

Urinary Symptom Profile Scale Translated into Chinese and Tested for Validity and Reliability in Postoperative Patients with Cauda Equina Syndrome

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Abstract: The Urinary Symptom Profile (USP) scale was translated into Chinese to evaluate its validity and reliability in postoperative patients with cauda equina syndrome (CES). After obtaining the consent of the original author, the translator-back-translation model was used to translate the original scale, and the cross-cultural adaptation and preliminary research was carried out. A convenience sampling method was used to select 136 patients with CES who had undergone surgery from two tertiary hospitals in Xi'an and Yantai cities for a questionnaire survey to evaluate its reliability and validity. The 10th item that did not meet the condition was deleted, and the Chinese version of the USP scale had 3 dimensions and 12 items. In the exploratory factor analysis, three common factors were extracted using the criterion that the eigenvalue was greater than 1, which was consistent with the dimensions of the original scale. The Cronbach's α coefficient for the scale was 0.876 and the retest reliability of the scale was 0.954. The correlation coefficients between the Chinese version of the USP scale and the male International Prostate Symptom Score and the female Lower Urinary Tract Symptom Score Scale were 0.889 and 0.874, respectively (both $P < 0.001$). The Chinese version of the USP scale has good reliability and validity and can effectively assess residual urinary symptoms in patients with CES after surgery.

Keywords: Urinary Symptom Profile Scale; cauda equina syndrome; Translation; Reliability; validity

1. Introduction

Cauda equina syndrome (CES) is a debilitating spinal disorder caused by compression of lumbosacral spinal canal nerve disease, severely affecting patients' quality of life [1, 2]. Once it occurs, it often represents an emergency and requires initial surgical treatment [3]. The clinical manifestations of CES are complex and include urinary tract symptoms, bowel dysfunction, perineal numbness, and loss of sexual function [4]; Among them, urinary tract symptoms are considered the most important factors for identifying CES [5]. However, once the urinary system is involved in CES, postoperative recovery is often unsatisfactory. According to the latest meta-analysis, the residual rate of urinary symptoms after CES was 43.3% in an average follow-up of 3 years [6]. The use of invasive urodynamics to assess the urinary tract after CES often represents a burden for patients [7] and even the measurement results differ greatly from the patients' subjective feelings [8]. The Urinary Symptom Profile (USP) scale was developed by Haab et al. developed. [9], which assessed patients' self-perception of urinary symptoms across three dimensions: urinary incontinence, overactive bladder, and dysuria. Unlike the International Prostate Symptom Score (IPSS) [10] and the Female Lower Urinary Tract Symptom Score (Female). Lower Urinary Tract Symptom Score (FLUTSS)[11], the USP scale can be applied to both genders without difference, which greatly improves research efficiency. The English version of the USP scale has been applied to the postoperative follow-up of CES patients [12] and has been translated into other language versions [13]. Therefore, this study is dedicated to translating and cross-cultural adaptation of the USP scale and further testing its reliability and validity in CES patients to fill the gap of missing urinary function examination in CES patients in China.

2. Materials and methods

2.1 Introduction of the USP scale

The USP scale included three dimensions (stress incontinence, overactive bladder, and low urinary flow) with 13 items. Each item was scored from 0 to 3 points. The first dimension score ranged from 0 to 9, the second dimension ranged from 0 to 21, and the third dimension ranged from 0 to 9. The total score was 39, with higher scores indicating more severe urinary tract symptoms. The internal consistency reliability was good and the Cronbach α value of each dimension was greater than 0.70(0.71-0.94)[9]

2.2 Localization of the scale

2.2.1 Translation and back-translation of the scale

The scale localization process was carried out by the original author Dr. Haab approved and the scale was translated into Chinese according to the requirements of the cross-cultural translation guidelines[14]. ①Translation: The USP was independently translated by two researchers (a Master, CET-6, Nursing and Orthopedics) who were good at English translation. ②Translation synthesis: An expert in spinal orthopedics (physician, associate senior) with 3 years of study experience in the United States compared the two translations to produce the Chinese version A3; The members of the research group compared the three versions of the translation with the original, discussed and revised them into the Chinese version A. ③Back translation: Two researchers who were proficient in English and had no contact with the scale (teachers of English department in universities and urologists of English major 8) independently translated the Chinese version A into B1 and B2. ④Synthesis of back translation: The research team members revised the back translation B1 and B2 to form the back translation B and sent it to the original author for review. According to the authors of the original scale, the Chinese version C was revised after discussion.

