Article title

Development and psychometric evaluation of The ICIQ-LTCqol: a self-report quality of life questionnaire for long-term indwelling catheter users

STRUCTURED ABSTRACT

Aims

Long-term indwelling catheterisation may affect health related quality of life, but clinical assessment and monitoring of people with indwelling catheters is poorly recorded because there are no validated measures to capture these criteria. In this paper, we describe the development of the ICIQ-Long Term Catheter quality of life (ICIQ-LTCqol), one of the modules of the ICIQ series, an international project to standardise assessment of lower pelvic dysfunction: www.iciq.net.

Methods:

In-depth interviews were conducted with 27 catheter-users and 4 informal carers and cognitive debriefing with a further 31 catheter-users and clinical experts to evaluate clarity and comprehensiveness. The draft 44 item questionnaire was then sent by post to 893 long-term catheter-users; the 370 completed questionnaires were used to test content validity, test re-test reliability and internal consistency (Cronbach α coefficient). Factor analysis alongside expert opinion was used to formulate the final questionnaire of 16 items. This was then sent by post to another 438 long-term catheter-users to evaluate domain scores.

Results:

The final questionnaire consists of 2 scored domains: catheter function and concern (9 items) and lifestyle impact (3 items) and 4 standalone items, relating to pads, pain, sexual activity and bladder spasm. Levels of missing data are good (mean 3.6%) with moderate to good agreement and acceptable internal consistency (Cronbach's alpha

0.76 and 0.74 for each domain respectively), suggesting acceptability and stability of the questionnaire.

Conclusion:
The ICIQ-LTCqol is a psychometrically robust self-report questionnaire for the clinical assessment and evaluation of health related quality of life for long-term catheter users.

KEYWORDS IDENTICAL TO THE MEDICAL SUBJECT HEADINGS:
psychometrics, questionnaires, urinary incontinence, catheter, quality of life

MANUSCRIPT TEXT

Introduction

Qualitative studies have highlighted the impact of a long-term indwelling catheter on an individual's body image and sexual function. Those with catheters recount a continuous swing between acceptance of the catheter and the stigma associated with it[1-3]. In one study of 62 community dwelling long-term catheter users, 55% reported moderate interference by the catheter in their everyday lives[4]. The potential associated problems and the psychological, physical and practical adjustments related to living with a catheter have not been well addressed, in part because there are no validated health related quality of life (HRQoL) tools specific to the catheterised population. Such a tool is required to allow accurate self-reported evaluation of the impact of an indwelling catheter and to identify opportunities for intervention and improvement to patient care. In this paper, we describe the development of the ICIQ-Long Term Catheter quality of life (ICIQ-LTCqol) questionnaire, one of the ICIQ series, an international project to standardise assessment of lower pelvic dysfunction[5].

Materials and Methods

The study was conducted in four Phases: exploratory interviews; cognitive debriefing; postal survey; and scoring system tests. Ethics approval was granted from Southmead local research ethics committee (LREC no: 07/Q2002/22)

Phase 1

Exploratory interviews

Thirty-one semi structured interviews involving catheter users and carers were conducted in the community from January 2007 to April 2008[6]. Purposive sampling was used to reflect the heterogenous nature of the population. Interview prompts and methodology were guided by grounded theory[7]**.** Verbatim transcripts were analysed for emerging themes and software NVivo7 was used to assist data handling and coding[8].

Phase 2

Cognitive debriefing

Face-to-face, structured interviews with the draft instrument were undertaken in 2008-2009 to ascertain acceptability, interpretation and relevance of items[8-10]. Participants registered at Southmead Hospital, Bristol, UK with an indwelling catheter of greater than three months duration completed the questionnaire and expressed thoughts and opinions regarding ease of completion, wording of question items and question relevance. Questionnaire completion was observed and timed. Expert opinion was sought with a focus on the clinical or research utility of the questionnaire.

Phase 3

Postal survey

Individuals registered with participating primary care practices identified through the Primary Care Research Network in the South and South West of England were identified according to their catheter prescription and invited to participate by their General Practitioner (GP) between June 2009 and July 2010. The questionnaire was developed to ensure it could be completed by the catheter user or by a proxy who could represent the views of the catheter user. Questionnaires were posted and return requested within 3 weeks.

