The Modified Urdu version of International Prostate Symptom Score: A psychometric validation study

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ABSTRACT

Objective: The objective of the current study was to develop an Urdu version of the International Prostate Symptom Score (IPSS-U) and validate it for Pakistani patients suffering from lower urinary tract symptoms (LUTS).

Material and Methods: IPSS-U was developed by a two-step forward and back translation and to evaluate its psychometric properties, a prospective study involving patients suffering from LUTS (n=267) was conducted at Outpatient Urology Department, Mayo Hospital, Lahore, Pakistan. Internal consistency and reproducibility were assessed using Cronbach's alpha and the Intra-Class Correlation Coefficient (ICC). Moreover, exploratory, and confirmatory factor analyses were performed to determine dimensionality of IPSS-U items.

Results: Overall reliability of IPSS-U was satisfactory (Cronbach's alpha=0.72, ICC of symptom questions=0.92 and ICC of QOL index=0.75). Exploratory factor analysis revealed that two factors were consistent, which together explained 59.8% of the variance. IPSS-U items 1, 3, 5 and 6 were components of the first factor whereas item 2, 4 and 7 were components of the second factor. All the items loaded high on their factors and there were no cross loadings. Moreover, confirmatory factor analysis also showed two-factor model, with acceptable fitting patterns.

Conclusion: IPSS-U is a valid and reliable non–gender specific instrument to assess the frequency and severity of LUTS in Urdu-speaking population.

Keywords: Lower urinary tract symptoms; patient-reported outcome measures; psychometric.

Introduction

The term lower urinary tract symptoms (LUTS) includes all urological symptoms related to voiding, storage and post-micturition, which are considered to be progressive, age-related, non-sex specific, non-organ-specific and have a negative impact on patient's quality of life (QOL).[1] International Prostate Symptom Score (IPSS)[2] is used frequently to quantify these symptoms not only in clinical practice but also in research. Although IPSS was originally designed to assess benign prostatic hyperplasia-related LUTS, it is widely used and acknowledged as a validated, non-disease specific and non-sex specific questionnaire.[3-6]

IPSS is an 8-item questionnaire (7-items to assess LUTS and one QOL question). The first seven items assess the frequency and severity of urinary symptoms; incomplete bladder emptying, frequency of urination, intermittency, urgency to urinate, poor urinary stream, straining and nocturia. These questions are scored from 0 to 5 and total symptoms score is obtained by adding the scores of all the seven questions (range 0-35). Scores of 0-7, 8-19 and 20-35 are graded as mild, moderate and severe LUTS, respectively. The 8th question assesses the disease-specific QOL using a scale of 0-6, with 0 indicating "delighted" and 6 "terrible". The IPSS has been translated and validated in many languages of the world.[6-11] However, it

has not been translated and validated in Urdu language which is a national language of Pakistan, and being spoken in several Asian countries. Therefore, the Urdu version of IPSS may not only be useful in assessing the severity of LUTS in Urdu speaking patients and guiding patient management but it is also an important research tool. Therefore, the aim of the current study was to develop an Urdu version of IPSS called IPSS-U and perform its psychometric analysis.

Material and methods

This prospective, psychometric validation study had two phases; the first phase involved the development of IPSS-U, whereas the second phase involved the psychometric analysis of the instrument.

Development of International Prostate Symptoms Score-Urdu (IPSS-U)

As per the guidelines of International Society of Pharmacoeconomics and Research Outcomes guidelines,[12] forward translation of IPSS was performed by two Urdu translation experts of the Oriental College, University of the Punjab, Lahore, Pakistan. Discrepancies in the Urdu version were settled and this version was reviewed by two urologists and 4 non-urologists. The Urdu version was back translated into English by two independent experts from the Department of English Language and Literature, University of the Punjab, Lahore, Pakistan. Discrepancies between the back translation and the original English version were settled by the investigators and final version of the instrument was developed.

Face and content validity

Face and content validity, and cultural compatibility were determined in a pilot study.[13] Findings of this study indicated that majority of the participants were not able to understand the response options of the first six items. Keeping in view of the findings of this study, response options of the first 6-items of IPSS-U were revised to a new 6-point Likert-scale of "not at all", "seldom", "sometimes", "often", "usually" and "almost always" which was understandable to all.

Psychometric testing of IPSS-U

Participants for psychometric analysis of IPSS-U were recruited from the Mayo Hospital, Lahore, Pakistan, during a period of 6 months (August 2016-January 2017). All adult patients with LUTS visiting the outpatient urology department at the said institute were eligible for inclusion in the study. Individuals aged<18 years, illiterate, catheterized, refused to participate or too ill to give consent were excluded from the study.

The first author approached the eligible patients and explained the aims and objectives, procedure and the nature of the study.

Those willing to participate were enrolled in the study and administered IPSS-U. Contact details were also obtained from the study participants for the test-retest procedure and the participants were contacted within 14 days of enrollment by the first author who administered the IPSS-U by telephonic interview. A period of two weeks is long enough to prevent recall but short enough to ensure that clinical change is unlikely to have occurred. The participants were asked to report the change in their health state since the first time they filled out the questionnaire. Those who reported no change in their complaints were included to determine test-retest reliability.

Ethical approval

The Human Ethical Committee of Punjab University College of Pharmacy, University of the Punjab, Lahore, Pakistan, reviewed and approved the protocol of the study. Moreover, permission from the Medical Superintendant, Department of Urology (Unit-I), Mayo Hospital, Lahore, Pakistan, was also obtained. All study procedures were performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. An informed consent was obtained from every individual prior to enrollment. Patients were assured about the confidentiality of their responses and their right to withdraw from the study with no penalty or adverse effects on their treatment.

Statistical analysis

Continuous variables were presented as mean ± standard deviation (SD), whereas the group variables were presented as number and percentages. The internal consistency of the IPSS-U was determined by Cronbach's α coefficient using cut-off value ≥0.70, for adequate internal consistency.[14] Reproducibility (test-retest reliability) was determined by intra-class correlation coefficient (ICC), with ICC ≥ 0.70 indicating good reliability.[15] The construct validity of IPSS-U was assessed by the exploratory factor analysis. To assess the suitability of the data for the factor analysis, Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity were examined. A minimum KMO value of 0.6[16,17] and significance (p<0.05) of Bartlett's test[18] are required for the factor analysis to be considered satisfactory. We used Principle Component Analysis with oblique rotation (oblimin) to determine dimensionality, considering only factors having eigenvalues ≥1.00 (Kaiser's criterion). Subsequently, confirmatory factor analysis was performed using the following indices of fit: CMIN/DF, root mean square error of approximation index (RMSEA), normed fit index (NFI), comparative fit index (CFI) and goodness of fit index (GFI). All statistical analysis was performed using IBM Statistical Package for the Social Sciences version 22.0 (IBM-SPSS Inc. Armonk, NY, USA) and AMOS version 24.0, with p<0.05 considered statistically significant.

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Results

Patient characteristics

Figure 1 depicts patient enrollment in the current psychometric validation study. The objective and nature of the study were explained to a total 416 eligible patients and IPSS-U was administered to consented 267 patients. Data of the patients who refused to participate were not available for comparison. Demographic characteristics of the study participants are shown in Table 1. The mean age of the respondents was 56.44±15.66 years, with majority of them being 18-65 years old. There was a predominance of married male patients with a primary level of education. Eighteen and 21% of the study participants were current, and former smokers, respectively.

Psychometric performance

Corrected item-total correlation values, internal consistency and test-retest reliability of the IPSS-U by gender are shown in Table 2. The corrected item-total correlation was 0.24-0.56. IPSS-U Item 4, 7 and 1 had the lower values, of which the item 1 also had the lower but acceptable communalities (0.33). The corrected item-total correlation value should be positive and more than 0.20 or even 0.30. The communalities should be greater than 0.10 or even 0.20.[19,20] Nonetheless, excluding these items did not significantly improve the Cronbach's alpha value of the scale so these items were retained. Cronbach's alpha value was
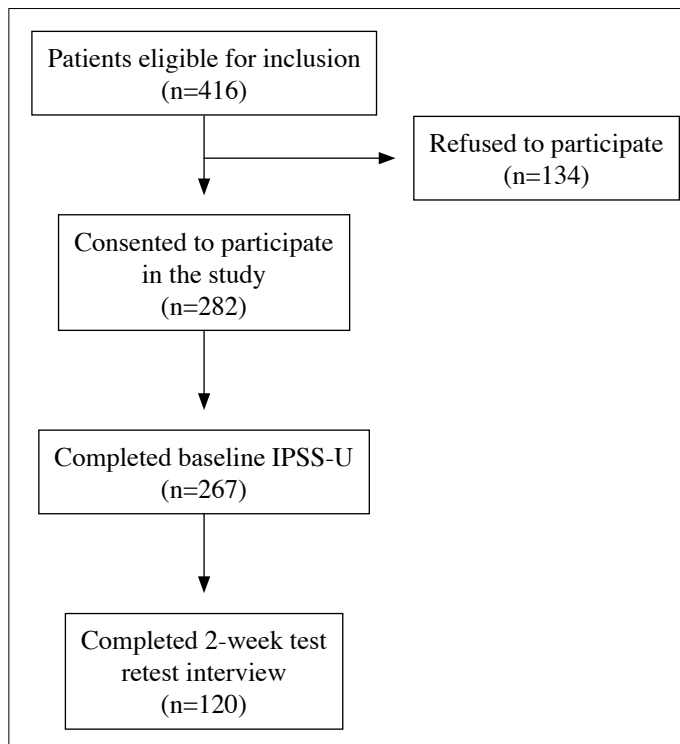
satisfactory (0.72) for the seven items related to urinary symptoms. Test-retest reliability was determined in 125 respondents who did not report any change in their complaints from the baseline. Overall the ICC of the IPSS-U total symptom and QOL scores were excellent in both male and female respondents.

A factor analysis was carried out on the seven items with oblique rotation (oblimin) to allow the factors to correlate among them. Individuals with missing data were eliminated listwise before the factor analysis. The KMO coefficient (0.73) indicated that the sample size in the present study was adequate and Bartlett's Test of sphericity ($\chi2=447.911$, $p<0.001$) revealed correlations among the IPSS-U items, and the data were suitable for factor analysis.

Figure 1. Patient characteristics

Table 1. Patient characteristics (n=267)

Characteristics	n (%)
Age (56.44±15.66) (yrs)	
18-65	193 (72.3)
>65	74 (27.7)
Gender	
Male	216 (80.9)
Female	51 (19.1)
Marital status	
Single	14 (5.2)
Married	225 (84.3)
Divorced	5 (1.9)
Widowed	23 (8.6)
Education	
Primary	128 (47.9)
Secondary	118 (44.2)
Tertiary	21 (7.9)
Strata	
Urban	175 (65.5)
Rural	92 (34.5)
Working Status	
Working	120 (44.9)
Not working	147 (55.1)
Economic Class	
Lower	245 (91.8)
Middle	22 (8.2)
Upper	--
Smoking status	
Non-smoker	163 (61.0)
Current smoker	48 (18.0)
Former smoker	56 (21.0)

Table 2. Descriptive statistics, internal consistency and reliability of study instrument

IPSS-U Items	Male			Female			Overall		
	n	Mean±SD	Corrected item-total correlation	n	Mean±SD	Corrected item-total correlation	n	Mean±SD	Corrected item-total correlation
Incomplete emptying	216	2.71±1.63	0.36	51	2.65±1.31	0.53	267	2.70±1.58	0.37
Frequency	216	3.60±1.37	0.48	51	3.55±1.15	0.22	267	3.59±1.33	0.42
Intermittency	216	2.96±1.63	0.50	51	1.61±1.63	0.52	267	2.70±1.71	0.52
Urgency	216	2.79±1.65	0.27	51	2.80±1.43	0.10	267	2.79±1.60	0.24
Weak stream	216	3.41±1.58	0.57	51	1.98±1.54	0.42	267	3.13±1.67	0.56
Straining	216	2.65±1.74	0.55	51	1.84±1.73	0.42	267	2.50±1.77	0.54
Nocturia	216	3.37±1.46	0.34	51	3.10±1.03	0.46	267	3.31±1.40	0.38
QOL index	216	3.56±1.39		51	3.25±1.59		267	3.50±1.43	
Total symptoms score	216	21.33±6.90		51	17.41±5.70		267	20.58±6.85	
	Male			Female			Overall		
Cronbach's alpha	0.72			0.66			0.72		
ICC									
Total symptom score	99	0.91		26	0.95		125	0.92	
QOL score	99	0.74		26	0.78		125	0.75	

ICC: intra-class correlation coefficient; IPSS-U: International Prostate Symptom Score-Urdu; QOL: quality of life

Table 3. Total variance explained and Eigenvalues

Factor	Initial eigen values			Extraction sums of squared loadings			Rotation sums of squared loadings[a]
	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %	Total
1	2.672	38.173	38.173	2.672	38.173	38.173	2.505
2	1.512	21.603	59.776	1.512	21.603	59.776	1.917
3	0.891	12.730	72.506				
4	0.624	8.912	81.418				
5	0.493	7.049	88.467				
6	0.459	6.558	95.025				
7	0.348	4.975	100.000				

Extraction Method: Principal Component Analysis. [a]. When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

We conducted an initial analysis to generate eigenvalues for each factor in the data. Both the Kaiser's criteria (Table 3) and the scree plot (Figure 2) revealed that two factors were consistent, which together explained 59.8% of the variance. Factor loading after rotation with <0.30 suppressed factor loading is shown in Table 4. Items clustering on the same factor showed that the first factor comprised of symptoms related to voiding and the second factor represented storage symptoms. Item loadings were high enough to be convergent and there were no cross loading that indicated good discriminant validity. Both voiding and storage sub-scales (0.77 and 0.64, respectively) had satisfactory reliabilities. As shown in Figure 3, confirmatory factor analysis revealed two-factor model, with satisfactory fitting patterns. The analysis confirmed the validity of all the parameters (Table 5).

Discussion

The main findings of the current study revealed that IPSS-U is a valid and reliable non-gender specific instrument for assessing LUTS in Urdu speaking population as it was found to have good discriminant, convergent, and constructive validities and reproducibility.

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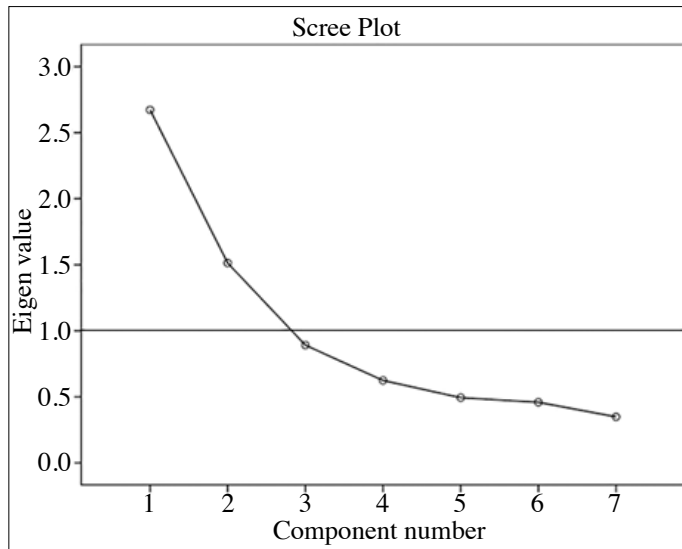
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Figure 2. Scree plot for factor solutions of items in the international prostate symptom score-Urdu
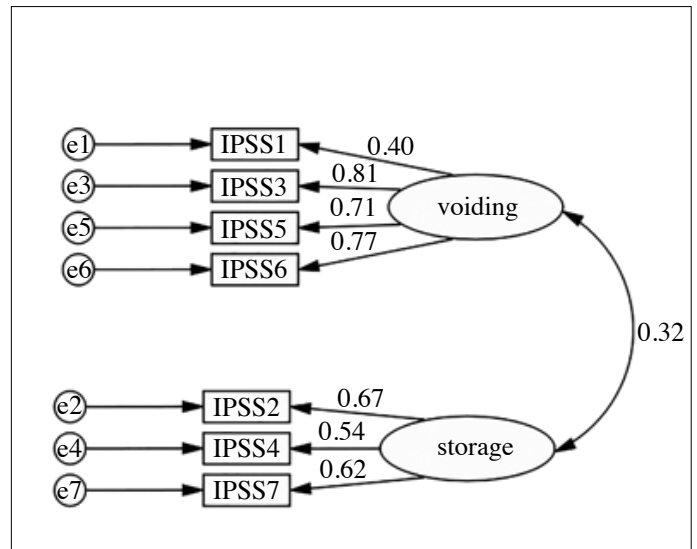

