

Design and validation of a scale for neurogenic lower urinary tract dysfunction secondary to spinal cord injury

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Abstract

Background: Spinal cord injury-induced neurogenic lower urinary tract dysfunction (SCI-NLUTD) tends to be accompanied by bowel dysfunction, sexual dysfunction, and psychological disorders. To date, a convenient and concise tool for the comprehensive assessment of these symptoms in patients with SCI-NLUTD has been lacking. **Objective:** This study aimed to design and evaluate a comprehensive patient-reported outcome measuring system for SCI-NLUTD patients to facilitate patient follow-up and treatment. **Methods:** A draft questionnaire was designed based on a review of the literature and input from patients and experts, and was refined using the Delphi method. The scale was administered to 185 patients with SCI-NLUTD. Reliability was assessed using Cronbach's alpha and test-retest reliability coefficients, while validity was evaluated through exploratory factor analysis, and in terms of content validity index, content validity ratio, and kappa statistics. **Results:** The final SCI-NLUTD scale includes 7 domains, 23 items, and 1 item assessing urination pattern. It demonstrated good internal consistency (Cronbach's alpha = 0.775) and test-retest reliability (0.731–0.998). Validity was confirmed (Kaiser–Meyer–Olkin = 0.784, content validity index ≥ 0.89 , content validity ratio ≥ 0.78 , and kappa statistics ≥ 0.89). Results were visualized using radar charts to facilitate clearer tracking of symptom profiles. **Conclusion:** The SCI-NLUTD scale is a reliable, valid, and convenient tool for comprehensive assessment of SCI-NLUTD symptoms, aiding in treatment planning and monitoring patients' quality of life.

Keywords: Neurogenic lower urinary tract dysfunction, Spinal cord injury, Questionnaire design, Comprehensive assessment, Radar chart

1. Introduction

The process of normal micturition is precisely controlled by coordination between the central and peripheral nervous systems.¹ Neurogenic lower urinary tract dysfunction (NLUTD) caused by spinal cord injury (SCI) is a condition characterized by a cluster of lower urinary tract symptoms and complications resulting from neurological impairment.² While SCI-NLUTD characteristically presents urinary symptoms, such as urinary incontinence and urinary retention, it also often involves bowel dysfunction,³ sexual dysfunction (SD),⁴ and psychological disorders.⁵ These symptoms exert negative psychological and physical effects on patients and can significantly impact their quality of life.⁶

Clinical assessment of SCI-NLUTD relies heavily on patient-reported outcome measures (PROMs).⁷ Accordingly, a comprehensive assessment of clinical symptoms is critical. To date, several scales for evaluating urinary symptoms have been developed and used, such as the Neurogenic Bladder

Symptom Scale,⁸ Qualiveen,⁹ International Consultation on Incontinence Questionnaire-Short Form,¹⁰ King's Health Questionnaire,¹¹ and Actionable Bladder Symptom Screening Tool.¹² In addition, several scales assess quality of life,⁶

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neurogenic bowel dysfunction,¹³ sleep quality,^{14,15} sexual function,¹⁶ and anxiety.¹⁷ Unfortunately, these scales only cover some aspects of patients' symptoms and/or quality of life. Current questionnaires are of limited value since they fail to comprehensively evaluate the full spectrum of symptoms in SCI-NLUTD patients. These questionnaires cannot provide an overall picture of symptom burden during treatment and follow-up. Comprehensive evaluation of patient status using all existing instruments is highly time-consuming and not feasible for the routine diagnosis and follow-up of patients with SCI-NLUTD. Hence, a comprehensive, concise, and intuitive patient-reported outcome questionnaire for patients with SCI-NLUTD is urgently required.

Our study was designed to develop a PROM scale to comprehensively assess the systemic symptoms associated with SCI-NLUTD. Moreover, the present study evaluated the performance of this newly developed standardized instrument in characterizing and quantifying the symptomatology of patients with SCI-NLUTD. A radar chart was further developed to better visualize changes in the patients' symptoms.

2. Materials and methods

The preliminary development of a comprehensive PROM scale was based on a literature review and patient interviews. The proposed items were reviewed by experts and modified based on their feedback. Participants with SCI-NLUTD completed the questionnaire. The scale's internal consistency, test-retest reliability, and validity were analyzed. The items were then presented as a radar chart.

