

# Development and Validation of a Symptom-based Scoring System for Bowel Dysfunction After Ileoanal Pouch Reconstruction

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and on behalf of the PROPS Scientific Committee

**Objective:** To utilize items identified as priorities by the Patient-Reported Outcomes after Pouch Surgery Delphi consensus study to create a validated tool for quantifying pouch function.

**Background:** The Patient-Reported Outcomes After Pouch Surgery Delphi consensus study identified 7 symptoms and 7 consequences as key domains for evaluating and analyzing ileoanal pouch function.

**Methods:** Pouch patients were recruited at inflammatory bowel disease centers and via patient advocacy websites. They were administered a questionnaire-based survey eliciting responses regarding the frequency of a variety of bowel symptoms. Associations between items and quality of life were computed in a score generation cohort of 298 patients by logistic regression modeling. Individual score values were designated to items to create an additive score titled the “Ileoanal Pouch Syndrome Severity Score.” Validity was tested in a subsequent cohort of 386 patients using receiver operating characteristic area under the curve. In addition, test-retest validity, convergent validity, and clinical validity were evaluated.

**Results:** After the determination of item weights, the range of possible scores was 0 to 145. Score ranges were then determined as cutoff values for “ileoanal pouch syndrome.” The score was then validated on the second patient cohort, with a receiver operating characteristic area under the curve of 0.83. Importantly, worsening severity of Ileoanal Pouch Syndrome score significantly correlated with higher rates of poor quality of life. Lastly, the questionnaire was rigorously validated

to show test–retest validity, convergent validity compared with other bowel function scores, and clinical validity.

**Conclusions:** This study developed a patient-centered, clinically useful scoring system that can quantify the range and severity of symptoms experienced by ileoanal pouch patients and their correlation with quality of life.

**Keywords:** clinical score, ileoanal pouch, inflammatory bowel disease, patient-reported outcomes

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Restorative proctocolectomy with ileal pouch anal anastomosis (IPAA) is the most frequently performed operation for patients with ulcerative colitis (UC) who fail medical therapy.<sup>1</sup> This operation is an important option in the treatments for UC and the most frequently performed restorative procedure, but it also inevitably results in significant changes in bowel function when compared with a patient with a native rectum.<sup>2–4</sup> Although a significant driver of this functional change is related to decreased water absorptive capacity from the colon, loss of the native reservoir capacity of the rectum, and changes to anorectal sensation, operative technique, and surgical complications also impact long-term function as well.<sup>5</sup>

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As colorectal surgeons strive to improve both techniques and outcomes for their patients, a standard measure of overall function is needed to allow for systematic comparison of patient outcomes across individual surgeons, centers, and studies. Importantly, the outcomes measured by clinicians and reported in research need to be outcomes that are meaningful to patients. Unfortunately, there has historically been a gap between what patients and clinicians perceive to be important. Brandsborg et al<sup>6</sup> showed that clinicians tended to overestimate the importance of frequent bowel movements and seepage of stool, 2 of the most widely reported outcomes in the pouch literature, while they underestimated the importance of urgency and incomplete evacuation. Furthermore, surgical literature describing ileoanal pouch function has focused on a set of arbitrary variables and is likely missing several additional symptoms that are bothersome to patients.<sup>2</sup>

The Patient-Reported Outcomes after Pouch Surgery (PROPS) Delphi consensus study sought to incorporate patient input into the assessments of quality of life (QoL) after ileoanal pouch surgery.<sup>7,8</sup> The study involved a panel of 195 patients, 62 surgeons, 48 gastroenterologists, and other clinicians participating in a rigorous Delphi process, patient focus group panels, and finally an expert consensus meeting to generate a consensus statement. This process resulted in the description of the “new normal” bowel function experienced by patients after ileoanal pouch surgery, which was termed “ileoanal pouch syndrome (IPS).” These descriptive factors were distilled into 7 symptoms and 7 consequences. Of note, this study did not determine whether these symptoms or consequences lead to a deterioration in QoL. Thus, the goal of the current study was to quantify the impact of each of these previously identified IPS domains on patient QoL. Our second aim was to develop a rigorously validated standardized clinical scoring system that identified patients with symptoms of IPS who are experiencing a decreased QoL because of these symptoms and consequences, thus providing clinicians with a validated tool for measuring IPS severity.

## METHODS

### Patient Recruitment

To be eligible for the study, patients had to have had a restorative proctocolectomy with an IPAA for UC, Crohn disease, or familial adenomatous polyposis syndrome followed by at least 12 months of restored intestinal continuity before study participation.

