The Italian Linguistic Validation of the Ureteral Stent Symptoms Questionnaire

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Purpose: We validated the Italian version of the Ureteral Stent Symptoms Questionnaire in male and female patients with an indwelling ureteral stent.

Materials and Methods: A double-back translation of the original Ureteral Stent Symptoms Questionnaire was performed by 3 urologists and 4 professional translators. A total of 78 patients (cases) with and 35 healthy subjects without (controls) an indwelling ureteral stent were asked to complete the Italian version of the Ureteral Stent Symptoms Questionnaire and a visual analog scale for pain as well as the International Prostate Symptom Score (men) and Urogenital Distress Inventory-6 plus Incontinence Impact Questionnaire-7 (women). Cases were evaluated at weeks 1 and 4 after stent placement, and at week 4 after removal, while controls were evaluated once. The psychometric properties of the questionnaire were analyzed.

Results: A total of 66 cases and 30 controls were suitable for analysis. The questionnaire showed good internal consistency in all domains except global quality of life compared with that of the International Prostate Symptom Score (Cronbach's α >0.75). Test-retest reliability was good except for the sexual matters domain (Pearson's coefficient >0.7). Relatively high correlation coefficients (greater than 0.65) were found for the visual analog scale for pain, the International Prostate Symptom Score, the Urogenital Distress Inventory-6 and the Incontinence Impact Questionnaire-7 with the corresponding Ureteral Stent Symptoms Questionnaire domains, suggesting good convergent validity. Sensitivity to change and discriminant validity were also good ($p < 0.001$).

Conclusions: The Italian version of the Ureteral Stent Symptoms Questionnaire is a reliable and robust instrument that can be self-administered to male and female Italian patients with an indwelling ureteral stent in the clinical and research settings.

Key Words: ureter, stents, questionnaires, Italy, quality of life

Ureteral stenting has become a routine part of the urological armamentarium but stent related discomfort is reported in a high proportion of patients (up to 80%) with a negative impact on health related QOL.[1] Therefore, the need for validated instruments to objectively measure the symptom complex and assess its influence on daily activities is warranted so that appropriate treatments can be tailored.

Recently Joshi et al developed and internally validated the USSQ, a self-administered, multidimensional instrument exploring stent related morbidity in 6 sections, including urinary symptoms, body pain, general health, work performance, sexual matters and additional problems.[2] Each section comprises several questions, of which the answers are summed to allocate an index score.

We translated and validated the USSQ in Italian. We also determined the correlation of its domains with corresponding established clinical outcome measures, such as a VAS for pain,[3] I-PSS[4] in men, and UDI-6[5] and IIQ-7[5] in women.

PATIENTS AND METHODS

Translation Process

Linguistic validation of the USSQ was performed through a multistep process, as recommended by Hutchinson et al.[6] The questionnaire was initially forward translated from English into Italian in parallel by 2 independent, native Italian speaking professional translators with English as the first foreign language. They tried and used a simple language that could be readily understandable even by individuals with a low sociocultural level. A first consensus meeting between the translators and 3 of us (GG, FM and CS) with professional experience in English speaking countries was done to compare the 2 versions and solve small differences, yielding a first consensus Italian version. Back-translation of this version was then done in parallel by 2 independent, native English speaking professional translators with Italian as the first foreign language. A second consensus meeting was held between the English mother tongue translators and all investigators, during which the original and back-

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translated versions were compared and their discordances were debated, resulting in a revision of the first consensus version. This revised translation was subsequently corrected for spelling and grammar by an Italian university teacher and the definitive version was edited and drafted. Finally, a pilot test was performed to assess whether the questionnaire was clear and appropriate by face-to-face interviews in 5 male and 5 female patients with an indwelling ureteral stent. No difficulties were reported in completing it and, thus, no further changes were made.

Subjects

A total of 78 consecutive male and female patients (cases) who were referred to the department of urology at University of Pisa during a 12-month period and who underwent Double-J® ureteral stent placement were enrolled in the current study. Inclusion criteria were unilateral temporary stent insertion for acute benign ureteral obstruction or placement after diagnostic/therapeutic upper urinary tract procedures. Exclusion criteria were 1) a history of or current treatment for lower urinary tract symptoms, chronic bacterial prostatitis, chronic pelvic pain syndrome and prostate cancer in men, 2) stress/urge/mixed urinary incontinence, lower urinary tract dysfunction and pregnancy in women and 3) chronic ureteral obstruction, obstruction due to malignancy, bleeding diathesis, history of bladder cancer, recurrent urinary tract infections, overactive bladder syndrome, neurological and psychiatric diseases and concomitant medication with α-blockers, anticholinergics, analgesics and other drugs, possibly interfering with lower urinary tract function or pain assessment, in men and women. We also excluded cases of complicated ureteroscopy, defined as 1) mucosal injury, edema or perforation, 2) multiple, large (more than 2 cm) or impacted stones, 3) stricture or 4) operative time exceeding 30 minutes. The same type of 6Fr Double-J ureteral stent (Percuflex®) of 3 lengths (26, 28 and 30 cm, respectively) according to patient height was inserted in all cases by experienced urologists.

During the same period 35 age matched male and female individuals (controls) who were referred to our outpatient clinic for preventive ultrasound and who had no history of major chronic diseases, reported no symptoms, and were found to be healthy and without a ureteral stent were also enrolled.

All subjects were fully informed about the purpose of the study, which was approved by the institutional review board. All provided written informed consent and completed a preliminary questionnaire about personal details, such as age, geographic area, education level, employment status, and urinary and sexual function.

Study Design

The Italian version of the USSQ was self-administered to all cases at weeks 1, 4 and 8 after stent placement. In all cases the stent was removed at week 4 after administering the questionnaire. We expected that symptoms would have been completely resolved 4 weeks after stent removal and answers to post-stenting questionnaire would be representative of the background pre-stenting condition. In addition, all cases were asked to complete a VAS for pain and the I-PSS (men) or UDI-6 and IIQ-7 (women) at the same times. Since a validated Italian version of the UDI-6 and IIQ-7 questionnaires was not available at enrolment, an Italian adapted version was administered.

Controls were evaluated with all questionnaires only once. It was in fact assumed that patients with an indwelling stent could be seen again within a few weeks because of clinical reasons, while controls would not be seen. Therefore, to let the study design fit clinical practice test-retest reliability was performed in cases only.

To assess reliability and validity the Italian version of USSQ was administered to cases at weeks 1, 4 and 8. Internal consistency was evaluated at weeks 1 and 4. Test-retest reliability was evaluated by comparing the scores at weeks 1 and 4.

Convergent validity was assessed by correlating the scores of some USSQ domains to those of corresponding validated measures. For study purposes the original additional problems section was split into 2 subsections, which were analyzed separately. The former, referred to as the additional problems section, comprises the 4 questions A1 to A4 and the latter comprises only the GQ on global QOL. The correlations were 1) the body pain index to the VAS for pain 2) the urinary symptoms index to the I-PSS and the single question on global QOL in the additional problems section to the single QOL question in the I-PSS in men, and 3) the urinary symptoms index to the UDI-6 and the general health index to the IIQ-7 in women.

Sensitivity to change was assessed by comparing scores with the stent in situ and after removal. Discriminant validity was evaluated by comparing the results of cases at week 4 with those of controls.

Statistical Analysis

Sample size calculation was based on convergent validity. The minimum number of subjects with stent per sex, ie 35, was estimated according to certain variables, including a correlation coefficient between the USSQ and individual questions of other validated questionnaires of at least 0.56 (the lowest found in the validation of the original questionnaire[2]), $\alpha = 0.05$, $\beta = 0.10$ and a response rate of at least 80%.

Most variables were nonnormally distributed according to the Kolmogorov-Smirnov test for normality. Internal consistency was evaluated by calculating Cronbach's α for each

TABLE 1. *Assessable study population baseline characteristics*

	Cases		Controls		p Value
No. subjects	66		30		
Male/female ratio	35/31		15/15		0.92
Median age (IQR)	57 (42–67)		53.5 (40–62)		0.56
No. Italian geographic origin (%):					0.65
North	9	(14)	5	(17)	
Central	36	(54)	16	(53)	
South	21	(32)	9	(30)	
No. education (%):					0.74
Primary school	17	(26)	7	(23)	
High school	35	(53)	15	(50)	
University	14	(21)	8	(27)	
No. employment status (%):					0.69
Student	3	(5)	1	(3)	
Employed	43	(65)	21	(70)	
Retired	20	(30)	8	(27)	
No. sexually active (%):					0.58
Yes	51	(77)	24	(80)	
No	15	(23)	6	(20)	

No subjects were unemployed.