2.2.2 Cultural debugging

In this study, a panel of seven experts was formed to conduct cultural debugging of the Chinese version of C and evaluate the cultural appropriateness of each item of the scale. Team members included two urologists, two spine surgeons, two orthopedic nurse specialists, and a psychologist knowledgeable in scale development. These included 4 senior titles, 2 associate senior titles and 1 intermediate title. Five had doctoral degrees and two had master's degrees. Experts were asked to assess the clarity of expression, content accuracy, dimensional correlation, and cultural equivalence of each of the scale's items, and experts were asked to provide suggestions for revising ambiguous items. Based on the opinions of experts, the research team members focused on determining the Chinese version of D.

2.2.3 Preliminary investigation

Using the convenience sampling method, a total of 20 patients with CES who underwent surgical treatment at Xijing Hospital of Air Force Medical University from May to November 2023 were selected. The Chinese version of the USP scale D was used for preliminary examination one month after surgery. Inclusion criteria: ①Patients with residual urinary tract symptoms after CES; ②Age ≥ 18 years; ③The ability to read and communicate normally; ④Voluntary participation in this study. Exclusion criteria: ①Diseases affecting urinary tract function, such as prostatic hyperplasia, cancer radiotherapy, etc. ② suffering from mental illness; ③long-term use of medications that cause abnormal urination; ④Cannot reach the hospital site during postoperative follow-up. The content of the interview mainly included how the respondents understood the items, what difficulties they encountered, and their cognitive process. It took 3 to 4 minutes for respondents to complete the scale. Based on the results of the preliminary survey, the Chinese version of USP Scale E was formed, which was the official test version.

2.3 Reliability and validity test of the Chinese version of the urinary tract symptom scale in postoperative patients with cauda equina syndrome

2.3.1 Subjects

In this study, the convenience sampling method was used to select CES patients undergoing surgical treatment at the Xijing Hospital of the Air Force Medical University (Xi'an) and the 970th Logistics Joint Hospital from January 2021 to April 2023 Support Force (Yantai) underwent survey objects. According to the principle that the sample size in the scale verification process is 10 times or more the number of

items on the scale [14], a sample size of ≥ 130 was required. The inclusion and exclusion criteria were the same as the preliminary survey. This study was approved by the Ethics Committee of Xijing Hospital (KY20232023-C-1).

2.3.2 Data collection

Four uniformly trained researchers (two from each hospital) studied patients with CES who still had urinary tract symptoms at postoperative follow-up. Before the survey, patients were introduced to the anonymous and voluntary nature of the survey and the scale was distributed after signing the informed consent form. A total of 140 questionnaires were distributed and 136 questionnaires were collected in this study, with an effective recovery rate of 97.14%. When male respondents completed the Chinese version of the USP scale, they completed the IPSS scale [10] simultaneously, and female respondents completed the FLUTS scale [11]. One week later, 30 patients from the formal survey were selected to complete the Chinese version of the USP again via telephone consultation.

2.3.3 Statistics

SPSS 26.0 software was used for statistical analysis. Measurement data conforming to normal distribution were expressed as mean \pm standard deviation and analyzed by independent sample t test. Non-normally distributed measurement data were described by median and quartile, and rank sum test was performed. Count data were expressed as frequency and percentage, and chi-square test was used for comparison. $P < 0.05$ was considered statistically significant. The validity of the scale was evaluated by content validity, construct validity and criterion-related validity. The reliability of the scale was evaluated by Cronbach's α coefficient, split-half reliability and test-retest reliability. Pearson correlation analysis was used to explore the correlation between the Chinese version of USP scale and IPSS scores and FLUTS scores.

3. Results

3.1 Cultural adaptation and pre-survey scale results

Based on the opinions of experts in various fields, the original authors and members of the research group, as well as the results of the preliminary survey, the content of the English version of USP was revised and adjusted as follows. ① Instruction language: the instruction language of the original scale "there is no right or wrong answer" was placed after "the choice that is most suitable for you", which was re-ordered according to cultural habits and modified to "there is no right or wrong answer to the following questions, please choose the choice that is most suitable for you". ② Item layout: In the original scale, the physical activity level in dimension 1 was explained centrally. For the convenience of reading, we adjusted it to explain the physical activity level in each item separately. Item 1 "severe physical activity" was defined as "running and jumping or coughing violently", item 2 "moderate physical activity" was defined as "climbing mountains or descending stairs", and item 3 "light physical activity" was defined as "walking or changing posture". ③ Expression modification: the guidance words "career or family life" in dimension 2 and 3 were considered by experts to be not clear enough. According to the Chinese expression habits, it is modified to "work or family life". ④ Item content: item 10, "How many times during a week did you leak urine during sleep or wake up with wet urine?" The last option given in the original scale was "many times a day". After discussion by experts, it was revised to "every day" after determining that this expression might lead to misunderstanding of the research subjects. After re-translating the revised version, the original author said that the meaning of this version was very close to the original item, and the re-formatting was more conducive to the reading and understanding of Chinese respondents.

