ORIGINAL CONTRIBUTION

Psychometric Evaluation of a New Patient-Completed Questionnaire for Evaluating Anal Incontinence Symptoms and Impact on Quality of Life: The ICIQ-B

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BACKGROUND: A psychometrically robust patient-completed questionnaire for anal incontinence, which reflects issues of importance to both clinicians and patients, was lacking for assessment purposes.

OBJECTIVE: This study aimed to determine the psychometric properties of a new questionnaire developed to address this need, the International Consultation on Incontinence Questionnaire-Bowels module.

DESIGN: Qualitative studies were used to refine the developmental version of the questionnaire. Quantitative studies were conducted to evaluate its psychometric properties.

SETTINGS: Patients were invited to complete the questionnaire via postal administration.

PATIENTS: Two hundred sixty-one patients with known bowel symptoms participated in the study (244 females, 17 males; mean age, 59.7 years (range, 24–92)).

MAIN OUTCOME MEASURES: The aspects of validity were evaluated in comparison with available evidence, responses to existing instruments, and physiological findings. Reliability was assessed through repeat administration of the questionnaire and evaluation of internal consistency by the Cronbach α coefficient. Responsiveness following treatment was evaluated by the use of the Wilcoxon signed rank test. Exploratory factor analysis was used to derive the final version of the questionnaire with evidence from the above studies.

RESULTS: The final questionnaire contains 17 questions arranged in 3 scored domains: bowel pattern, bowel control, and quality of life, with 4 unscored items included to evaluate important issues from a clinical or patient perspective. The questionnaire demonstrated acceptable validity, "good" to "very good" reliability, and reasonable response to changes in symptom and quality-of-life status following intervention.

LIMITATIONS: Response rates varied according to location.

CONCLUSIONS: The International Consultation on Incontinence Questionnaire Bowel module is a psychometrically robust, self-report instrument for the evaluation of anal incontinence and its impact on quality of life. It is suitable for use in individuals with anal incontinence of varying causes. It includes a scoring system for use in clinical practice and research.

KEY WORDS: Fecal incontinence; Quality of life; Questionnaires; Terminology; Outcome assessment.

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Anal incontinence is socially debilitating, isolating, and more prevalent than is commonly assumed,[1–3] yet the accurate evaluation of the symptoms and the impact on the quality of life experienced by affected individuals has been hampered through a lack of robust self-report questionnaires.[4–6] Although several high-quality questionnaires are available within the published literature, their limitations include, to varying degrees, exclusion of flatus incontinence, limited or absent quality-of-life evaluation, and a failure to involve patients at the questionnaire design stage, thus resulting in limited or weak measurement of issues most important to patients. Evaluation of measurement characteristics is also lacking for a number of the available self-report instruments. Evidence of a questionnaire's ability to measure what it claims to measure (validity), in a consistent and stable manner (reliability) with an ability to detect change (sensitivity to change) are fundamental characteristics particularly required for health care evaluation.[7–10]

We aimed to provide a universally applicable, psychometrically robust, comprehensive symptom and quality-of-life self-completion questionnaire for anal incontinence (including flatus incontinence) that reflected both clinicians' and patients' perspectives. Qualitative studies reported elsewhere[11] identified the most important issues for individuals with anal incontinence, and the clinical perspective was determined from multidisciplinary clinical experts to develop items for the new questionnaire. This approach was required to identify items that could potentially be more sensitive indicators of the impact of anal incontinence than those used in currently available instruments.

This article details the studies conducted to evaluate the psychometric properties of this new questionnaire—the International Consultation on Incontinence Questionnaire-Bowels (ICIQ-B). The ICIQ-B was developed as one questionnaire of a series included in the ICIQ project[12] (www.iciq.net).

MATERIALS AND METHODS

Qualitative studies were conducted to refine the developmental questionnaire in terms of clarity, ambiguity, and understanding. Parallel substudies, detailed below, were undertaken by using the refined instrument to gather data for quantitative evaluation. Patients with anal incontinence symptoms who were scheduled to attend an outpatient appointment, or had attended in the preceding month, were identified at St. Mark's Hospital, London; Southmead and Frenchay Hospitals, Bristol; and the Bristol Royal Infirmary, United Kingdom. Six hundred ninety-eight consecutively presenting individuals were invited to participate by completing the ICIQ-B by post between February 2006 and August 2007. Ethics approval was granted from Harrow, Southmead, and Central and South Bristol local research ethics committees.

Validity

Content Validity. To ensure the relevance of the question items included, the ICIQ-B was circulated to a team of multidisciplinary clinical experts and refinements or modifications were invited. Face-to-face, structured cognitive interviewing was also undertaken with a convenience sample of potential responders, namely, individuals with symptoms of anal incontinence of varied origin, to establish whether the developmental instrument was acceptable to potential recipients. Observation of questionnaire completion preceded interviews that focused on the applicability, relevance, and clarity of question items to maximize accurate completion of the questionnaire.[7–9,13–16] Content validity was further explored during postal administration by the evaluation of levels of missing data per item. Overall response rates were analyzed to indicate the feasibility of the questionnaire for self-completion.[8,9]

Construct Validity. Construct validity was investigated in all completed questionnaires. The ICIQ-B findings were expected to reflect published evidence, for example, that flatus incontinence is more prevalent than either liquid or stool incontinence.[17–19] The proportion of individuals reporting symptoms were compared and confidence intervals reported to evaluate the differences between symptom categories.[20,21]

Convergent Validity. The St. Mark score,[22] which evaluates a number of concepts similar to the ICIQ-B, was used to examine relationships between patients' reports using the Spearman rank correlation coefficient.[23]