Content validity

The Postal survey was analysed to rule out potentially problematic question items or items that appeared irrelevant or could pose difficulties for self-report through analysis of missing data.

Reliability

Two components were evaluated to establish reliability: stability and internal consistency.

Stability

After a 2 to 3 week interval, all participants who returned a completed questionnaire were invited to complete an identical retest questionnaire. The timeframe was such that changes in QOL status were expected to be minimal but recall of original responses would be unlikely. Using the weighted Kappa statistic (κ) and graphical representation, baseline and retest responses were evaluated to determine the proportion of identical responses and degree of difference between responses.

Internal consistency

Baseline data from all completed questionnaires were analysed to evaluate internal consistency using Cronbach's Coefficient Alpha (α). A value between 0.7 and 0.9 is considered to indicate acceptable homogeneity between question items with limited redundancy.

Item reduction and factor analysis

Data was reviewed to identify a spectrum of 'robust' to 'poorly' performing items. Floor and ceiling effects were also analysed and a correlation matrix was calculated to identify areas of overlap (>0.7 indicated high correlations between item pairs). Exploratory principal factor analysis identified underlying domains within the question item pool, guided a scientific scoring system for clinical use and assisted in item reduction. Clinical expert opinions and views from the user representative along with evidence from interviews conducted in Phases 1 and 2 highlighted potential items for removal to ensure balance between the psychometric and clinimetric evidence[11].

Derivation of the scoring system

The data were examined to explore the justification for a scoring system and to provide guidance on how to calculate such a score for use in practice.

Phase 4

Testing the scoring system

The final version was resent by post between June and September 2012 to relevant community dwelling individuals identified by their GP according to their catheter prescription status. Content validity and stability analyses were conducted as in Phase 2 for the domain scores and response rates were calculated to establish acceptability of the final questionnaire. Domain score distribution was calculated along with mean and median average values to evaluate the appropriateness of the scoring system in a new population of respondents.

Results

Phase 1

Twenty seven individuals with catheters and 4 carers took part in exploratory interviews to generate the content for the new questionnaire. A long form draft comprising over 100 items relating to demographic information, health related quality of life, cost and abilities and needs was generated[6].

Phase 2

Cognitive debriefing

Thirty one further catheter users (Table I) participated in consecutive rounds of interviews to refine the original questionnaire and produce the “developmental” version. Additional insight was provided by six healthcare professionals consisting of clinical, questionnaire design and health economics experts. Content validity interviews resulted in 14 versions of the questionnaire. All refinements were re-evaluated in subsequent interviews in an iterative manner. Modifications focussed around clarifying instructions and phrases, and refining response categories to make them more intuitive. Interviewing continued and minor changes were made until the questionnaire was completed easily and only idiosyncratic comments arose. The final version (developmental ICIQ-LTCqol) contained 44 items and took 10 minutes to complete. Three items contained two part response frames enabling individuals to reflect differences between day and night time. Thirty seven items also contained a

subsequent section that addressed the perceived “bother” of the issue under investigation.

Phase 3

Postal survey

The developmental ICIQ-LTCqol was administered via 64 GP practices to 893 long-term catheter users in the South and South West of England. Completed questionnaires were returned by 370 individuals.

Content validity

Content validity was evaluated by analysis of the level of missing data in the returned postal questionnaires. The percentage of missing data per item was calculated for the complete baseline questionnaire data (n=370) and ranged from 2-48%. The question item referring to the participants’ leakage from the urethra at night displayed the highest level of missed data (48%), indicating a poorly performing item. The “bother” items also accounted for elevated missing data (7-46%) and for this reason were considered separately for the ongoing analyses. Three items evaluating *prevention of sex life*, *intimacy* and establishing *who in the relationship was affected* exhibited acceptable levels of missing data for such sensitive items, 6%, 8% and 6% respectively. With the identified items omitted, missing data ranged between 2 and 5% which is considered acceptable.

Reliability

The developmental ICIQ-LTCqol was completed twice by 108 individuals over a 2-3 week time interval to provide data on the stability of the questionnaire.

