



## Research Article

# Simplified Chinese version of the international prostate symptom score and the benign prostatic hyperplasia impact index: cross-cultural adaptation, reliability, and validity for patients with benign prostatic hyperplasia

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## ABSTRACT

**Background:** The aim of this study was to translate and cross-culturally adapt the international prostate symptom score (IPSS) and benign prostatic hyperplasia impact index (BII) into simplified Chinese for mainland Chinese patients with benign prostatic hyperplasia (BPH).

**Methods:** The original English IPSS and BII were translated into simplified Chinese versions based on cross-cultural adaptation guidelines. Internal consistency was evaluated with Cronbach's  $\alpha$ , then test-retest reliability with intraclass correlation coefficients (ICCs) in stable patients. The validity of these two adaptations was tested by the correlation between the IPSS and BII with visual prostate symptom score (VPSS) and 36 items Short Form Health Survey (SF-36). The floor and ceiling effects were calculated by the proportion of participants who obtained the highest and lowest possible score.

**Results:** A total of 105 native Chinese-speaking patients with BPH were enrolled. Cronbach's  $\alpha$  was over 0.75 for the simplified Chinese IPSS (IPSS 0.815; IPSS-symptom 0.782) and 0.709 for the simplified Chinese BII, indicating acceptable internal consistency. The ICCs for the test-retest reliability were over 0.75 (IPSS,  $r = 0.836$ ; IPSS-symptom,  $r = 0.801$ ; IPSS-quality of life,  $r = 0.794$ ; BII,  $r = 0.758$ ), indicating excellent test-retest reliability. There were very good positive correlations between IPSS and BII ( $r = 0.605$ ), as well as VPSS ( $r = 0.634$ ), and very good or good negative correlations between IPSS-QoL and SF-36 physical functioning ( $r = -0.621$ ), and vitality ( $r = -0.659$ ), and between BII and SF-36 physical functioning ( $r = -0.421$ ). No floor or ceiling effect was detected in the simplified Chinese IPSS and BII.

**Conclusions:** This study indicates that the simplified Chinese IPSS and BII are reliable and valid measurements of the symptom and quality of life among Chinese patients with BPH, which is likely to be widely used in this population.

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## 1. Introduction

Benign prostatic hyperplasia (BPH) is a common condition in middle-aged and older men.<sup>1,2</sup> It typically develops after the age of

40 years, and its prevalence ranges from >50% at 60 years to as high as ~90% at 85 years of age.<sup>3</sup> BPH patients suffer from lower urinary tract symptoms (LUTS), including obstructive (incomplete emptying, intermittent voiding, weak stream, straining) and irritative (frequent voiding, urgency, nocturia) urinary symptoms.<sup>4,5</sup> With changes in sleep patterns, anxiety and embarrassment, altered mobility, changes in leisure, daily living, and sexual activities, patients with LUTS due to BPH experience a significant deterioration in the quality of life (QoL).<sup>6</sup> In addition, BPH can also

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lead to more serious complications, such as acute urinary retention, recurrent urinary tract infections, hematuria, bladder calculi, as well as renal dysfunction.<sup>3,7</sup>

Patient-reported outcome measures, usually in the form of a questionnaire, provide a method for the standardized collection of data from patients. The first version of the International Prostate Symptom Score (IPSS) was created in 1992 by the American Urological Association (AUA) for the assessment of the aging male with LUTS due to BPH, which was originally called the AUA symptom index (AUA-SI).<sup>8</sup> It originally consisted of seven questions, lacking the QoL question, then the World Health Organization added the QoL question and adopted the AUA-SI as the final IPSS.<sup>9</sup> The IPSS was considered to be an easy, self-administered questionnaire with an application even in primary healthcare clinics. The AUA committee also developed the BPH Impact Index (BII) to assess the impact of BPH symptoms on patients' physical and mental health.<sup>10</sup> The BII is a self-administered questionnaire with four questions about urinary problems during the past month regarding physical discomfort, worry about health, how bothersome symptoms are, and whether the symptoms are interfering with doing usual activities.