Criterion Validity. Patients who had undergone anorectal physiology testing within the previous month of completion of the ICIQ-B formed the subgroup to evaluate criterion validity. Hypotheses were generated a priori regarding expected correlations between physiology test results and responses within the questionnaire and were evaluated by the use of the Spearman rank correlation coefficient.[23]

Reliability

Stability. A subsample of respondents was identified who were scheduled to commence treatment for their symptoms after a minimum 3-week interval from completion of the baseline ICIQ-B. These participants were invited to complete a further identical retest questionnaire, before starting any treatment, to compare responses and evaluate the stability of item responses when symptoms were expected to remain stable. Differences between test and retest responses were appraised by the use of the weighted κ statistic.[24,25]

TABLE 1. Samples and demographic characteristics of studies used in the psychometric testing of the ICIQ-B: total baseline sample

Substudy group	*Invited*	*Participated*
Content validity	Total, 698; females, 634; males, 64	Total, 261; females, 244; males, 17
Construct validity	Mean age, 56.7 y; range, 17.4–92.4	Mean age, 59.7 y; range, 24.2–92.1
Convergent validity		Response rate = 37.4%
Internal consistency		
Criterion validity	Total, 382; females, 367; males, 15	Total, 164; females, 162; males, 2
		Mean age, 60.8 y; range, 24.2–92.1
		Response rate = 42.9%
Stability	Total, 104; females, 96; males, 8	Total, 79; females, 72; males, 7
		Mean age, 58.3 y; range, 25.0–88.6
		Response rate, 76.0%
Sensitivity to change	Total, 79; females, 72; males, 7	Total, 51; females, 46; males, 5
		Mean age, 60.9 y; range, 28.1–88.6
		Response rate, 64.6%

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.

Internal Consistency. All data from the baseline questionnaire were used to evaluate internal consistency—the degree to which the questionnaire examined similar issues from different perspectives. This was analyzed using the Cronbach α coefficient (α) where a value between 0.7 and 0.9 indicated acceptable homogeneity between items with limited redundancy.[26,27]

Sensitivity to Change

Responsiveness of the ICIQ-B to detect changes in symptom or quality-of-life status was evaluated by the completion of a third questionnaire by a subsample of respondents following planned treatment. Patients underwent biofeedback therapy (conservative) or insertion of a sacral nerve stimulator (surgical) and completed the third ICIQ-B at the end of treatment or 2 weeks after insertion. The Wilcoxon signed rank test of ordinal paired data[23] was used to compare the difference between baseline and outcome data.

Item Reduction and Development of a Scoring System

The draft questionnaire contained 56 question items and required reduction to promote clinical usefulness and to reduce respondent burden. Data gathered in the above studies provided evidence as to how each question item performed, guiding decisions on the removal of question items. A correlation matrix was calculated to identify overlapping items (>0.7 indicated high correlations between item pairs). An important step at this stage was to consult once more with the clinical experts to ensure the clinometric relevance of the questionnaire in addition to its psychometric robustness.[28] Multidisciplinary meetings were arranged and consensus clinical opinion, together with the evidence from the quantitative studies and the original patient interview data, were considered to identify the items for inclusion in the final ICIQ-B. An exploratory factor analysis was undertaken, which underwent varimax rotation, to explore the underlying structure of the questionnaire, identify possible domains, assist item reduction, and facilitate the development of a clinical scoring system. Exploratory factor analysis was used in preference to principal components analysis because of the desire to understand the underlying relationship between question items and to identify common factors by comparison with a simple reduction in the number of question items.[29] Factor loadings of less than 0.4 were considered to indicate poor loading onto a factor.[30] A preliminary analysis of the psychometric properties of the scoring system was then performed to evaluate its applicability to the existing data.

RESULTS

The substudy types, sample sizes, and response rates are presented in Table 1.

Validity

Content Validity. A group of multidisciplinary clinical experts (n = 16) and patients in a clinical setting with varying levels of anal incontinence (n = 19: 15 females, 4 males; median age, 59 years (range, 28–77)) refined the questionnaire until it was considered easily understood and all inclusive regarding the symptoms and impact of anal incontinence. The overall return rate of the postal questionnaire was 37.4% (61.5% in the Bristol hospitals and 33.6% in St. Mark's Hospital, London). Levels of missing data were examined in the baseline dataset (total baseline sample: n = 261, 244 females, 17 males; mean age, 59.7 years (range, 24–92)). Missing data ranged from 1% to 29% per item. Items that were anticipated to be problematic accounted for the highest levels of missing data (16%–29%), for example, "incontinence associated with constipation." The remaining question items reported missing data at the acceptable level of 5% or less, with the final version of the questionnaire demonstrating mean missing data of 3.7%.

TABLE 2. Psychometric properties of final questions included in the ICIQ-B: validity and reliability

Domain	*Question items*	*Missing data, %*	*Reliability (κ value)*	*Cronbach α (α)*
Bowel pattern	Bowel opening frequency per 24 h	5	Moderate (0.60)	0.61
	Bowel opening frequency at night	4	Moderate (0.54)	
	Urgency	3	Good (0.71)	
	Antidiarrheal medication use	6	Very good (0.84)	
	Anal pain/soreness	2	Good (0.62)	
Bowel control	Staining underwear	1	Good (0.72)	0.83
	Frequency of liquid stool leakage control	3	Moderate (0.55)	
	Frequency of solid stool leakage control	4	Moderate (0.56)	
	Frequency of flatus leakage control	2	Good (0.69)	
	Frequency of mucus leakage control	6	Good (0.67)	
	Unexplained incontinence	6	Good (0.61)	
	Unpredictability	4	Good (0.63)	
Quality of life	Embarrassment	3	Good (0.73)	0.82
	Awareness of toilet location	2	Very good (0.80)	
	Plan according to bowels	2	Good (0.65)	
	Stay home more often	2	Good (0.72)	
	Overall interference	3	Moderate (0.60)	
Unscored items	Incontinence on individual's mind	5	Good (0.64)	N/A
	Straining required to open bowels	4	Very good (0.84)	N/A
	Sexual activity restriction	6	Good (0.70)	N/A

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels; N/A = not applicable.

