety in pediatric patients with IBD.

While it is generally believed that disease-specific anxiety is common among individuals living with the disease, studies of this construct are just beginning to emerge. A study of 294 adults with diagnosed IBD (Keeton, Mikocka-Walus, & Andrews, 2015) demonstrated that all participants, but 11, reported significant IBD-related concerns despite the majority (74%) being in remission. Concerns and worries were measured using one open-ended question, and responses were then thematically coded. Four themes were identified; they included concerns related to quality of life (51%), unpredictability (35%), symptoms (34%), and treatments (19%). A handful of other qualitative studies also support the prevalence of IBD-specific distress related to managing the physical symptoms of IBD such as bowel movement urgency and fatigue (Czuber-Dochen, Dibley, Terry, Ream, & Norton, 2013; Dibley & Norton, 2013). These studies point to the need for more communication with medical providers to manage symptoms and concerns.

Among pediatric samples, one small qualitative study suggests that youth diagnosed with IBD may be particularly susceptible to developing disease-specific fears because of having to balance uncertain periods of stable health status (Lynch & Spence, 2008), which can in turn contribute to a subjective sense of vulnerability (Nicholas et al., 2007). More recent evidence suggests that psychological interventions for individuals with chronic illness and comorbid distress may only be efficacious when illness-specific perceptions are addressed (Knoop, van Kessel, & Moss-Morris, 2012; Wiborg, Knoop, Frank, & Bleijenberg, 2012), highlighting the need to measure and target disease-related emotional factors.

Little is known about the etiology, impact, or treatment of pediatric IBD-specific anxiety, in part, because of the lack of definition and instrumentation to measure this construct; thus, the IBD-Specific Anxiety Scale (IBD-SAS) was created. There are overlapping features between IBD-specific anxiety and somatic symptom disorder. Somatic symptom disorder is an excessive focus on one or more somatic symptoms accompanied by marked distress or functioning impairment. Somatic symptoms can be related to a medical condition, but the distress is excessive than what would be expected; IBD-specific anxiety extends beyond significant focus and worry about physical symptoms, to include other areas of concern related disease management and adjustment. Specifically, IBD-specific anxiety is defined as worry that is disproportionate to context, or unrealistic overestimation of negative outcomes, surrounding the reoccurrence and implication of physical symptoms, treatment, and medical procedures associated with IBD (Casati, Toner, de Rooy, Drossman, & Maunder, 2000; Dorrian, Dempster, & Adair, 2009). This anxiety may be present during disease relapse, as well as in periods of remission (Reigada et al., 2015).

The initial version of the IBD-SAS (Reigada et al., 2011) contained 11-items and was developed by a multidisciplinary team of investigators including experts in the field of anxiety and pediatric chronic illness, gastroenterologists, and families with children with IBD. The measure was further revised (to the current version) to include additional areas of disease concern (e.g., worries pertaining to height, growth, medical treatment response, etc.). Revisions were informed by the clinical knowledge gained through the assessment and treatment of comorbid anxiety disorders in pediatric IBD in an open pilot (Reigada et al., 2015) and a randomized controlled trail. While the development of the IBD-SAS preceded publication of the *Journal of Pediatric Psychology* (JPP) guidelines for measure development (Holmbeck & Devine, 2009), the following strategies, that overlap with key features of the JPP criteria, were used to develop the IBD-SAS: (1) clearly establishing a research and clinical need for the instrument, and (2) consideration of content validity, which included (i) creating a well-defined construct with a specified purpose and target population; and (ii) item generation based on clinical experience, empirical literature, related instruments, and consultation with experts and target population.

Early use of this measure has provided preliminary evidence that items on the IBD-SAS differentiate IBD-specific anxiety from Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV anxiety conditions (i.e., social anxiety, generalized anxiety, panic disorder, and separation anxiety), depressive symptoms, and IBD-specific quality of life (Reigada et al., 2011). Also of note, this study found that elevated

IBD-specific anxiety symptoms, rather than general anxiety or depressive symptoms, were associated with greater utilization of medical services and decreased social functioning among adolescents with IBD. In other studies, significant reductions in IBD-specific anxiety, measured by the IBD-SAS, was found immediately following receipt of a 13-week health sensitive cognitive behavioral treatment (Reigada, et al., 2015) and 3 months later. This finding provides preliminary evidence that the IBD-SAS may be sensitive to treatment effects.

