VALIDATION OF INDONESIAN VERSION OF IPSS

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ABSTRACT

Objective: *This study aims to validate the Indonesian version of International Prostate Symptom Score (IPSS) to ensure similar purpose and quality as the original version.* ***Material & method:*** *Validation and reliability of IPSS-Ina was performed on 174 subjects divided into 87 benign prostate hyperplasia (BPH) patients and 87 non-BPH subjects as a control group. A total of 33 patients in the BPH group then underwent TURP. Validation was assessed by correlating the IPSS score-Ina with a quality of life score (QoL). Reliability was tested by internal consistency with Cronbach α and test-retest trials. Sensitivity to changes in IPSS-Ina post-therapy was tested by comparing the mean IPSS before and after transurethral resection of the prostate (TURP) therapy.* ***Results:*** *Correlation between IPSS-Ina score with quality of life (QoL) was 0.85 ($p < 0.001$), showing strong correlation. Results of Cronbach's α 0.93; while test-retest trials with the intraclass correlation coefficient (ICC) 0.99; which indicates a very good reliability. The mean initial IPSS-Ina (20.97 ± 4.4) with post-TURP (4.82 ± 1.77) differed significantly ($p < 0.001$).* ***Conclusion:*** *IPSS-Ina proved excellent validation and reliability and was sensitive to symptomatic change after therapy. IPSS-Ina have the same goals and the quality of the original version.*

Keywords: *International prostate symptom score, Indonesia, validation, reliability.*

ABSTRAK

Tujuan Penelitian: *Penelitian ini bertujuan untuk memvalidasi IPSS versi terjemahan Bahasa Indonesia, sehingga memiliki tujuan dan kualitas yang sama dengan versi originalnya.* ***Bahan & Cara:*** *Validasi dan reliabilitas IPSS-Ina dilakukan pada 174 subjek yang terbagi menjadi 87 pasien BPH dan 87 subjek non-BPH sebagai kelompok kontrol. Sebanyak 33 pasien pada kelompok BPH kemudian menjalani TURP. Validasi dinilai dengan mengkorelasikan nilai skor IPSS-Ina dengan skor kualitas hidup (QoL). Reliabilitas diuji dengan menilai internal consistency dengan Cronbach α dan uji test-retest. Sensitivitas IPSS-Ina terhadap perubahan paska terapi diuji dengan membandingkan rerata IPSS sebelum dan sesudah terapi TURP.* ***Hasil:*** *Nilai korelasi skor IPSS-Ina dengan skor kualitas hidup (QoL) sebesar 0.85 ($p < 0.001$) yang menujukkan adanya korelasi yang kuat. Hasil Cronbach α 0.93; sedangkan uji test-retest dengan intraclass correlation coefficient (ICC) 0.99; yang menunjukkan reliablitas yang sangat baik. Rerata IPSS-Ina inisial (20.97 ± 4.4) dengan paska TURP (4.82 ± 1.77) berbeda bermakna ($p < 0.001$).* ***Simpulan:*** *IPSS-Ina terbukti menunjukkan hasil validasi dan reliabilitas yang sangat baik dan sensitif terhadap perubahan gejala paska terapi. IPSS-Ina terbukti memiliki tujuan dan kualitas yang sama dengan versi originalnya.*

Kata kunci: *International prostate symptom score, Indonesia, validasi, reliabilitas.*

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INTRODUCTION

Lower urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH) often occur in older men.[1] The prevalence of BPH increased with age, 50% at age 60 years and reached 88% at age 80 years.[2] Thus, with increasing life expectancy to 70.9 years in Indonesia based on a survey in 2010, it will also increase the incidence of BPH in Indonesia.[3] BPH with LUTS can decrease quality of life and productivity.

The need to measure symptoms to facilitate decision-making in treatment and follow-up in clinical practice and research, encouraging

a consultative body on BPH sponsored by the WHO to use the International Prostate Symptom Score (IPSS) as an instrument to measure symptoms.[4] IPSS has been translated in many languages, especially in Europe.[5-7] Translated versions of IPSS is validated to ensure similarity in meaning and intent with American version of IPSS by the committee on measurements of the American Urological Association (AUA).[8]

Indonesian version of IPSS has been widely used in various hospitals in Indonesia, to assist decision-making in the treatment of BPH. However there has been no research to validate IPSS. Validation of an Indonesian version of IPSS is needed to ensure similarity in meaning, purpose and quality to the original version.