3.2 General information from respondents

Of the 136 patients, 88 were from Xijing Hospital and 48 were from the 970th Hospital, including 72 men and 64 women. Age ranged from 19 to 78 (49.59 ± 12.38) years. Education level: 75 cases from middle school or below, 26 cases from senior high school or technical secondary school, 35 cases from middle school or higher. There were 98 cases of lumbar disc herniation, 31 cases of lumbar spinal stenosis, 5 cases of lumbar spondylolisthesis, and 2 cases of lumbosacral tumor.

3.3 Project analysis

According to the item scores, the 27% respondents with the highest total score were classified as "high group", and the 27% respondents with the lowest total score were classified as "low group". Independent sample t test results showed that item 10 "How many times in a week have you leaked urine while sleeping or woke up with wet urine?" The cut-off value (CR) was 1.434 ($P=0.160$), and the CR values of other items were all greater than 3. The correlation coefficient between item 10 and the total score was 0.291 ($P<0.01$), and the correlation coefficient of the corrected total score was 0.273, which were all less than 0.400. The Cronbach's α coefficient of the total scale was 0.872, and the Cronbach's α coefficient was 0.876 after deleting item 10, indicating that item 10 was not highly correlated with the total scale and other items.

3.4 Validity analysis

3.4.1 Content validity

According to the content validity scoring criteria [15], 7 experts from cultural commissioning were invited to participate in the expert consultation. Item 10 "How many times in a week do you leak urine while sleeping or wake up with wet urine?" The Item-content validity index (I-CVI) was 0.57. The I-CVI of other items ranged from 0.86 to 1.00. Spine surgeons and nursing experts believe that night urine leakage is rare in patients with CES, and very few patients can control such events by forbidding water before sleep. After full discussion by the research team, item 10 was considered to be deleted in combination with the low homogeneity between item 10 and the total scale in the project analysis. After deleting item 10, the scale-content validity index (S-CVI) was 0.95.

3.4.2 Construct validity

After deleting item 10, the remaining 12 items were analyzed by exploratory factor analysis. The KMO value was 0.826, and Bartlett spherical test $\chi^2=1125.196$ ($P<0.001$), indicating that the data were suitable for factor analysis. Three common factors with eigenvalues greater than 1 were extracted by principal component analysis, scree plot (FIG. 1) and variance maximization orthogonal rotation, and the cumulative variance contribution rate of the three factors was 75.602%. The loading of each item on the corresponding common factor was greater than 0.4, and there was no double loading phenomenon. The common factor 1 (overactive bladder) contained items 4, 5, 6, 7, 8, and 9, the common factor 2 (low urinary flow) contained items 11, 12, and 13, and the common factor 3 (stress urinary incontinence) contained items 1, 2, and 3.

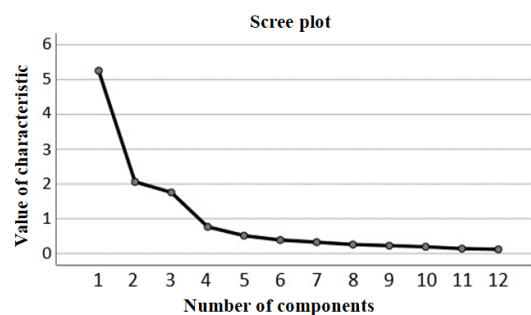


Figure 1: Lithotripsy diagram of the Chinese version of the Urinary Tract Symptom Scale

3.4.3 Criterion related validity

The correlation coefficients between the total score of the Chinese version of USP and the total score of IPSS in men and the total score of FLUTS in women were 0.889 and 0.874, respectively (both $P<0.001$), indicating that the Chinese version of USP had good criterion correlation validity.

3.5 Reliability test

After deleting 10 items, the Cronbach's α coefficient of the Chinese version of USP was 0.876, showing good internal consistency. The Cronbach's α coefficients of the three dimensions were 0.842, 0.905 and 0.891, respectively. In addition, the split-half reliability of the total scale and three dimensions were 0.763, 0.861, 0.904 and 0.919, respectively. In order to further verify the stability of the scale, 30

randomly selected patients were followed up by telephone one week later to fill in the scale again. The results showed that the test-retest reliability of the total scale and three dimensions were 0.954, 0.969, 0.938 and 0.919, respectively, which indicated that the scale had a high test-retest reliability.