The IPSS and BII had been found to be valid and reliable patient-reported outcome measurements for patients with LUTS or BPH in previous studies.<sup>11–14</sup> Both these two scales have been translated and adapted into other languages, such as Urdu, Arabic, Spanish, Japanese, and traditional Chinese–Hong Kong, or Mandarin in Malaysian, while a simplified Chinese version for mainland Chinese residents is not available.<sup>15–18</sup> The objectives of this study were to translate the IPSS and BII for simplified Chinese and to assess the factor structure, internal consistency, test-retest reliability, validity, as well as floor and ceiling effects of the simplified Chinese IPSS and BII in mainland Chinese patients with LUTS due to BPH.

## 2. Methods

### 2.1. Ethical considerations

The full study protocol was approved by the Research Ethics Committee from Yueyang Hospital of integrated traditional Chinese and Western Medicine. Informed consent was obtained from all patients involved in the study with no amendments (No. 2016LCSY030).

### 2.2. Cross-cultural adaptation and translation

#### 2.2.1. Stage I: translation of the IPSS and BII into simplified Chinese language and synthesis

The forward translation was conducted by two native bilingual Chinese-speaking translators independently (T1 and T2), one was a urologist, and the other was a professional English translator; then, the two translated versions (T1 and T2) were compared for any inconsistencies and synthesized into T1-2. It was then back-translated into English by two independent native English-speaking professional translators (B1 and B2), who did not know the original English IPSS and BII in advance. The translated versions (T1, T2, T1-2, B1, and B2) were compared with the original English version by all the translators and a bilingual expert committee, consisting of a senior English teacher, a urologist, and a cross-cultural translation expert. A prefinal simplified Chinese IPSS and BII was established by consensus from all the translators and the expert committee.

After all, 31 BPH patients with LUTS met the following inclusion criteria: (1) native simplified Chinese speakers, (2) men who were 45 years old or older with LUTS due to BPH, and (3) had no reading difficulty in Chinese, were enrolled to complete the prefinal

simplified Chinese IPSS, and BII. The patients finished the questionnaire, and they were asked if the items were clear and easy to understand. Suggestions and doubts were also collected from these patients. All the translators and the expert committee discussed and revised the prefinal simplified Chinese IPSS and BII according to these details as the final version.

#### 2.2.2. Stage II: test of the final version

A booklet covering the final simplified Chinese IPSS, BII, as well as the visual prostate symptom score (VPSS), 36 items Short Form Health Survey (SF-36), and Patients' Global Evaluation (PGE) was used in the study. Meanwhile, participant demographic information was also included, including age, disease duration, and so on.

### 2.3. Patients

The study involved native simplified Chinese-speaking men at least 45 years of age, with LUTS due to BPH, who consecutively consulted in Yueyang Hospital of integrated traditional Chinese and Western Medicine, Shanghai Seventh People's Hospital, and Longhua Hospital, Shanghai University of Traditional Chinese Medicine.

The sample size of such a cross-cultural adaptation should meet two conditions; the sample size should be above 100 and over seven times the number of items. The IPSS had eight items, and BII had 10 items; therefore, at least 100 patients were needed to be enrolled.<sup>19</sup>

### 2.4. Instruments

#### 2.4.1. International prostate symptom score

IPSS evaluated a combination of voiding symptoms (IPSS-symptom) and QoL related to voiding (IPSS-QoL). The IPSS-symptom allows the patient to choose 1 of 6 answers indicating the increasing severity of the particular symptom. The answers are assigned points from 0 to 5. The total score of IPSS-symptom ranges from 0 to 35, with higher scores indicating greater BPH symptom-related impact.<sup>6</sup> The IPSS-QoL is a six-point Likert scale, with a higher score indicating lower QoL impacted by BPH symptoms. The simplified Chinese IPSS is in [Supplementary table 1](#).

#### 2.4.2. Benign prostatic hyperplasia impact index

The BII measures physical discomfort, worry, bother, and interference with usual activities, then the physical discomfort, worry, and bother items have a four-point Likert scale, and the interference with usual activities item has a five-point Likert scale. The total score ranges from 0 to 13, with higher scores indicating greater BPH symptom-related impact.<sup>10</sup> The simplified Chinese BII is in [Supplementary table 2](#).