The current scale includes 20 questions pertaining to how often, within the past 2 weeks, youth "worried" about their IBD symptoms and medical treatment, as well as their concerns regarding disease impact on school, social relations, and body image. Items are rated on a six-point Likert scale ranging from 0 to 5 points (0 = *never*, 5 = *always*) with higher scores relating to more IBD-specific anxiety. The analyses of the psychometric properties and factor structure of the IBD-SAS have not previously been conducted and is the rationale for the present study. Establishing a psychometrically sound instrument will provide a mechanism by which IBD-related anxiety can be identified, and subsequently treated, and allow for empirical testing of the impact of disease-specific anxiety on emotional and physical outcomes.

The aim of this study was to evaluate the psychometric properties of the IBD-SAS in a large, geographically diverse sample of adolescents aged 12–18 years with IBD, namely, its factor structure, using exploratory and confirmatory factor analyses (EFA and CFA), and internal consistency. We also sought to evaluate the external validity of the IBD-SAS by examining the association between this measure with indices of IBD-related quality of life and IBD severity. We hypothesized that the IBD-SAS would have the strongest association with IBD health-related quality of life (HRQoL). IBD HRQoL assesses subjective perception of health state and includes several overlapping domains with IBD-SAS, including disease and bowel functioning as well as emotional and social functioning (Mouzas & Pallis, 2000). We predicted a low to moderate correlation between IBD-SAS and disease activity. While distress increases when disease is exacerbated (Mikocka-Walus, Knowles, Keefer, & Graff, 2016), we have demonstrated that IBD-specific anxiety is also frequently present when disease is in remission (Reigada et al., 2015). In addition, based on our previous work (Reigada et al., 2011), we expected a significant, moderate correlation between IBD-SAS and nondisease-specific measures of anxiety and depressive symptoms.

Methods

The present cross-sectional study is nested within an ongoing longitudinal, Internet-based study conducted by the Crohn's and Colitis Foundation of America (CCFA) Partners Kids and Teens Registry. The CCFA Kids and Teens registry is a large, geographically diverse Internet-based cohort of children and adolescents diagnosed with IBD. Recruitment methods included e-mails to the CCFA registry, social media, print advertisements, word of mouth, and promotion at CCFA chapter meetings and fundraising events. Children and adolescents between the ages of 12 and 18 years, with a self-reported diagnosis of IBD (Crohn's disease [CD], ulcerative colitis [UC], or indeterminate colitis) and Internet access met the inclusion criteria for this study.

Between March 2014 and August 2016, all eligible participants were offered the IBD-SAS at the time they completed the primary CCFA Partners survey, which included questions about participants' demographics, HRQoL, mental health, and disease functioning. Two samples were collected to accomplish study aims. First, Sample 1 ($n = 141$) was collected for the EFA. Next, Sample 2 ($n = 140$) was collected for the CFA. The study protocol was approved by the institutional review board at the University of North Carolina, Chapel Hill, NC, and Vanderbilt University, Nashville, TN.

Measures

All measures included in this study were completed by adolescent participants. Symptoms of general anxiety and depression were measured using the Patient-Reported Outcome Measurement Information System (PROMIS; Ader, 2007). The pediatric version of the PROMIS is a modified version of the adult PROMIS (Irwin et al., 2010) and measures physical, mental, and social aspects of health using a Likert-type response scale ranging from 1 *Never* to 5 *Almost always*. Each domain was measured using the four-item short forms. Scores for each domain are used to generate a *T*-score, with an *M* of 50 and *SD* of 10. Criterion validity and responsiveness of pediatric PROMIS have been demonstrated among a pediatric IBD sample (Arvanitis et al., 2016). For this study, internal consistency of PROMIS items was good ($\alpha = 88$) and excellent ($\alpha = .91$) on anxiety and depression domain items, respectively.

IBD HRQoL was measured using the IMPACT-III (Otley et al., 2002). This instrument contains 35 questions, on a five-point Likert scale, focusing on issues relating to the bowel, body image, functional/social impairment, emotional impairment, tests/treatments, and systematic impairment. The full measure has documented construct validity and excellent reliability ($\alpha = .92$) (Otley et al, 2006). Internal consistency of IMPACT items in the current study sample was excellent ($\alpha = .95$).

