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Cotterill N[1], Norton C[2], Avery K[3], Abrams P[1], Donovan J[3]
***1.** Bristol Urological Institute, **2.** Burdett Institute of Gastrointestinal Nursing, **3.** University of Bristol*

DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF THE ICIQ ANAL INCONTINENCE MODULE: THE ICIQ-B

Hypothesis / aims of study

Under the aegis of the International Consultation on Incontinence, the ICI Modular Questionnaire (ICIQ) project (www.iciq.net) is developing a comprehensive and universally applicable modular questionnaire for the assessment of a variety of pelvic symptoms, including those of the lower urinary tract, lower bowel and vagina. The ICIQ aims to standardise assessment and promote the widespread use of self-completion questionnaires in clinical practice and research, and to facilitate comparisons between different treatment strategies and different patient groups. A new module to assess anal incontinence symptoms and their impact on quality of life, the ICIQ-B, incorporated the perspectives of both clinical experts and symptomatic patients to devise the draft instrument (1). The studies below describe the psychometric evaluation of the final version of the ICIQ-B.

Study design, materials and methods

Studies of mixed design were undertaken to evaluate the questionnaire in individuals who represented potential respondents. Samples comprised adult clinic patients of varying ages, with varying symptoms and levels of anal incontinence. The psychometric properties of the ICIQ-B were evaluated in accordance with standard methods of psychometric testing (2):

(i) *Content validity* – 56 items were generated for inclusion in the ICIQ-B through qualitative studies described elsewhere (1). Clinical experts' comments were sought on the draft instrument. Structured interviews were also undertaken with 19 patients having varying levels of anal incontinence, to assess the acceptability and applicability of the questionnaire to potential respondents (15 females, 4 males, mean age 57.7 years, range 28-77 years). Missing data was examined in a postal survey forming the baseline dataset for the quantitative validation studies (total baseline sample: n=261: 244 females, 17 males, mean age 59.7 years, range 24 to 92).

(ii) *Construct validity* – the ability of the ICIQ-B to reflect theories underlying anal incontinence was examined in individuals from the total baseline sample. The ability of the ICIQ-B to detect a difference in the prevalence of different types of anal incontinence in addition to difference in prevalence with increasing age was investigated by Chi square (χ^2) analyses.

(iii) *Stability* – the questionnaire was examined in a three week test-retest reliability analysis of 79 patients (72 females, 7 males, mean age 58.3 years, range 25 to 89) prior to attendance at anal incontinence clinics when their symptoms were expected to remain stable. The data were presented graphically to enable analysis of paired differences between test and retest responses to individual items. Agreement was further analysed using the weighted Kappa (κ) statistic.

(iv) *Internal consistency* – the reliability of the ICIQ-B was further investigated by Cronbach's coefficient alpha (α) using data provided by the total baseline sample (n=261).

(v) *Sensitivity to change* - 51 respondents (46 females and 5 males, mean age 60.9 years, range 28 to 89) who underwent biofeedback or sacral nerve stimulator implantation for their symptoms, completed a third questionnaire post-treatment to evaluate its ability to detect change. The Wilcoxon signed ranks test was used to compare baseline and outcome data (3).

(vi) *Item reduction* – A principal factor analysis was undertaken to identify underlying domains within the question item pool and along with data from all of the above studies, question items were identified for removal from the final ICIQ-B. Clinical expert opinions and the patients' perspective were also considered to ensure important items were not overlooked in light of the statistical findings (3).

Results

The study confirms the psychometric properties of the ICIQ-B:

(i) *Content validity* - interviews with patients and review by clinical experts indicated that ICIQ-B items were well-interpreted and covered all important domains. Missing data was low for most items (mean 3.7%).

(ii) *Construct validity* – the ICIQ-B distinguished between the prevalence of different types of anal incontinence: 92% flatus, 84% liquid/soft stool and 63% solid stool (χ^2=95.7, P<0.001), with flatus incontinence more common than any other type. A trend of increasing incontinence with age was exhibited (20-29 year olds - 4% prevalence; 60-69 year olds - 29% prevalence) however this was not found to be statistically significant.

(iii) *Stability* – test-retest reliability was 'moderate' to 'very good' for all question items using the weighted kappa statistic, (10 items 'moderate', 41 items 'good', 4 items 'very good') . Crude agreement ranged from 80 to 96% for all items and between 77 and 99% of retest responses were identical or within one response category of the test response.

(iv) *Internal consistency* – Cronbach's alpha coefficient was high for the total set of question items at 0.94 indicating redundancy of some items. The Cronbach's alpha statistics were also high for the domains assessing symptoms (0.90) and quality of life (0.92) separately, indicating redundancy within both item pools.

(v) *Sensitivity to change* – Reduction in the occurrence of symptoms was detected in 36 of 51 items for all patients following treatment. The magnitude of reduction ranged from 1 to 18% in the subgroup managed conservatively and 1 to 43% in the subgroup managed surgically. 19 of the 55 question items analysed were found to be significantly sensitive to change following treatment at the 0.05 significance level (15 symptom items and 4 quality of life items).

(vi) *Item reduction* – Three underlying factors were identified from the question item pool: bowel pattern, bowel control and quality of life consisting of 5 items, 7 items and 5 items respectively. Three simple additive scores were indicated for these domains according to the factor analysis data. Four further standalone, unscored items are included to encompass assessment of stool type, straining, incontinence being on the individuals mind and sexual activity restriction. The reliability and sensitivity to change of the scores were further evaluated and are displayed below.

Table 1: Properties of domain scores obtained from the final ICIQ-B

Derived domain scores	Reliability Kappa (crude agreement %)	Sensitivity to change (P-value)
Bowel pattern	Good (92.7)	0.0035
Bowel control	Good (91.2)	0.0020
Quality of life	Good (92.8)	0.0006

Interpretation of results

The ICIQ-B has been shown to be psychometrically robust, exhibiting good levels of validity, reliability and sensitivity to change. This study has indicated that the questionnaire accurately reflects the content of the concept it claims to measure, performs in a consistent, stable and reproducible manner and is able to detect a change in symptom and quality of life status following intervention. Consequently, users can be confident that the questionnaire is reliably measuring what is intended, and provides a legitimate and valid summary of symptoms of anal incontinence and their impact on quality of life.

Concluding message

The ICIQ-B provides a comprehensive, robust, universally-applicable, condition-specific, self-completion questionnaire to assess the symptoms and impact of anal incontinence. The ICIQ-B will be of use in clinical practice and research providing a comprehensive summary of anal incontinence and its impact on quality of life for baseline assessment and outcome evaluation.

References

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Was the Declaration of Helsinki followed?	**Yes**
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