#### 2.4.3. Visual prostate symptom score

VPSS is an alternative questionnaire used to avoid the aforementioned problems when using the IPSS. It can be used to assess urinary frequency during daytime and nighttime, the stream of urine, and the QoL by means of pictograms.<sup>20</sup>

#### 2.4.4. The short form health survey (SF-36)

The SF-36 is used to evaluate patients' QoL with eight dimensions, ranging from 0 (poor health) to 100 (good health).<sup>21</sup> It was suggested that the simplified Chinese version of the SF-36 functioned in the general population of China quite similarly to the original American population tested.<sup>22</sup>

#### 2.4.5. Patients' global evaluation

A 7-point Likert scale ranging from "completely recovered," "much improved," "slightly improved," "slightly worsened," "much

worsened,” to “worse than ever” was used to evaluate participants’ overall status.<sup>23</sup>

### 2.5. Statistical analysis

Data were tabulated using Microsoft EXCEL, and rigorous statistical analyses were performed using IBM SPSS Statistics Version 21.0 (IBM Corp., Armonk, NY).

#### 2.5.1. Internal consistency

Exploratory factor analysis was performed by the principal-component analysis.<sup>24</sup> Cronbach’s  $\alpha$  was used to assess the internal consistency of the scales. Generally, a Cronbach’s  $\alpha > 0.7$  is regarded as acceptable. All the completed baseline data of the Chinese IPSS and BII were included in the analysis.<sup>19</sup>

#### 2.5.2. Reliability

The intraclass correlation coefficients (ICCs) were used to evaluate the test-retest reliability of Chinese IPSS and BII. An ICC above 0.7 is considered to show good reliability. As the patients did not wish to stop their treatment, only the patients who reported “no change” on the patients’ global evaluation were enrolled in the test-retest reliability evaluation.

#### 2.5.3. Validity

In the absence of a gold standard for BPH, criterion validity could not be evaluated. To assess criterion-related validity, we examined construct validity. We evaluated the relationships between the Chinese IPSS, BII, as well as VPSS, and SF-36 using the Pearson correlation coefficients ( $r$ ), where  $r > 0.40$  was considered satisfactory ( $r > 0.80$  is considered excellent, 0.61–0.80 very good, 0.41–0.60 good, 0.21–0.40 fair, and 0–0.20 poor).<sup>19</sup> All the completed baseline simplified Chinese IPSS, BII questionnaires with VPSS, as well as SF-36 scores were included in the analysis.

#### 2.5.4. Floor and ceiling effects

Distributions of the items in simplified Chinese IPSS and BII were checked for floor and ceiling effects, and more than 15% of respondents who achieved the lowest or highest possible total score were considered with floor and ceiling effects.<sup>19</sup> All the completed baseline simplified Chinese IPSS and BII questionnaires were included in the analysis.

## 3. Results

### 3.1. Testing of the prefinal version

Thirty-one questionnaires that included suggestions about the prefinal Chinese IPSS, and BII were used; 13 were active, and 18 were retired. Participants had no problems completing the Chinese IPSS and BII. Table 1 summarizes the patients’ characteristics.

### 3.2. Description of the sample

In total, 105 native Chinese-speaking male patients participated in the study, with a mean age of  $65.5 \pm 12.8$  years (Table 2). The duration of BPH was 3 to 96 months.

Workers (41/105) comprised the majority of patients, followed by farmers (19/105), policemen (11/105), and administrators (5/105). For the test-retest reliability, all patients were asked to complete the questionnaires again after a 2-week interval. In total, 103 patients completed the second round of questionnaires, and data from 57 patients rated as “no change” on the global evaluation were analyzed for test-retest reliability (Table 2). Of the remaining

**Table 2**

Factor analyses for the simplified Chinese IPSS and BII items with promax-rotated factor loadings

Item	Principal component coefficients $\geq 0.4$		
	Factor 1	Factor 2	Factor 3
IPSS			
Incomplete emptying	0.543		
Frequency	0.426		
Intermittency	0.610		
Urgency	0.594		
Weak stream		0.435	
Urinate hard	0.602		
Nocturia		0.576	
Quality of life			0.540
BII			
Physical discomfort	0.737		
Worry		0.536	
Bothersome		0.609	
Kept from usual activities	0.650		

BII, benign prostatic hyperplasia impact index; IPSS, international prostate symptom score.