IBD-specific anxiety was measured using the 20-item IBD-SAS, which was described earlier.

Disease activity was measured using the Short Crohn's Disease Activity Index (SCDAI; Thia et al., 2011) and the Pediatric Ulcerative Colitis Activity

Index (PUCAI; Turner et al., 2007) for CD and UC, respectively. These indices have been validated and are in wide use in both research and clinical care. The total sum scores of the SCDAI and PUCAI were transformed into categorical activity: none (SCDAI <150; PUCAI <10), mild (SCDAI 150–218; PUCAI 10–34), moderate (SCDAI 219–450; PUCAI 35–65), and severe (SCDAI = 450+; PUCAI = 65+).

Statistical Analyses

EFA was used as a first step in identification of the factor structure of the IBD-SAS in Sample 1 ($n = 141$), followed by CFA in Sample 2 ($n = 140$). For the initial EFA, factor structure of the IBD-SAS was conducted by examining the fit of one-, two-, three-, and four-factor models. We decided on the number of factors using both empirical (i.e., goodness-of-fit indices) and theoretical criteria (i.e., if the meaning of the factor is interpretable) and the practical/clinical utility of the factor (e.g., do at least two items load onto all factors, are any of the items redundant). Good fit was indicated by SRMR values close to .08 or below, RMSEA values close to ≤.06, CFI values close to .95 or greater. CFA procedures were used to confirm superior model fit of empirical and clinically relevant models derived from the EFA. All EFA and CFA analyses, except where indicated otherwise, were conducted using Mplus, version 7.2 (Muthén & Muthén, 1998–2014). Maximum likelihood estimation was used for both EFA and CFA, while geomin rotation was used for EFA. An item was considered to load onto a parent factor if its standardized loading was ≥|.40| (Comrey & Lee, 1992). Items with loadings above this threshold on two or more factors were considered to have cross-loaded.

Unstandardized Cronbach alpha coefficients were used to estimate internal item consistency of the total IBD-SAS and for each factor. Convergent validity of the IBD-SAS was examined using a series of correlational analyses (Pearson for continuous and Spearman for ordinal variables) with measures theoretically expected to be moderately to strongly associated with IBD-specific anxiety, including IBD HRQoL (IMPACT-III), general (nonhealth focused) anxiety and depression (PROMIS), and IBD severity (PUCAI/SCDAI). Following convention, a correlation between .40 and .59 was considered "moderate," between .60 and .79 was considered "strong," and >.80 was deemed "very strong" (Evans, 1996). SPSS Statistics software version 23 was used for descriptive, reliability, and validity analyses.

Results

Participants

Combining Samples1 and 2, participants included 281 adolescents, ages 12–18 ($M = 14.8$, $SD = 1.78$) years; 51% were male. Most self-identified as Caucasian (90%) and had a diagnosis of CD (79%). In total, 19% were diagnosed with IBD by the age of 10 years. Based on self-reported IBD activity (current), 68% ($n = 192$) were in remission, 18% ($n = 50$) had mild activity, 10% ($n = 28$) had moderate activity, and <1% ($n = 1$) had severe activity. Current corticosteroid treatment was reported by 11% ($n = 30$) and more than half of the sample ($n = 160$, 57%) were on biologic therapy to treat their disease. Mother education level included less than high school (2%), high school (6%), some college (15%), college (42%), and graduate school (35%). Father education level included less than high school (1%), high school (13%), some college (16%), college (40%), and graduate school (30%). The sample was geographically diverse with participants residing in 40 U.S. states and 3 foreign countries. Participant characteristics by Sample 1 and Sample 2 are displayed in Table I.

Table I. *Characteristics of Participants by Sample*

Variable	Sample 1 ($n = 141$)	Sample 2 ($n = 140$)
Age *M* (*SD*)	14.81 (1.78)	14.52 (1.93)
Male %s	57	45
Caucasian %	92	86
Mother's education *M* (*SD*)	4.01 (1.00)	4.04 (0.92)
Father's education *M* (*SD*)	3.87 (1.03)	3.87 (1.05)
CD %	81	76
Age at diagnosis *M* (*SD*)	9.86 (3.13)	10.42 (3.21)

Note. Mother and father education scale is 1 = less than high school, 2 = high school, 3 = some college, 4 = college, and 5 = graduate school.
CD = Crohn's disease.

