214

Artibani W[1], Pesce F [2], Prezioso D[3], Scarpa R[4], Tubaro A[5], Zattoni F[6]
1. University of Padua, Padua, Italy, 2. Policlinico GB Rossi, Verona, Italy, 3. Federico II University, Naples, Italy, 4. San Luigi Gonzaga Hospital, Turin, Italy, 5. S. Andrea Hospital, Rome, Italy, 6. S. Maria della Misericordia Hospital, Udine, Italy

VALIDATION OF THE UROGENITAL DISTRESS INVENTORY IN ITALIAN WOMEN WITH LUTS. THE FLOW STUDY.

Hypothesis / aims of study
The Urogenital Distress Inventory (UDI) is a condition-specific 19-items questionnaire comprising 3 domains: symptoms related to stress urinary incontinence (SUI: 2 items), detrusor overactivity (i.e. irritative symptoms or IS with 6 items), and bladder obstruction (i.e. obstructive/discomfort symptoms or 'OS' with 11 items). Each domain investigates specific information about absence/presence of symptoms as well as the relative degree of bother for each symptom. According to updated literature, internationally UDI is a highly recommended questionnaires for assessing urinary incontinence symptoms (Donovan et al 2002).
Prior to our study, no validated questionnaire was available in the Italian language for assessment of UI symptoms and bother altogether. UDI was thus validated by the FLOW study group according to international standard procedures for psychometric and linguistic validation, and administered to a sample of Italian women with lower urinary tract symptoms (LUTS).
Study design, materials and methods
The validation process consisted of forward and backward translation, test of comprehension, discriminant validity, test-retest reliability and internal consistency test. A first set of women was interviewed after they had filled in the questionnaires. A comprehension rate was built as the percentage of correctly understood questions and pre-coded answers of all items on a small group of subjects. 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. 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. Cronbach's alpha was calculated for internal consistency analysis. Analyses took into account total UDI score and subscale scores. The latter are obtained by transforming the mean value of all responded items into a 0-100 score. The total score is the sum of the subscale scores.
Results
Nine women completed the comprehension test. 53 cases and 53 controls were then enrolled. All cases were eligible for the test-retest.
The comprehension rate was 97.1%: two out of 9 patients did not correctly understand the correct time frame; however the original version was generic too, therefore the questionnaire was not changed.
The calculated value of Cronbach's alpha was 0.70 and 0.80 for SUI and OS respectively; whereas a lower value resulted for IS and total score (about 0.65 for each score). When the items regarding "bedwetting" or "large amount of leakage" were excluded from IS scale, Cronbach's alpha increased up to 0.70.
Pearson's coefficients between ratings were 0.42, 0.37, 0.94, 0.9 respectively for IS, OS, SUI, and total score ($p<0.001$). Cases and controls were discriminated by ANOVA ($p<0.001$) for all scores.
Interpretation of results
A high correlation between ratings was observed for SUI and total score- indicating a good test-retest reliability - whereas much variability was found for IS and OS. This might be due to the fact that the latter subscales are composed by a higher number of items than SUI scale, thus more susceptible to subjective variations.
Internal consistency is generally considered 'good' when the alpha coefficient value is >0.7. Alpha coefficients calculated for all subscales were above 0.7, except IS. In this domain, day-, night- time frequency and urgency were significantly correlated each other (Pearson's $r>=0.34$, $p<0.001$), whereas "bedwetting" and "large amount of urine leakage" were not.

Concluding message

These data show that the UDI questionnaire is generally easy to understand, internally consistent, has a good reliability and a high discriminant validity. These data also confirm psychometric properties which were observed in the original version.

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