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DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF THE ICIQ NOCTURIA MODULE: THE ICIQ-N

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. Nocturia is the complaint that the individual has to wake at night one or more times to void (1). It is a prevalent condition, occurring in men and women of all ages, and is one of various lower urinary tract symptoms (LUTS) that people report to be troublesome (2). However, few studies have exclusively assessed nocturia and its impact on people's lives (2). Under the aegis of the ICI, a new module to assess both the level and impact on QoL of nocturia, the ICIQ-N, has been developed and evaluated. It is 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 ICIQ-N and to examine its psychometric properties in accordance with standard methods of psychometric testing:

(i) *Content validity* – items were determined following a combination of systematic reviewing of previous questionnaires (3), expert consensus committee and interviews with 9 consecutive patients (8 males, 1 female, mean age 67.3 years, range 44 to 85) with nocturia, 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 (QoL) of nocturia 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 clinics with varying levels of nocturia (total baseline sample: n=242: 190 males, 52 females, mean age 65.0 years, range 20 to 88).

(ii) *Construct validity* – the ability of the ICIQ-N to reflect theories underlying nocturia was examined in groups of individuals from the total baseline sample. The ability of the ICIQ-N to distinguish between those with nocturia one, two and three or more times per night was investigated using a one-way analysis of variance. Simple additive QoL scores were computed for the questionnaire to facilitate analyses (range 0-58; higher score indicates greater severity).

(iii) *Stability* – the reliability of the questionnaire was examined in a two week test-retest analysis of 42 patients (27 males, 15 females, mean age 65.9 years, range 20 to 87) attending urology clinics with varying levels of nocturia. 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. Simple additive total scores were computed for the questionnaire to facilitate analyses (range 0-85; higher score indicates greater severity).

(iv) *Internal consistency* – the reliability of the ICIQ-N was further investigated by Cronbach's coefficient alpha (α) 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 levels of nocturia. Significance was determined at the 5% level. Ethical approval was granted by the Local Research Ethics Committee.

Results

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

(i) *Content validity* - interviews and review by clinical and social science experts indicated that ICIQ-N items were well-interpreted and covered all important domains. The postal response rate was acceptable (58%), with most items demonstrating low levels of missing data (mean 1.7%, range 0 to 4.1%).

(ii) *Construct validity* – the ICIQ-N clearly differentiated between individuals with different levels of nocturia. As anticipated, those with nocturia three or more times per night reported much higher scores (mean 29.3, range 2 to 50) than those with nocturia once or twice per night (mean scores 16.6 and 19.3, range 4 to 25 and 0 to 44, respectively).

(iii) *Stability* - test-retest reliability was very good overall for individual items. For items using four 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 'quite a bit' to 'moderately') ranged from 67 to 100%. 0 to 10% of patients moved two categories. For items using wider 11-point visual analogue scales, 100% of patients reported identical ratings or moved a maximum of three categories. Following further analyses, 16 of 21 items exhibited 'good' to 'very good' stability, with crude agreements of 83 to 100% and Kappa values of 0.61 to 1.00 (*P*<0.0001 to *P*<0.05 for all but one item). The remaining five items exhibited 'moderate' stability, with crude agreements of 83 to 88% and Kappa values of 0.50 to 0.59 (*P*<0.0001 to *P*<0.05 for all). The score patterns obtained by patients at test and retest are shown in Table 1. Agreement between test and retest scores was 'good' (92%), with a high Kappa value of 0.76 (*P*<0.0001).

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

Scores observed	Test	Retest
Mean	29.6	29.5
Median	30.5	30.5
Range	1 to 56	1 to 54
95% confidence interval	25.2 to 33.9	25.5 to 33.5

(iv) *Internal consistency* – Cronbach's alpha coefficient was high for the total set of questions (0.92 and 0.98 for males and females, respectively). The Cronbach's alpha statistics for the domains assessing symptoms, male and female sexual matters and condition-specific QoL were 0.79, 0.75, 0.97 and 0.93, respectively.

Interpretation of results
The ICIQ-N 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 validity) and performs in a consistent, stable and reproducible manner. 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 and impact on QoL of nocturia. Whilst the high Cronbach's alpha indicates that the questionnaire has excellent internal consistency, it also indicates some redundancy. The ICIQ-N is undergoing further evaluation, including item reduction, further refinement of the scoring system and international implementation.

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

References
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