Item Distributions

Table II displays item *M*s and *SD*s for all IBD-SAS questions. The means were close to the lower bound of the 0–5 scale, ranging from .59 to 1.61. All items had a positive skew. The overall mean of the 20-item IBD-SAS across Samples 1 and 2 was 18.82 ($SD = 18.94$), with scores ranging between 0 and 75.

Exploratory Factor Analysis (Sample 1)

Comparison of fit and information indices suggested the superiority of a four-factor model (see Table III for factor loadings): $\chi^2(116) = 185.44$, $p < .001$, CFI = .97, RMSEA = .07 (CFit $p = .08$), SRMR = .03, BIC = 7,068.45, followed by the three-factor model: $\chi^2(133) = 273.76$, $p < .001$, CFI = .84, RMSEA = .09 (CFit $p < .001$), SRMR = .04, BIC = 7,072.63; two-factor model: $\chi^2(151) = 397.12$, $p < .001$, CFI = .89, RMSEA = .11 (CFit $p < .001$), SRMR = .06, BIC = 7,106.92; and one-factor model: $\chi^2(170) = 588.07$, $p < .001$, CFI = .82, RMSEA = .13 (CFit $p < .001$), SRMR = .07, BIC = 7,203.85. However, in the four-factor model, one factor was

Table II. *IBD-SAS Item Ms and SDs*

Item (range: 0–5)	*M* (*SD*) Sample 1	*M* (*SD*) Sample 2	*M* (*SD*) Total
4. Having a flare up	0.94 (1.16)	1.26 (1.50)	1.10 (1.35)
5. Eating foods that may bother your IBD	1.11 (1.40)	1.30 (1.43)	1.20 (1.42)
6. Having pain	1.13 (1.30)	1.38 (1.50)	1.26 (1.41)
7. Having no control over your body	0.70 (1.07)	0.91 (1.34)	0.80 (1.21)
10. The side effects of IBD medicine (i.e., side effects are problems that the IBD medicine might cause such as bloating and mood swings)	0.79 (1.20)	1.16 (1.51)	0.97 (1.37)
13. Missing taking your medication	0.59 (.94)	0.79 (1.16)	0.69 (1.06)
14. That your medication is not working	0.78 (1.13)	0.92 (1.42)	0.85 (1.28)
20. What will happen in the future because of IBD (i.e., needing surgery)?	1.15 (1.36)	1.61 (1.78)	1.38 (1.60)
12. Having to go to the hospital or visit your doctor	0.64 (1.08)	0.94 (1.28)	0.79 (1.19)
15. What your friends will think if you have IBD symptoms in front of them?	0.67 (1.12)	0.99 (1.42)	0.83 (1.29)
16. Leaving your house because of IBD symptoms	0.50 (.88)	0.75 (1.22)	0.62 (1.07)
17. Not being able to attend school because of IBD symptoms	0.75 (1.23)	1.08 (1.61)	0.91 (1.44)
18. Not being able to keep up or hang out with other kids because of IBD	0.70 (1.20)	1.06 (1.45)	0.88 (1.46)
19. Not doing well in physical activities because of IBD*	0.96 (1.40)	1.07 (1.53)	1.02 (146)
2. Having to go, and not having access to a bathroom	0.86 (1.16)	1.14 (1.35)	1.00 (1.27)
3. Having bloody stool	0.48 (.77)	0.80 (1.31)	0.64 (1.08)
8. Your height	0.87 (1.35)	0.86 (1.25)	0.86 (1.30)
9. Your weight	1.01 (1.35)	1.21 (1.52)	1.11 (1.43)
1. Having to go to the bathroom without warning	0.82 (1.02)	0.99 (1.28)	0.90 (1.16)
11. Having medical procedures (i.e., drawing blood, endoscopy)	0.81 (1.15)	1.21 (1.46)	1.01 (1.33)
Total	16.24 (17.35)	21.41 (20.14)	18.82 (18.94)

Note. IBD = inflammatory bowel disease; IBD-SAS = IBD-Specific Anxiety Scale.