Figure 3. Schematized structure of International prostate symptom score-Urdu

Table 4. Pattern matrix[a] after Oblimin rotation

| IPSS-U items | Factor | |
	1 "Voiding symptoms"	2 "Storage symptoms"
Item 3	0.877	
Item 6	0.848	
Item 5	0.789	
Item 1	0.517	
Item 4		0.776
Item 2		0.762
Item 7		0.746

Extraction Method: Principal Component Analysis. Rotation Method: Oblimin with Kaiser Normalization. aRotation converged in 4 iterations.

Table 5. Confirmatory factor analysis adjustment parameters

Parameters	Acceptable cut-off	Results
CMIN/DF	<3 good; <5 sometimes permissible[21]	2.801
GFI	>0.95 excellent; >0.90 traditional; >0.80 sometimes permissible[21]	0.96
AGFI	>0.80[21]	0.92
NFI	>0.90[22]	0.92
RAMSEA	<0.05 good; 0.05-0.10 moderate; 0.10 bad[21]	0.08
PCLOSE	>0.05[21]	0.05

The response options of the first six items of IPSS-U are different from the original IPSS (English version). Because our pilot study to assess the clarity, relevance and interpretation of each question of IPSS-U and its response options indicated that the majority of Pakistani did not comprehend the word to word translation of the response options of the said items.[13] Therefore, response options of the first six items of IPSS-U had a 6-point Likert-scale of "not at all", "seldom", "sometimes", "often", "usually" and "almost always" that was understandable to all individuals. In this study, IPSS-U was found to be a reliable instrument to assess LUTS in males as well as females. The overall (both males and females) internal consistency of IPSS-U was satisfactory and comparable to the original English IPSS. Similar to the findings of an earlier study,[6] the Cronbach's alpha was slightly lower in females (0.66), which is still acceptable. The

two week test-retest reliability in individuals with no change in their complaints from the baseline was excellent and comparable to the other versions of IPSS.[6-12] As expected, factor analysis yielded two independent factors in our IPSS modified for Urdu-speaking people. Incomplete bladder emptying, intermittency, poor stream and straining were components of the first factor (Voiding symptoms), whereas frequency, urgency to urinate and nocturia storage symptoms were components of the second factor. The correlation analysis and factor analysis revealed a good constructive validity of IPSS-U. Furthermore, confirmatory factor analysis also showed two-factor model, with good fitting patterns. CMIN/DF, RMSEA, NFI, CFI and GFI were within the acceptable ranges.[21,22] For future use in research or clinical practice, our IPSS-U can be obtained online from MAPI research Trust. Though, we achieved the desired objective of

this study, the responsiveness of IPSS-U still needs to be determined. Moreover, the accuracy of the answers to IPSS-U items should be determined in future investigations (self-completion vs. physician-assisted completion of the instrument).

In conclusion, our modified Urdu version of IPSS is found to be a valid and reliable tool to assess the frequency and severity of LUTS in Pakistani males and females. We recommend the use of this instrument in both clinical practice and research for Urdu-speaking patients worldwide.

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