Patient recruitment was primarily performed by advertising the study via the Crohn and Colitis Foundation (CCF) website ([crohnscolitisfoundation.org](http://crohnscolitisfoundation.org)), as well as by sending recruitment letters to patients in the CCF-affiliated “IBD Partners” database, which contains patients who have previously expressed interest in participating in inflammatory bowel disease (IBD) research and includes information on which patients underwent an IPAA procedure for UC. The IBD Partners database contains self-reported patient data, which was validated against the electronic clinical record and found to have high validity as far as patient diagnosis and patient surgical course.<sup>9</sup>

Additional recruitment was performed through a concerted effort by the PROPS Research Study Group Expert Panel who are all members of the CCF-sponsored Surgical Research Network and Clinical Research Alliance, which consists of colorectal surgeons and gastroenterologists practicing across the United States with a focus and interest in patients with IBD. Enlisted

centers were required to identify patients who underwent IPAA at their institution and to verify that intestinal continuity remained intact. After internal review board approval, participating centers forwarded recruitment information letters to those patients meeting inclusion criteria, with a link to the study information page. On this link, patients were informed about the study procedure in detail, and those interested in participating had the opportunity to opt into the study and proceed with completing several online questionnaires detailed below.

The study also recruited an additional cohort of 50 healthy adult patients, without any gastrointestinal conditions, which was done via an online invitation to healthy volunteers. The online questionnaires were sent to all subjects from the principal site using REDCap, which was used to store and manage data.<sup>10</sup>

### Development of the Basic Questionnaire

The primary draft of the initial questionnaire included items identified in the PROPS Delphi Consensus study,<sup>7</sup> which were then carefully worded into a questionnaire format based on a thorough review of the literature including other available questionnaires/scoring systems that addressed similar domains, and with input from a panel of experts and patient advocates. This included questions that described symptoms and consequences flagged by patients during the PROPS Delphi consensus process. As part of the PROPS Delphi study, the lead authors moderated 4 panel discussions with 53 patients, as well as a final consensus meeting with 89 patients. These semi-structured conversations then allowed the study team to create a draft instrument. Question wording was further refined by a group of experts from the Surgical Research Network with special interest in the field of bowel function after pouch surgery, as well as 12 patient volunteers who were not part of the initial questionnaire development. After distribution of the draft to the first 50 patients, the questionnaire was queried for test/retest reliability and was further modified with patient input as far as the clarity of its wording, as necessary. Ultimately, the questionnaire items asked participants about the presence of symptoms/consequences and the frequency of their occurrence across a spectrum of 5 possible answers: never; rarely (<1/month); sometimes (<1/week); weekly; or daily.

### IPS Severity Score Derivation

The weighted IPS severity (IPSS) score was developed based on the questionnaire results from the first 298 prospectively enrolled patients who answered the questionnaire draft in its entirety, and also responded to a single question pertaining to their QoL: “Overall, how much is your quality of life influenced by your bowel function?” Patients were asked to respond using a Likert scale ranging from 0 to 9, where 0 indicated no impact on QoL and 9 indicated extremely poor impact on QoL.

To start, each question within the questionnaire draft was assessed for impact on QoL. We then calculated the association of the question to QoL by logistic regression analyses using major impact on QoL as the primary outcome, defined as a Likert scale score of 5 to 9. To create an additive model based on the sum of scores, the beta weights from the logistic regression model were used. We then used the minimum beta weight to serve as 1 point, all other betas were divided by this minimum and rounded to the nearest integer for their additive effect. The effects showing similar strength when answers to questions were coded as yes/no were simplified accordingly. Similarly, when effects that showed similar values between a 3-point spread of

answer choices, the questionnaire was simplified to the lowest possible point spread of answer choices that would still maintain response discrimination and reproducibility as far as impact on QoL and achieve a succinct, consolidated set of questions, and answer options.

The individual maximal scores for each symptom and consequence were added to make the maximal IPSS score. Participants were then divided into quintiles based on IPSS score and the range of the scores was utilized to determine classification of the 5 groups: “No IPS,” “minor IPS,” moderate IPS,” “severe IPS,” and “extremely severe IPS.” The exact quintile score cutoffs were slightly adjusted to develop more straightforward and clinically practical cutoffs to delineate the 5 severity groups.

### Validity of the IPSS Score

The validity of the IPSS score was tested on a second cohort of prospectively recruited patients (n = 386). The sensitivity and specificity of the IPSS score in predicting poor QoL was analyzed by receiver operating characteristic (ROC) curves of the score versus groups reporting good/moderate versus poor QoL. For each QoL group, the mean and standard deviation of the IPSS score was calculated, and score differences between groups were tested by the Kruskal-Wallis test. A table comparing IPS severity group with the corresponding QoL of life groups (good, moderate, poor QoL) was used to assess the prediction model.