2.1. Design of the comprehensive neurogenic lower urinary tract dysfunction scale

Based on a review of the literature, patient interviews, and existing scales (Neurogenic Bladder Symptom Score, International Erectile Function Rating Scale, Female Sexual Function Index, Neurogenic Bowel Dysfunction score, 7-item Generalized Anxiety Disorder Scale, Pittsburgh Sleep-Quality Index), the SCI-NLUTD scale (SCI-NLUTDS) was designed to assess the clinical symptoms of patients diagnosed with SCI-NLUTD.^{2,8,14} This newly designed questionnaire comprised 7 domains with 34 items, with each item rated on a 1–5 or 1–6 point sub-scale. A higher total score indicated more severe symptoms. The scale was evaluated in terms of accuracy, importance, familiarity coefficient (Ca), and judgment coefficient (Cs) by employing the Delphi method. The expert authority coefficient (Cr) indicated the reliability of the assessment results, a value >0.7 being considered acceptable. Cr was the average of Ca and Cs. The coefficients of variation for accuracy and importance served as key indicators of the consistency of experts' opinions and were

required to be <0.15. Kendall's *W* was utilized to assess the agreement among experts, and values ≥ 0.2 were taken as acceptable.

2.2. Patient recruitment

On approval by the Institutional Ethics Committee (KYLL-202209-036), patients presenting to the Qilu Hospital of Shandong University and the Second Affiliated Hospital of Shandong University of Traditional Chinese Medicine, Shandong, China, completed the SCI-NLUTDS twice. If patients had difficulty understanding any item, they were allowed to ask the doctor for clarification. The inclusion criteria were as follows: (i) Aged ≥ 18 years; (ii) Diagnosed with SCI-NLUTD by a combination of relevant history and supplementary examinations (magnetic resonance imaging, urodynamics, etc.); (iii) Patient had sustained SCI at least 5 years ago to ensure adequate adjustment and stable assessment of the condition. In addition, relevant demographic data were collected. To obtain retest results, patients were required to complete the SCI-NLUTDS again approximately 2–4 weeks later.

2.3. Item analysis

The item analysis aimed to establish the homogeneity of scale items. The items were expected to discriminate between respondents with different levels of symptom severity. The critical ratio method was used to analyze the questionnaire items to ensure that there was no ceiling or floor effect.

2.4. Reliability

Cronbach's alpha was used to assess the questionnaire's reliability, with scores ranging from 0 to 1; values close to 1 indicated high reliability and homogeneity. After 2–4 weeks, a follow-up was conducted with the patients by telephone or mailing to assess test-retest reliability. The test-retest reliability reflects the stability and consistency of a test over time. Scores span from 0 to 1, and a higher correlation score indicates better consistency and stability of the pre- and post-measurements.

2.5. Validity

Validity refers to the ability of a scale to measure the items/components it is intended to.⁷ Exploratory factor analysis and correlation analysis were used to assess the questionnaire's validity. The number of factors was estimated using the principal component extraction method. Our goal was to work out a simple solution with a minimum number of factors. The Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and Bartlett's sphericity test demonstrated that the correlation matrix was suitable for factor analysis. In addition, KMO

values ≥ 0.6 were considered acceptable. The Short Form 36 Health Survey (SF-36) is a comprehensive instrument for measuring quality of life and health conditions. For criterion validity, we analyzed correlations between the total scale and its domains and between the total scale and the SF-36. Content validity reflects the degree of agreement between the scale items and the construct they are intended to measure. It was assessed in terms of the content validity index (CVI), content validity ratio (CVR), and kappa statistics.

2.6. Radar diagram

Radar diagrams are visualization tools that can illustrate qualitative aspects using quantitative indicators.¹⁸ To clarify changes in the patients’ clinical symptoms, the scale was presented as a radar chart, with the coordinates for each axis derived from the corresponding domain scores.

2.7. Statistical analyses

All statistical analyses were performed using the Statistical Package for the Social Sciences 25.0, IBM, USA. Continuous variables were reported as means, and group differences were compared using the Mann–Whitney *U* test. A $p < 0.05$ was considered statistically significant.

