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Avery K[1], Abrams P[1], Chadwick M[1], Donovan J[2]
1. Bristol Urological Institute, 2. University of Bristol

DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF THE ICIQ URINARY AND BOWEL INCONTINENCE MODULES: THE ICIQ-UI AND ICIQ-BI

Hypothesis / aims of study

The modular International Consultation on Incontinence Questionnaire (ICIQ) is 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, new modules to assess urinary and bowel incontinence, the ICIQ-UI and ICIQ-BI, have been developed and evaluated. Urinary incontinence is the complaint of any involuntary leakage of urine (1). Bowel (anal) incontinence is "the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem" (2). These conditions are observed among adults of all ages and are known to be bothersome, with the ability to impair an individual's quality of life (QoL) (2). The modules are intended to be universal, applicable to a wide range of individuals, including adult 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 modules and to examine their psychometric properties in accordance with standard methods of psychometric testing:

(i) *Content validity* – 72 items for the ICIQ-UI and 76 items for the ICIQ-BI were determined following a combination of systematic reviewing of previous questionnaires, expert consensus committee and interviews with 43 consecutive patients with urinary incontinence (29 females, 14 males, mean age 60.4 years, range 32 to 88) and 14 with bowel incontinence (7 males, 7 females, mean age 63.5 years, range 45 to 85), with the intention that the resulting questionnaires would provide comprehensive measures of the frequency, severity and impact on QoL of urinary and bowel incontinence 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 urology and colorectal clinics with varying levels of urinary and bowel incontinence (ICIQ-UI total baseline sample: n=210: 184 females, 26 males, mean age 56.8 years, range 18 to 100; ICIQ-BI total baseline sample: n=48: 33 females, 15 males, mean age 50.8 years, range 22 to 80).

(ii) *Construct validity* – the ability of the modules to reflect theories underlying urinary and bowel incontinence was examined in groups of individuals from the total baseline samples. The ability of the ICIQ-UI to detect a difference in the prevalence of different types of urinary incontinence between males and females was investigated by Chi square (χ^2) analyses. Univariable regression was used to determine if the ICIQ-UI could detect a difference in the level and impact on QoL of symptoms between individuals with different types of urinary incontinence and to determine if the ICIQ-BI could detect a difference in the level and impact of bowel incontinence between men and women. Simple additive scores were computed for the questionnaires to facilitate analyses (ICIQ-UI range 0-389, ICIQ-BI range 0-517; higher score indicates greater severity).

(iii) *Convergent validity* - the degree of association between comparable items in the ICIQ-BI and another measure of a related concept, the Wexner Continence Grading Scale – modified (WCGS-Kamm) (3) was investigated using Spearman's rank correlation coefficient (r_s). The association between ICIQ-BI and WCGS-Kamm scores was also investigated using Pearson's product moment correlation coefficient (r).

(iv) *Stability* – the questionnaires were examined in a two week test-retest reliability analysis of 127 patients (111 females, 16 males, mean age 55.8 years, range 18 to 100) attending urology clinics and 27 patients (15 females, 12 males, mean age 55.6 years, range 33 to 80) attending colorectal clinics with varying levels of urinary and bowel incontinence. Agreement between test and retest responses to individual items and overall scores was examined by graphical analysis of paired differences and the weighted Kappa (κ) statistic.

(v) *Internal consistency* – the reliability of the questionnaires was further investigated by Cronbach's coefficient alpha (α) using data provided by the total baseline samples.

Various sampling methods were employed to develop and evaluate the modules in samples who represented potential respondents, comprising adults of all ages, with or without different symptoms and levels of urinary and bowel incontinence. Significance was determined at the 5% level. Ethical approval was granted by the Local Research Ethics Committee.

Results

(i) *Content validity* - interviews and review by clinical and social science experts indicated that items were well-interpreted and covered all important domains. The postal response rate was acceptable (ICIQ-UI: 51%; ICIQ-BI: 56%), with low missing data for most items (ICIQ-UI mean: 4.3%; ICIQ-BI mean: 4.6%).