### Test–Retest Validity Testing

Test–retest reliability of the questionnaire was established in a cohort of individuals who agreed to complete the same questionnaire a second time, ~2 weeks later. Test–retest reliability of the questionnaire was assessed by Cohen Kappa with a kappa value of <0.4 regarded as poor or moderate agreement, 0.4 to 0.75 as fair to good agreement, and >0.75 as excellent agreement.

### Convergent Validity Testing

Convergent validity was established by comparing the IPSS score for each participant to 5 additional questionnaire-based scoring systems that have been previously developed to study similar domains of bowel function. These scores included (1) Wexner Incontinence score<sup>11</sup>—a 5-item score used to quantify severity of incontinence based on patient rates of gas, liquid, and solid incontinence and their use of pads and life style adjustments; (2) the Vaizey Incontinence Score<sup>12</sup>—a 7-item score used to quantify the severity of incontinence that includes the variables reported by the Wexner score, as well as offering additional assessment of use of constipating medications and urgency; (3) the Memorial Sloan Kettering bowel function instrument<sup>13</sup>—a 19-item bowel function score validated in rectal cancer patients with low anterior resection syndrome, previously reported to be also altered in patients with ileoanal pouches,<sup>2,14</sup> and helpful because it includes 3 subscores for frequency, dietary changes, and urgency; (4) the Fecal Incontinence Quality of Life questionnaire<sup>15</sup> (FIQoL)—a tool validated to evaluate the impact of fecal incontinence on 4 aspects of patients’ QoL: lifestyle, coping behavior, depression or self-perception, and level of embarrassment; and also previously found to be impacting patients with ileoanal pouches; and (5) the Low Anterior Resection Syndrome score (LARS) score<sup>16</sup>—a 5-item questionnaire used to quantify severity of low anterior rectal syndrome. To establish convergent validity, scores were compared

using linear trend estimations given that all scoring systems were ordinal.

### Clinical Validity Testing

To determine whether the score was sensitive to detect differences between groups of patients based on clinical variables, the scores were also administered to healthy control volunteers. In addition, participants were asked to self-report on their personal history of relevant clinical variables and outcomes, previously assessed to be reliable when compared to chart reviews by the CCF IBD partners researchers,<sup>17,18</sup> including a variety of common complications after IPAA that might impact pouch function. IPSS scores were compared between groups based on the presence or absence of these variables using student *t* tests with unequal variance. Our hypothesis was that patients with major clinical variables such as evolution to Crohn disease, anastomotic leaks, or pouchitis may have higher scores because of the worse function and worse QoL.

**TABLE 1.** Participant Demographic and Clinical Data

Variable	Derivation Cohort (n = 298), n (%)	Validation Cohort (n = 386), n (%)
Age (SD)	47.6 (15.5)	46.6 (14.3)
Male sex	135 (45.3)	146 (39.9)
Diagnosis		
Ulcerative colitis	287 (96.3)	354 (96.7)
Crohn disease	4 (1.3)	0 (0.0)
FAP	0	6 (1.6)
Other	7 (2.3)	6 (1.6)
Pouch type		
J-pouch	282 (94.6)	357 (97.5)
S-pouch	9 (3.0)	1 (0.3)
W-pouch	2 (0.7)	1 (0.3)
Other	5 (1.6)	7 (1.9)
Indication for surgery		
Bleeding/pain/BMs	246 (82.8)	303 (83.0)
Cancer	14 (4.7)	22 (6.0)
Other	37 (12.5)	40 (11.0)
Operative stages		
One	25 (8.5)	25 (6.8)
Two	145 (49.2)	154 (42.1)
Three	125 (42.4)	187 (51.1)
Laparoscopic	123 (41.4)	173 (47.3)
Short-term complications		
Anastomotic leak	10 (3.4)	13 (3.4)
Abscess	56 (18.8)	63 (16.2)
Bleeding	19 (6.4)	22 (5.7)
Ileus	56 (18.8)	73 (18.8)
Wound infection	38 (12.8)	50 (12.9)
Dehydration	42 (14.1)	65 (16.8)
Other	70 (23.5)	97 (25.0)
Long-term complications		
Pouchitis	177 (59.4)	229 (59.0)
Cuffitis	44 (14.8)	55 (14.2)
SBO	63 (21.1)	85 (21.9)
SBO requiring surgery	25 (8.4)	30 (7.7)
Incisional hernia	23 (7.7)	33 (8.5)
Fistula	39 (13.1)	35 (9.0)
Pelvic infection	9 (3.0)	12 (3.4)
Pouch stenosis	31 (10.4)	34 (8.8)
Other	39 (13.1)	36 (9.3)
Late Crohn diagnosis	62 (20.9)	79 (21.6)

BMs indicates bowel movements FAP, familial adenomatous polyposis; SBO, small-bowel obstruction.

