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DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF THE ICIQ VAGINAL SYMPTOMS QUESTIONNAIRE: THE ICIQ-VS

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. Vaginal symptoms, particularly those attributed to pelvic organ prolapse, commonly exist with urinary incontinence and vice versa, and may affect the quality of life of many women (1). Under the aegis of the ICI, a new module to assess vaginal symptoms, the ICIQ-VS, has been developed and evaluated. The ICIQ-VS is intended to be universal, applicable to a wide range of individuals, including all adult women over the age of 18, in both the developed and the developing world.

Study design, materials and methods

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

(i) *Content validity* – 47 items were determined following a combination of systematic reviewing of previous questionnaires, expert consensus committee and interviews with 14 consecutive adult females with vaginal symptoms (mean age 58.4 years, range 33 to 82), with the intention that the resulting questionnaire would provide a comprehensive and psychometrically robust instrument for the evaluation of the frequency, severity and impact on quality of life of vaginal symptoms, including those attributed to pelvic organ prolapse, vaginal discomfort, dryness and dyspareunia. Levels of missing data were examined to assess the acceptability of items in a postal survey of a sample of women attending two urogynaecology clinics with varying levels of vaginal symptoms (total baseline sample: n=218: mean age 55.7 years, range 25 to 99).

(ii) *Construct validity* – the ability of the ICIQ-VS to reflect theories underlying vaginal symptoms was examined in groups of individuals from the total baseline sample. Univariable regression (2) was used to determine if the ICIQ-VS could detect a difference in the level and impact of symptoms between a sample of community-based women and a sample of women patients attending a urogynaecology clinic. Simple additive scores were computed for the questionnaire to facilitate analysis (range 0-307; higher score indicates greater severity).

(iii) *Stability* – the reliability of the questionnaire was examined in a four-week test-retest analysis of 34 women (mean age 58.4 years, range 37 to 81 years) attending urogynaecology clinics with varying levels of vaginal 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 (2).

(iv) *Internal consistency* – the reliability of the ICIQ-VS was further investigated by Cronbach's coefficient alpha (α) (2) using data provided by the total baseline sample.

(v) *Sensitivity to change* - the responsiveness of the questionnaire was assessed in a sample of women undergoing surgical treatment for vaginal symptoms (n=20: mean age 58.6 years, range 39 to 81). The percentage change in the presence of symptoms between baseline and follow-up (approximately 12 weeks) was calculated. The Wilcoxon signed ranks test (2) was used to determine whether symptom levels differed significantly. In addition, the difference between the mean symptom scores at baseline and follow-up was examined using the one-sample paired t-test.

Various sampling methods were employed to develop and evaluate the questionnaire in individuals who represented potential respondents, comprising samples of clinic and community-based women of varying ages, with or without different symptoms and levels of vaginal symptoms. Significance was determined at the 5% level (2). Ethical approval was granted by the Local Research Ethics Committee.

Results

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

(i) *Content validity* - interviews and review by clinical and social science experts indicated that ICIQ-VS items were well-interpreted and covered all important domains. The postal response rate was acceptable (74%), with most items demonstrating low levels of missing data (mean 2.4%, range 0 to 9.2%).

(ii) *Construct validity* – the ICIQ-VS clearly distinguished between clinic attendees and community-based women. As expected, women patients attending urogynaecology clinics reported significantly higher mean scores (94.7, range 0 to 270) than women in the community (9.2, range 0 to 79) (P<0.0001, 95% confidence interval –98.9 to –71.9).

(iii) *Stability* – test-retest reliability was good overall for individual items. For items using 4 or 5-point Likert response frames, the percentage of women reporting identical ratings or moving a maximum of just one category between the time points (e.g. from 'occasionally' to 'sometimes') ranged from 79 to 100%. 0 to 17% of women moved two categories. For items using wider 11-point visual analogue scales, 78 to 100% of women reported identical ratings or moved a maximum of three categories. Following further analyses, 24 of 47 items exhibited 'good' to 'very good' stability, with crude agreements of 86 to 100% and Kappa values of 0.62 to 1.00 (P<0.0001 to P<0.01 for all). The remaining items exhibited 'fair' to 'moderate' stability, with crude agreements of 72 to 89% and Kappa values of 0.23 to 0.60 (P<0.0001 to P<0.05 for all), except one item that demonstrated 'poor' reliability (agreement 87%, Kappa value 0.18, P>0.05). Agreement between test and retest scores (Table 1) was 'moderate' (84%), with a Kappa value of 0.51 (P<0.0001)

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

Scores observed	Test	Retest
Mean	86.6	78.3
Median	79.5	73.5
Range	9 to 267	2 to 256
95% confidence interval	67.6 to 105.6	59.6 to 97.0

(iv) *Internal consistency* – Cronbach's alpha coefficient was high (0.94) for the total set of items. Cronbach's alpha statistics for domains assessing symptoms, quality of life and sexual matters were 0.95, 0.93 and 0.98 respectively.

(i) *Sensitivity to change* - there was an observed decrease (ranging from 2.6 to 78.3%) in the percentage of women reporting symptoms or impact on all but one of the 24 symptom items following treatment (P<0.001 to P<0.05), with all but nine of these reaching statistical significance. Symptom scores improved significantly following treatment (mean score 37.2 and 19.3 before and after respectively, t= 2.26, P=0.0361).

Interpretation of results

The ICIQ-VS exhibits good psychometric properties. Consequently, users can be confident that the questionnaire is reliably measuring what is intended, and provides a legitimate and valid summary of the level and impact on quality of life of vaginal symptoms. Preliminary analyses have also indicated that the questionnaire is sensitive to change, although further assessment with a larger surgical series and in response to other individual treatments is required. Whilst the high Cronbach's alpha indicates that the questionnaire has excellent internal consistency, it also indicates some redundancy. The ICIQ-VS is undergoing further evaluation, including item reduction, further refinement of the scoring system and international implementation.

Concluding message

The ICIQ-VS meets the need for a comprehensive, robust, universally-applicable, condition-specific, self-completion questionnaire to assess a wide range of vaginal symptoms and their impact. The ICIQ-VS will be of use in epidemiological and outcomes research and routine clinical practice, where a comprehensive summary of the level and impact of vaginal symptoms is required.

References

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