Stability

Reliability was evaluated by identical agreement between responses provided at each administration of the questionnaire. Over 90% of participants provided identical responses or only altered by one response category for nineteen items, suggesting stability over time. Fourteen items demonstrated “good” or “very good” agreement (0.61-

0.94 weighted κ statistic)**.** The one item considered to exhibit “very good” agreement was that which evaluated catheter type. This was expected to remain constant as no significant changes in catheter status were anticipated. The 13 items that demonstrated “good” agreement were to be strongly considered for the final questionnaire.

Internal consistency

All data from completed baseline questionnaires (n=370) were included in the evaluation of internal consistency. Cronbach’s alpha coefficient (α) was very high for the total set of question items at 0.96, indicating excellent internal consistency but also redundancy of some items. This was expected, given the exhaustive number of items contained in the developmental version.

Item reduction and factor analysis

The developmental ICIQ-LTCqol contained 44 question items; Cronbach’s alpha (α) indicated some item redundancy. Selecting items for the final questionnaire was necessary to provide the briefest but most comprehensive evaluation and to enhance acceptability to users **(Figure 1).** During initial item reduction eleven items were removed that offered little value to the final questionnaire due to high intercorrelation coefficients, high levels of missing data, poor evidence of reliability and issues that were rarely reported by users.

Preliminary factor analysis

Initial unrestricted exploratory factor analysis was conducted on the remaining 33 items. Six factors were identified with eigenvalues greater than one that explained 92.3% of the variance. Cronbach’s alpha coefficient was acceptable at 0.71, four items did not load onto a factor and the questionnaire was considered too long for practical purposes. Thus, further items were identified for removal by the clinical expert team. Repeated iterations of exploratory factor analyses according to the statistical findings, patient perspective and clinical opinion were conducted to identify the most appropriate arrangement for the final questionnaire. Judgment and subjective compromise by the

study team balanced the needs for a comprehensive questionnaire that was as brief as possible whilst demonstrating the strongest psychometric properties.

Final factor analysis

Factor analysis of an eventual 16 items identified two factors with eigenvalues greater than one that explained 100% of the variance. Exploration with Varimax rotation found factor loadings that ranged from 0.46 to 0.68. Nine items loaded heavily onto one factor (factor loadings: 0.46 - 0.68) and three items loaded onto the second factor (factor loadings: 0.64 - 0.67) (**Table II).** Four items did not load well onto any factor – pad use, pain, bladder spasm and prevention of sexual activity. However, these were identified as essential for inclusion from the clinical or users' perspectives, so were retained as standalone items. Cronbach's alpha value for these 16 items was 0.72 and for each domain indicated homogeneity with minimal redundancy: 0.76 for "catheter function and concern", 0.74 for "lifestyle impact". The final version contains three items to document gender, date of birth and catheter type. **Table III** shows the psychometric properties of the final measurement question items**.**

Derivation of the scoring system

The data for the domains of 'Catheter function and concern' and 'Lifestyle impact' had adequate Cronbach's alpha coefficients, reasonably consistent factor loadings and standard deviations so that simple additive scores were indicated and item weighting was not necessary. Two simple domain scores were inferred, requiring frequency responses largely coded 0 "never" to 4 "always". The four items that did not load well were included as unscored items due to their clinical utility. The unscored items exhibited acceptable reliability and had reasonable levels of missing data (2-6%). The inclusion of these items was therefore justified in terms of their psychometric properties.

Phase 4

Testing the scoring system

The final 16 item questionnaire was tested in a new population of long-term catheter users. A total of 26 primary care practices identified 438 individuals with long-term

catheters who then received the ICIQ-LTCqol through the post; 215 completed and returned the questionnaire (response rate 49%). A further 59 completed the questionnaire three weeks after the initial send-out to investigate the stability of the questionnaire.

Descriptive statistics were calculated for the domain scores from the new population data and evaluated for content validity and stability, as detailed below.

Catheter function and concern score

Values of the observed scores did not fully represent the extent of the possible scoring system although scores were achieved in the upper quartile of the available score. Missing data was low (0-5.1%) and the weighted Kappa statistic indicated good agreement (0.63) (**Table IV**).

Lifestyle impact score

Values of the observed scores represented the complete range of possible scores within this domain, supporting the ability of the ICIQ-LTCqol to detect varying levels of QOL impact. Although no items had complete data, none had more than 4.2% missed responses per item and agreement was good (Weighted Kappa statistic 0.77).