## RESULTS

After recruitment efforts, 812 patients volunteered to participate in the study and 684 patients (84.2%) met the inclusion criteria by completing over 80% of the responses to the questionnaire, as well as answering our QoL question.

Approximately 25% of participants were recruited through the CCF blog or IBD Partners email list, 42% were recruited through hospital-specific database invitations, 14% were involved in the PROPS Delphi consensus and wished to continue participation, and the remainder learned of the study through

## Ileoanal Pouch Syndrome Severity Index

### A Over the last 3 months have you experienced any of the following symptoms?

- A1. Accidental bowel leakage ("fecal incontinence", "accidents") of either gas, liquid or solid stool?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- A2. Soiling and involuntary staining of sanitary items, pads, or underwear with fecal material?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- A3. Sudden, strong urge to have a bowel movement that makes you rush to the toilet?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- A3. Excessively frequent or unpredictable bowel movements?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- A4. The need to return to the bathroom soon after having what felt like a complete bowel movement, sometimes within minutes?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- A5. The need to spend a lengthy (excessive) amount of time on the toilet to feel fully and securely emptied?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- A6. Discomfort, irritation, soreness, burning or pain in the bottom, especially with passage of stool or cleaning after passage of stool?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week

Patients with an ileoanal pouch often experience bowel symptoms and/or make lifestyle changes to compensate for their altered internal anatomy. These symptoms may vary and change over time. In responding to this questionnaire, please tick only one box for each question. Although you may find it difficult to select only a single answer because your symptoms vary from day to day, please choose the answer that best describes your daily life.

In answering the questions below, please think about your typical pouch function and the impact it has had on your daily life during the last 3 months.

### B Over the course of the last 3 months have you had to make any of the following accommodations?

- A7. Need to awake at night to have a bowel movement and/or clean up because of pouch-related issues?
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- C3. Adjust or modify my behavior and the way I approach intimate situations, relationships, and sexual encounters.\*
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- \*Examples could include, but are not limited to, situations that require opening up to a romantic partner, as well as need for special planning to be intimate with another person.
- C4. Adjust, modify, or change jobs; alter responsibilities at home, school, or in any other social life roles.\*
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- \*Examples may include situations where you may choose to defer from having a more public role at work or may feel that you need to avoid speaking in class; or that you cannot take a job assignment or a promotion that requires travel.
- C5. Experience negative mental, emotional, or psychological symptoms or distress.\*
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- \*Examples could include, but are not limited to, anxiety and/or embarrassment about difficult or irregular bowel function, fear that loud abdominal gurgling may be overheard; concern about fecal smell; concern about potential future pouch failure; distress caused by being or feeling different from others.

### To help manage my pouch, I...

- B1. Manipulate my diet, abstain from eating certain types of foods, and/or plan to eat at certain times of the day to help adjust my pouch function.
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- B2. Take medicines\* that may help regulate or slow down my pouch function.
- \*Examples could include, but are not limited to, Lomotil, Imodium, Fiber supplement
- Yes  
 No
- B3. Use pads or sanitary items
- No  
 Yes

### C Over the course of the last 3 months have you had to make any of the following compromises?

#### Because of my pouch, I...

- C1. Experience altered sleep, diminished energy, or fatigue.
- No, never  
 Yes, less than once a week  
 Yes, at least once per week
- C2. Plan my activities around the location and/or availability of a toilet.\*
- \*Examples could include, but are not limited to, shopping, travel, concerts, parties, movies, church, and overnight visits.
- No, never  
 Yes, less than once a week  
 Yes, at least once per week

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FIGURE 1. Final ileoanal pouch syndrome questionnaire.

social media or word of mouth. In total, 58.4% of participants identified as female, 95.8% carried a diagnosis of UC and had a J-pouch configuration.

From the total cohort, 298 early prospective responders were included in the derivation cohort and 386 were included in the validation cohort after their subsequent prospective recruitment. The derivation and validation cohorts were similar with regard to demographic and clinical factors (Table 1).