Construct Validity. A higher prevalence of flatus than fecal incontinence was reported by study participants (n = 230, 92.0% prevalence, 95% CI 88.6–95.4), and minimal overlap was demonstrated between the confidence intervals for each type of incontinence, in particular, between solid stool incontinence (n = 157, 63.3% prevalence, 95% CI 57.3–69.3) liquid/soft stool (n = 208, 84.2% prevalence, 95% CI 79.6–88.8), and flatus. This suggests that the ICIQ-B was able to clearly distinguish between the prevalence of the 3 types of anal incontinence and reflected theories published in the literature. Further evaluation of the types of incontinence reported by males and females found little evidence of any differences between sexes, although the smaller number of male participants is noted. These findings support the general lack of consensus in the evidence regarding the differences in symptoms between sexes.

Convergent Validity. The correlation between responses to the ICIQ-B and the St. Mark score with regard to frequency of liquid stool and flatus incontinence were "moderate" (0.63 and 0.67) and "strong" (0.75) for solid stool incontinence. Items that evaluated overall impact on lifestyle were also moderately correlated (0.61). Questions that assessed concepts thought to be more weakly associated, such as sanitary protection and staining of undergarments demonstrated "weak" correlations (0.23–0.51). *P* values were significant at the.001 level for all correlation coefficients.

Criterion Validity. Associations between anorectal physiology test findings and patients' reports of symptoms in the ICIQ-B were undertaken within a subsample of patients for whom results were available (n = 164, 162 females, 2 males; mean age, 60.8 years (range, 24–92)). Associations between parameters such as reduced anal sphincter pressure and increased undergarment staining reported in the ICIQ-B were analyzed and found to be "weak" (Spearman r_s, 0.03–0.14).

Reliability

Stability. Seventy-nine patients (mean age, 58.3 years; range, 25–89) completed the ICIQ-B twice, once at baseline and again after a 3-week time interval. Agreement, analyzed by the weighted κ statistic, was "good" to "very good" for 45 items overall. In the final version of the ICIQ-B, all items exhibited "good" to "very good" agreement apart from 3 question items (Table 2), which were retained, however, because of their perceived importance (clinicians' or patients' views).

Internal Consistency. The Cronbach α coefficient was very high at 0.94 for the total set of question items. Cronbach α values were also high for the developmental items assessing symptoms (0.90) and quality of life (0.92) separately. These results indicated not only excellent internal consistency, but also redundancy within both item pools, supporting the need for item reduction.

Sensitivity to Change

Fifty-one respondents (46 females, 5 males; mean age; 60.9 years; range, 28–89) who underwent conservative or surgical intervention for their symptoms completed the ICIQ-B a third time. Patients' reports of at least "some"

TABLE 3. Psychometric properties of final questions included in the ICIQ-B: sensitivity to change

Scale	Pretreatment mean score	Posttreatment mean score	P
Bowel pattern	9.2	8.3	.004
Bowel control	23.8	19.8	.002
Quality of life	17.5	14.9	.0006

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.

level of a symptom or impact on quality of life were compared pre- and postintervention to evaluate the questionnaire's ability to detect change following treatment. Nineteen question items were found to detect improvement following treatment, at the .05 significance level: 15 symptom items and 4 quality-of-life items. In the final version of the questionnaire 8 symptom items were retained that were responsiveness to change and 3 were quality-of-life items (Table 3).

Item Reduction and Development of a Scoring System

In the first phase of item reduction, 21 items were removed that offered little value to the final questionnaire on the basis of high intercorrelation coefficients, high levels of missing data, no evidence of sensitivity to change, and floor effects where issues were "never" reported by symptomatic patients. Clinical experts also identified items for removal such as "abdominal pain with or without incontinence" because of the lack of specificity for incontinence, corroborated by qualitative patient interview data. The importance of issues to patients was also revisited using the original interview data. Items such as "unpredictability of incontinence" and "sexual activity restriction" were retained because of the necessity to provide measurement indicators of relevance to individuals with symptoms (Fig. 1).

An initial unrestricted exploratory factor analysis was conducted on the remaining 25 symptom items and 10 quality-of-life items.

Symptom Question Items. Five initial factors were identified with eigenvalues greater than one that explained 82.6% of the variance in the question items. Exploration of the 5 factors found factor loadings that ranged from 0.40 to 0.76 across 3 factors with little variability explained by the further 2 factors. Models containing 2 and 3 factors were therefore examined to identify clusters of items and indicate redundant items. In each case, a varimax rotation was applied to clarify interpretation. Thirteen items loaded heavily onto one factor (factor loadings, 0.42–0.76) and 6 items loaded onto the second factor (factor loadings, 0.43–0.60). Six items did not load well onto any factor in these models (loadings, <0.38 for all): bowel opening frequency by night, amount of liquid and solid stool leakage, unpredictability, incontinence on the individuals' mind, and anal pain/soreness (Table 4). The Cronbach α value for these 25 items was 0.86. This result was within the acceptable range of 0.7 to 0.9, but indicated that there may still be some redundancy among the items included. The evidence from the original validation and reliability studies was therefore reexamined more critically. This stage essentially required judgment decisions to make the final questionnaire as brief as possible without compromising the assessment provided, and to retain the items that demonstrated the strongest psychometric properties.