**Table 1**

Demographic characteristics of participants in the three study stages

Characteristic	Pre-final group (n = 31)	Validity group (n = 105)	Reliability group (n = 57)
Age, years	64.1 $\pm$ 10.4	65.5 $\pm$ 12.8	64.7 $\pm$ 11.9
Disease duration, weeks	33.78 $\pm$ 60.96	34.05 $\pm$ 67.01	32.93 $\pm$ 62.44
Occupation, active/retired	13/18	49/56	23/34
IPSS	19.05 $\pm$ 5.38	18.74 $\pm$ 5.09	18.01 $\pm$ 4.21
IPSS-symptom	15.01 $\pm$ 6.25	14.97 $\pm$ 6.06	14.15 $\pm$ 5.93
IPSS-QoL	4.05 $\pm$ 2.69	4.12 $\pm$ 2.08	4.15 $\pm$ 2.06
BII	/	4.83 $\pm$ 1.24	4.39 $\pm$ 1.15
VPSS	/	15.56 $\pm$ 5.13	15.04 $\pm$ 5.39
VPSS-symptom	/	12.11 $\pm$ 5.88	12.05 $\pm$ 5.41
VPSS-QoL	/	3.44 $\pm$ 1.09	3.15 $\pm$ 1.12
SF-36			
Physical functioning	/	60.34 $\pm$ 22.51	62.33 $\pm$ 21.65
Role-physical	/	19.98 $\pm$ 25.31	24.01 $\pm$ 20.45
Bodily pain	/	45.33 $\pm$ 16.45	49.50 $\pm$ 15.91
General health	/	51.32 $\pm$ 17.27	51.30 $\pm$ 16.86
Vitality	/	53.70 $\pm$ 17.25	56.82 $\pm$ 16.94
Social functioning	/	78.66 $\pm$ 26.36	81.79 $\pm$ 21.05
Role-emotional	/	35.96 $\pm$ 41.52	36.03 $\pm$ 36.06
Mental health	/	60.36 $\pm$ 17.88	61.49 $\pm$ 15.68

IPSS, international prostate symptom score; QoL, quality of life; BII, benign prostatic hyperplasia impact index; SF-36, 36 items short form health survey; VPSS, visual prostate symptom score.

46 patients, 22 patients were rated as “slightly improved,” 10 patients as “much improved,” 2 patients as “completely recovered,” 12 patients as “slightly worsened,” and none as “much worsened” or “worse than ever”.

### 3.3. Psychometric properties

#### 3.3.1. Participants and missing data

The Chinese IPSS and BII showed satisfactory acceptability, with a completion time of  $3.02 \pm 1.95$  minutes and  $2.57 \pm 1.39$  minutes, respectively. Participants had no problems completing the Chinese IPSS and BII.

#### 3.3.2. Internal consistency

Factor analysis of the simplified Chinese IPSS and BII were performed with the Promax rotation; meanwhile, a three-factor structure was extracted in IPSS, and a two-factor structure in BII, respectively. Factor 1 of IPSS included items of incomplete emptying, frequency, intermittency, urgency, urinating hard; Factor 2 contained items of weak stream, and nocturia; then QoL to Factor 3. Physical discomfort, and kept from usual activities, belonged to Factor 1 of BII, then worry and bothersome to Factor 2 of BII. Loadings of all items were presented in Table 2. Cronbach's  $\alpha$  was 0.815 for the Chinese IPSS, 0.782 for IPSS-symptom, and 0.709 for the Chinese BII, indicating high levels of internal consistency (Table 3).

#### 3.3.3. Reliability

In total, 103 patients completed the second questionnaire round, at an interval of  $9.31 \pm 3.79$  days; 57 patients rated “no change” were included in the test-retest analysis. The Chinese IPSS and BII scores were slightly lower in the retest rather than in the first test. The ICCs for the test-retest reliability were over 0.75 (IPSS,  $r = 0.836$  [0.786 to 0.886]; IPSS-symptom,  $r = 0.801$  [0.703 to 0.899]; IPSS-QoL,  $r = 0.794$  [0.680 to 0.908]; BII,  $r = 0.758$  [0.663 to 0.851]), indicating excellent test-retest reliability (Table 3).