### Item Selection

Sixteen items showed significant correlation to QoL. Of note, all 7 symptoms and all 7 consequences identified in the previous Delphi consensus study that were included in the draft questionnaire showed a significant impact on QoL and were therefore included in the final multivariable model. One domain, emptying difficulties, required 2 questions to separate the concepts of clustering and fragmentation. Initial univariate analysis showed that in most questions, the RR differences between the 5-point answer spread overlapped somewhat and could be simplified to “no/never,” “less than once a week,” or “at least once a week” in 14 questions. Two questions pertaining to medication use and pad use could be simplified even further to a “yes” or “no” answer, as seen in the final version of the IPSS score (Fig. 1). The correlation with QoL was then recalculated using these consolidated answer options and the new RRs were designated score values accordingly (Tables 2 and 3).

The total possible score range was 1 to 145. After dividing participants into quintiles and adjusting score cutoffs for practical use,

the score range for “no IPS” was a total score of less than 15 points. The score range for escalating severities of IPS were as follows: “minor IPS” was a total score of 15 to 29; “moderate IPS” was a total score of 30 to 44; “severe IPS” was a total score of 45 to 60; and “extremely severe IPS” was a total score of 61 and higher (Table 4).

### Establishing IPSS Score Validity

#### Ability to Predict QoL: Validation in a Prospective Cohort

We prospectively recruited 386 patients to validate the IPSS score that was initially developed in the first 298 patient volunteers. The receiver operating characteristic curve showed an area under the curve of 0.83 in the prospective validation cohort (Fig. 2). A score within the range meeting definition for “no IPS” was associated with a poor QoL in 7.7% of patients. In contrast, a score within the range of “severe” or “extremely severe” IPS was associated with a poor QoL of 64.3% and 88.7%, respectively (Fig. 2).

#### Test–Retest Reliability

In total, 399 patients completed the repeat questionnaire 2 weeks after the original administration and after having attested that they did not have an episode of pouchitis in between the test and retest. The score showed significant test–retest reliability with kappa values of 0.90, thereby showing fair to good/excellent agreement in all 16 questions included in the proposed score.

**TABLE 2.** PROPS Symptoms Odd Ratios for Major Impact on Quality of Life and Respective Weighted Score Assignments

	N	Odds Ratio for Major Impact on QoL	P	Points
<b>Symptoms</b>				
<b>Accidental leakage</b>				
Never	156	1	—	0
< 1x/week	87	2.29 (1.34, 3.91)	0.0025	3
≥ 1x/week	55	3.66 (1.88, 7.13)	0.0001	4
<b>Soiling</b>				
Never	158	1	—	0
< 1x/week	80	1.34 (0.78, 2.31)	0.2845	1
≥ 1x/week	59	4.22 (2.14, 8.33)	< 0.0001	5
<b>Urgency</b>				
Never	165	1	—	0
< 1x/week	79	2.73 (1.57, 4.75)	0.0004	3
≥ 1x/week	54	12.49 (5.3, 29.41)	< 0.0001	9
<b>Frequent/unpredictable BMs</b>				
Never	166	1	—	0
< 1x/week	50	5.28 (2.62, 10.65)	< 0.0001	6
≥ 1x/week	80	7.28 (3.92, 13.51)	< 0.0001	7
<b>Need to return to bathroom</b>				
Never	105	1	—	0
< 1x/week	103	2.15 (1.22, 3.78)	0.0078	3
≥ 1x/week	80	4.92 (2.66, 9.09)	< 0.0001	5
<b>Excessive toilet time</b>				
Never	165	1	—	0
< 1x/week	47	1.56 (0.81, 2.99)	0.1834	2
≥ 1x/week	86	3.64 (2.08, 6.38)	< 0.0001	4
<b>Perianal discomfort</b>				
Never	80	1	—	0
< 1x/week	114	2.71 (1.46, 5.04)	0.0016	3
≥ 1x/week	104	7.43 (3.83, 14.38)	< 0.0001	7
<b>Nocturnal symptoms</b>				
Never	58	1	—	0
< 1x/week	56	3.01 (1.37, 6.62)	0.0062	4
≥ 1x/week	184	3.94 (2.04, 7.62)	< 0.0001	5

BM indicates bowel movements.

