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FURTHER VALIDATION OF THE ICIQ-SF IN A CLINICAL TRIAL POPULATION

Hypothesis / aims of study
The ICIQ-SF was developed by an expert committee established by the International Consultation on Incontinence (ICI) and the validation data have been published previously [1]. The purpose of our work is to further evaluate the reliability and construct validity of the ICIQ-SF in a clinical trial population.

Study design, materials and methods
The ICIQ-SF was administered to 760 incontinent women with stress, urge or mixed urinary incontinence in an ethical committee approved clinical trial. Women also completed a validated incontinence-specific quality of life questionnaire (Incontinence Quality of Life questionnaire; I-QOL) and a validated global impression of severity question (PGI-S) [2]. The ICIQ-SF consists of three scored items (frequency of leakages, usual amount of leakages and the impact on daily life) and a self-identification of symptoms item. The total score is the sum of the three scored items yielding a score ranging from 0 to 21 with higher scores indicating more severe incontinence and impact. The I-QOL total score ranges between 0 and 100 (worst and best possible condition-specific quality of life, respectively). The PGI-S is a one question single-state scale that asks patients to rate their bladder condition as normal, mild, moderate or severe. The test-retest reliability of ICIQ-SF after 3 days was evaluated using the intra-class correlation coefficient (ICC). ICCs above .60 suggest satisfactory stability and ICCs greater than .80 are excellent [3]. Women were also asked to start keeping incontinence diaries for 7 days approximately one week after completing the second ICIQ-SF. Incontinence episode frequency per week (IEF) was computed from these diaries. The construct validity of the ICIQ-SF was assessed using the Spearman's correlation coefficients comparing the ICIQ-SF with IEF, I-QOL and PGI-S.

Results
701 women completed both test and re-test ICIQ-SF questionnaires. Intra-class correlations and the 95% confidence lower limits are presented in Table 1. The total score and interference with daily life item had excellent stability (both ICCs = .83). Items measuring the frequency of leakage and the usual amount of leakage had lower but acceptable ICCs. Correlations between the ICIQ-SF and the three measures of incontinence are presented in Table 2. As expected, higher correlations between the incontinence frequency item and the IEF and between impact item and I-QOL were observed. Correlations between all items and total score with the PGI-S were moderate.

Table 1. Intra-class Correlations (ICC) for reproducibility of ICIQ-SF

Item	ICC	95% Lower Limit
1 (frequency of leakage)	.66	.81
2 (usual amount of leakage)	.68	.64
3 (interference with daily life)	.83	.63
Total (items 1+2+3)	.83	.81

Table 2. Spearman's correlations between ICIQ-SF and three measures of incontinence (all $p < .001$)

Item	IEF (n=688)	I-QOL (n=758)	PGI-S (n=760)
1 (frequency of leakage)	.49	-.27	.25
2 (usual amount of leakage)	.28	-.38	.35
3 (interference with daily life)	.31	-.60	.38
Total (items 1+2+3)	.42	-.62	.44

Interpretation of results
Excellent ICCs for the interference with daily life item and the total score and acceptable ICCs for the other two items were observed. The lower ICC for the frequency and amount of leakage items were most likely due to the fact that the frequency and amount of leakages have higher inherent variability. Although women are asked to report the frequency and usual amount of their leakages, they may still be biased by the frequency and amount of leakages on the days immediately before they complete the questionnaire. Significant though moderate correlations between the ICIQ-SF total score and the three outcome variables measuring different aspects of incontinence confirm the construct validity of the ICIQ-SF total score. Very strong correlations are not desirable since they often indicate a redundancy between the questionnaire of interest and the other measures (that is they may be measuring exactly the same thing). The association between the frequency item and the IEF from the diary is limited by the structure of the question (grouping the number of leakages into 6 nonlinear categories as opposed to asking exactly how often leaks occurred).

Concluding message
The ICIQ-SF is a reliable and a valid measure of the severity and impact of stress, urge and mixed type of incontinence in a clinical population.

1. ICIQ: A brief and Robust Measure for Evaluating the Symptoms and Impact of Urinary Incontinence. Neurouol Urodynam 2004;23:322-330
2. Validation of two Global Impression Questionnaires for Incontinence. Am J Obstet Gynecol 2003;189:98-101
3. The Measurement of Observer Agreement for Categorical Data. Biometrics 1977;33:159-174