Table III. *Standardized Factor Loadings for Four-Factor Model*

Item	Sample 1				Sample 2			
	F1	F2	F3	F4	F1	F2	F3	F4
4. Having a flare up	**.79**	.06	.02	.06	**.89**	N/A	N/A	N/A
5. Eating foods that may bother your IBD	**.82**	.04	−.14	−.01	**.74**	N/A	N/A	N/A
6. Having pain	**.82**	.14	−.12	.02	**.81**	N/A	N/A	N/A
7. Having no control over your body	**.68**	.23	.06	−.01	**.82**	N/A	N/A	N/A
10. The side effects of IBD medicine (i.e., side effects are problems that the IBD medicine might cause such as bloating and mood swings)	**.77**	−.21	.06	.26	**.75**	N/A	N/A	N/A
13. Missing taking your medication	.31	.01	.05	.24	**.40**	N/A	N/A	N/A
14. That your medication is not working	**.69**	.08	.02	.10	**.80**	N/A	N/A	N/A
20. What will happen in the future because of IBD (i.e., needing surgery)?	.38	.29	.13	.15	**.75**	N/A	N/A	N/A
12. Having to go to the hospital or visit your doctor	−.12	**.67**	.18	.26	N/A	**.55**	N/A	N/A
15. What your friends will think if you have IBD symptoms in front of them?	.18	**.43**	.24	.09	N/A	**.67**	N/A	N/A
16. Leaving your house because of IBD symptoms	.22	**.42**	.36	−.03	N/A	**.80**	N/A	N/A
17. Not being able to attend school because of IBD symptoms	.11	**.85**	.05	−.10	N/A	**.83**	N/A	N/A
18. Not being able to keep up or hang out with other kids because of IBD	.01	**.99**	−.03	−.02	N/A	**.88**	N/A	N/A
19. Not doing well in physical activities because of IBD[a]	.30	**.59**	−.07	.16	N/A	**.85**	N/A	N/A
2. Having to go, and not having access to a bathroom	.01	.05	**.87**	.02	N/A	N/A	**.77**	N/A
3. Having stool (bowel movements) containing blood[b]	.28	−.11	**.60**	−.10	N/A	N/A	**.83**	N/A
8. Your height	.05	.01	−.02	**.87**	N/A	N/A	N/A	**.40**
9. Your weight	.23	.21	−.02	**.48**	N/A	N/A	N/A	**.94**
1. Having to go to the bathroom without warning	.26	.08	**.61**	.03	N/A	N/A	N/A	N/A
11. Having medical procedures (i.e., drawing blood, endoscopy)	.09	**.44**	.11	.21	N/A	N/A	N/A	N/A

Note. Items in bold type were considered for factor loading interpretation. Factor 1 = F1; Factor 2 = F2; Factor 3 = F3; Factor 4 = F4; IBD = inflammatory bowel disease.

[a]In Sample 1, this question read: "Not doing well in sports or dancing because of IBD."

[b]In Sample 1, this question read "Having bloody stool."

composed of only two items. A similar problem was present for the three-factor model.

Improvements to the four-factor model were made in light of the imperfect fit of the model, modification indices suggesting areas of ill-fit, and review of item content. In total, two items were removed (from the model, they were administered to all participants) and the content of two items was changed on the basis of

these criteria. For example, a large, statistically significant modification index suggested the addition of correlated residual terms between Items 1 and 2. Further inspection of these items revealed that they were almost identical in content and, as a result, Item 1 was removed. A similar rationale was used with Items 11 and 12. Several authors have cautioned against undertaking model modifications purely on the basis of modification indices, as these changes are less likely to replicate in other samples. We have adopted this recommendation and provide practical and theoretical justification for changes to the model from EFA to CFA.