This study was conducted to validate an Indonesian version of IPSS, to evaluate the symptoms associated with an enlarged prostate and patient management but also as an important research tool both nationally and internationally. By knowing the validity of IPSS Indonesian language version, will make urologists, doctors and other health workers in Indonesia more confident in evaluating and making treatment decisions in BPH using the Indonesian version of IPSS.

OBJECTIVE

The purpose of this study was to validate an Indonesian version of IPSS to evaluate the symptoms associated with an enlarged prostate and patient management.

MATERIAL & METHOD

The study was conducted by giving questionnaires of an Indonesian version of IPSS (IPSS-Ina) to two groups of samples, the test group and the control group. The test group is a group of patients with BPH, above 50 years of age and able to understand and fill IPSS-Ina. Patients who can not understand the content of the questionnaire and have a history of prostate cancer, diabetes, neurological disorders, prostatitis, cystitis, urinary tract infection, urethral stricture, kidney stones, psychiatric disorders, trauma or pelvic surgery, BPH surgery, permanent cystostomy, and drug use that affects bladder function were excluded from the study.

The control group was subjects without BPH, with addition of inclusion criteria for age 18-49 years and can understand the contents of the questionnaire. Exclusion criteria is problems or a history of problems related to urinary tract, patients with BPH, history of kidney disease, bladder, or other chronic diseases related to the urinary tract.

Both groups were asked to complete the IPSS-Ina themselves, with assistance provided if needed. Subjects in the test group will be asked to complete the IPSS questionnaire again one week after the initial assessment. Reassessment is intended to test the reliability/consistency of IPSS-Ina.

In addition, some subjects in the group who underwent transurethral resection of the prostate (TURP), were asked to fill the IPSS questionnaire 30 days after the treatment. IPSS score reassessment is intended to test the sensitivity of IPSS-Ina to changes in the patient condition (in this case after undergoing TURP).

IPSS validity was tested by correlating IPSS scores with QoL scores. The reliability of the IPSS-Ina were also tested in two ways, by testing internal consistency and test-retest test on the sample. Test of internal consistency obtained by calculating Cronbach α coefficient of the IPSS-Ina. Limitation Cronbach α coefficient range from 0 (very unreliable) to 1 (very reliable), generally scores above 0,8 indicates an acceptable level of reliability. While the test-retest test will analyze the subject IPSS score at the initial sample with the same subject score results at one week after the initial examination. Reliability of test-retest test done by assessing theintra-class correlation coefficient (ICC), which also has a limited value of 0 (very unreliable) to 1 (very reliable).

Sensitivity to changes in IPSS-Ina will be tested by performing comparison of IPSS score on the sample before TURP with IPSS scores in the same subject 30 days after TURP.

RESULTS

A total of 174 subjects were included in this study, 87 patients with BPH as the test group and 87 control subjects. Table 1 shows the characteristics of the two study groups. The mean age of the BPH group was 67.2 ± 7.7 years compared with the mean age of the control group, i.e. 27.8 ± 5.1 years. Besides that, the total IPSS-Ina score was higher in patients with BPH (20.54 ± 5.11) compared with the control group (3.78 ± 1.64). Distribution of IPSS in the control group entirely was in the category of mild symptoms, while the BPH group dominated the category of severe symptoms in 65.5% while the rest are in the category of moderate symptoms (34.5%).

The results of Spearman rank-correlation test between the IPSS-Ina score with QoL score

Table1. Characteristics of study group.

Variable	Control group	Test group (BPH patients)
N	87	87
Age (years)	27.8 ± 5.1	67.2 ± 7.7
IPSS-Ina score	3.78 ± 1.64	20.54 ± 5.11
IPSS-Ina score category		
• Mild (0-7)	87 (100%)	0 (0%)
• Moderate (8-19)	0	30 (34.5%)
• Severe (20-35)	0	57 (65.5%)
QoL-Ina score	1.48 ± 0.85	4.37 ± 0.89

Table2. Distribution of IPSS-Ina questionnaire answers.

Item	Mean score in test group (BPH patients)	Mean score in control group	p
IPSS Q1	3.53 ± 1.07	0.84 ± 0.71	< 0.001
IPSS Q2	2.80 ± 0.96	0.77 ± 0.66	< 0.001
IPSS Q3	2.57 ± 1.23	0.38 ± 0.68	< 0.001
IPSS Q4	2.66 ± 1.18	0.32 ± 0.65	< 0.001
IPSS Q5	3.25 ± 1.25	0.33 ± 0.56	< 0.001
IPSS Q6	3.02 ± 1.44	0.29 ± 0.48	< 0.001
IPSS Q7	2.67 ± 1.34	0,90 ± 0.71	< 0.001
Total of IPSS-Ina	20.54 ± 5.11	3.78 ± 1.64	< 0.001
QoL	4.37 ± 0.891	1.48 ± 0.85	< 0.001

Tabel 3. Reliability test.

Item	Mean score in initial test	Mean score of test - retest	Internal consistency *	ICC
IPSS Q1	2.18 ± 1.62	2.17 ± 1.59	0.91	0.992
IPSS Q2	1.79 ± 1.31	1.83 ± 1.31	0.92	0.989
IPSS Q3	1.48 ± 1.48	1.48 ± 1.48	0.92	0.991
IPSS Q4	1.47 ± 1.50	1.45 ± 1.50	0.92	0.988
IPSS Q5	1.79 ± 1.75	1.79 ± 1.72	0.91	0.988
IPSS Q6	1.66 ± 1.74	1.67 ± 1.75	0.92	0.994
IPSS Q7	1.78 ± 1.41	1.76 ± 1.39	0.94	0.988
Total score of IPSS-Ina	12.16 ± 9.22	12.10 ± 9.18	0.93	0.998
QoL	2.93 ± 1.69	2.94 ± 1.68	-	0.994

*Internal consistency values expressed by the value of Cronbach's α, and each value shows the effect when removing items from the calculation of the value of the question α (e.g.: If the IPSS Q1 omitted from the questionnaires, the results obtained to be 0.91)

showed the results of 0.858 ($p < 0.001$). These results indicate a strong correlation. So that the IPSS-Ina score closely related to the perceived quality of life research subjects.

IPSS-Ina ability to distinguish between BPH patients and the control group is also proved by IPSS-Ina score that was significantly different between patients with BPH and control group ($p < 0.001$). Table 2 showed the distribution of IPSS-Ina questionnaire answers between both BPH and control groups.

Internal consistency of IPSS-Ina with Cronbach coefficient α shows the value of 0.93, with a range of Cronbach's α values for each question of IPSS-Ina ranged from 0.91 to 0.94. This value indicates a high reliability. Test-retest reliability were carried out at intervals of 1 week, with intraclass correlation coefficient (ICC) showed the value of 0.998 ($p < 0.001$). Table 3 shows the mean score of test-retest for each question of IPSS-Ina

Tabel 4. Sensitivity to changes.

Item	Mean score of initial test	Mean score after TURP	Mean difference	p
IPSS Q1	3.70 ± 1.16	0.91 ± 0.63	2.79 ± 1.21	< 0.001
IPSS Q2	2.55 ± 0.90	0.48 ± 0.71	2.06 ± 1.22	< 0.001
IPSS Q3	2.55 ± 1.30	0.64 ± 0.70	1.91 ± 1.46	< 0.001
IPSS Q4	2.70 ± 1.13	0.66 ± 0.74	2.06 ± 1.48	< 0.001
IPSS Q5	3.67 ± 1.31	0.88 ± 0.74	2.79 ± 1.61	< 0.001
IPSS Q6	3.42 ± 1.64	0.70 ± 0.58	2.73 ± 1.64	< 0.001
IPSS Q7	2.39 ± 1.50	0.55 ± 0.83	1.85 ± 1.78	< 0.001
Total score of IPSS-Ina	20.97 ± 4.46	4.82 ± 1.77	16.15 ± 5.19	< 0.001
QoL	4.24 ± 0.792	1.79 ± 0.65	2.45 ± 0.93	< 0.001

Sensitivity of IPSS-Ina to changes in patient condition as result of therapy given was calculated by comparing IPSS-Ina score before and after treatment. TURP performed in 37.9% of BPH patients group (33 of 87 BPH patients), with mean age of 67.36 ± 7.34 years.

Mean score of initial IPSS-Ina (20.97 ± 4.46) with a mean post-TURP score (4.82 ± 1.77) differed significantly ($p < 0.001$). Similarly, the mean QoL score between initial IPSS-Ina and post-TURP also showed significant difference ($p < 0.001$) with mean difference of 2.45 ± 0.93. Table 4 shows the difference of IPSS-Ina in BPH patients before and after TURP.

DISCUSSION

IPSS not only can help to evaluate symptoms associated with an enlarged prostate and patient management but can also become an important research instrument so the validation of IPSS into Indonesian version needs to be done. This study showed that IPSS-Ina has excellent validity and reliability.

Demographic data show that the BPH patients had a mean age over 60 years when compared to control subjects. This is in line with epidemiological data showing that the prevalence of BPH increases with age, approximately 50% at the age of 60 years.[2]

Validation is done by correlating the results of IPSS-Ina with a score of quality of life (Quality of Life/QoL) subjects, and obtained results of 0.858 ($p < 0.001$) indicating a strong correlation. This value is higher than the correlation between the original version of the IPSS (American English) with a score QoL conducted Barry MJ, et al (1992) when validating the original version of IPSS shows the value of 0.77; which also shows a fairly good correlation. IPSS-Ina proved closely related to the perceived quality of life research subject, the more severe the symptoms experienced the lower the perceived quality of life. This suggests that the IPSS-Ina quite valid to assess symptoms of LUTS.

Furthermore, IPSS-Ina is also able to distinguish between BPH patients and control patients by looking at the score that proved significantly different between the two. This suggests that the IPSS-Ina sufficiently intelligible to subjects with everyday language of Indonesia, so it can provide results that correspond to the symptoms experienced by both BPH patients and control patients (non-BPH), and showed that the mean score of IPSS-Ina significantly higher in the group of BPH (20.54 ± 5.11) compared with the control group (3.78 ± 1.64) ($p < 0.001$).

Reliability of IPSS-Ina tested by two methods, namely by assessing internal consistency coefficient Cronbach α and test-retest conducted with intervals of 1 week, assessed with the intraclass correlation coefficient (ICC). Cronbach's α values showed good IPSS-Ina reliability which is 0.93. It's not much different from the value of Cronbach's α IPSS original version is 0.86, Cronbach's α values even IPSS-Ina is better than the value from other languages of IPSS such as Spanish version (0.79) or the Malay language (0.68).[6-8]

The reliability test with test-retest method with the intraclass correlation coefficient (ICC) also showed very good results are 0.99, which is also in line with the results of original version of IPSS with ICC values 0.92, which also shows a very good

reliability. This suggests that if the IPSS-Ina used multiple times with intervals in patients who have not received the therapy will result in values that are not much different from previous results. Once again, it shows that the IPSS-Ina can be understood easily by the subject with Indonesian language so as to provide results that correspond to the symptoms experienced.

However, if the patient received treatment, IPSS-Ina also proved to be able to assess based on symptoms/improvement of symptoms experienced by the subject. This is proved in 33 BPH patients who underwent TURP give initial mean score of IPSS-Ina (20.97 ± 4.46) with a mean score IPSS-Ina post-treatment (4.82 ± 1.77) were significantly different ($p < 0.001$) with a mean difference 16.15 ± 5.19. The same thing was also obtained from the question of quality of life (QoL) in the IPSS-Ina which showed a significant result ($p < 0.001$) with a mean difference between initial IPSS-Ina and post-TURP of 2.45 ± 0.93. This suggests that the IPSS-Ina is sensitive to the changes and can be used as an additional instrument for assessing post-therapy symptoms in BPH. Table 5 shows the comparison of validity and reliability between IPSS-Ina and the original (IPSS-Am).

Tabel 5. Comparison of validity and reliability.

	IPSS-Ina	IPSS-Am
Correlation value with QoL	0.85	0.77
Cronbach α	0.93	0.86
ICC	0.99	0.92

CONCLUSION

Indonesian version of IPSS has proven excellent validity and excellent reliability and not different from the original IPSS. Therefore IPSS-Ina has shown similar purpose and function as the original version.

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