**TABLE 3.** PROPS Consequence Odd Ratios for Major Impact on Quality of Life and Respective Weighted Score Assignments

	N	Odds Ratio for Major Impact on QoL	P	Points
<b>Consequences</b>				
Need to plan activities				
Never	154	1	—	0
< 1x/week	74	2.79 (1.57, 4.96)	0.0005	3
≥ 1x/week	70	11.05 (5.34, 22.85)	< 0.0001	8
Diet change				
Never	99	1	—	0
< 1x/week	64	4.11 (2.04, 8.28)	< 0.0001	5
≥ 1x/week	135	11.73 (6.23, 22.07)	< 0.0001	8
Alter sleep habits				
Never	101	1	—	0
< 1x/week	48	4.19 (2.00, 8.77)	0.0001	5
≥ 1x/week	149	8.12 (4.5, 14.62)	< 0.0001	7
Modify behavior				
Never	196	1	—	0
< 1x/week	63	3.78 (2.05, 6.96)	< 0.0001	5
≥ 1x/week	39	8.69 (3.47, 21.79)	< 0.0001	7
Adjust job				
Never	236	1	—	0
< 1x/week	28	1.35 (0.42, 4.3)	0.6152	1
≥ 1x/week	34	5.84 (1.62, 21.04)	0.007	6
Mental impact				
Never	153	1	—	0
< 1x/week	73	3.05 (1.7, 5.45)	0.0002	4
≥ 1x/week	72	18.15 (8.05, 40.91)	< 0.0001	10
Need for pads				
No	221	1	—	0
Yes	77	2.95 (1.69, 5.15)	< 0.001	3
Medication to decrease frequency				
No	146	1	—	0
Yes	152	2.70 (1.69, 4.31)	< 0.001	3

### Convergent Validity

We assessed convergent validity by using responses from all 684 participants that allowed the calculation of the Wexner score, Vaizey score, MSK-BFI, LARS score, and the FIQoL. We hypothesized that these scores would be convergent with IPS because they cover similar sets of domains, with overlapping symptoms and consequences. Linear trend tests were used to examine differences in these scores among the range of IPS severity categories, and all scores showed significant correlation with the IPSS score (Table 5). Specifically, and as expected, the Wexner, Vaizey, LARS, and MSK-BFI subscore totals increased with IPS total score, indicative of worse function. Similarly, FIQoL subscale scores decreased with increasing IPS severity levels, also indicative of worse function.

### Clinical Score validation

IPSS scores were compared between patients who underwent IPAA surgery versus normal controls. We found a significant difference between mean IPSS scores of healthy control patients and pouch patients ( $8.1 \pm 12$  vs  $42.9 \pm 25$ ,  $P < 0.001$ ). In

addition, patients who reported either short-term or long-term surgical complications during their IPAA recovery had significantly higher scores than patients without complications, consistent with known literature on complications and demographic variables that can cause bowel dysfunction after the IPAA surgery (Table 6).

### DISCUSSION

The development of the IPSS score represents an important step forward in the postoperative clinical care of ileoanal pouch patients. This score provides a systematic framework to assess bowel dysfunction for patients who were previously overlooked. In fact, the sentiment of being forgotten by their physicians, surgeons, and other health care practitioners after their “cure” from the diagnosis of UC by a surgical procedure was expressed by many patients who participated in the PROPS Delphi Study.<sup>7,8</sup>

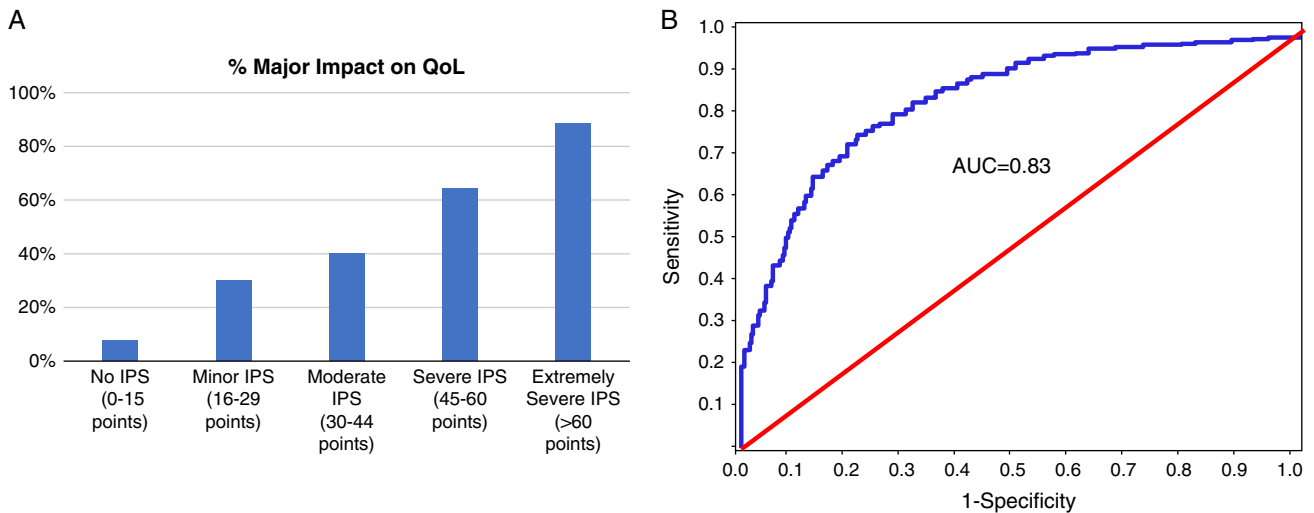
This score will directly impact the quality of our research and improve the overall QoL of patients with an IPAA. With the generation and validation of the IPSS score, clinicians now have an important tool to measure patient-centered outcomes that will quantify pouch function and standardize the reporting of outcomes across centers and studies in the future. With the ability to measure the range of function experienced by pouch patients, researchers will be able to zero in on which variations in surgical technique and medical management may improve function and ameliorate complications such as pouchitis. The IPSS score will also facilitate the assessment of interventions to improve bowel function and track bowel dysfunction over time. Finally, the IPSS score will help inform future patients who are considering whether they should undergo an IPAA in the preoperative setting by correlating their age and demographic details against score-derived information pertaining to bowel function across a range of common demographic variables.