The text of Item 19 was changed from Samples 1 to 2 from "Not doing well in sports or dancing because of IBD?" to "Not doing well in physical activities because of IBD?" to capture physical activity broadly rather than specific activities. That is, children who did not play sports or dance might answer this item negatively, as originally worded, because it did not apply to them, when their IBD may affect their performance in other physical activities in which they did participate. Additionally, Item 3 was revised from Samples 1 to 2 from "Having bloody stool" to "Having stool (bowel movements) containing blood" to increase clarity of wording. Item 1 was removed, as it was judged to be too similar to Item 2 and, thus, redundant. Item 11 was also removed as anxiety regarding "Having medical procedures" is not, necessarily, specific to IBD, and it was felt that this item might assess more general anxiety related to medical procedures, as opposed to anxiety related to IBD, specifically. Finally, Items 13 and 20 were retained in CFA, despite factor loadings <.40 cutoff, as both items were deemed to be too clinically useful to drop and loaded significantly in CFA. Using this slightly amended and reduced item pool (now 18 items), the four-, three-, and two-factor models were submitted to CFA using Sample 2.

Confirmatory Factor Analysis (Sample 2)

CFA was conducted in an attempt to cross-validate the EFA results and compare the three models of the IBD-SAS. Comparison of fit and information indices suggested the superiority of a four-factor model (see Table III for factor loadings): $\chi^2(129) = 259.19$, $p < .001$, CFI = .92, RMSEA = .09 (CFit $p < .001$), SRMR = .05, BIC = 7,599.34, when compared with the three-factor model: $\chi^2(132) = 302.98$, $p < .001$, CFI = .90, RMSEA = .10 (CFit $p < .001$), SRMR = .06, BIC = 7,628.29; and two-factor model: $\chi^2(134) = 304.06$, $p < .001$, CFI = .90, RMSEA = .10 (CFit $p < .001$), SRMR = .06, BIC = 7,619.49. Factor 1 of the IBD-SAS had high loadings on items that assessed anxiety related to the occurrence of physical symptoms of IBD, in particular pain and disease relapse, and the treatment of IBD-related symptoms. Factor 2 had high loadings on items that assessed anxiety associated with the impact of IBD on engaging in social, physical, and school activities and general mobility (e.g., leaving the house). Factor 3 seems to reflect anxiety related directly to bowel movements. Factor 4 seems to reflect anxiety related to height and weight disruption that can accompany IBD.

In Sample 2, all four factors of the IBD-SAS were significantly correlated. Factors 2 and 4 are the most highly intercorrelated, $r\ (138) = .93$, $p < .001$, followed by Factors 1 and 2, $r\ (138) = .82$, $p < .001$; and Factors 1 and 4, $r\ (138) = .71$, $p < .001$. Factors 2 and 3, $r\ (138) = .53$, $p < .001$, and Factors 3 and 4, $r\ (138) = .47$, $p < .001$, are also highly intercorrelated. Factors 1 and 3, however, are relatively orthogonal, $r\ (138) = .25$, $p = .02$.

Reliability

The IBD-SAS showed excellent overall internal consistency (20-item; Cronbach's $\alpha = .95$) and the deletion of two items (1 and 11) did not improve the overall reliability of the scale (18-item; $\alpha = .95$). Factors 1 and 2 demonstrated excellent internal reliability ($\alpha = .92$ and .91, respectively), while Factor 3 was acceptable ($\alpha = .73$) and Factor 4 fell within the questionable range ($\alpha = .66$).

External Validity

On the PROMIS, *T*-score means were 46.76 ($SD = 10.26$) and 43.58 ($SD = 8.65$), for anxiety and depression, respectively. For the IMPACT, the *M* was 134.31 ($SD = 18.94$). As shown in Table IV, correlation coefficients relevant to construct validation provide support that the IBD-SAS has convergent validity, which is congruent with our hypotheses. The total 20-item IBD-SAS, as well as Factor 1 and Factor 2, displayed a strong significant negative correlation with IBD HRQoL, measured by the IMPACT. IBD-SAS Factor 3 and Factor 4 had a negative moderate to strong relationship with IBD HRQoL. Significant positive moderate to strong correlations were found between total score and factors of the IBD-SAS and measures of anxiety, depression, and disease activity.

Discussion

The current study aimed to evaluate the factor structure and psychometric properties of the IBD-SAS in a geographically diverse, nonclinical sample of 281 youth with IBD. Overall, the current study findings provide preliminary reliability and validity support for the IBD-SAS. Based on empirical and theoretical criteria, we found that the IBD-SAS is best represented as a four-factor model. Factor 1 captured worry related to the physical symptoms and medical treatment of IBD.