3. Results

3.1. Expert information

Ten physicians and four nurses evaluated the questionnaire in the first round, and six physicians and four nurses did so in the second round. The panels included urologists, general surgeons, rehabilitation specialists, and psychologists involved in the treatment of NLUTD. The response rate in both rounds was 100%. Work experience ranged from 3 to 30 years in the first round and 6–25 years in the second (Table 1).

3.2. Establishment of scale

Based on a literature review and existing NLUTD guidelines and scales, a primary questionnaire containing 34 items was drafted: urine storage symptoms (5 items), urination symptoms (5 items), sexual function (5 for men and 5 for women), intestinal symptoms (4 items), psychiatric symptoms (4 items), pain symptoms (2 items), and sleep quality (4 items). The questionnaire was then evaluated by experts using the Delphi method. Based on expert feedback, a revised questionnaire with 28 items across eight subscales was developed: Urine storage symptoms (5 items), urination symptoms (2 items), post-micturition symptoms (3 items), sexual function (3 for men and 3 for women), intestinal symptoms (5 items), psychiatric symptoms (2 items), pain symptoms (2 items), and sleep quality (3 items).

Table 1. General information about the experts

| Information | The first round | | The second round | |
|-------------------------|-----------------|--------------------|------------------|--------------------|
| | Number | Constituent ratio% | Number | Constituent ratio% |
| Gender | | | | |
| Man | 6 | 42.86 | 5 | 50 |
| Women | 8 | 57.14 | 5 | 50 |
| Occupation | | | | |
| Doctor | 10 | 71.43 | 6 | 60 |
| Nurse | 4 | 28.57 | 4 | 40 |
| Work experience (years) | | | | |
| <10 | 4 | 28.57 | 4 | 40 |
| 10–20 | 7 | 50.00 | 3 | 30 |
| 20–30 | 3 | 21.43 | 3 | 30 |

Based on the results of the two rounds of expert evaluation, the Cr values were 0.864 and 0.912, indicating that the expert consultation results were credible (Table 2). The coefficient of variation was < 0.15 in the second round, suggesting the agreement among the experts’ opinions (Table 3). Kendall’s *W* of importance and accuracy was 0.235 and 0.223 ($p < 0.001$), respectively, demonstrating statistical significance but modest agreement among experts (Table 2).

3.3. Demographic summary

Patients with NLUTD ($n = 185$; 115 males and 70 females) were recruited and completed the questionnaire. The average age of the patients was 51.50 ± 15.54 years (range: 18–85) (Table 4).

3.4. Item analysis

The critical ratio method was used to analyze the questionnaire items. The total scores of all respondents were arranged in descending order, with the top 27% of respondents classified as the high-score group and the bottom 27% as the low-score group. Differences between the two groups were compared. Since the scores in each domain did not follow a normal distribution, a Mann–Whitney *U* test was performed for each domain. All items showed good discriminative ability ($p < 0.05$) except for the item assessing the frequency of fecal incontinence ($p = 0.051$). Accordingly, this item was removed from the questionnaire (Table 5).

3.5. Reliability analysis

Cronbach’s alpha for all items, exclusive of the male and female sexual function domains, was 0.720. After the removal of the fecal incontinence frequency item, it increased to 0.722, indicating an acceptable internal consistency. Item-by-item analysis revealed that the post-micturition symptoms domain (Cronbach’s alpha = 0.422) was significantly affected by

Table 2. Expert authority coefficients and Kendall's W for importance and accuracy across two Delphi rounds

| Rounds | Familiarity (Cs) | Judgment basis (Ca) | Authority degree (Cr) | Items | Kendall's W | χ^2 | p -value |
|--------|------------------|---------------------|-----------------------|------------|---------------|----------|------------|
| 1 | 0.806 | 0.922 | 0.864 | Importance | 0.265 | 122.312 | <0.001 |
| | | | | Accuracy | 0.095 | 43.936 | 0.097 |
| 2 | 0.853 | 0.968 | 0.912 | Importance | 0.235 | 63.467 | <0.001 |
| | | | | Accuracy | 0.223 | 60.301 | <0.001 |