Discussion

The 16 item ICIQ-LTCqol is a psychometrically robust, valid and reliable addition to clinical and research practice. Its derivation from patient interviews and qualitative findings suggest it accurately reflects the content of the concept it claims to measure and performs in a consistent, stable and reproducible manner. Users can be confident that the questionnaire provides a legitimate and valid summary of the impact on QOL for those living with a long term indwelling catheter.

The question items are organised over two domains and takes less than ten minutes to complete by an individual or proxy. It provides a self-report evaluation in the specific

areas of ‘catheter function and concern’ and ‘lifestyle’ factors. The domains are underpinned by a scientifically justified clinical scoring system. Four further standalone questions ensure comprehensiveness.

This is the first tool to address QOL in long-term catheter users. An earlier tool, the C-IQoL[12] was psychometrically robust but excluded an initial qualitative exploration phase; rather the authors modified the original I-QoL[13] questionnaire to be catheter specific. The assumption that existing urinary incontinence items retain relevance to long term catheter users was correct in some cases, such as worry about smell. However, in our study more sensitive indicators were identified through the qualitative exploration, such as perceived confidence in catheter equipment, reinforcing the notion that “only those who experience symptoms can report on the more subjective elements”.[10]

Patient-centred terminology was also highlighted through the qualitative methodology. Themes appeared similar to question items already contained in the C-IQoL but the perspective of the question was distinctly different and considered to be more in tune with catheter users’ experiences. For example, catheter leakage is a significant factor for QOL evaluation. However in this study, leakage ‘being on the individual’s mind’ was found to be a more pertinent question than concerns about actually getting wet. This captures more accurately the impact of the ever present concern about catheter leakage, which is an alternative concept to the physical act of getting wet.

A further finding was that the catheter can have assistive rather than negative connotations traditionally incorporated into QOL measures. The lifestyle impact domain contains response frames iteratively developed by study participants that reflect this potential improvement to health related quality of life. The responses also reflect the complexity of co-morbidity causing an impact, rather than the catheter itself. The unique development process of the ICIQ-LTCqol enabled user-centred concepts to be captured and reflect the user experience.

Limitations

Response rates were less than 50% for both postal phases of this study which should be acknowledged as a potential issue regarding the acceptability and content validity of the questionnaire. It is recognized however that during phase three the questionnaire was a lengthy tool which increases respondent burden and can reduce response rates. During the questionnaire development stage there is a trade-off between; including a large number of items in order to gather sufficient data to provide evidence for removal or retention of the key questions for the resulting tool, and accepting that the large number of items is likely to reduce the response rate as has been evidenced in other questionnaire design studies[14]. In addition, it is highlighted that this population has a higher rate of comorbidities by comparison with other urological questionnaire design studies and questionnaires were not completed during clinic appointments or with known patient groups, which can significantly reduce the occurrence of non-response[15-17]. Therefore the reported response rates were considered encouraging. It is recommended to further evaluate questionnaires beyond their initial development studies in order to continue to strengthen the associated evidence base. Evaluation of response rates when using the ICIQ-LTCqol in research and clinical settings, and in specific populations, is therefore encouraged.

Sensitivity to change is the ability of a tool to detect change when real change occurs and will be a valuable addition to the psychometric properties profile for this tool. In the current study this evaluation was not possible as it requires examination of the questionnaire in a group who are undergoing intervention of known effect. This would be difficult as there are no evidence based catheter related interventions that have been shown to improve health related quality of life. We recommend that the ICIQ-LTCqol be incorporated widely into intervention trials to examine how it performs and to compare results with proxy indicators of improvement to provide data regarding sensitivity.

The generalizability of the results may be limited as the entire range of the ‘catheter function and concern’ scoring system was not utilised by the study population.

Observed scores did range into the upper third of available scores but were largely in the lower, less impacted, scoring range. This could suggest that individuals were less bothered by their catheter issues either due to the seriousness of their comorbidities or their fitness levels. We recommend further exploration of the ICIQ-LTCqol in a population who are specifically known to have more problematic catheters or those who are less well.

Conclusions

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. Reflecting the user's perspective is essential for health related quality of life evaluation and ascertaining whether experience of the catheter is acceptable or whether improvements should be sought. This was intrinsic to the development of the ICIQ-LTCqol ensuring clinical applicability and user relevance.

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