

STRESS URINARY INCONTINENCE AND QUALITY OF LIFE. RELIABILITY OF THE SWEDISH VERSION OF THE ICIQ-LUTSQOL IN PAPER AND ELECTRONIC FORM.

Hypothesis / aims of study

Stress urinary incontinence (SUI) is common in adult women. It may be very distressful and impact on quality of life is an important outcome in clinical practice and research settings. Electronic collection of data is becoming more common and has several advantages.

The International Consultation on Incontinence Modular Questionnaire (ICIQ) promotes the usage of high quality standardised instruments for the assessment of urinary incontinence and its impact on quality of life. Since its funding in 1998 several instruments have been developed by the ICIQ, among them the condition specific quality of life instrument ICIQ-LUTSqol.(1) The instrument consists of 19 items derived from the King's Health Questionnaire. All items are scored 1-4 and in addition each item has a scale of bother (1-10). The overall score is 19-76, with greater values indicating increased impact on quality of life. Bother scales are not included in the overall score. The instrument has been translated to several languages and has received the highest grade of recommendation from the National Institute for Health and Clinical Excellence.(2) It is established in terms of internal consistency, construct validity and responsiveness in women with SUI.(3) However the test-retest reliability has not yet been examined in this population, nor has it been tested in an electronic version. Thus the aim of this study is to examine the reliability of the Swedish paper and electronic versions of the condition specific quality of life instrument ICIQ-LUTSqol in women with SUI.

Study design, materials and methods

This reliability study was embedded in a randomised controlled trial (RCT) comparing a web-based treatment programme for SUI with a treatment programme sent by post. 250 women aged 18-70, with SUI at least once weekly were recruited via the project's website. The diagnosis of SUI was based on a validated questionnaire (ICIQ-UI SF), 2-day bladder diary and a telephone interview with urotherapist. Women with symptoms indicating need of physical examination were excluded. Both groups had 3 months of treatment, mainly pelvic floor muscle training. The paper version of the ICIQ-LUTSqol was used before randomisation and as part of the first follow-up.

The reliability of the instrument was examined as follows:

Internal consistency was evaluated by calculation of Cronbach's alpha values. For the paper version baseline data from all 250 women was used. Calculations for the electronic version were based on 54 women.

Test-retest was done in two different settings (1 and 2 below) and evaluated with intraclass correlations and Spearman's correlation coefficients of overall scores. Each individual item was further examined with weighted kappa values.

1. *Paper vs paper version* 103 women included in the RCT answered the paper version twice at baseline. Those who received more than a week of treatment before answering the instrument the second time were excluded (n=24) as well as those with <6 or >42 days between answering occasions (n=1). Calculations are based on 78 women.

2. *Paper vs electronic version* 56 women answered the instrument twice at the first follow-up, once in paper and once in electronic version. A link to the electronic version was sent to the women by email either before (n=19) or after (n=37) the follow-up. The electronic version was developed to look like the paper version as much as possible. Women with <6 or >42 days between answering occasions were excluded (n=2). Calculations are based on 54 women.

Data was analysed in SPSS version 18.0. The calculation of intraclass correlation is based on a two-way random anova model. Non-parametric test were used for comparison of groups.

Results

The mean age of the women included in the RCT was 48,6 (SD 10,2) years. The majority was highly educated, 54% had 3 years of university studies or more. Mean overall score in the ICIQ-LUTSqol before randomisation was 33,7 (SD 7,5). There were no significant differences between women included in the different parts of the reliability study compared with all women in the RCT.

Internal consistency

The Cronbach's alpha for the paper version was 0,87 and for the electronic version 0,86.

Test-retest

Paper vs paper version

Mean interval between answering occasions was 18,1 days (SD 3,1; range 14-28). Mean overall scores and their correlations are shown in Table I. Each individual item's weighted kappa value ranged from 0,46-0,84, mean 0,61 (SD 0,10). Weighted kappa values for bother scales ranged from 0,51-0,76, mean 0,62 (SD 0,07).

Paper vs electronic version

Mean interval between answering occasions was 15,0 days (SD 7,8; range 6-36). Mean overall scores and their correlations are shown in Table I. Each individual item's weighted kappa value ranged from 0,34-0,84, mean 0,61 (SD 0,13). Weighted kappa values for bother scales ranged from 0,37-0,70, mean 0,57 (SD 0,10). The order in which the two different versions were answered did not affect the results.

Table I. Test-retest analysis of the paper and electronic versions of the ICIQ-LUTSqol in women with stress urinary incontinence; overall scores with intraclass correlation and Spearman's correlation coefficients.

		Overall Score Mean (SD)	Intraclass Correlation	Spearman`s Correlation coefficient
Paper vs paper N=78	Paper 1	32,9 (8,1)	0,95*	0,90*
	Paper 2	33,1 (8,9)		
Paper vs electronic N=54	Paper	28,4 (6,8)	0,92*	0,86*
	Electronic	29,7 (7,0)		

* p<0,001. Figures in brackets are standard deviations (SD).

Interpretation of results

The ICIQ-LUTSqol is a reliable instrument that can be used for collection of quality of life data in women with SUI. This study adds new data on the reliability of the paper version of the instrument and shows that it can also be used in an electronic version. Intraclass correlation coefficients of > 0,8 demonstrate excellent test-retest reliability, Spearman correlation coefficients of > 0,5 indicate large correlations and weighted kappa values of 0,6-0,8 are considered good; criteria that are met in our results. In this study the majority of the women were highly educated and all of them were enough acquainted with the Internet to be able to register online. This should be taken into consideration before using the electronic version in other settings.

Concluding message

The condition specific quality of life instrument ICIQ-LUTSqol is reliable in women with SUI and it can be used in an electronic version.

References

1. Kelleher CJ, Cardozo LD, Khullar V, Salvatore S. A New Questionnaire to assess the quality of life of urinary incontinent women. BJOG 1997; 104:1374 -79.
2. Urinary incontinence: The management of urinary incontinence in women. Nice clinical guidelines. London 2006.
3. Coyne K, Kelleher C. Patient reported outcomes: The ICIQ and the state of the art. Neurourol Urodyn 2010; 29:645-51.

Specify source of funding or grant	Swedish Council for Working Life and Social Research. Jämtland County Council, Sweden. Västerbotten County Council (ALF), Sweden.
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	The Regional Ethical Review Board in Umeå nr08-124M 2008-09-16 + additional decision 2009-11-05.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes