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ITALIAN VALIDATION OF PELVIC PAIN AND URGENCY/FREQUENCY PATIENTS SYMPTOMS SCALE (PUF) QUESTIONNAIRE

Hypothesis / aims of study
In 2000 Parsons et al. developed a new questionnaire for Interstitial Cystitis/Pain Bladder Symptoms (IC/PBS) titled "the Pelvic Pain and Urgency/Frequency (PUF) Patient Symptom Scale" on the basis of their clinical experiences (1). As a tool for estimating IC/PB symptoms, the PUF scale is for grading pelvic pain including intercourse related symptoms, various urination bother symptoms, and the consequent discomfort. Parsons et al. argued that this questionnaire can be used in predicting the results of the potassium sensitivity test (PST), and can be helpful in diagnosing IC/PBS in all patients presenting with pelvic pain or bladder pain. The purpose of this study was to translate the English-written PUF scale into an Italian version that objectifies the degree of the symptoms in order to diagnose IC/PBS and to assess the linguistic validation of the Italian version in a population of IC/PBS patients versus healthy volunteers . We aimed for domestic researchers to be able to use the Italian version in clinical research and in the clinical treatment of domestic IC/PBS patients.

Study design, materials and methods
The original English version of the PUF was first translated into Italian by two independent professional translators, both native Italian speakers (forward translation). The two translations were compared and examined in a meeting between the translators (reconciliation). Afterwards, a panel of physicians, expert in IC/PBS, judged the translation to determine its accuracy and equivalence to the English version and to determine content validity. A native English speaker fluent in spoken Italian, who was not involved in the first translation, then retranslated the Italian version of the questionnaire into English. Both physicians and English native-speaker translator examined this translation-back-translation process, until all participants agreed that the original and back-translated version were equivalent. The final version was administered to a study population of patients affected by IC/PBS and a convenient sample of healthy volunteers. The study population was a sample of Italian patients (male and female). Participants were enrolled during urological visits in italian urogical outpatient centers. Inclusion criteria were: (i) over 18 years of age (ii) ability to read and write Italian (iii) absence of any previously diagnosed neuropsychiatric disorders that could influence responses to the questionnaire, (iv) recent diagnosis of IC/PBS (v) no specific treatment for IC/PBS. Exclusion criteria were (i) other known causes of pelvic pain (bacterial cystitis with positive urine culture, oncological causes, bladder stones), (ii) use of urological/neurological medications like anti-cholinergic or antipsychotic medications, (iii) neurological disorders that might result in voiding dysfunction (iv) recent surgery of the urinary tract. Data on LUTS (in terms of frequency, nocturia, urgency, dysuria, and pain according to the International Continence Society definition) were prospectively collected. Each patient also completed the PUF symptom scale questionnaire at baseline and two weeks later. Investigations including blood tests (routine renal and liver function tests), urine tests (culture and citologic), renal ultrasonography, cystoscopy with hydrodistension. All patients were assessed, counseled, and followed up by urologists from each centre. The test-retest reliability of the questionnaire was tested on IC/PBS patients and in healthy volunteers with a negative history of IC/PBS. The translated Italian version of the questionnaire was filled in by them twice with a 2-weeks interval and the test-retest reliability was analyzed. We determined a coefficient of internal consistency for each question and domain (symptoms score and bother score) as well as for the PUF total score of both questionnaires (baseline and after 2 weeks). The reliability of the questionnaire was calculated using Cronbach's alpha, which was considered weak, moderate or high if the value was found less than 0.6, between 0.6 and 0.8, or equal to or greater than 0.8, respectively. The test–retest reliability was assessed for all patients in the sample by calculating Pearson's concordance correlation coefficient for each question and domain and for the total score, both at baseline and after 15 days (r range between −1.00 to +1.00, where +1.00 indicates the strongest positive association). Discriminatory ability of the questionnaire was then evaluated by the Mann-Whitney U test of the scores of the healthy individuals and the patients. Moreover, Pearson's Correlation Coefficient was used to verify the correlation between PUF score and severity of LUTS, cystoscopic findings and bladder capacity.

Results
Fifty healthy volunteers with a negative history of IC/PBS and 40 patients with IC/PBS associated LUTS filled out the questionnaire. Of the former fifty healthy individuals 17 were males and 33 were females, all the participants completed the questionnaire the second time 2 weeks after the initial assessment. Their mean age was 30 (range, 19-45) years. The mean PUF (± standard deviation [SD]) total score was 2.2 ± 2.5 (mean symptom score, 1.7 ± 1.3; mean bother score, 0.7 ± 2.1). Regarding the patients, 4 were male and 36 were female. Their mean age was 52 (range 33-74) years. Their mean PUF (± SD) total score was 24.29 ± 7.3 (mean symptom score, 15.35 ± 4.7; mean bother score, 8.9 ± 2.8).
The test-retest reliability coefficients for symptom score, bother score, and total score were 0.853, 0.864, and 0.855, respectively (P<0.001 for all three). The overall Cronbach's alpha was 0.974. The Mann-Whitney U test revealed significant differences between scores of the 50 healthy patients and 40 with IC/PBS (U=1.50, Z= –4.93 for symptom score: U=0, Z= –4.91 for bother score: U=0, Z= –4.95 for total score; P<0.001 for all three). Common presenting LUTS in 40 patients included: urgency (36 patients, 90%), frequency (38 patients, 95%), nocturia (35 patients, 87,5%), dysuria (40 patients, 100%), and pelvic pain/bladder pain (40 patients, 100%). The PUF score correlated well with the presence/absence of each individual LUTS component: urgency (P=0.002), frequency (P=0.009), nocturia (P<0.001), dysuria (P=0.002), and pelvic pain (P<0.001). All 40 patients underwent cystoscopy with hydrodistension and renal ultrasonography. In 17 out of 40 (42.5%) of the patients grade 3 glomerulations were found, grade 2 in 13 out of 40 (32,5%) and grade 1 in 10 out of 40 (25%). No alterations were found in renal and bladder

ultrasonography. Higher mean PUF total scores were noted in patients with grade 3 glomerulation cystoscopic findings (P=0.024). Mean bladder capacity at hydrodistension were 460 ml (± 120 ml). A higher PUF score was associated with smaller bladder capacity (correlation= –0.497, P=0.001).

Interpretation of results

Parsons et al proposed the PUF scale as a non-invasive and accurate diagnostic tool in the assessment of patients with interstitial cystitis (1-2). A PUF score of 15 or higher was associated with an 84% chance of a positive with the intravesical potassium sensitivity test.

The test-retest reliability was demonstrated based on 90 pairs of Italian version of PUF scales (50 from healthy volunteers and 40 from IC/PBS patients) of completed 2 weeks, which resulted in a reliability coefficient of 0.97. The Mann-Whitney U test for the scores between healthy individuals and IC/PBS patients confirmed the good discriminatory ability of the questionnaire in patients with different severity of LUTS. Our results demonstrated that the PUF score related well to symptom severity, presence of frequency, nocturia, urgency, dysuria, and pain and it was closely related to investigation outcomes especially endoscopically and with bladder capacity.

Concluding message

The Italian version of PUF questionnaire is reliable and has good discriminatory ability for assessment in patients with IC/PBS. The PUF score correlates well with symptom severity as well as endoscopic abnormalities and bladder capacity in patients with IC/PBS.

References

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