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Article title

Psychometric evaluation of a new patient-completed questionnaire for evaluating anal incontinence symptoms and impact on quality of life: the ICIQ-B.

Running Head

Patient assessment for anal incontinence

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The authors do not have any associations that might pose a conflict of interest in connection with the submitted article.

Educational funding was provided to the lead author by North Bristol NHS Trust, Bristol, UK.

Oral poster presentation at the annual meeting of the International Continence Society, Cairo, Egypt, October 22nd to 24th, 2008.

Manuscript word count: 3611

Abstract word count: 299

All authors had direct involvement in the study, were involved in drafting and revising the manuscript and approved the final version for submission.

STRUCTURED ABSTRACT

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 Bowel 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 and 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

- 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 Cronbach's alpha coefficient;
- Responsiveness following treatment was evaluated using Wilcoxon signed ranks 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 three scored domains: bowel pattern, bowel control and quality of life, with four 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.

Keywords (all terms from Medical Subject Heading list)

Fecal incontinence; quality of life; questionnaires; terminology; outcome assessment.

TEXT

Introduction

Anal incontinence is socially debilitating, isolating and more prevalent than is commonly assumed,[1-3]. Yet accurate evaluation of the symptoms and impact on 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 healthcare 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 in order to identify items that could potentially be more sensitive indicators of the impact of anal incontinence than those used in currently available instruments.

This paper 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 sub-studies, detailed below, were undertaken using the refined instrument to gather data for quantitative evaluation. Patients with anal incontinence symptoms who were due 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, UK. Six hundred and 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***

In order 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 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, in order to establish whether the developmental instrument was acceptable to potential recipients. Observation of questionnaire completion preceded interviews that focussed on the applicability, relevance and clarity of question items in order to maximise 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 analysed 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's score,[22], which evaluates a number of similar concepts to the ICIQ-B, was used to examine relationships between patients' reports using the Spearman's 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 evaluated using the Spearman's rank correlation coefficient,[23].

Reliability

- ***Stability***

A sub-sample of respondents was identified who were scheduled to commence treatment for their symptoms following a minimum three week interval from completion of the baseline ICIQ-B. These participants were invited to complete a further identical retest questionnaire, prior to 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 using the weighted Kappa statistic,[24,25].

- ***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 analysed using Cronbach's coefficient alpha (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 completion of a third questionnaire by a sub-sample 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 two weeks following

insertion respectively. The Wilcoxon signed ranks 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 reduce respondent burden. Data gathered in the above studies provided evidence as to how each question item performed, guiding decisions on 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 clinimetric 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 in order to identify the items for inclusion in the final ICIQ-B. An exploratory factor analysis was undertaken, which underwent varimax rotation, in order 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 due to the desire to understand the underlying relationship between question items and identify common factors, by comparison with 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 sub-study 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%.

- ***Construct validity***

A higher prevalence of flatus than faecal incontinence was reported by study participants (n=230, 92.0% prevalence, 95% confidence interval (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), and liquid/soft stool (n=208, 84.2% prevalence, 95% CI 79.6-88.8), and flatus. This suggests the ICIQ-B was able to clearly distinguish between the prevalence of the three 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 genders, although the smaller number of male participants is noted. These findings support the general lack of consensus in the evidence regarding differences in symptoms between genders.

- ***Convergent validity***

The correlation between responses to the ICIQ-B and the St. Mark's score with regard to frequency of liquid stool and flatus incontinence were 'moderate' (0.63 and 0.67 respectively) 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 underwear demonstrated 'weak' correlations (0.23-0.51). P-values were significant at the 0.001 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 sub-sample 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 underwear staining reported in the ICIQ-B were analysed and found to be 'weak' (Spearman's 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 following a three week time interval. Agreement, analysed by the weighted Kappa 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 however retained due to their perceived importance (clinicians' or patients' views).

- ***Internal consistency***

Cronbach's alpha coefficient was very high at 0.94 for the total set of question items. Cronbach's alpha values were also high for the developmental items assessing symptoms (0.90) and quality of life (0.92) separately. These results indicated 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' level of a symptom or impact on quality of life were compared pre and post intervention to evaluate the questionnaire's ability to detect change following treatment. Nineteen question items were found to detect improvement following treatment, at the 0.05 significance level - 15 symptom items and 4 quality of life items. In the final version of the questionnaire eight symptom items were retained that were responsiveness to change, and three 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' due to 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 due to the necessity of providing measurement indicators of relevance to individuals with symptoms (Figure 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 five factors found factor loadings that ranged from 0.40 to 0.76 across three factors with little variability explained by the further two factors. Models containing two and three 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 six 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's alpha value for these 25 items was 0.86. This result was within the acceptable range of 0.7 to 0.9 but indicated there may still be some redundancy among the items included. The evidence from the original validation and reliability studies was therefore re-examined more critically. Essentially this stage required judgement decisions in order to make the final questionnaire as brief as possible without compromising the assessment provided, and which demonstrated the strongest psychometric properties.

Quality of life items

Analysis of the ten remaining items that evaluated quality of life identified only one 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's alpha 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 re-examination of the available data (ten symptom items and four 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 fifteen symptom and six 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 individuals mind (factor loadings 0.07 and 0.33). The decision was therefore made to include these questions as stand-alone items due to their clinical utility and importance to symptomatic patients. The Bristol Stool Form scale was also included as a further standalone item.

This item pool achieved a sufficient Cronbach's alpha coefficient value (0.80) to indicate measurement of related concepts with minimal redundancy.

The final factor analysis undertaken for quality of life items yielded one factor with an eigenvalue greater than one (3.01) which explained all of the variance in the question items (Table 7). All items except 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 due to its necessity for assessment. The Cronbach's alpha 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 three domains were termed "bowel pattern", "bowel control" and "quality of life" due to the items contained and three 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 the existing dataset to carry out 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 to detect varying levels of symptoms and impact. Reliability of the final ICIQ-B was found to be 'good' across all domains and all three domains were responsive to change ($P<0.05$).

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, recognised the importance of clinical relevance and also reflected the lived experience of those with symptoms, while also exhibiting 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 (CCS),[31] and the Fecal Incontinence Quality of Life Scale (FIQL),[32]. While the CCS 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 FIQL provides detailed impact evaluation but initial question items for fecal incontinence, excluding flatus, were derived through input from clinical expert and health service researchers rather than 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 females,[34]. Items regarding '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 in order for users to judge the confidence they can

place in the measurements made,[9]. This is of critical importance in healthcare 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. 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 reliant on postal administration,[32]. Higher response rates in questionnaire design studies have been achieved (61%-93%) when using direct approach of patients in 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% respectively), 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 to 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 non-responders, and the sub-study groups were also similar, suggesting 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's 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 physiologic tests. Conflict between physiologic findings and patients' self-reports are well documented. The main problem with the hypothesised associations is that they assume a causal effect between one physiological finding and one symptomatic outcome and while 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].

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 the ICIQ-B was sufficiently psychometrically robust to place confidence in the results obtained which is crucial for its intended use in healthcare 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 standardise 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.

Acknowledgments

The authors thank the patients and clinical experts who participated in this study, and North Bristol NHS Trust, UK, who contributed educational funding for the lead author. Jenny Donovan is an NIHR Senior Investigator.

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