Quality-of-Life Items. Analysis of the 10 remaining items that evaluated quality of life identified only 1 factor with an eigenvalue greater than one (5.24). The next factor identified was found to have an eigenvalue of 0.72 and therefore was not considered further. In addition, the factor identified accounted for 92.6% of the variance in the question items. Factor loadings ranged from 0.44 to 0.85, and all items loaded onto the factor (Table 5). However, the Cronbach α value for this group of items was high (0.89) and indicated redundancy among this item pool.

Final Factor Analysis. Fourteen further question items were removed following reexamination of the available data (10 symptom items and 4 quality-of-life items). Considerations for the removal of items included levels of missing data, evidence of reliability and sensitivity to change, and perceived importance according to symptomatic patients and clinical experts. Further factor analyses were then undertaken with the remaining 15 symptom and 6 quality-of-life question items. Two factors with eigenvalues greater than one (4.07 and 1.26) were yielded among the symptom items which explained 89.4% of the variance in the question items (Table 6). All items loaded onto these factors (factor loadings, 0.44–0.87), with the exception of the items regarding straining and incontinence being on the individual's mind (factor loadings, 0.07 and 0.33). The decision was made, therefore, to include these questions as stand-alone items because of their clinical utility and importance to symptomatic patients. The Bristol Stool Form scale was also included as a further stand-alone item. This item pool achieved a sufficient Cronbach α coefficient value (0.80) to indicate measurement of related concepts with minimal redundancy.

The final factor analysis undertaken for quality-of-life items yielded 1 factor with an eigenvalue greater than one (3.01) that explained all of the variance in the question items (Table 7). All items, with the exception of 46a, which evaluated sexual activity restriction (factor loading, 0.34), loaded onto the factor (factor loadings, 0.45–0.78). This item was retained as a stand-alone item because of its necessity for assessment. The Cronbach α coefficient (0.82) suggested that further items could be removed, but this would result in the loss of important quality-of-life issues.

The resulting 3 domains were termed "bowel pattern,"

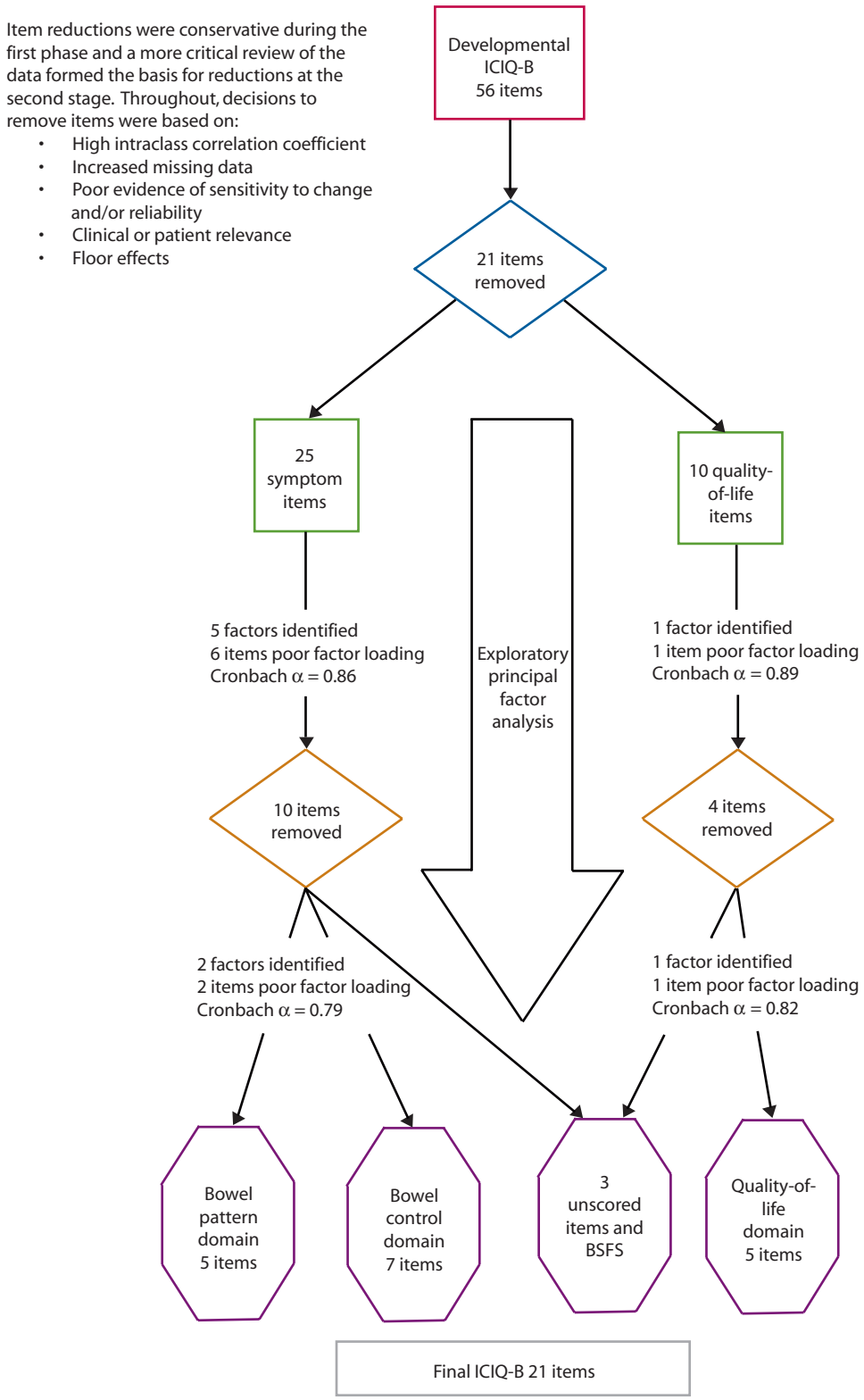


FIGURE 1. Item reduction process for the ICIQ-B. ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels; BSFS = Bristol Stool Form Scale.