(ii) *Construct validity* – the ICIQ-UI clearly distinguished between the types of urinary incontinence reported by males and females (χ^2=27.7, P<0.001), with stress incontinence more common among women, in contrast to men who reported more urge incontinence. Mixed incontinence exceeded stress and urge incontinence in both sexes. There was also a statistically significant difference in the level and impact of symptoms between individuals with different types of urinary incontinence (P=0.0002), with greater severity among individuals with urge and mixed incontinence. The ICIQ-BI clearly differentiated between males and females (P=0.019), with significantly higher mean scores among women (mean 110.2, range 17 to 435) than men (mean 45.3, range 19 to 105).

(iii) *Convergent validity* – agreement between ICIQ-BI and WCGS-Kamm items ranged from moderate to strong (Spearman's r_s 0.48 to 0.89, P<0.0001 to P<0.01 for all). The ICIQ-BI score also correlated well with the WCGS-Kamm score (Pearson's r 0.74, P<0.0001).

(iv) *Stability* – test-retest reliability was good overall for individual items. For items using three to six-point Likert response frames, the percentage of individuals reporting identical ratings or moving a maximum of one category between the time points (e.g. from 'quite a bit' to 'moderately') ranged from 64 to 100% (ICIQ-UI) and 89 to 100% (ICIQ-BI). 0 to 32% (ICIQ-UI) and 0 to 8% (ICIQ-BI) of individuals moved two categories or more. For items using wider 11-point visual analogue scales, 82 to 100% (ICIQ-UI) and 96 to 100% (ICIQ-BI) of individuals reported identical ratings or moved a maximum of three categories. Following further analyses, 66 of 72 ICIQ-UI items and 34 of 37 ICIQ-BI symptom items exhibited 'good' to 'very good' stability, with crude agreements of 74 to 100% and Kappa values of 0.61 to 1.00 for the ICIQ-UI (P<0.0001 to P<0.001 for 70 items, P>0.05 for two items) and crude agreements of 89 to 99% and Kappa values of 0.56 to 0.97 for the ICIQ-BI (P<0.0001 to P<0.001 for all). The remaining six ICIQ-UI items exhibited 'fair' to 'moderate' stability, with crude agreements of 74 to 90% and Kappa values of 0.20 to 0.60 (P<0.0001 for four items, P>0.05 for two items). The stability of the remaining three ICIQ-BI items was 'moderate', as indicated by crude agreements of 89 to 91% and Kappa values of 0.56 to 0.60 (P<0.001 for all). Agreements between test and retest scores for the ICIQ-UI and ICIQ-BI were 'good' (89%) and 'very good' (96%), with high Kappa values of 0.68 (P<0.0001) and 0.89 (P<0.0001), respectively.

(v) *Internal consistency* – Cronbach's alpha coefficient was high for the total set of items in the ICIQ-UI (0.82 for males, 0.93 for females) and the ICIQ-BI (0.98). The Cronbach's alpha statistics for ICIQ-UI domains assessing symptoms, male and female sexual matters and condition-specific QoL were 0.95, 0.82, 0.85 and 0.95, respectively, and for ICIQ-BI domains assessing symptoms and condition-specific QoL were 0.97 and 0.96.

Interpretation of results

The ICIQ-UI and ICIQ-BI have been shown to be psychometrically robust, exhibiting good levels of reliability and validity. Consequently, users can be confident that the questionnaires reliably measure what is intended, and provide a legitimate and valid summary of the frequency, severity and impact on QoL of urinary and bowel incontinence. Whilst the high Cronbach's alphas indicate that the questionnaires have excellent internal consistency, they also indicate some redundancy. The questionnaires are undergoing further evaluation, including item reduction, refinement of the scoring systems and international implementation.

Concluding message

The ICIQ-UI and ICIQ-BI supply the need for comprehensive, robust, universally-applicable, condition-specific questionnaires to assess the symptoms and impact of urinary and bowel incontinence. They will be of use in epidemiological and outcomes research and routine clinical practice, where a comprehensive summary of these conditions is required.

References

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