Table 3. Mean importance, mean accuracy, and coefficients of variation for each scale item in the first and second Delphi rounds

| Items | The first round | | | | The second round | | | |
|---|-----------------|--------------------------|---------------|--------------------------|------------------|--------------------------|---------------|--------------------------|
| | Importance | | Accuracy | | Importance | | Accuracy | |
| | Average value | Coefficient of variation | Average value | Coefficient of variation | Average value | Coefficient of variation | Average value | Coefficient of variation |
| Frequency of urgency | 4.500 | 0.163 | 4.500 | 0.163 | 4.700 | 0.136 | 4.300 | 0.149 |
| Frequency of nocturia | 4.500 | 0.163 | 4.500 | 0.183 | 4.700 | 0.098 | 4.900 | 0.061 |
| Frequency of leakage | 4.929 | 0.052 | 4.643 | 0.193 | 5.000 | 0.000 | 5.000 | 0.000 |
| Volume of urine leakage | 4.714 | 0.125 | 4.643 | 0.175 | 4.800 | 0.125 | 4.700 | 0.136 |
| Frequency of urination | 4.571 | 0.180 | 4.571 | 0.159 | 4.500 | 0.111 | 4.900 | 0.061 |
| Frequency of dysuria | 4.500 | 0.163 | 4.286 | 0.205 | 4.800 | 0.125 | 4.800 | 0.083 |
| Frequency of urination waiting | 4.286 | 0.205 | 4.357 | 0.186 | | | | |
| Urination delay time | 4.286 | 0.256 | 4.357 | 0.223 | 4.600 | 0.144 | 4.200 | 0.143 |
| Frequency of drip after urination | | | | | 4.600 | 0.144 | 4.800 | 0.083 |
| Frequency of incomplete urination | 4.143 | 0.201 | 4.214 | 0.256 | 4.700 | 0.098 | 5.000 | 0.000 |
| Residual urine volume | 4.714 | 0.148 | 4.643 | 0.155 | 4.900 | 0.061 | 4.800 | 0.083 |
| Erection confidence intensity (male) | 4.071 | 0.236 | 4.286 | 0.205 | 4.500 | 0.149 | 4.700 | 0.098 |
| Frequency of erectile dysfunction after sexual stimulation (male) | 4.071 | 0.236 | 4.214 | 0.223 | | | | |
| Frequency of difficulty in erectile maintenance (male) | 4.000 | 0.250 | 4.214 | 0.240 | 4.600 | 0.144 | 4.800 | 0.083 |
| Sexual intercourse completion difficulty (male) | 4.071 | 0.217 | 4.286 | 0.205 | | | | |
| Sexual satisfaction (male) | 3.786 | 0.319 | 4.429 | 0.164 | 4.500 | 0.149 | 4.900 | 0.061 |
| Sexual desire level (female) | 3.643 | 0.322 | 4.143 | 0.221 | 4.100 | 0.131 | 4.800 | 0.083 |
| Confidence in sexual impulse (female) | 3.714 | 0.277 | 4.000 | 0.231 | | | | |
| Frequency of orgasm (female) | 3.714 | 0.277 | 4.286 | 0.186 | | | | |
| Frequency of sexual intercourse pain (female) | 3.857 | 0.257 | 4.286 | 0.186 | 4.100 | 0.131 | 4.800 | 0.083 |
| Sexual life satisfaction (female) | 4.000 | 0.250 | 4.143 | 0.179 | 4.200 | 0.143 | 4.800 | 0.083 |
| Frequency of defecation | 4.429 | 0.141 | 4.643 | 0.131 | 4.800 | 0.083 | 4.900 | 0.061 |
| Defecation time | 4.000 | 0.211 | 4.071 | 0.254 | 4.900 | 0.061 | 4.900 | 0.061 |
| Frequency of tenesmus | 4.071 | 0.196 | 4.000 | 0.283 | 4.600 | 0.144 | 4.900 | 0.061 |
| Frequency of constipation or incontinence | 4.500 | 0.163 | 4.500 | 0.139 | | | | |
| Frequency of fecal incontinence | | | | | 4.900 | 0.061 | 5.000 | 0.000 |
| Frequency of constipation | | | | | 4.900 | 0.061 | 5.000 | 0.000 |
| Frequency of tension and anxiety | 4.429 | 0.164 | 4.143 | 0.221 | 4.600 | 0.144 | 4.900 | 0.061 |
| Frequency of worry | 4.429 | 0.164 | 4.214 | 0.223 | | | | |
| Frequency of lack of interest | 4.000 | 0.211 | 4.000 | 0.283 | | | | |
| Frequency of depression and despair | 4.286 | 0.205 | 4.143 | 0.239 | | | | |
| Frequency of feeling depressed and lack of interest | | | | | 4.600 | 0.144 | 4.800 | 0.083 |
| Frequency of urination pain | 4.571 | 0.159 | 4.571 | 0.136 | 4.400 | 0.111 | 4.700 | 0.098 |
| Frequency of bladder filling pain | 4.500 | 0.183 | 4.429 | 0.164 | 4.500 | 0.111 | 4.800 | 0.083 |
| Sleep time | 4.071 | 0.217 | 4.571 | 0.108 | 4.300 | 0.149 | 4.800 | 0.083 |
| Frequency of taking sleep-promoting drugs | 3.929 | 0.245 | 4.357 | 0.186 | 4.500 | 0.111 | 4.900 | 0.061 |
| Frequency of external factors affecting sleep | 4.000 | 0.211 | 4.214 | 0.204 | 4.700 | 0.098 | 4.900 | 0.061 |
| Frequency of drowsiness | 4.000 | 0.231 | 4.214 | 0.204 | | | | |