"bowel control," and "quality of life" because of the items contained, and 3 simple additive scores were indicated according to the relatively equal contribution of each item to the domain (Tables 6 and 7). Scores were calculated from

TABLE 4. Exploratory factor analysis including factor loadings and eigenvalues for the ICIQ-B symptom items following varimax rotation

	Factor loading	
Question item	*F1*	*F2*
Usual bowel opening frequency (24 h)		0.45
At worst bowel opening frequency (24 h)		0.51
Incontinence warning		0.56
Urgency		0.60
Straining to open bowels		0.43
Antidiarrheal use		0.56
Underwear staining	0.55	
Usual frequency of liquid stool incontinence	0.76	
At worst frequency of liquid stool incontinence	0.70	
Usual frequency of solid stool incontinence	0.67	
At worst frequency of solid stool incontinence	0.65	
Control flatus leakage	0.61	
Usual frequency of mucus incontinence	0.63	
At worst frequency of mucus incontinence	0.63	
Unexplained incontinence	0.63	
Incontinence with exertion	0.43	
Ability to discriminate between flatus and stool	0.42	
Incomplete evacuation of bowels	0.49	
Ability to wipe clean after bowel opening	0.50	
Bowel opening frequency (night)		0.38
Amount of liquid stool incontinence	0.30	
Amount of solid stool incontinence	0.38	
Unpredictability	0.28	
Incontinence on the individual's mind	0.32	
Anal pain/soreness	0.24	
Eigenvalue	5.76	2.15
Proportion of variance	0.41	0.15
Cronbach α coefficient	0.86	

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.

TABLE 5. Exploratory factor analysis including factor loadings and eigenvalues for the ICIQ-B quality-of-life items following varimax rotation

Question item	*Factor loadings*
Worry regarding smell	0.52
Restriction of physical activities	0.84
Restriction of social activities	0.84
Restriction of sexual activities	0.44
Embarrassment	0.65
Toilet location awareness	0.70
Plan according to bowels	0.81
Diet restriction	0.68
Stay home more	0.85
Overall bowel interference	0.77
Eigenvalue	5.24
Proportion of variance	0.93
Cronbach α coefficient	0.89

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.

the existing dataset to conduct the preliminary exploration of its psychometric properties (Table 8), although a new dataset will be required to formally evaluate the scoring system. Values of the observed scores largely represented the range of possible scores within the domains supporting the ability of the ICIQ-B (Fig. 2) to detect varying levels of symptoms and impact. The reliability of the final ICIQ-B was found to be "good" across all domains, and all 3 domains were responsive to change ($P < .05$).

DISCUSSION

The ICIQ-B provides a comprehensive, psychometrically robust, self-report questionnaire for use in individuals with anal incontinence of varying causes. The need for the ICIQ-B was supported by the lack of an instrument for anal incontinence that included flatus in addition to liquid and solid stool incontinence, recognized the importance of clinical relevance, and also reflected the lived experience of those with symptoms, and also exhibited evidence of validity, reliability, and sensitivity to change. Two of the most commonly used assessment tools in this field are acknowledged, the Cleveland Clinic Continence Grading Scale[31] and the Fecal Incontinence Quality of Life Scale.[32] Although the Cleveland Clinic Continence Grading Scale includes flatus, it is intended for clinician completion and fails to capture issues of particular relevance to patients, such as urgency and detailed quality-of-life issues. The Fecal Incontinence Quality of Life Scale provides detailed impact evaluation, but the initial question items for fecal incontinence, excluding flatus, were derived through input

TABLE 6. Factor analysis results for the final 2 symptom domains of the ICIQ-B following varimax rotation

	Factor loadings	
Question item	*Bowel pattern*	*Bowel control*
Bowel opening frequency (night)	0.51[a]	0.15
Usual bowel opening frequency (24 h)	0.44[a]	0.16
Urgency	0.57[a]	0.10
Antidiarrheal use	0.49[a]	0.23
Anal pain/soreness	0.54[a]	0.01
Underwear staining	0.14	0.51[a]
Control liquid stool leakage	0.04	0.80[a]
Control solid stool leakage	0.16	0.80[a]
Control flatus leakage	0.30	0.65[a]
Control mucus leakage	0.05	0.87[a]
Unexplained incontinence	0.02	0.69[a]
Unpredictability	0.04	0.57[a]
Eigenvalue	1.26	4.07
Proportion of variance	0.21	0.68
Cronbach α coefficient	0.80	

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.
[a]Indicates loading onto a factor.

TABLE 7. Factor analysis results for the final quality-of-life domain of the ICIQ-B following varimax rotation

	Factor loadings	
Question item	*Quality of life*	*Quality of life (2)*
Embarrassment	0.45[a]	0.23
Toilet location awareness	0.62[a]	0.02
Plan according to bowels	0.78[a]	0.20
Stay home more	0.77[a]	0.13
Overall bowel interference	0.61[a]	0.12
Eigenvalue	3.01	
Proportion of variance	1.05	
Cronbach α coefficient	0.82	

As indicated by the poor factor loadings, a second quality of life factor was not indicated.
ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.
[a]Indicates loading onto a factor.

from clinical expert and health service researchers rather than from patients. The justification for creating the ICIQ-B was the need for an "anal incontinence" tool that reflected both patients' and clinicians' perspectives.

