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ORIGINAL RESEARCH

Validation of the Swahili version of the International Prostate Symptom Score at a private, nonprofit general hospital in Dar es Salaam, Tanzania

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Abstract

Background

Accuracy in translating the International Prostate Symptom Score (IPSS) into different languages is essential to ensure that it is comparable to the original version and acceptable to the target population. We aimed to develop and validate a Swahili version of the IPSS (sIPSS).

Methods

We conducted a cross-sectional study involving 53 patients presenting with lower urinary tract symptoms to the Aga Khan Hospital in Dar es Salaam, Tanzania, from April through December 2018. We enrolled 53 patients with confirmed benign prostatic hypertrophy and 32 control patients with suspected or confirmed urolithiasis. We assessed the face validity and discriminative validity of the sIPSS using standard statistical constructs, including Cronbach's alpha, intraclass correlation coefficients (ICC), the receiver operating characteristic curve, and Spearman's rank correlation coefficient. Test-retest reliability was assessed by comparing baseline sIPSS scores with those obtained after 1 week for all participants, and sensitivity to change was assessed by comparing baseline scores to those at 4 to 6 weeks after treatment in the BPH group.

Results

The sIPSS had excellent internal validity (Cronbach's alpha, 0.86), comparable to that of the original IPSS. The test-retest reliability of the sIPSS was high (ICC, 0.84), and the mean improvement in sIPSS score 4 to 6 weeks after treatment was 9.7 ± 6.4 .

Conclusions

For use in the Tanzanian population, the sIPSS is reliable, valid, and sensitive to change.

Keywords: Cronbach's alpha, internal consistency, Swahili, International Prostate Symptom Score, test-retest reliability, validity, Tanzania

Introduction

Benign prostatic hypertrophy (BPH) is a common condition, and its prevalence has increased up to 50% in the past 20 years among men older than 50 years.^[1] BPH is clinically important when it is associated with symptoms, such as lower urinary tract symptoms (LUTS).

Given the clinical relevance of BPH symptoms, efforts have been made to standardize the evaluation of BPH symptoms and assess their impact on patient well-being. The measurement committee of the American Urological As-

sociation (AUA) designed and validated a symptom index (AUA-7) for BPH,^{[2],[3]} and the International Consultation on Benign Prostatic Hyperplasia (26-27 June 1991 in Paris, France) recommended that research questionnaires include patients' perceptions regarding the impact of symptoms on quality of life (QoL).^[4] Subsequently, the International Scientific Committee, under the patronage of the World Health Organization and the International Union Against Cancer, endorsed the use of the AUA-7 with additional questions on QoL.^[4] This final tool is what is known as the International Prostate Symptom Score (IPSS) questionnaire.^{[5],[6]}

The IPSS is widely used in research and clinical settings to assess the severity of LUTS, guide treatment, and evaluate patients' responses to treatment. The IPSS is self-administered and requires only a few minutes to complete. Self-administration may reduce the biases that could arise if patient responses were influenced by physician or health worker administration; thus, compared with other instruments, the IPSS may more accurately reflect patients' perceptions of LUTS.[7] The English (US) version is the original IPSS questionnaire, and several translations are now in widely used in clinical practice and research.[2],[3],[8]-[11] Accuracy is essential when translating the IPSS into different languages to ensure that the translated version is both comparable to the original version and acceptable to the target population. It is particularly important that the IPSS correctly categorizes patient symptoms because this information is used to guide treatment.

In a recent study conducted in India, Jindal et al.[12] showed that patients who did not use English as their first language misinterpreted the IPSS and that this significantly affected patient outcomes. Johnson et al.[13] showed that patients who had low education levels often misinterpreted questions on the AUA-7 and, therefore, received inappropriate treatment. Swahili is the official language of Tanzania and is the language of instruction in primary and secondary schools and often at postsecondary institutions. The majority of Tanzanians use Swahili in their day-to-day communication. However, to the best of our knowledge, before the study reported herein, there was no validated Swahili version of the IPSS questionnaire. This study aimed to develop a Swahili version of the IPSS (sIPSS) and assess the validity and reliability of this new translated version.

Methods

We conducted a cross-sectional study of patients who presented to the Aga Khan Hospital in Dar es Salaam, Tanzania, with lower urinary tract symptoms. The questionnaire underwent translation into Swahili followed by a pilot study. The internal consistency (Cronbach's alpha), validity (Spearman's rank correlation), test-retest reliability (intraclass correlation [ICC]), and sensitivity to change (effect size index, [ESI]) of the final questionnaire were assessed.

Translation of the International Prostate Symptoms Score into Swahili

The IPSS asks patients 7 questions about their experiences, in the past month, respectively, with 7 potential LUTS: frequency of urination, incomplete bladder emptying, straining, intermittency, urgency, nocturia, and weak urine stream. For each question, the patient can choose 1 of 6 responses on a scale from 0 to 5 (0 = did not experience this symptom in the past month; 1 = at least once; 2 = less than half of the time; 3 = half of the time; 4 = more than half the time; 5 = always). The total symptom score is the sum of the responses to the 7 questions. The severity of LUTS, based on the total score, can be graded as mild (0-7), moderate (8-19), or severe (20-35).[2]

The translation of the English version of the IPSS into Swahili was guided by a standardized process provided by Mapi Research Trust. The English IPSS was translated into Swahili by a professional translator, followed by 2 independent back-translations by healthcare professionals. The original and back-translated questionnaires were compared by the study's principal investigator, and modifications were made based on suggestions from the individuals involved in this process. The final sIPSS was piloted with 10 BPH patients who were interviewed to evaluate their comprehension of the questions and to identify unclear words or phrases. All 10 participants understood the questionnaire well and found the words and phrasing to be clear.[8]

Study sample

We validated the sIPSS using questionnaire responses from 85 patients recruited from the Aga Khan University Hospital, Tanzania, from April through December 2018. The study included 53 patients aged 50 years and older with LUTS and urologist-confirmed BPH. Also included were 32 control patients, aged 18 to 49 years, with suspected or confirmed urolithiasis. BPH diagnoses were based on laboratory investigations or clinical criteria garnered from medical history-taking and physical examination (including digital rectal examination). Exclusion criteria were as follows: comorbid conditions, such as uncontrolled diabetes mellitus, use of diuretics, history of previous pelvic trauma, previous surgical procedures for BPH or prostate cancer, and inability to understand questions on the sIPSS. Patients with prostatitis or BPH were not recruited as controls.

Table 1. Sociodemographic variables and sIPSS scores of patients with benign prostatic hyperplasia and control patients with confirmed or suspected urolithiasis at a private general hospital in Dar es Salaam, Tanzania, April through December 2018

Variable	Cases (n=53)	Controls (n=32)	P value
Age, years, mean \pm SD	59.6 \pm 8.0	33.2 \pm 6.9	<0.001
Education level			
None	2 (3.8)	1 (3.1)	0.93
Primary	4 (7.5)	3 (9.4)	
Secondary	13 (24.5)	6 (18.8)	
Tertiary	34 (64.2)	22 (68.8)	
sIPSS score			
0-7	14 (26.4)	28 (87.5)	<0.001
8-21	29 (54.7)	3 (9.4)	
22-35	10 (18.9)	1 (3.1)	

Values are n (%) unless otherwise indicated.

sIPSS, Swahili version of the International Prostate Symptom Score questionnaire; SD, standard deviation

Table 2. The distribution of responses to individual sIPSS items among patients with benign prostatic hyperplasia (n=53) and control patients with confirmed or suspected urolithiasis (n=32) at a private general hospital in Dar es Salaam, Tanzania, April through December 2018

Questionnaire item	sIPSS score											
	0		1		2		3		4		5	
	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls
(1) Emptying	13 (24.5)	23 (71.9)	12 (22.6)	6 (18.8)	7 (13.2)	2 (6.2)	11 (20.8)	0 (0)	5 (9.4)	0 (0)	5 (9.4)	1 (3.1)
(2) Frequency	10 (18.9)	20 (62.5)	13 (24.5)	8 (25)	10 (18.9)	2 (6.2)	11 (20.8)	1 (3.1)	6 (11.3)	1 (3.1)	3 (5.7)	0 (0)
(3) Intermittency	17 (32.1)	27 (84.4)	11 (20.8)	4 (12.5)	4 (7.5)	1 (3.1)	7 (13.2)	0 (0)	6 (11.3)	0 (0)	8 (15.1)	0 (0)
(4) Urgency	21 (39.6)	29 (90.6)	6 (11.3)	2 (6.2)	9 (17.0)	0 (0)	10 (18.9)	0 (0)	2 (3.8)	0 (0)	5 (9.4)	1 (3.1)
(5) Weak stream	12 (22.6)	24 (75)	4 (7.5)	3 (9.4)	14 (26.4)	4 (12.5)	10 (18.9)	0 (0)	7 (13.2)	0 (0)	6 (11.3)	1 (3.1)
(6) Hesitancy	20 (38.5)	26 (81.2)	7 (13.5)	2 (6.2)	10 (19.2)	2 (6.2)	7 (13.5)	1 (3.1)	3 (5.8)	0 (0)	5 (9.6)	1 (3.1)
(7) Nocturia	2 (3.8)	9 (28.1)	14 (26.4)	13 (40.6)	14 (20.8)	13 (15.6)	15 (28.3)	1 (3.1)	7 (13.2)	1 (3.1)	4 (7.5)	3 (9.4)

All values are n (% of group size).

Responses for questions 1-6: 0, Not at all; 1, Less than 1 in 5 times; 2, Less than half of the time; 3, Half of the time; 4, More than half of the time; 5, Almost always

Responses for question 7: 0, None; 1, 1 time; 2, 2 times; 3, 3 times; 4, 4 times; 5, At least 5 times

sIPSS, Swahili version of the International Prostate Symptom Score questionnaire

Study procedures

The sIPSS was administered at baseline and at 2 follow-up time points, namely, 1 week after baseline (to evaluate test-retest reliability) and 4 to 6 weeks after baseline (to evaluate sensitivity to change). The data from the questionnaires were entered into Excel (Microsoft Corp., Redmond, WA, USA) spreadsheets, cleaned, and finally transferred to SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA) for analysis.

The study protocol was approved by the Ethics and Research Committee of the Aga Khan University; permission was obtained from Mapi Research Trust to translate the IPSS into Swahili. All study participants provided written consent before starting any study activity.

Data analysis

To characterize study participants, descriptive statistics were generated using frequencies and percentages for categorical variables and means and standard deviations (SDs) for continuous variables. The internal consistency of the sIPSS was evaluated using Cronbach's alpha coefficient; test-retest reliability was evaluated using the ICCs of paired data of participant responses at baseline and 1 week after baseline. The sensitivity to change of the sIPSS was evaluated by comparing the mean scores of BPH patients before and after treatment (either surgical or medical) using paired-samples *t* tests. Sensitivity to change was also assessed using Guyatt's statistic, obtained by dividing the mean differences between baseline and follow-up sIPSS scores by the mean SD of scores in the control group. Sensitivity to change (ESI) was calculated by dividing the mean difference in scores before and after treatment by the SD. The sensitivity and specificity of the sIPSS were evaluated by calculating the area under the receiver operating characteristic (AUROC) curve using a cutoff value of 7.5.^[10]

Sample size

The minimum sample size was calculated using the following formula:

$$n = 1 + \frac{2(Z\alpha + Z\beta)2k}{(\ln C_0)2(k-1)}$$

Where,

n = the expected sample size,

α = the probability of type I error;

β = the probability of type II error (1 – power of the test);

and *k* = the number of replicates.

Using a significance level of 0.05 and 80% power, a specified correlation coefficient of 0.9, and an expected correlation coefficient of 0.95, we calculated a minimum sample size of 49 participants.

Table 3. Validity and reliability of the sIPSS when evaluated with patients with benign prostatic hyperplasia (n=53) and control patients with confirmed or suspected urolithiasis (n=32) at a private general hospital in Dar es Salaam, Tanzania, April through December 2018

Questionnaire item	ICC ^a		Internal consistency		Mean ± SD test score		Mean ± SD retest score		Mean difference ^b		
	Overall	Controls	Cases	Controls	Cases	Controls	Cases	Controls	Controls	Cases	
(1) Emptying	0.94	1.00	0.91	1.00	0.95	0.5±1.0	2.1±1.7	0.5±1.0	2.0±1.6	<0.001	0.1
(2) Frequency	1.00	1.00	1.00	1.00	1.00	0.6±1.0	2.0±1.5	0.6±1.0	2.0±1.5	<0.001	<0.001
(3) Intermittency	1.00	1.00	1.00	1.00	1.00	0.2±0.5	2.0±1.9	0.2±0.5	2.0±1.9	<0.001	<0.001
(4) Urgency	1.00	1.00	1.00	1.00	1.00	0.2±0.9	1.6±1.7	0.2±0.9	1.6±1.7	<0.001	<0.001
(5) Weak stream	1.00	1.00	1.00	1.00	1.00	0.5±1.1	2.3±1.6	0.5±1.1	2.3±1.6	<0.001	<0.001
(6) Hesitancy	1.00	1.00	1.00	1.00	1.00	0.4±1.1	1.6±1.7	0.4±1.1	1.6±1.7	<0.001	<0.001
(7) Nocturia	0.92	0.99	0.86	0.99	0.92	1.4±1.5	2.5±1.3	1.4±1.5	2.4±1.3	<0.001	0.1
(8) QoL	0.92	0.85	0.94	0.92	1.00	2.4±2.8	3.7±1.8	2.1±2.6	3.7±1.8	0.4	-0.04

^aP<0.001 for all ICCs

^bPaired-samples t tests yielded no statistically significant differences

ICC, intraclass correlation coefficient; QoL, quality of life; SD, standard deviation; sIPSS, Swahili version of the International Prostate Symptom Score questionnaire

Results

In total, 85 patients (53 BPH patients and 32 control patients) participated in the study. Compared with the control group, the BPH group was significantly older (mean difference, 26.4 years; $P<0.001$) and had a significantly higher mean baseline sIPSS ($P<0.001$) (Table 1). At baseline, the sIPSS scores ranged from 1 to 33 in the BPH group and 0 to 31 in the control group; thus, neither cases nor controls scored the maximum possible IPSS score of 35 (Table 2).

Values of the receiver operating characteristic curve for individual items on the sIPSS ranged from 0.64 to 0.84, indicating that these items achieved a high level of discrimination between BPH patients and control patients. The AUROC for the sIPSS was 0.78 (standard error of the mean, 0.04; 95% confidence interval, 0.70-0.87) (Figure 1). The sIPSS correlated highly with the Swahili QoL question (Spearman rank correlation coefficient, 0.72; $P<0.001$).

The reliability of the sIPSS was high, with ICC values ranging from 0.85 to 1.00 in both the BPH and control groups (Table 3). In the control group, the question regarding QoL yielded the lowest ICC value (0.85), whereas in the BPH group, the question regarding nocturia yielded the lowest ICC value (0.86).

The sIPSS was sensitive to change in our patient population. The mean sIPSS score at baseline (i.e., before treatment; mean [±SD], 14.0±8.4) was significantly higher than the mean score at follow-up (i.e., after treatment; mean, 6.0±4.9; $P<0.001$) (Table 4). Our analysis of the sIPSS's sensitivity to change at 1 month after treatment in the BPH group determined a mean improvement of 7.9±5.8, corresponding to an ESI of 0.94.

Significant differences were observed between the BPH and control groups for individual items on the sIPSS, indicating that the sIPSS had a high discriminative validity for distinguishing between patient groups (Table 5). The mean difference between the scores of the BPH and control groups was largest for the total sIPSS score ($P<0.001$). The change in score from baseline to follow-up was also largest for the total sIPSS score ($P<0.001$). Overall, the sensitivity and reliability of the sIPSS are similar to those of the IPSS validated in the United States (Table 6).

Discussion

The IPSS has been used in both clinical and research settings in Africa; however, its use has been limited owing to low levels of literacy, particularly English language literacy, in African populations.[14] To our knowledge, ours was the first study to validate an IPSS version translated into an African language. The original IPSS has been translated into several languages from regions outside of Africa,[9],[11],[15]-[20] and studies of these translated versions have demonstrated their validity and reliability to be similar to those of the original IPSS. In the present study, the mean age of BPH patients was

59.6± 8.0 years and that of control patients was 33.2±6.8 years; these ages were similar to those reported in studies of the IPSS translated into Arabic,[10] Farsi,[17],[18], Mandarin,[9] and Cantonese.[21]

In the present study, BPH and control patients had similar levels of education. Most of the patients in the present study had at least a secondary level of education, and no patients requested assistance to complete the questionnaire. Studies have used a variety of methods to evaluate the validity of translated versions of the IPSS, most concluding that

the translated versions have good validity[22]; this accords with our finding that the sIPSS had good discriminative validity to distinguish between BPH patients and control patients. Other studies have also found that translated versions of the IPSS discriminate well between cases and controls. In a comparison of BPH patients and healthy controls recruited from Malaysia, Quek et al.[9] reported a significant difference in the mean total scores yielded by a Mandarin version of the IPSS.[9] In Nigeria, authors showed that patients with at least a secondary level of education were able to under-

Table 4. Mean scores before and after treatment, mean differences between the scores, effect size indices, and Guyatt statistics of the sIPSS components when evaluated with patients with benign prostatic hyperplasia (n=53) and control patients with confirmed or suspected urolithiasis (n=32) at a private general hospital in Dar es Salaam, Tanzania, April through December 2018

Questionnaire item	Mean ± SD score before treatment	Mean ± SD score after Treatment	Mean difference ^a	ESI ^b	Guyatt's statistic ^c
(1) Emptying	2.0±1.7	1.1±1.1	0.9	0.57	0.93
(2) Frequency	2.0±1.5	0.8±0.9	1.2	0.77	1.17
(3) Intermittency	1.9±1.9	0.9±1.2	1.0	0.54	2.17
(4) Urgency	1.6±1.6	0.6±0.8	0.9	0.58	1.04
(5) Weak stream	2.3±1.7	0.9±1.0	1.4	0.81	1.25
(6) Hesitancy	1.6±1.7	0.7±0.9	1.0	0.58	0.89
(7) Nocturia	2.5±1.3	1.2±1.0	1.3	0.99	0.90
sIPSS	14.1±8.3	6.2±4.9	7.9	0.94	1.35
(8) QoL	3.7±1.8	1.5±1.1	2.21	1.22	0.80

^aP<0.001

^bn=52 for cases in the sensitivity to change/ESI analysis; ESI = mean difference/SD before treatment

^cGuyatt's statistic = mean difference/SD of control group

ESI; effect size index; QoL, quality of life; SD, standard deviation; sIPSS, Swahili version of the International Prostate Symptom Score questionnaire

Table 5. Discriminative validity of the sIPSS components when evaluated with patients with benign prostatic hyperplasia (n=53) and control patients with confirmed or suspected urolithiasis (n=32) at a private general hospital in Dar es Salaam, Tanzania, April through December 2018

Questionnaire item	Test score, mean ± SD		Mean difference	P value
	Controls	Cases		
(1) Emptying	0.5±1.0	2.1±1.7	1.6	<0.001
(2) Frequency	0.6±1.0	2.0±1.5	1.4	<0.001
(3) Intermittency	0.2±0.5	2.0±1.9	1.8	<0.001
(4) Urgency	0.2±0.91	1.6±1.7	1.4	<0.001
(5) Weak stream	0.5±1.1	2.3±1.6	1.8	<0.001
(6) Hesitancy	0.4±1.1	1.6±1.7	1.2	<0.001
(7) Nocturia	1.4±1.5	2.5±1.3	1.1	<0.001
sIPSS	3.8±5.8	14.1±8.4	10.3	<0.001
(8) QoL	2.4±2.7	3.7±1.8	1.3	<0.001

QoL, quality of life; SD, standard deviation; sIPSS, Swahili version of the International Prostate Symptom Score questionnaire

Table 6. Comparison between the original English IPSS and the Swahili version evaluated with patients with benign prostatic hyperplasia (n=53) and control patients with confirmed or suspected urolithiasis (n=32) at a private general hospital in Dar es Salaam, Tanzania, April through December 2018

Statistical construct	IPSS version	
	English	Swahili
Correlation with item 8	0.77	0.72
Discriminatory power (AUROC ± SE)	0.85±0.03	0.78±0.04
Test–retest reliability	0.92	0.84
Internal consistency (Cronbach's alpha)	0.86	0.92
Sensitivity to change (effect size index)	1.44	0.94
Discriminative validity	<i>P</i> <0.001	<i>P</i> <0.001

AUROC, area under the receiver operating characteristic curve; IPSS, International Prostate Symptom Score questionnaire; SE, standard error

stand and complete the IPSS without assistance.[23] Ham-mad et al.[10] reported that BPH patients had significantly higher total scores than controls after completing an Arabic language version of the IPSS.

We found that individual sIPSS items correlated strongly with the QoL question on the sIPSS. This finding was similar to that reported for the original IPSS[2] and the Arabic version of the IPSS,[10] and it confirms that the sIPSS is a valid tool for assessing the impact of LUTS on the QoL of BPH patients in our context.

Our assessments of the test–retest reliability and internal consistency of the sIPSS revealed high ICCs ranging from 0.85 to 1.00, though none were statistically significant. Higher ICCs correspond with higher levels of reliability. We did not expect patient symptoms to change before retesting 1 week after baseline. Treatment was initiated for all BPH patients around the time of retesting; treatment responses to BPH-associated LUTS are generally gradual and reach their peak about 1 month after treatment initiation.[1],[3] Our findings regarding the test–retest reliability of the sIPSS were similar to those calculated in studies of the IPSS versions translated into Mandarin (ICC, 0.98),[7] Spanish (ICC, 0.87),[18] Arabic (ICC, 88),[9] and Farsi (ICC, 0.78)[17] and indicate that the sIPSS has excellent test–retest reliability.

We found that the Cronbach's alpha values for individual questions on the sIPSS ranged from 0.92 to 1.00. These values for internal consistency were somewhat better than those reported for the original IPSS (ICC, 0.86) and are above the threshold of 0.9 that is considered excellent for QoL assessment tools used in clinical settings.[24] Our findings regarding the internal consistency of individual items were similar to those obtained by studies of the Mandarin (Cronbach's alpha, range, 0.90-0.98),[9] and Arabic (Cronbach's alpha, range, 0.78-0.85),[10] versions of the IPSS, and our values

were higher than those reported from studies of the Farsi (Cronbach's alpha, 0.7),[17] and Urdu (Cronbach's alpha, 0.72)[20] versions of the IPSS.

The ESI value (0.94) determined by our analysis indicates that the sIPSS has a high sensitivity to change, although the ESI of the sIPSS is lower than that reported for the original IPSS (1.44).[9] A study of the Mandarin version of the IPSS reported an ESI of 1.66,[9] while a study of the Spanish version of the IPSS reported an ESI of 2.52.[6] The high values of the ESI reported for the Spanish version of the IPSS may have been due to higher pretreatment IPSS scores in their study sample compared with those observed in the present study.

Our receiver operating characteristic curve analysis revealed that the individual sIPSS items had high discriminative validity for distinguishing between BPH patients and control patients. We found AUROC values ranging from 0.64 to 0.84, which are comparable to the reported AUROC values (0.850±0.030) for the original IPSS,[2] higher than that reported for the Spanish language IPSS (0.50±0.020),[6] but lower than that reported for the Arabic IPSS (0.93±0.09).[10] Thus, overall, our findings suggest that the sIPSS has high discriminative validity, comparable to other versions of the tool.

Limitations

Our study had limitations that may affect the interpretation of its findings. We recruited individuals who were under the age of 50 as controls in view of excluding those with LUTS or BPH, conditions more commonly afflicting older men.[2],[8] Thus, BPH and control patients were not age matched. Nevertheless, this limitation does not affect our finding that the sIPSS had validity and reliability levels similar to those of the original IPSS because validation of the original IPSS was also conducted among patients and controls with dissimilar ages.[8]

Conclusions

Our study showed that the psychometric properties of the sIPSS are similar to those of the original IPSS, as well as to those of other translated versions of the IPSS. We found that the sIPSS had excellent internal consistency, test–retest reliability, and sensitivity to change. We, therefore, conclude that the sIPSS is a reliable and valid tool for assessing LUTS in men diagnosed with BPH, and we recommend its use in both clinical and research settings in Tanzanian and other Swahili-speaking populations.

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