residual urine volume. Removing this item rose the Cronbach's alpha to 0.504. The gastrointestinal symptoms domain had a

Cronbach's alpha of 0.520 after the fecal incontinence item was taken out. The sleep domain showed a poor and unstable

Table 4. General information about the patients

| Items | Man (n=115) | Women (n=70) |
|-------------------------------|--------------|--------------|
| Age (mean±standard deviation) | 50.82±16.028 | 52.06±16.074 |
| Mode of urination | | |
| Indwelling catheters | 18 | 10 |
| CIC | 53 | 32 |
| Volitionally voiding | 44 | 28 |

Abbreviation: CIC: Clean intermittent catheterization.

Table 5. Item analysis

| Items | Mann–Whitney <i>U</i> test | <i>p</i> -value |
|--|----------------------------|-----------------|
| Frequency of urgency | 551.000 | <0.001 |
| Frequency of nocturia | 528.000 | <0.001 |
| Frequency of leakage | 459.000 | <0.001 |
| Volume of urine leakage | 511.000 | <0.001 |
| Frequency of urination | 598.000 | <0.001 |
| Frequency of dysuria | 338.500 | <0.001 |
| Urination delay time | 342.500 | <0.001 |
| Frequency of drip after urination | 355.000 | <0.001 |
| Residual urine volume | 767.500 | 0.004 |
| Frequency of incomplete urination | 438.500 | <0.001 |
| Frequency of defecation | 798.000 | 0.005 |
| Defecation time | 902.500 | 0.070 |
| Frequency of tenesmus | 716.000 | 0.001 |
| Frequency of fecal incontinence | 951.000 | 0.079 |
| Frequency of constipation | 484.000 | <0.001 |
| Frequency of tension and anxiety | 300.500 | <0.001 |
| Frequency of feeling depressed and lack of interest | 294.000 | <0.001 |
| Frequency of urination pain | 694.000 | <0.001 |
| Frequency of pain during bladder filling | 701.500 | <0.001 |
| Sleep time | 655.000 | <0.001 |
| Frequency of drugs promote sleep | 749.500 | <0.001 |
| Frequency of external factors affect sleep | 476.000 | <0.001 |
| Frequency of difficulty in erectile maintenance (male) | 621.500 | <0.001 |
| Sexual life satisfaction (male) | 628.500 | <0.001 |
| Frequency of ejaculation delay (male) | 627.500 | <0.001 |
| Sexual desire level (female) | 823.000 | 0.011 |
| Sexual life satisfaction (female) | 800.500 | 0.006 |
| Frequency of sexual pain (female) | 792.000 | 0.004 |

internal consistency (Cronbach’s alpha = −0.595), and its removal improved overall consistency (Cronbach’s alpha >0.5). Test–retest reliability after four weeks demonstrated strong temporal stability (Pearson correlation: 0.721–0.998, *p*<0.001) (Table 6). The sexual function domain demonstrated excellent internal consistency, with Cronbach’s an alpha value of 0.994 for males and a value of 0.981 for females.