The patient-centered approach to the development of this instrument was critical and cannot be overstated. Measuring patient-reported outcomes such as bowel function without asking patients what outcomes they should be reporting and prioritizing represents a major deficit in the literature. Brandsborg et al<sup>6</sup> studied differences in perception of pouch dysfunction between clinicians and patients and found that clinicians performed no better than random probability at choosing the 5 most important symptoms as perceived by patients. Furthermore, surgeons often focus on short-term technical outcomes, whereas patients focus on factors affecting long-term QoL.<sup>19</sup> This finding is of particular interest when considering the bowel function symptoms and consequences identified in the PROPS Delphi consensus study. By using these items as the basis for the IPSS Score, we hope to emphasize the importance of the patient experience while creating a practical and relevant tool for clinicians to use in a variety of forums.

Although alternative bowel function scores can be used to assess pouch function and QoL, the IPSS score is unique in that it was entirely developed in a population of patients with

**TABLE 4.** Derivation Cohort IPS Score Categories and Rates of Good, Moderate, and Poor Quality of Life (QoL)

	n	Good QoL (%)	Moderate QoL (%)	Poor QoL (%)
No IPS (0–15 points)	40	83.3	14.6	2.1
Minor IPS (16–29 points)	65	69.2	23.1	7.7
Moderate IPS (30–44 points)	61	34.4	41.0	24.6
Severe IPS (45–60 points)	64	10.9	45.9	42.2
Extremely severe IPS (> 60 points)	58	5.2	24.1	70.7



**FIGURE 2.** A, Percent of patients in which pouch function had a major impact on quality of life based on the severity of ileoanal pouch syndrome. B, Receiver operating characteristic area under the curve of IPSS score predicting major impact of pouch function on quality of life. AUC indicates area under the curve.

pouches, and items are weighted differently based on patient input. Interestingly, many of the symptoms have been included in the majority of previous studies on pouch function. However, additional symptoms that are less prevalent in the literature such as perianal discomfort and excessive toilet time also make up an important component of the score. Likewise, the IPSS score includes a list of consequences of bowel function specifically designed and validated by the cohort of pouch patients. These consequences may also be present in patients who have managed some of their daily bowel function symptoms with aggressive dietary or medical manipulations. Thus, it is critical to include them when discussing the overall patient experience with a pouch. Ultimately, the inclusion of both symptoms and consequences will aim to create a highly sensitive and specific score for quantifying pouch function that can specifically track changes in function based on the use of different treatment modalities during and after surgery.

As part of the initial questionnaire, patients also self-reported on a multitude of clinical variables, focusing mostly on relevant short and long-term complications after pouch creation.

Although the data are entirely self-reported, they do allow for preliminary comparisons of mean IPSS scores based on the presence of these important clinical variables. As hypothesized, patients who experienced complications such as pelvic sepsis, anastomotic leak, ileus, fistula, pouchitis, have overall higher IPSS scores, indicating worse pouch function. Although these comparisons are only preliminary, they provide an important foundation for future studies to ensure that this patient-centered score also maintains high clinical relevance.