Table IV. *Correlations Between IBD-Specific Anxiety Total and Factors With IBD HRQoL, Anxiety, Depression, and Disease Activity*

Measure	IBD-SAS	F1	F2	F3	F4	IMPACT: HRQoL	PROMIS: anxiety	PROMIS: depression
IBD-SAS	–							
F1	.96	–						
F2	.93	.84	–					
F3	.74	.67	.63	–				
F4	.61	.52	.50	.27	–			
IMPACT: HRQoL	−.85	−.81	−.81	−.61	−.52	–		
PROMIS: anxiety	.65	.65	.58	.48	.40	−.66	–	
PROMIS: depression	.67	.65	.61	.45	.49	−.69	.68	–
Disease activity	.55	.50	.52	.53	.26	−.60	.35	.35

Note. All correlations significant at $p < .01$.

Factor 1 = F1; Factor 2 = F2; Factor 3 = F3; Factor 4 = F4; HRQoL = health-related quality of life IBD = inflammatory bowel disease; IBD-SAS = IBD-Specific Anxiety Scale.

Factor 2 had high loadings on worry items that were associated with the impact of IBD on engaging in social and physical activities. Factor 3 related directly to worry regarding bowel movements. Factor 4 included worry related to height and weight disruption that can accompany IBD. Of note, some factors within the IBD-SAS were strongly correlated potentially suggesting the subscales measure slightly similar manifestations of distress. Nonetheless, the four factors would be useful if clinicians or clinical researchers have a particular interest in assessing particular domains of concern.

Findings regarding convergent validity of the IBD-SAS are promising and provide preliminary support for use of the IBD-SAS as a brief instrument to examine IBD-specific anxiety among adolescents diagnosed with IBD. Congruent with our a priori hypothesis, higher IBD-SAS scores were associated with lower HRQoL. That is, youth with increased worries about their IBD was likely to also reported having worsened HRQoL. While disease severity (Otley et al., 2002; Perrin et al., 2008; van der Have et al., 2014) and internalized conditions, including anxiety and depressive symptoms (Loonen, Grootenhuis, Last, Koopman, & Derkx, 2002) and psychiatric disorders (Gray, Denson, Baldassano, & Hommel, 2011), are established determinants of HRQoL, this report demonstrates that IBD-specific anxiety may also be strongly linked with HRQoL. Based on our sample, IBD-SAS displayed a stronger association with HRQoL compared with reports of general anxiety and depressive symptoms, and disease activity, suggesting these two constructs are more closely related supporting convergent validity.

The strong association between IBD-SAS and HRQoL, measured by the IMPACT-III, makes sense. The 35-item IMPACT-III measures patient perception of their health status and the impact of their illness on their physical, social, and emotional functioning (Otley et al., 2002). The IMPACT-III also includes six questions that assess worry or feeling afraid pertaining to disease exacerbation, health problems in the future, presence of bloody stool, dating, and having an operation. However, there are several key differences between the IMPACT-III and IBD-SAS. The IBD-SAS captures worry over a specific 2-week timeframe, while the IMPACT-III does not specify a time frame. Furthermore, the questions pertaining to worry on the IMPACT-III are embedded in different domains, thus not easily usable, nor is there psychometric data that support the use of this measure in this manner. While both the IMPACT-III and the IBD-SAS capture other overlapping domains of interest including issues related to school, body image, medication, and pain to name a few, the IBD-SAS captures how often one worries about these domains, while the IMPACT-III assesses the degree to which youth perceive their IBD gets in the way, bothers them and the associated feelings (e.g., anger). Despite overlapping or convergent domains of interest between IBD-specific anxiety and HRQoL, there is a divergence between construct definitions and in measurement, which supports the distinction between these constructs.

The IBD-SAS was also strongly correlated with measures of general, nonhealth, measures of anxiety and depressive symptoms, and moderately associated with disease activity. The strength of these relationships was greater than expected. One study found that a disease-specific measure was superior to generic measures when examining quality of life in pediatric IBD, as it had fewer ceiling effects and demonstrated more variability in scores, suggesting greater sensitivity to change (Loonen et al., 2002). In a similar fashion, this study provides preliminary support that IBD-specific anxiety may be more closely associated with HRQoL, and vice versa, compared with measures used to detect psychiatric symptoms and disorders (e.g., social phobia, separation anxiety, generalized anxiety, and depression disorders) that are not necessarily circumscribed to disease adjustment. Furthermore, disease activity and IBD-specific anxiety are seemingly associated, but this relationship may be

more complex as IBD-specific anxiety, by definition, can be present in the absence of disease activity.