3.6. Validity test

The KMO value for the scale was 0.767. The result of Bartlett’s sphericity test was 3,624.323 (*p*<0.001) (Table 7).

An exploratory factor analysis was conducted to assess the questionnaire’s validity. The cumulative explained variance was 74.423%, and the principal component analysis yielded six domains (Table 8). However, considering the clinical symptoms, it was divided into seven domains. The correlation coefficients between each domain and the total scale score ranged from 0.365–0.631 (*p*<0.05). The correlation coefficient between the SF-36 and the total scale was −0.225 (*p*<0.05) (Table 9). Through the evaluation of nine experts, the CVI of the scale ranged from 0.89 to 1.00 (>0.78), and the kappa statistics were from 0.89 to 1.00 (>0.74), indicating strong agreement among experts. A CVR value of 0.78–1.00 implied that the experts’ opinions were relatively uniform (Table 10).

3.7. Radar chart

Our scale, comprising 7 domains, 23 items, and 1 item assessing urination patterns, was constructed (Appendix). To visually display changes in patients’ clinical symptoms, a radar chart was plotted, and the coordinates were derived from the corresponding domain scores (Figure 1). The radar chart clearly demonstrates changes in patients’ symptoms, aiding in clinical decision-making. In a typical example, after completing the questionnaire, the generated radar chart showed pronounced psychological symptoms, whereas pain symptoms were minimal. After a 4-week follow-up, the radar chart indicated that the patient’s urination and post-micturition symptoms improved, and psychological symptoms also showed improvement (Figure 2).

However, this radar chart is currently in the preliminary testing phase and has not yet undergone systematic validation by clinicians. The case example cited in the paper is solely intended to demonstrate the basic functionality of this visualization tool.

4. Discussion

Neurogenic lower urinary tract dysfunction caused by SCI has a significant negative impact on patients’ quality of life. Patients with SCI-NLUTD may experience a variety of urological, sexual, intestinal, psychological, and pain-related symptoms. Based on a review of the literature and the opinions of patients and experts, the SCI-NLUTDS was developed to comprehensively assess these patients’ symptoms. This scale allows clinicians to rapidly assess patients’ current symptoms and to monitor changes in symptom severity during follow-up. Scores are visualized using radar charts, enabling patients and physicians to track symptom changes over time.

Neurogenic lower urinary tract dysfunction caused by SCI can result from traumatic (e.g., injuries) or non-traumatic causes (e.g., tumors, infections, ischemia). Symptoms due to neurological damage vary, including urine

Table 6. Reliability and test–retest reliability of the scale

| Items | Reliability analysis | | | | Test–retest reliability | |
|---------------------------|----------------------|-----------------|---------------------|-----------------|-------------------------|-----------------|
| | Cronbach's α | Number of items | Cronbach's α | Number of items | Pearson correlation | <i>p</i> -value |
| Total amount scale | 0.720 | 22 ^a | 0.725 | 20 ^b | 0.803 | <0.001 |
| Urine storage symptoms | 0.647 | 5 | 0.647 | 5 | 0.755 | <0.001 |
| Urination symptoms | 0.558 | 2 | 0.558 | 2 | 0.750 | <0.001 |
| Post-micturition symptoms | 0.422 | 3 | 0.504 | 2 | 0.852 | <0.001 |
| Intestinal symptoms | 0.410 | 5 | 0.520 | 4 | 0.721 | <0.001 |
| Psychological symptoms | 0.923 | 2 | 0.923 | 2 | 0.731 | <0.001 |
| Pain symptoms | 0.685 | 2 | 0.685 | 2 | 0.796 | <0.001 |
| Sleep quality | –0.595 | 3 | –0.595 | 3 | - | - |
| Sexual function (male) | 0.994 | 3 | 0.994 | 3 | 0.998 | <0.001 |
| Sexual function (female) | 0.981 | 3 | 0.981 | 3 | 0.997 | <0.001 |

Note: ^aSexual function is not included. ^bSexual function, residual urine volume, and frequency of fecal incontinence are not included.

