

ICIQ PROTOCOL FOR THE DEVELOPMENT OF ALTERNATIVE LANGUAGE VERSIONS OF THE ICIQ-UI SF: THE ARABIC ICIQ-UI SF

Hypothesis / aims of study

Research into the prevalence and impact of urinary incontinence in the Middle East is limited, and relatively little is known about the role of racial and ethnic differences in the prevalence of incontinence. Several self-completion questionnaires have been developed to assess incontinence, but most are lengthy and have been developed for use in specific patient groups. The ICIQ-UI SF has been developed to supply the need for a brief and simple questionnaire that can be used across the population in both clinical practice and research. The development of such a questionnaire would enable cross-cultural and cross-national comparisons to be explored. The ICIQ-UI SF comprises three scored items to assess the frequency, amount and impact on life of urinary incontinence (score range 0-21; higher score indicates greater severity) and an unscored self-diagnostic item to assess the perceived causes of leakage (1). It has been translated into 35 languages to date following standard guidelines, with psychometric confirmation being completed or ongoing in many languages. The development and validation of an Arabic version of the ICIQ-UI SF is reported here.

Study design, materials and methods

The ICIQ-UI SF was translated according to standard guidelines (2):

1. Literal translation and adaptation to the cultural context and lifestyle related to the Arabic language, undertaken by a bilingual native Arabic speaker.
2. Back-translation into English by a bilingual native English speaker.
3. Review of the back-translation by a panel of native English speakers to identify errors and discrepancies in meaning.
4. Modifications to the translation, and re-translation of items where necessary, to resolve problems and identify further discrepancies.
5. Second back-translation (as before).
6. Review of the back-translation (as before).
7. Pre-testing for equivalence to confirm content/face validity and acceptability by administration of the translated questionnaire to a sample of patients (n=20: 15 females, 5 males, mean age 45.7 years, range 19 to 77) presenting with varying levels and types of incontinence at urology clinics in two Middle-Eastern teaching hospitals.

The final Arabic ICIQ-UI SF was produced following minor adaptations. Studies were then undertaken, according to standard methods of psychometric testing, to confirm that the psychometric properties of the scale had been retained throughout the adaptation process:

- (i) *Content validity* - levels of missing data were examined to assess the acceptability of items in a sample of adults attending a urology clinic with varying levels of urinary incontinence (total baseline sample: n=131: 87 females, 44 males, mean age 37.8 years, range 18 to 73).
- (ii) *Construct validity* - the ability of the ICIQ-UI SF to reflect theories underlying urinary incontinence was examined in groups of individuals from the total baseline sample. The ability of the ICIQ-UI to detect a difference in the prevalence of different types of incontinence reported by men and women was investigated using chi square (χ^2) analysis (3). Univariable regression (3) was used to determine if the questionnaire could detect a difference in symptom severity between individuals with different types of incontinence.
- (iii) *Stability* - the reliability of the questionnaire was examined in a two week test-retest analysis of 102 patients (68 females, 34 males, mean age 37.7 years, range 17 to 73) attending urology clinics with varying levels of urinary incontinence. 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 (3).
- (iv) *Internal consistency* - the reliability of the ICIQ-UI was further investigated by Cronbach's coefficient alpha (α) (3) using data provided by the total baseline sample.

- (v) *Sensitivity to change* - the responsiveness of the questionnaire was assessed in a sample of individuals undergoing pharmacotherapy and/or macroplastique injectables for urinary incontinence (n=53: 35 females, 18 males, mean age 37.2 years, range 16 to 73). The percentage change in the presence of symptoms between baseline and follow-up (approximately four weeks) was calculated. The Wilcoxon signed ranks test (3) was used to determine whether symptom levels differed significantly. In addition, the difference between mean symptom scores at baseline and follow-up was examined using the one-sample paired t-test.

Significance was determined at the 5% level (3). Ethical approval was granted by the Local Research Ethics Committee.

Results

- (i) *Content validity* - missing data were rare (<1%) for all items, indicating that items are well interpreted and cover all important domains.
- (ii) *Construct validity* - the questionnaire clearly detected a statistically significant difference between the types of incontinence reported by males (9% stress, 71% urge and 2% mixed incontinence) and females (13% stress, 22% urge and 44% mixed incontinence) ($\chi^2=35.4$, $P<0.0001$), with stress incontinence more predominant in women than men, in contrast to men where urge incontinence was most commonly reported. There was also a statistically significant difference in scores between individuals with different types of incontinence ($P<0.0001$), with a greater level and impact among individuals with mixed incontinence (mean score 13.4) in comparison to those with stress or urge incontinence alone (mean scores 12.0 and 10.7 respectively).
- (iii) *Stability* - the three symptom items demonstrated excellent stability, with 89 to 99% of individuals reporting identical ratings or moving a maximum of one response category (e.g. from 'a small amount' to 'a moderate amount') between test and retest. These findings were supported by crude agreements of 94 to 97% and Kappa values of 0.83 to 0.91 ($P<0.0001$) for all items. Agreement between test and retest scores (mean 12.9 and 12.8, respectively) was also 'very good' (96%), with a Kappa value of 0.85 ($P<0.0001$).
- (iv) *Internal consistency* - the Cronbach's alpha coefficient for the three symptom items was 0.71, indicating a high level of internal consistency.
- (v) *Sensitivity to change* - there was an observed decrease (ranging from 25 to 26%) in the percentage of patients reporting symptoms on all three symptom items following treatment, each of which reached statistical significance ($P<0.0001$ for all). Symptom scores were also significantly improved following treatment (mean score 12.6 and 6.8 before and after respectively, $t=11.2$, $P<0.0001$).

Interpretation of results

Evidence has been found to confirm that the Arabic ICIQ-UI SF is valid, reliable and responsive, indicating that the psychometric properties of the questionnaire have remained constant throughout the adaptation process. Furthermore, the findings of the psychometric testing of the Arabic ICIQ-UI SF confirm those found for the UK-English ICIQ-UI SF.

Concluding message

It is important to adhere to standard guidelines when translating/adapting a questionnaire for use in alternative languages or cultures. There are approximately 280 million Arabic-speaking people in 22 Arabic countries worldwide. The development of the Arabic ICIQ-UI SF contributes to the development of a standard questionnaire that can be universally-used in clinical practice and research across the world. The universal use of the ICIQ-UI SF will enable the aggregation of data from different cultures and settings in multi-national studies, which are increasingly being conducted, and enable minority ethnic groups to be included in national studies that would otherwise be excluded, leading to bias.

References

1. The ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodyn* 2004; 23(4). (In press).
2. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol* 1993; 46: 1417-32.
3. 1991. Practical statistics for medical research. London: Chapman and Hall.