4. Discuss

4.1 The Chinese version of USP scale

This study aims to translate the Chinese version of USP into Chinese and verify its reliability and validity in patients with urinary symptoms after CES. According to the cross-cultural research tools or the guidelines for scale translation, adaptation and validation, the original English scale was scientifically translated, back-translated and culturally adjusted. After communicating with the author of the original scale, Dr. Haab, the members of the research team discussed and revised the Chinese version of USP. Experts from urology, spine surgery, nursing, psychology and other fields were included in the process of translating the scale into Chinese. Patients after CES were also pre-surveyed by cognitive interviews to ensure that the content of the scale was scientific, easy to understand and acceptable.

4.2 Item analysis of the Chinese version of USP scale

In item analysis, item 10 "correlation of adjusted total items" was 0.273, less than 0.400, which had poor correlation with other items. The Cronbach's α coefficient of the total scale was 0.872, and the item 10 was deleted and increased to 0.876, indicating that the item 10 was not closely related to the common factor. Combined with the opinions of spine surgery experts, the research team members further discussed, considering that item 10 is rare in CES patients and can be controlled by patients' water prohibition, so item 10 was deleted.

4.3 Validity of the Chinese version of USP

S-CVI \geq 0.90 and I-CVI \geq 0.78 were required when the number of experts was \geq 6. After deleting item 10, the minimum I-CVI of each item was 0.86, and the S-CVI of the total scale was 0.95, which indicated that the content validity of the modified Chinese version of USP was good. In addition, three common factors with eigenvalues $>$ 1 were obtained by exploratory factor analysis, which explained 75.602% of the variance, which was consistent with the original scale. The loading amounts of the remaining item factors were all greater than 0.40, which met the item screening criteria [16], and there was no need to continue deleting items. In addition, the Chinese version of USP has a good correlation coefficient with the widely used IPSS scores in men and FLUTS scores in women, indicating that the Chinese version of USP has good criterion correlation validity and can effectively evaluate the postoperative urinary symptoms of CES patients.

4.4 Reliability of the Chinese version of USP

Reliability is an indicator that reflects the truth of the results obtained by the test tool (scale) [17]. It is generally believed that Cronbach α coefficient is acceptable in the range of 0.70-0.80, and 0.80-0.90 is very good [18]. The Cronbach's α coefficient of the total score of the Chinese version of USP was 0.876, and the Cronbach's α coefficient of each dimension was 0.842-0.905, indicating that the item correlation of the Chinese version of USP was good. In addition, higher test-retest reliability coefficients indicate better scale stability across time. The test-retest reliability of each dimension of the Chinese version of USP was 0.938-0.969 ($>$ 0.70), indicating good stability [19]. The split-half reliability reflects the internal consistency of the scale, and when the coefficient is greater than 0.70, the scale is considered good [20]. The split-half reliability of the Chinese version of USP was more than 0.7 in all dimensions and overall, indicating that the scale had good consistency.

4.5 Practicability and limitations of the Chinese version of USP

Urinary dysfunction in CES patients is a process of long-term recovery, and self-assessment of CES patients using validated scales during follow-up has become one of the main ways to obtain postoperative information [21, 22]. The Chinese version of USP was revised by rigorous translation and cultural adaptation process, with scientific content, clear expression, short time consuming and high practicability. In addition, in the process of item analysis, combined with the characteristics of CES patients, the item

10 "how many times in a week have you leaked urine during sleep or found wet urine when you woke up" was deleted to make the Chinese version of USP more consistent with China's national conditions and CES patients' conditions. There are some limitations of this study: 1. Due to the time limit of emergency surgery for CES patients, the preoperative USP scale data are not available. Whether the Chinese version of USP scale is suitable for patients with preoperative urinary symptoms of CES needs to be investigated; (2) Due to the small number of CES cases, the Chinese version of USP has only been preliminarily tested for reliability and validity. Follow-up studies need to expand the sample size, and further verify the scientific validity and practicability of the scale in different clinical manifestations and even other urinary tract diseases.

5. Conclusions

In this study, the urinary tract symptom scale has three dimensions and 12 items. The scale has good performance in language accuracy, cultural adaptability, structural consistency and test verification. It has high reliability, validity and applicability, and can be applied to investigate postoperative urinary function in patients with cauda equina syndrome in the Chinese environment. In view of the large population and the large number of patients in China, it is more convenient, efficient and feasible to follow up the results of postoperative urinary function results by patients with cauda equina syndrome.

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