The ICIQ-B includes assessment of flatus incontinence, which is often overlooked or purposely not included in questionnaires of this nature, despite its importance to patients.[33] The inclusion of flatus incontinence was found necessary from the results of qualitative studies undertaken during the development of the ICIQ-B and also indicated in a study undertaken by Cockell to modify the Fecal Incontinence Quality of Life scale for a population of postpartum women.[34] Items regarding the "unpredictability of incontinence" and the "embarrassment" associated with incontinence were also included as a direct result of patient input. The increased relevance of this new questionnaire to the population of interest is highlighted through comments made by patients during interviews:

> *These* [questions] *were like having a conversation with somebody, they really understood the problem.*

Detailed psychometric evaluation of the ICIQ-B was necessary to provide evidence of its capabilities for users to judge the confidence they can place in the measurements made.[9] This is of critical importance in health care considering the implications of use. The ICIQ-B exhibits high levels of validity, reliability, and sensitivity to change, indicating its applicability in clinical practice and research. The low levels of missing data indicate the relevance and acceptability of the final ICIQ-B.

The overall response rate of the ICIQ-B in the postal administration was lower than expected, but several factors need to be considered. Given the length of the developmental questionnaire and the sensitive nature of the subject, it was anticipated that optimum return rates would not be achieved. This was evident in previous validation studies with response rates as low as 16% when relying on postal administration.[32] Higher response rates in questionnaire design studies have been achieved (61%–93%) when using a direct approach with patients in the clinic and follow-up of known patient groups.[32,35–37] Higher response rates were exhibited in the retest and sensitivity-to-change subgroups in this study (76.0% and 64.6%). Similarly, in previous studies, an existing relationship with respondents appeared to encourage increased participation. Comparisons between study sites also highlighted higher response rates in Bristol in comparison with London (61.5% vs 33.6%). It is well known that response rates tend to be lower in London because of the highly mobile population. In terms of population characteristics, the respondents who participated in the study were similar to the nonresponders, and the substudy groups were also similar, suggesting that the data were representative of the adult population with anal incontinence approached to participate.

The ICIQ-B findings were consistent with well-evidenced theories and exhibited agreement with patient reports of similar concepts measured using the St. Mark score, providing evidence of construct and convergent validity. It was not possible to establish criterion validity with certainty because of the need to rely on comparisons with physiological tests. Conflict between physiological findings and patients' self-reports are well documented. The main problem with the hypothesized associations is that they assume a causal effect between one physiological finding and one symptomatic outcome, and although some of these relationships appear sensible, it must be appreciated that the relationship is not necessarily linear.[6,38–40] Anal continence requires coordination of varied aspects of the nervous and gastrointestinal system, influenced by health status, and practical and psychological factors. Presence or absence of symptoms and associations with functional or anatomical impairments are therefore less clear-cut.[41]

TABLE 8. Descriptive statistics and psychometric properties of the 3 domain scores within the ICIQ-B using the developmental dataset

Domain	*Score range*	*Observed score range*	*Mean score (SD)*	*Median score*	*Reliability κ (crude agreement %)*	*Sensitivity to change (P value)*
Bowel pattern	1–21	1–19	8.2 (3.5)	8	Good (92.7)	.0339
Bowel control	0–28	2–28	19.7 (6.6)	22	Good (91.2)	.0025
Quality of life	0–26	0–26	16.8 (6.6)	17	Good (92.8)	.0001

ICIQ-B = International Consultation on Incontinence Questionnaire-Bowels.

Initial number

ICIQ-B (04/08)

CONFIDENTIAL

DAY MONTH YEAR
Today's date

Many people experience bowel accidents or bowel leakages. We are trying to find out how many people experience these symptoms and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been over the PAST THREE MONTHS.

1 Please write in your date of birth: DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

Bowel pattern

3 On average how many times do you open your bowels in 24 hours?
(Tick one box for 'usual' and tick one box for 'at worst')

	(a) Usual	(b) At worst
less than once	☐ 1	☐ 1
one to three times	☐ 2	☐ 2
three to ten times	☐ 3	☐ 3
ten or more times	☐ 4	☐ 4

(c) How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
not at all — a great deal

4 How often do you open your bowels during the night from going to bed to sleep until you get up in the morning? *(Tick one box)*

	(a)
never	☐ 0
once	☐ 1
twice	☐ 2
three times	☐ 3
four or more times	☐ 4

(b) How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
not at all — a great deal

ICIQ-B (04/08)

5 Do you have to rush to the toilet when you need to open your bowels?
(Tick one box)

	(a)
never	☐ 0
rarely	☐ 1
some of the time	☐ 2
most of the time	☐ 3
always	☐ 4

(b) How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
not at all — a great deal

FIGURE 2. The final ICIQ-B questionnaire.

