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Chadwick M A[1], Avery K[1], Abrams P[1]
1. Bristol Urological Institute

DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF THE ICIQ BOWEL SYMPTOMS MODULE: THE ICIQ-BS

Hypothesis / aims of study

The modular International Consultation on Incontinence Questionnaire (ICIQ) is currently being developed to produce a comprehensive and universally-applicable questionnaire for the assessment of a variety of pelvic symptoms, including those of the lower urinary tract, lower bowel and vagina, in clinical practice and research. Under the aegis of the ICI, a new module to assess bowel symptoms, the ICIQ-BS, has been developed and evaluated.

Bowel symptoms are extremely common and are wide-ranging in their frequency and severity. While many symptoms can be attributed to intestinal diseases, the vast majority are described as functional, without any underlying pathology. Whilst transient symptoms may be less problematic, chronic recurrent symptoms can have a significant effect on quality of life (QoL). Regardless of underlying pathology, the goal of clinicians and patients alike is to alleviate symptoms or to manage symptoms where cure is not achievable. Self-completion questionnaires are highly effective in monitoring changes in symptoms and the impact they have. The ICIQ-BS is being developed to fulfil the need for a comprehensive, robust, condition-specific self-completion questionnaire to assess bowel symptoms and their impact on QoL. It is intended to be applicable to a wide range of individuals, including men and women of all ages ($\geq$18 years) in both the developed and developing world.

Study design, materials and methods

Studies of mixed design were undertaken to develop the ICIQ-BS and to examine its psychometric properties in accordance with standard methods of psychometric testing:

(i) *Content validity* – 56 items were determined following a combination of systematic reviewing of previous questionnaires, expert consensus committee and interviews with 14 consecutive patients with bowel symptoms (7 males, 7 females, mean age 63.5 years, range 45 to 85), with the intention that the resulting questionnaire would provide a comprehensive assessment of the frequency, severity and impact on QoL of bowel symptoms in men and women. Levels of missing data were examined to assess the acceptability of items in a postal survey of a sample of adults attending colorectal clinics with varying levels of bowel symptoms (total baseline sample: n=76: 39 males, 37 females, mean age 60.2 years, range 22 to 88).

(ii) *Stability* – the questionnaire was examined in a two week test-retest reliability analysis of 26 patients (13 males, 13 females, mean age 60.6 years, range 35 to 88) attending colorectal clinics with varying levels of bowel symptoms. The data were presented graphically to enable analysis of paired differences between test and retest responses to individual items and overall scores. Agreement was further analysed using the weighted Kappa (κ) statistic (1). Simple additive scores were computed for the questionnaire to facilitate analysis (range 2-379; higher score indicates greater severity).

(iii) *Internal consistency* – the reliability of the ICIQ-BS was further investigated by Cronbach's coefficient alpha (α) (1) using data provided by the total baseline sample.

Various sampling methods were employed to develop and evaluate the questionnaire in individuals who represented potential respondents, comprising samples of clinic adults of varying ages, with or without different symptoms and levels of bowel symptoms. Significance was determined at the 5% level (1).

Ethical approval was granted by the Local Research Ethics Committee.

Results

The study confirms the psychometric properties of the ICIQ-BS, including various aspects of validity and reliability:

(i) *Content validity* - interviews and review by clinical and social science experts indicated that ICIQ-BI items were well-interpreted and covered all important domains. The postal

response rate was acceptable (53%), with most items demonstrating low levels of missing data (mean 0.9%, range 0 to 7.7%).

(ii) *Stability* - test-retest reliability was good overall for individual items. For items using three to five-point Likert response frames, the percentage of patients reporting identical ratings or moving a maximum of just one category between the time points (e.g. from 'occasionally' to 'sometimes') ranged from 89 to 100%. 0 to 11% of patients moved two categories or more. For items using wider 11-point visual analogue scales, 89 to 100% of patients reported identical ratings or moved a maximum of three categories. Following further analyses, 14 of 16 symptom items exhibited 'good' to 'very good' stability, with crude agreements of 83 to 96% and Kappa values of 0.61 to 0.82 (P<0.0001 for all). The remaining two items exhibited 'moderate' stability, with crude agreements of 89 and 96% and Kappa values of 0.51 and 0.55 (P<0.001 for both). The score patterns obtained by patients at test and retest are shown in Table 1. Agreement between test and retest scores was 'good' (91%), with a Kappa value of 0.74 (P<0.0001).

Table 1 Characteristics of scores obtained by patients at test and retest

Scores observed	Test	Retest
Mean	45.7	38.3
Median	29	24
Range	7 to 189	4 to 182
95% confidence interval	26.2 to 65.1	19.9 to 56.5

(iii) *Internal consistency* - Cronbach's alpha coefficient was very high for the total set of questions (0.96). The Cronbach's alpha statistics for the domains assessing symptoms and condition-specific QoL were 0.87 and 0.97, respectively.

Interpretation of results

The ICIQ-BS has been shown to be psychometrically robust, exhibiting good levels of reliability and validity. The present study has indicated that the questionnaire accurately reflects the content of the concept it claims to measure (content validity), adequately reflects known theories relating to the concepts underlying the questionnaire (construct and convergent validity) and performs in a consistent, stable and reproducible manner (reliability). Consequently, users can be confident that the questionnaire is reliably measuring what is intended, and provides a legitimate and valid summary of the frequency, severity of bowel symptoms and their impact on QoL. Whilst the high Cronbach's alpha indicates that the questionnaire has excellent internal consistency, it also indicates some redundancy. The ICIQ-BS is undergoing further evaluation, including item reduction, further refinement of the scoring system and international implementation.

Concluding message

The ICIQ-BS supplies the need for a comprehensive, robust, universally-applicable condition-specific self-completion questionnaire to assess the symptoms of bowel symptoms and their impact. The ICIQ-BS will be of use in epidemiological and outcomes research as well as routine clinical practice, where a comprehensive summary of bowel symptoms and their impact is required.

References

1. 1991. Practical statistics for medical research. London: Chapman and Hall.

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