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THE FLOW STUDY: VALIDATION OF FOUR QUESTIONNAIRES ON SYMPTOMS AND QUALITY OF LIFE IN ITALIAN WOMEN WITH LUTS

Aim of Study

No validated questionnaires are available for assessing symptoms and quality of life (QOL) in Italian women with LUTS. More in general, little is known about the impact of LUTS and the related bother on QOL in women.

In the context of a large multi-centre observational study of women with LUTS (FLOW-Female LUTS: Observational Study in Women), we translated into Italian and validated three female-specific questionnaires: 1) ICIQ-LF Female [the long form of the ICI questionnaire]; 2) ICIQ-SF [the short form of the ICI questionnaire]; 3) UDI [the Urogenital Distress Inventory]. Moreover, we tested whether a modified version of IPSS [the International Prostate Symptom Score] can be applied to women. In it, the QoL single question refers to urinary symptoms generically, in spite of the specific reference to prostatic disease of the original IPSS. This new version was named W-IPSS [Women IPSS].

Methods

The validation process consisted of the following steps: forward and backward translation, test of comprehension, discriminant validity (i.e., the ability of the questionnaire to discriminate between healthy and ill subjects) and test-retest reliability (i.e., stability of responses over a short period). We translated questionnaires into Italian following the standard procedure, as detailed in Knudsen et al (2000). The comprehension of questionnaires was tested by interviewing women after they had filled in the questionnaires. A comprehension rate was built for each questionnaire as the percentage of correctly understood questions and pre-coded answers of all items by all patients. A case-control study was then performed. Cases were defined as women aged = 18 year affected by LUTS from at least 3 months and with negative dipstick. Controls were defined as healthy women of comparable age. All women were enrolled consecutively. Both cases and controls filled in two questionnaires (Table 1). In order to evaluate reliability, cases were retested after 7 days and a correlation analysis was performed between the first and the second measurement (Pearson's r). Discriminant validity was assessed by comparing the scores of cases and controls with ANOVA.

Table 1 – Sample size for each questionnaire

	ICIQ- LF	ICIQ- SF	UDI	W-IPSS
Comprehension	15	10	10	15
Cases – Visit 1 (Retest)	71 (69*)	50 (46*)	54 (53*)	75 (74*)
Controls	81	50	56	83

*Questionnaires available for test-retest analysis

Results

In general, 93.5% of items were easily and correctly understood by patients. The average test-retest correlation coefficient ranged between 0.75 for UDI and 0.86 for ICIQ-SF. Correlation coefficients were statistically significant for all questionnaires items. The questionnaires were generally able to discriminate between healthy and ill subjects.

For ICIQ-LF the comprehension rate was 99.4%. Four out of 16 patients did not understand "hesitancy" (item 30) correctly: therefore it was retranslated into Italian. The average test-retest correlation coefficient between ratings was 0.84 and was greater than 0.9 for more than 15 items ($p < 0.0001$ for all). Distribution of responses was statistically ($p < 0.001$) different in cases and controls, with the exception of sexual matters and QOL related to daily activities.

ICIQ-SF was well understood by all patients, with a comprehension rate of 99.1%. A high and significant correlation between ratings was also observed: r ranged from 0.91 to 0.94

($p < 0.0001$) for items 3 (frequency of leakage), 4 (quantity), 5 (impact on daily life), while being lower (0.64) for item 6 (circumstances of leakage). Cases and controls were discriminated at ANOVA ($p < 0.001$).

As far as UDI is concerned, "daytime frequency", "urgency", "incontinence", "incomplete voiding" and "push on vaginal walls to have bowel movement" were found difficult to understand by patients (2 subjects out of 10). The average test-retest correlation coefficient was 0.8 for symptoms ($p < 0.001$) and 0.72 for its associated bother ($p < 0.001$). The presence or absence of symptoms discriminated healthy from ill patients.

Finally, in W-IPSS two items were difficult to understand for more than 25% of cases ("intermittency" and "nocturia"). The average test-retest correlation coefficient between ratings was 0.76 ($p < 0.0001$). "Intermittency" had the weakest correlation coefficient ($r = 0.57$). ANOVA differentiated cases from controls at all items.

Conclusions

These data of the validation process of the 4 questionnaires show that they are generally easy to understand, and have a good to excellent reliability and a high discriminant validity. Overall, the questionnaire with the best psychometric properties appears to be the ICIQ both in the long and short form. The validation process is still in progress. Further analyses are planned in order to test internal consistence, construct validity (by comparing questionnaires to uroflowmetry, voiding diary and SF-36) and sensitivity to change (by rating questionnaires again after a 1-year follow up).

Reference

Knudsen HC, Vazquez-Barquero JL, Welcher B, Gaite L, Becker T, Chisholm D, Ruggeri M, Schene AH, Thornicroft G (2000). Translation and cross-cultural adaptation of outcome measurements for schizophrenia. EPSILON Study 2. European Psychiatric Services: Inputs Linked to Outcome Domains and Needs. Br J Psychiatry Suppl 2000;(39):s8-14.