6 **Do you use medications (tablets or liquids) to <u>stop</u> you opening your bowels?** *(Tick one box)*

(a)

never ☐ 0
less than once a month ☐ 1
less than once a week ☐ 2
less than once a day ☐ 3
about once a day ☐ 4
several times a day ☐ 5

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

7 **Do you experience pain/soreness around your back passage?** *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

Bowel pattern score: sum scores 3a - 7a ☐☐

ICIQ-B (04/08)

Bowel control

8 **Do you experience any staining of your underwear or need to wear pads because of your bowels?** *(Tick one box)*

(a)

never ☐ 0
less than once a month ☐ 1
less than once a week ☐ 2
less than once a day ☐ 3
everyday ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

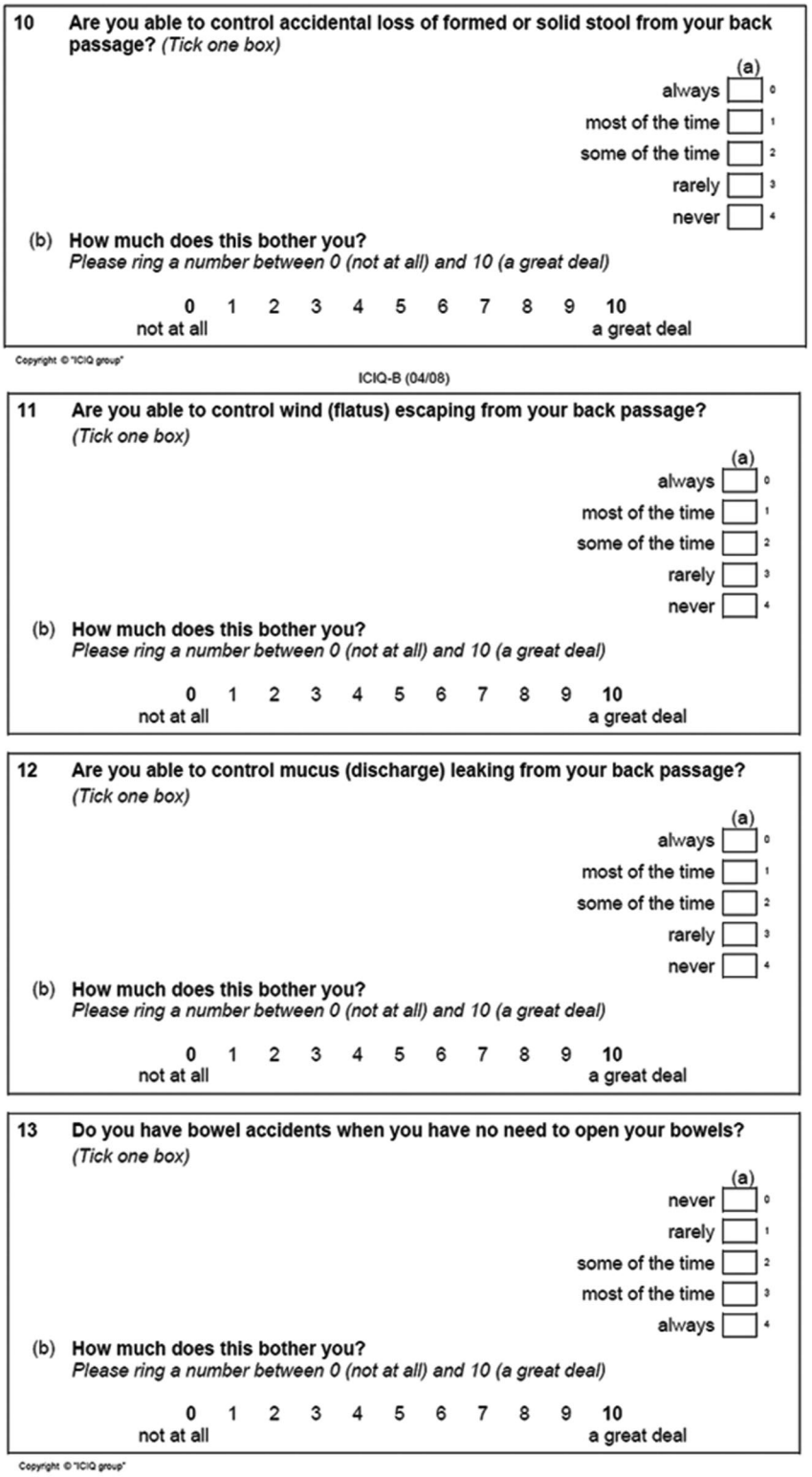
9 **Are you able to control watery or loose stool leaking from your back passage?** *(Tick one box)*

(a)

always ☐ 0
most of the time ☐ 1
some of the time ☐ 2
rarely ☐ 3
never ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal



10 **Are you able to control accidental loss of formed or solid stool from your back passage?** *(Tick one box)*

(a)

always ☐ 0
most of the time ☐ 1
some of the time ☐ 2
rarely ☐ 3
never ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ-B (04/08)

11 **Are you able to control wind (flatus) escaping from your back passage?** *(Tick one box)*

(a)

always ☐ 0
most of the time ☐ 1
some of the time ☐ 2
rarely ☐ 3
never ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

12 **Are you able to control mucus (discharge) leaking from your back passage?** *(Tick one box)*

(a)

always ☐ 0
most of the time ☐ 1
some of the time ☐ 2
rarely ☐ 3
never ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

13 **Do you have bowel accidents when you have no need to open your bowels?** *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ-B (04/08)

14 Are your bowel accidents or leakages unpredictable? *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

Bowel control score: sum scores 8a – 14a ☐☐

Other bowel symptoms

15 Using the pictures please indicate how your bowel movements are most of the time? *(Tick all boxes that apply)*

(a)

separate hard lumps like nuts (hard to pass)  ☐ 1
sausage-shaped but lumpy  ☐ 2
like a sausage but with cracks on its surface  ☐ 3
like a sausage or snake – smooth and soft ☐ 4
soft blobs with clear cut edges (easy to pass)  ☐ 5
fluffy pieces with ragged edges, a mushy stool  ☐ 6
watery, no solid pieces  ☐ 7

