20

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FINAL DEVELOPMENT OF THE ICIQ VAGINAL SYMPTOMS QUESTIONNAIRE (THE ICIQ-VS)

Hypothesis / aims of study

Under the aegis of the International Consultation on Incontinence, whose scientific programmes are organised by the ICS, 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. Vaginal symptoms, particularly those attributed to pelvic organ prolapse, commonly coexist with urinary incontinence and affect the quality of life of many women. A new questionnaire module to assess vaginal symptoms, the ICIQ-VS, has been developed and validated and has now undergone factor analysis to allow the questionnaire to be reduced to its optimum length. The ICIQ-VS provides an instrument for characterising the severity of vaginal symptoms, measuring their impact on quality of life and evaluating treatment outcome. It is designed for application to all adult women over the age of 18 and for use in both clinical practice and research.

Study design, materials and methods

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

(i) *Content validity:* A developmental version of the ICIQ-VS was determined following a systematic review of previous questionnaires, an expert consensus committee and interviews with 14 adult females (mean age 58.4 years, range 33–82) with vaginal symptoms, including those attributed to pelvic organ prolapse, vaginal discomfort, dryness and dyspareunia. The ICIQ-VS comprised 14 items relating to vaginal symptoms (13 with a sub-question on the degree of problem caused) and 10 relating to sexual matters (9 with a problem sub-question). Response rates and levels of missing data were examined to assess the acceptability of items in a postal survey of a sample of 141 symptomatic urogynaecology clinic patients.

(ii) *Construct validity:* The ability of the ICIQ-VS to reflect theories underlying vaginal symptoms was examined by comparing the prevalence of vaginal symptoms and sexual matters between the 141 symptomatic urogynaecology clinic patients and a sample of 77 community-based women. Differences between the populations were examined using Chi-square and Fisher's exact tests where appropriate.

(iii) *Stability:* The reliability of the questionnaire was examined in a four-week test-retest analysis of 34 symptomatic urogynaecology clinic patients (mean age 58.4 years, range 37–81). 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-VS was further investigated by calculating Cronbach's alpha coefficient (α) for the items relating to vaginal symptoms and sexual matters, using the postal survey data of symptomatic urogynaecology clinic patients.

(v) *Sensitivity to change:* The percentage change in the presence of vaginal symptoms and sexual matters between baseline and follow-up (approximately 12 weeks) was calculated in 66 women undergoing surgical treatment for vaginal symptoms. The Wilcoxon signed ranks test was used to determine whether symptom levels differed significantly.

(vi) *Item reduction and scoring system:* A factor analysis was performed to investigate groupings of symptoms that could be combined into a single score or profile of scores. In addition, items that did not load well on any factors were considered for removal from the final questionnaire.

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 all but one vaginal symptom demonstrating low levels of missing data (<3%). As expected, higher rates of missing data were observed for the more sensitive sexual matter items (<13% for all but one).

(ii) *Construct validity:* The ICIQ-VS clearly distinguished between women in the community and symptomatic women attending urogynaecology clinics, who reported much higher prevalence of vaginal symptoms and sexual problems (P<0.0001 for the majority of items). Non-significant differences were only observed for one vaginal symptom and one sexual problem.

(iii) *Stability:* Test-retest reliability was good for 11 of the 14 symptoms (Kappas varied from 0.40 to 0.75) and for 9 of the 10 sexual matter items (Kappas 0.40 to 1.00). For items using four or five-point Likert response frames, the percentage of women reporting identical ratings or moving just one category between the time points (e.g. from 'occasionally' to 'sometimes') ranged from 79 to 100%. 0–17% of women moved two categories.

(iv) *Internal consistency:* Cronbach's alpha was high, both for the vaginal symptom questions grouped together (0.81) and for the items relating to sexual matters (0.90). This indicates good internal consistency.

(v) *Sensitivity to change:* Following treatment, large decreases were observed in the reporting frequency and level of each vaginal symptom (P<0.0001), apart from one. Whilst decreases were also observed in items relating to sexual matters, the majority did not demonstrate statistically significant differences following treatment.

(vi) *Item reduction and scoring system:* Principal factor analysis identified a number of vaginal symptoms and sexual matter items that did not load well on any factors. Items that also demonstrated poor validity and reliability, and which were not considered essential clinically, were removed from the final version. A number of domains were identified to assess vaginal symptoms and sexual problems and a scoring system considered.

Interpretation of results

The ICIQ-VS questionnaire exhibits good psychometric properties. Consequently, users can be confident that it reliably measures what is intended and provides a legitimate and valid summary of the level of vaginal symptoms and their impact on quality of life. Moreover, it is sensitive to change and can reliably quantify changes in symptom levels following treatment.

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. It 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. The ICIQ-VS has been exhaustively tested and is now ready for use.

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