Strengths of our study include the use of a novel, Internet-based cohort study, which allowed for a geographically diverse sample and decoupled survey administration from clinic appointments. This is important, as it avoided the potential for overestimation of anxiety when participants complete surveys at the time of stressful clinical encounters. Some limitations should be considered. All study data were based on adolescent self-report. However, prior work in our adult IBD cohort has demonstrated the validity of patient self-report of diagnoses of CD and UC (confirmed by medical records in 96% of participants). Furthermore, constructs such as anxiety are most appropriately captured through self-report. The relative homogeneity of the participant sample with regard to race, parent education/socioeconomic status, and disease severity is another limitation. Although the current sample is similar in demographic background to other samples previously reported in the literature (Gray et al., 2011; Mackner & Crandall, 2007), the extent to which our findings are generalizable to all adolescents with IBD, particularly those from lower socioeconomic status or from an ethnic minority background, is unknown. Although participant disease severity at the time of survey administration varied, the majority of the adolescents fell within inactive or mild disease severity ranges. Patients with severe disease exacerbations may have been underrepresented in our study; therefore, it is unknown to what extent these findings generalize to patients during acute episodes of disease inflammation. Future studies using recruitment within medical settings may provide further information regarding IBD-specific anxiety in this pediatric condition. The variability in factor loadings between Samples 1 and 2, while not uncommon, also underscores the importance of additional work replicating the factor structure found in the current study. Finally, correlations may be inflated because of common method variance.

Future validation research for the IBD-SAS is required. The high correlation between factors *could* be suggestive of a more complex, higher-order structure, where Factors 2 and 4 form a second-order factor. Future research should examine the possible interrelationships between the four factors of this scale and evaluate the potential for a higher-order structure. In addition, the clinical utility of this measure would be enhanced by establishing clinical cutoff scores and minimal important differences. However, it is likely that this measure will need to be used in tandem with some marker of disease activity or health status. For instance, when disease is in remission, elevated reports of IBD-specific anxiety are likely unwarranted and may signal adolescents that need more support or psychological intervention (Reigada et al., 2014).

However, when disease is active, this measure may also be useful. Carrying on with normal activities when IBD symptoms are present (not severe) is typically an important goal for the long-term functioning of children with IBD. Take for instance youth with frequent and unpredictable bowel movements. If they report high anxiety around bowel movements or bathroom access, they may require additional guidance to generate strategies (e.g., sit near the bathroom/exit at restaurants and movies and download a restroom locator application on their smartphone) and contingency plans (e.g., carry an emergency kit of wet wipes, an extra set of underwear and pants, and a plastic bag for soiled clothes) to increase confidence to continue to engage in their regular activities. Therefore, while the IBD-SAS can be used to detect potential pediatric IBD patients in distress, follow-up assessment and clinical judgment, which contextualize health anxiety symptoms within a health status framework, are recommended.

In conclusion, pediatric IBD patient medical care has begun to extend beyond the assessment and treatment of disease symptoms and management to incorporate disease-related psychosocial factors that may also contribute to disease factors and quality of life. Our study findings may have important implications for clinicians and clinical researchers. Identifying young people for whom IBD-specific anxiety is a clinical issue is a critical first step. The IBD-SAS is a psychometrically sound instrument that is brief and can be completed in waiting rooms, during medical visits, or between visits from the comfort of a patient's own home. Health providers should consider querying patients directly about how disease-specific anxiety may impact IBD management and quality of life. When warranted, education and further support may alleviate mild anxiety, and when appropriate, a referral to a mental health specialist should be provided. Clinical researchers can use the IBD-SAS to investigate factors that contribute to vulnerability for increased disease-specific anxiety, whether these symptoms contribute to disease processes (e.g., inflammation reoccurrence), and the degree to which these symptoms disrupt disease management as well as well-being and functioning.

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