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

Bristol Stool Form Scale O'Donnell, L.J.D. et al (1990)

ICIQ-B (04/08)

16 Do you need to strain to open your bowels? *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

17 Is the possibility of having a bowel accident on your mind? *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

Sexual impact

18 **Do you restrict your sexual activities because of your bowels?** *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4
not applicable ☐ 5

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ-B (04/08)

Quality of life

19 **Do your bowels cause you to feel embarrassed?** *(Tick one box)*

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

20 **Do your bowels cause you to make sure you know where toilets are?**
(Tick one box)

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

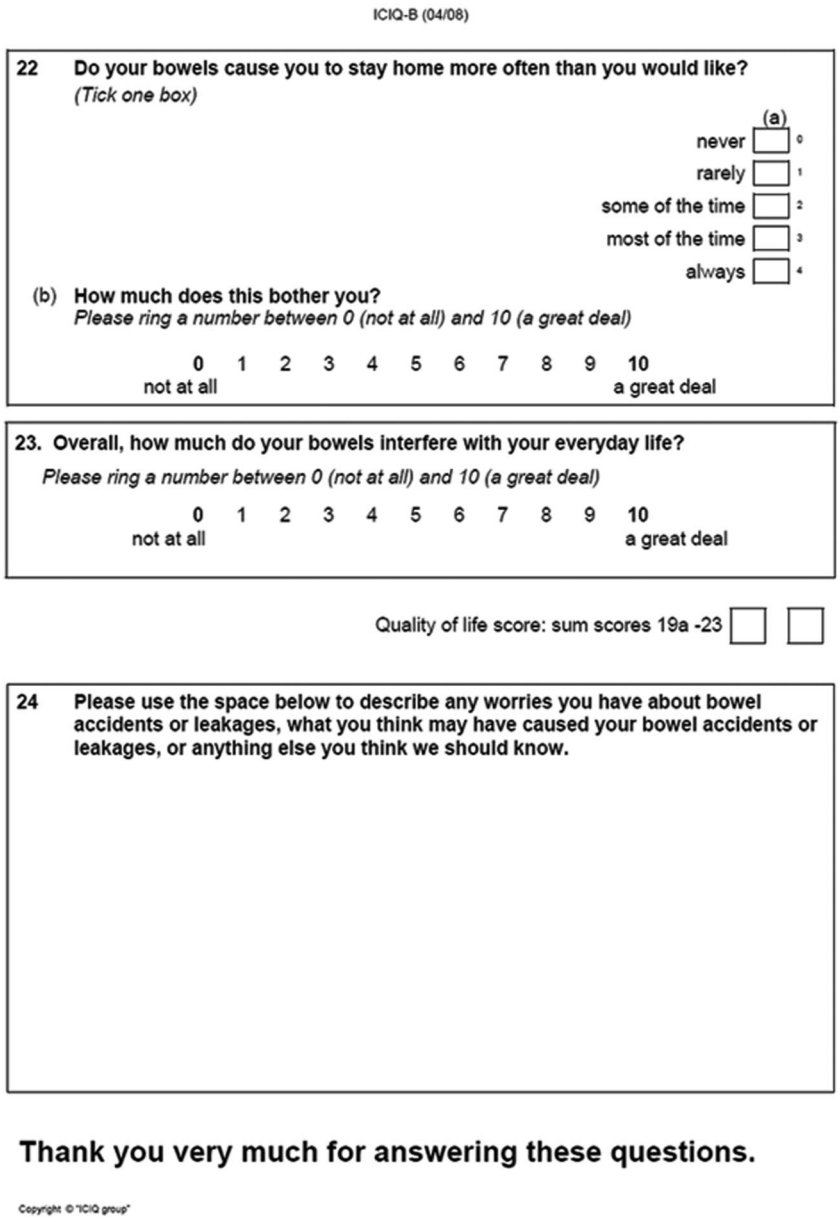
21 **Do your bowels cause you to make plans according to your bowels?**
(Tick one box)

(a)

never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal



ICIQ-B (04/08)

22 **Do your bowels cause you to stay home more often than you would like?**
(Tick one box)

(a)
never ☐ 0
rarely ☐ 1
some of the time ☐ 2
most of the time ☐ 3
always ☐ 4

(b) **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
not at all — a great deal

23. **Overall, how much do your bowels interfere with your everyday life?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
not at all — a great deal

Quality of life score: sum scores 19a -23 ☐ ☐

24 **Please use the space below to describe any worries you have about bowel accidents or leakages, what you think may have caused your bowel accidents or leakages, or anything else you think we should know.**

Thank you very much for answering these questions.

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Reliability of the ICIQ-B both for individual items and the derived scoring system was demonstrated, reinforcing its applicability in ongoing monitoring for patients. Sensitivity to change was also established, making the ICIQ-B well suited to outcome evaluation for both clinical treatment and research into new or existing interventions.

The use of mixed methodology in the development of the ICIQ-B was effective in producing a data-rich evidence base during the qualitative studies from which to generate question items, reinforced by rigorous quantitative studies. This ensured that the ICIQ-B was sufficiently psychometrically robust to place confidence in the results obtained, which is crucial for its intended use in health care settings. Further evaluation studies will also need to be undertaken to provide evidence of the ICIQ-B's applicability in a range of clinical and research settings. The ICIQ-B provides a robust tool to standardize the assessment of anal incontinence and reflect the patient's perspective of the severity of their symptoms and impact on quality of life. Thus, the ICIQ-B will provide improved assessment capability in this important and relatively neglected area of clinical practice. Its use in clinical practice and research is encouraged and can be accessed through the ICIQ website (www.iciq.net).

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