#### 3.3.4. Validity

We evaluated the relationships between the Chinese IPSS, BII, VPSS, and SF-36 by the Pearson correlation coefficient. There were very good positive correlations between IPSS and BII ( $r = 0.605$ ), as well as VPSS ( $r = 0.634$ ), and very good positive correlations were also observed between IPSS-symptom and VPSS-symptom ( $r = 0.708$ ), as well as between IPSS-QoL and VPSS-QoL ( $r = 0.725$ ) (Table 4).

There were very good negative correlations between IPSS-QoL and SF-36 physical functioning ( $r = -0.621$ ) and vitality ( $r = -0.659$ ). Then there were good negative correlations between IPSS-QoL and SF-36 role-physical ( $r = -0.533$ ), general health ( $r = -0.503$ ), as well as vitality ( $r = -0.427$ ); a good negative correlation was also observed between BII and SF-36 physical functioning ( $r = -0.421$ ) (Table 4).

**Table 3**

Internal consistency and test-retest reliability of the simplified Chinese IPSS and BII

Scales	Number of items	Cronbach's $\alpha$ (n = 105)	ICC (n = 57)
IPSS	7	0.815	0.836 [0.786 to 0.886]
IPSS-symptom	6	0.782	0.801 [0.703 to 0.899]
IPSS-QoL	1	/	0.794 [0.680 to 0.908]
BII	4	0.709	0.758 [0.663 to 0.851]

BII, benign prostatic hyperplasia impact index; IPSS, international prostate symptom score.

**Table 4**

Pearson correlation coefficient ( $r$ ) of the simplified Chinese IPSS and BII with VPSS, and SF-36

Score	IPSS	IPSS-symptom	IPSS-QoL	BII
IPSS	/	0.840*	0.731**	0.605*
IPSS-symptom	0.840*	/	0.392	0.534
IPSS-QoL	0.731*	0.392	/	0.319
BII	0.605*	0.534	0.319	/
VPSS	0.634*	0.628*	0.452	0.692*
VPSS-symptom	0.693*	0.708*	0.308	0.418*
VPSS-QoL	0.306	0.291	0.725*	0.393
SF-36				
Physical functioning	-0.329*	-0.227*	-0.621*	-0.421*
Role-physical	-0.267	-0.196	-0.533*	-0.304
Bodily pain	-0.391	-0.205*	-0.427	-0.395*
General health	-0.284*	-0.213	-0.503*	-0.293*
Vitality	-0.124	-0.390*	-0.659*	-0.182
Social functioning	-0.308*	-0.285*	-0.336	-0.219*
Role-emotional	-0.315*	-0.114	-0.347	-0.287
Mental health	-0.226	-0.201	-0.495*	-0.330*

BII, benign prostatic hyperplasia impact index; IPSS, international prostate symptom score; SF-36, short form health survey; VPSS, visual prostate symptom score.

Notes: \*Correlation is significant at the 0.05 level (2-tailed).

#### 3.3.5. Floor and ceiling effects

There was no floor or ceiling effect of the simplified Chinese IPSS and BII.

## 4. Discussion

### 4.1. Study summary

This was the first simplified Chinese version of IPSS and BII developed based on the cross-cultural adaptation guidelines. In the study, we demonstrated that the simplified Chinese versions of IPSS and BII were both valid, reliable and internally consistent instruments for assessing patients with BPH, which displayed no floor or ceiling effects. All items in the simplified Chinese version of IPSS and BII had loadings of  $>0.40$  in each factor. Furthermore, the Cronbach's  $\alpha$  of 0.815 and 0.709 indicated good internal consistency of these two scales. The test-retest results (ICC = 0.836 for IPSS, ICC = 0.758 for BII) confirmed excellent reliability. In addition, it was revealed that IPSS correlated well with BII and VPSS, and IPSS-QoL correlated well with SF-36. These results, taken together, demonstrated that the simplified Chinese versions of IPSS and BII were useful in evaluating Chinese patients with BPH in both clinical practice and research settings.

### 4.2. The measurement properties compared with other versions

The assessment of all the cross-cultural IPSS and BII adaptations of other languages was conducted for the measurement properties.<sup>15–18,25–27</sup> The summary of the measurement properties regarding the original and cross-cultural IPSS and BII adaptations is shown in Table 5.

**Table 5**  
The summary of the measurement properties of cross-cultural IPSS and BII adaptations

Score	Sample size	Factor analysis	Internal consistency	Test-retest reliability	Construct validity
<b>IPSS</b>					
Arabic-United Arab Emirates	76	/	<b>Cronbach's <math>\alpha</math></b> IPSS-symptom 0.85	<b>ICC</b> IPSS-symptom 0.88 IPSS-QoL 0.71	/
Japanese	103 with BPH and 23 asymptomatic men	<b>Factor loading:</b> Factor 1 Item 1 0.39 Item 2 0.38 Item 3 0.39 Item 5 0.36 Item 6 0.41 Factor 2 Item 4 0.45 Item 7 0.36	<b>Cronbach's <math>\alpha</math></b> IPSS-symptom 0.83	<b>ICC</b> IPSS-symptom 0.82 IPSS-QoL 0.71	/
Malay-Malaysian	20 men with LUTS, and 20 controls	/	<b>Cronbach's <math>\alpha</math></b> IPSS-symptom 0.68 IPSS-QoL 0.79	<b>ICC</b> IPSS-symptom 0.70 IPSS-QoL 0.79	/
Mandarin-Malaysian	39 with BPH and 29 control	/	<b>Cronbach's <math>\alpha</math></b> IPSS-symptom for BPH 0.96 –0.98 IPSS-symptom for control 0.86 –0.98	<b>ICC</b> IPSS-symptom for BPH 0.93–0.99 IPSS-symptom for control 0.97–0.99	/
Simplified Chinese	105	<b>Factor loading:</b> Factor 1 Item 1 0.543 Item 2 0.426 Item 3 0.610 Item 4 0.594 Item 6 0.602 Factor 2 Item 5 0.435 Item 7 0.576 Factor 3 Item 8 0.540	<b>Cronbach's <math>\alpha</math></b> IPSS 0.836 IPSS-symptom 0.782	<b>ICC</b> IPSS 0.836 IPSS-symptom 0.801 IPSS-QoL 0.794	<b>Pearson's correlations</b> BII 0.605 VPSS 0.634 VPSS-symptom 0.693 VPSS-QoL 0.306
Spanish	59 with BPH and 68 control	/	<b>Cronbach's <math>\alpha</math></b> IPSS-symptom 0.79	<b>ICC</b> IPSS-symptom 0.87 IPSS-QoL 0.59	<b>Pearson's correlations</b> EQ-5D 0.07–0.36 EQ-5D VSA –0.29 PGWBI dimension 0.14–0.41
Urdu-Pakistanis	267	<b>Factor loading:</b> Factor 1 Item 1 0.517 Item 3 0.877 Item 5 0.789 Item 6 0.848 Factor 2 Item 2 0.762 Item 4 0.776 Item 7 0.746	<b>Cronbach's <math>\alpha</math></b> IPSS 0.72	<b>ICC</b> IPSS-symptom 0.92 IPSS-QoL 0.75	/
Traditional Chinese-Hong Kong	233	<b>Corrected item-total correlation</b> Item 1 0.58 Item 2 0.38 Item 3 0.57 Item 4 0.30 Item 5 0.57 Item 6 0.42 Item 7 0.20	<b>Cronbach's <math>\alpha</math></b> IPSS 0.71	<b>ICC</b> IPSS-symptom 0.80 IPSS-QoL 0.70	<b>Pearson's correlations</b> IPSS-symptom ICIQ-UI SF 0.47 IPSS-QoL IIQ-7 0.46 SF 12 PCS –0.17 SF 12 MCS –0.21
<b>BII</b>					
Japanese	103 with BPH and 23 asymptomatic men	<b>Factor loading:</b> Factor 1 Item 1 0.51 Item 2 0.48 Item 3 0.51 Item 4 0.50	<b>Cronbach's <math>\alpha</math></b> 0.90	<b>ICC</b> 0.67	/



## Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Conflicts of interest

The authors declare that they have no competing interests.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pnrl.2022.04.001>.

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