

DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF A SELF REPORT QUALITY OF LIFE QUESTIONNAIRE FOR INDIVIDUALS WITH LONG TERM INDWELLING CATHETER: THE ICIQ-LTCQOL

Hypothesis / aims of study

Long-term indwelling catheters are commonly associated with complications which are known to be detrimental to quality of life (1). Clinical assessment and monitoring of patients with urinary catheters is also known to be poorly recorded (2). To date no questionnaire has been developed that incorporated the perspectives of both clinical experts and symptomatic patients to devise the draft instrument. This study aimed to develop such a tool for use in clinical practice and research, to reflect the users' perspective of life with a long-term catheter. This questionnaire was developed as part of the ICIQ modular questionnaire (www.iciq.net), which 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. The studies below describe the psychometric evaluation of the final version of this new questionnaire: the ICIQ-LTCqol.

Study design, materials and methods

Studies of mixed design were undertaken to evaluate the questionnaire in individuals who represented potential respondents. Samples comprised adult community patients of varying ages, with diverse reasons for catheterisation. The psychometric properties of the ICIQ-LTCqol were evaluated in accordance with standard methods of psychometric testing (3):

- (i) *Content validity* – In excess of 100 items were generated for inclusion in the draft ICIQ-LTCqol through initial qualitative studies with 27 patients (14 females, 13 males, median age 71 years, range 28 to 88 years). Clinical experts' comments were sought on the draft instrument. Structured interviews were also undertaken with 31 patients who were catheterised for varying amounts of time and for broadly ranging reasons, to assess the acceptability and applicability of the developmental questionnaire to potential respondents (15 females, 16 males, median age 75 years, range 29-92 years). Missing data for the refined instrument containing 44 question items was examined in a postal survey forming the baseline dataset for the quantitative validation studies (total baseline sample: n=370: 117 females, 165 males - gender not reported for 88 individuals, median age 77 years, range 21 to 98 years).
- (ii) *Stability* – the questionnaire was examined in a three week test-retest reliability analysis of 108 patients (43 females, 51 males - gender not reported for 14 individuals, median age 74 years, range 41 to 98 years) who had their catheter inserted longer than three months prior to the mail-out and who were not undergoing any catheter related intervention. 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.
- (iii) *Internal consistency* – the reliability of the ICIQ-LTCqol was further investigated by Cronbach's coefficient alpha (α) using data provided by the total baseline sample (n=370).
- (iv) *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-LTCqol. Clinical expert opinions and the patients' perspective were also considered to ensure important items were not overlooked in light of the statistical findings.
- (v) *Testing scoring system* – The final version of the questionnaire was employed in a further postal survey of 215 community dwelling patients (75 females, 129 males - gender not reported for 11 individuals, median age 80 years, range 20 to 101 years) in order to test the newly developed scoring system's validity and stability.

Results

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

- (i) *Content validity* - interviews with patients and review by clinical experts indicated that ICIQ-LTCqol items were well-interpreted and covered all important domains. Missing data was low for most items (mean 3.6%).
- (ii) *Stability* – test-retest reliability was 'moderate' to 'good' for most question items in the final questionnaire using the weighted kappa statistic (9 items 'moderate', 6 items 'good', 1 item 'poor').
- (iii) *Internal consistency* – Cronbach's alpha coefficient was high for the total set of question items at 0.96 indicating redundancy of some items. This was expected, given the exhaustive number of items contained in the developmental version of the questionnaire. Twenty five items were removed that offered little value to the final questionnaire on the basis of high intercorrelation coefficients, high levels of missing data, poor evidence of reliability, patients unable to answer and issues that were rarely reported by patients. The opinions of patients and clinical experts also guided the removal of items to ensure decisions were not made according to the statistical evidence alone.
- (iv) *Item reduction* – Two underlying factors were identified from the question item pool: 'catheter function and concern' and 'lifestyle impact' consisting of 9 items and 3 items respectively. Two 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 additional pad use, pain, bladder spasm and prevention of sexual activity.
- (v) *Testing scoring system* - The final nineteen item version of the questionnaire used in the further postal survey achieved a response rate of 54% with 7.2% missing data.

Table 1: Further evaluation of the scoring system for the final ICIQ-LTCqol

Derived scores	domain	Possible score range	Observed score range	Mean score (sd)	Median score	Reliability Kappa
Catheter function and concern		0-42	0-33	14.5 (7.8)	14	Good (0.63)
Lifestyle impact		0-15	0-15	8.6 (3.8)	8	Good (0.77)

Interpretation of results

The ICIQ-LTCqol has been shown to be psychometrically robust, exhibiting good levels of validity and reliability. This study has indicated that the questionnaire accurately reflects the content of the concept it claims to measure 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 impact on quality of life of living with a long term indwelling catheter from the users' perspective. Sensitivity to change evaluation will be a valuable addition to the psychometric properties profile for this tool to know whether quality of life changes can be detected when they occur in relation to catheter related intervention. However, this requires examination in a group of individuals who are undergoing intervention of known effect which is difficult to ascertain with this device.

Concluding message

The ICIQ-LTCqol provides a comprehensive, robust, universally-applicable, device-specific, self-completion questionnaire to assess the impact of living with a long term catheter from the individual's perspective. The necessity to reflect the patient's perspective is paramount for quality of life evaluation. This was intrinsic to the development of this tool ensuring clinical applicability through involvement of clinical experts but primarily patient relevance through involvement of catheter users at all stages of the development process. The nineteen item ICIQ-LTCqol will be of use in clinical practice and research providing a comprehensive summary of these individuals for baseline assessment and ongoing monitoring.

References

1. O'Donohue D, Winsor G, Gallagher R, Maughan J, Dooley K, Walsh J. Issues for people living with long-term urinary catheters in the community. *British Journal of Community Nursing* (2010) 15(2); 65-70
2. Getliffe K, Newton T. Catheter-associated urinary tract infection in primary and community health care. *Age and Ageing* (2006) 35(5); 477-481
3. Streiner D, Norman G. *Health measurement scales: a practical guide to their development and use*; New York, Oxford University Press, 2004.

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