There are several limitations of the present study that are worth mentioning. First, the majority of patients also had their surgery at a high-volume IBD center or are actively involved in the CCF. This feature represents the possibility of recruitment bias to the study cohort, as the participants were not randomly selected from the overall population of pouch patients. Furthermore, the cohort used to generate the score is heavily weighted toward a population of patients from the United States, with ~13% of participants from outside of the country. Therefore, the data might not be translatable to patients from other countries with cultural differences regarding how bothersome some symptoms are or in

**TABLE 5.** Convergent Validity—Comparison of IPSS Score and Additional Bowel Function Scores Based on IPSS Score Severity

	IPSS Category					P
	None n = 128	Mild n = 142	Moderate n = 134	Severe n = 117	Extremely Severe n = 165	
Total IPS score	9.0 ± 5.8	24.1 ± 4.1	38.0 ± 4.1	52.5 ± 4.6	76.1 ± 10.4	—
FIQoL lifestyle	3.9 ± 0.2	3.8 ± 0.3	3.6 ± 0.4	3.2 ± 0.6	2.6 ± 0.8	< 0.001
FIQoL coping	3.8 ± 0.2	3.6 ± 0.4	3.3 ± 0.5	3.0 ± 0.6	2.3 ± 0.7	< 0.001
FIQoL depression	4.3 ± 0.5	4.0 ± 0.5	3.7 ± 0.7	3.4 ± 0.8	2.8 ± 0.8	< 0.001
FIQoL embarrassment	3.8 ± 0.4	3.6 ± 0.6	3.5 ± 0.6	3.2 ± 0.6	2.7 ± 0.8	< 0.001
LARS score	11.1 ± 7.4	16.9 ± 7.9	21.1 ± 8.7	26.3 ± 6.7	33.2 ± 5.8	< 0.001
Wexner Incontinence Score	1.2 ± 2.1	2.7 ± 3.0	4.3 ± 3.2	5.9 ± 3.6	9.9 ± 4.4	< 0.001
Vaizey Incontinence Score	1.6 ± 2.2	3.3 ± 2.9	5.3 ± 3.3	6.8 ± 3.9	12.1 ± 5.1	< 0.001
MSK-BFI Frequency	10.8 ± 2.4	10.9 ± 2.0	10.8 ± 2.1	11.2 ± 2.0	11.9 ± 2.3	< 0.001
MSK-BFI dietary	9.4 ± 3.3	10.5 ± 2.8	11.8 ± 3.5	12.6 ± 3.3	14.8 ± 3.0	< 0.001
MSK-BFI urgency	11.9 ± 3.7	14.7 ± 3.0	15.6 ± 3.1	17.3 ± 2.5	18.4 ± 2.1	< 0.001

MSK-BFI indicate Memorial Sloan Kettering Bowel Function Instrument.



**TABLE 6.** Comparison of IPSS Scores Based on the Presence of Self-reported Clinical Variables\*

Risk Factor	Risk Factor Present? n (%)		P
	Yes	No	
Age below 30	38.8 (22)	41.7 (25)	0.28
Male	38.2 (22)	43.6 (26)	< 0.01
FAP diagnosis	51.8 (28)	40.9 (25)	0.04
Short-term complications			
Anastomotic leak	57.3 (31)	40.8 (24)	< 0.001
Abscess	47.1 (27)	40.1 (24)	< 0.01
Bleeding	49.0 (30)	40.9 (24)	0.04
Ileus	46.4 (24)	40.2 (25)	0.01
Wound infection	46.9 (26)	40.5 (24)	0.02
Dehydration	52.0 (26)	39.4 (24)	< 0.001
Long-term complications			
Pouchitis	45.2 (24)	35.8 (24)	< 0.001
Cuffitis	53.9 (25)	39.3 (24)	< 0.001
SBO requiring surgery	45.8 (24)	40.1 (25)	< 0.01
Incisional hernia	44.5 (24)	41.1 (25)	0.33
Fistula	52.6 (27)	40.0 (24)	< 0.001
Pelvic infection	58.1 (29)	40.8 (25)	< 0.001
Pouch stenosis	49.9 (28)	40.5 (24)	< 0.01

\*Reported as mean (SD).

FAP indicates familial adenomatous polyposis; SBO, small-bowel obstruction.

countries with higher variation in surgical technique. Additional international cohorts are needed to further validate the score in these specific situations.

In summary, the new IPSS score aims to modernize how clinicians study pouch function by centering the development and validation of the severity score around variables obtained directly from patients in a patient-centered and systematic process that magnified the patient voice at every step of the data collection process. This ensures that patient needs and concerns are prioritized in the future measurement of success of various interventions that are designed to treat pouch function and dysfunction. Additional studies are needed to validate this measure and to specifically evaluate how surgical techniques and clinical management decisions affect IPSS scores in IBD patients. The authors aim to accomplish this goal in a future study evaluating IPSS scores in patients from rigorously maintained multi-institutional databases that accurately track patient factors and postoperative courses, and it is anticipated that this work will be used to help guide care of these patients in the future.

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