Table 7. The Kaiser–Meyer–Olkin and Bartlett's sphericity test of the scale

| Test | Score |
|----------------------------|-----------|
| Kaiser–Meyer–Olkin | 0.767 |
| Bartlett's sphericity test | |
| Pseudo Chi-square | 3,624.323 |
| Degrees of freedom | 253 |
| <i>p</i> -value | <0.001 |

Table 8. Exploratory factor analysis of the scale

| Component matrix after rotation | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|--|--------|-------|-------|-------|-------|-------|-------|
| Frequency of difficulty in erectile maintenance (male) | 0.958 | | | | | | |
| Sexual life satisfaction (male) | 0.972 | | | | | | |
| Frequency of ejaculation delay (male) | 0.968 | | | | | | |
| Sexual desire level (female) | –0.961 | | | | | | |
| Sexual life satisfaction (female) | –0.959 | | | | | | |
| Frequency of sexual pain (female) | –0.948 | | | | | | |
| Frequency of urgency | | | 0.736 | | | | |
| Frequency of nocturia | | | 0.721 | | | | |
| Frequency of leakage | | | | | 0.949 | | |
| Volume of urine leakage | | | | | 0.956 | | |
| Frequency of urination | | | 0.614 | | | | |
| Frequency of dysuria | | | | 0.734 | | | |
| Urination delay time | | | | 0.627 | | | |
| Frequency of drip after urination | | | | 0.725 | | | |
| Defecation time | | | | | | | 0.608 |
| Frequency of constipation | | | | | | | 0.692 |
| Frequency of tension and anxiety | | 0.898 | | | | | |
| Frequency of feeling depressed and lack of interest | | 0.890 | | | | | |
| Frequency of urination pain | | | | | | 0.778 | |
| Frequency of pain during bladder filling | | | | | | 0.828 | |
| Frequency of defecation | | 0.508 | | | | | |
| Frequency of tenesmus | | | | | | | 0.780 |
| Frequency of incomplete urination | | | 0.439 | | | | |

storage, voiding, and post-voiding dysfunction.¹⁹ In this study, 56.76% of patients reported urinary incontinence, and 51.89% experienced urinary retention. SCI-NLUTD is also associated with SD, bowel dysfunction, and autonomic dysregulation. Comprehensive symptom assessment is crucial for diagnosis and treatment. PROMs are valuable for evaluating clinical outcomes but often lack comprehensive coverage of all relevant symptom domains.²⁰ Existing tools are time-consuming and do not capture the full spectrum of symptoms. In this study, we designed a comprehensive, concise, and intuitive tool (SCI-NLUTDS) to assess systemic symptoms related to SCI-NLUTD. The scale was developed through a structured, stepwise process. A draft questionnaire was designed based on a literature review and feedback from patients and professionals. After two rounds of expert assessment, an initial scale was obtained. Following this, item analysis, reliability testing, validity testing, and retest reliability testing were performed on the scale. This tool can assist physicians in formulating individualized treatment plans for patients with SCI-NLUTD.

The patients' quality of life can be negatively impacted by SCI-NLUTD, leading to anxiety and depression. Studies by Williams and Murray²¹ and Lude *et al.*²² indicate that patients with SCI may suffer from an array of potential psychological issues, including an increased risk of depression and anxiety (approximately 22.2% of the population has

Table 9. Correlation coefficients of the total score with each domain and the Short Form 36 Health Survey

| Variables | Urine storage symptoms | Urination symptoms | Post-micturition symptoms | Sexual function | Intestinal symptoms | Psychological symptoms | Pain symptoms | SF-36 |
|----------------------|------------------------|--------------------|---------------------------|-----------------|---------------------|------------------------|---------------|---------|
| Pearson correlations | 0.581** | 0.589** | 0.631** | 0.466** | 0.447** | 0.498** | 0.365** | −0.227* |
| <i>p</i> -value | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.02 |
| Number | 185 | 185 | 185 | 185 | 185 | 185 | 185 | 185 |

Note: **p*<0.05; ***p*<0.01.
Abbreviation: SF-36: Short Form 36 Health Survey.

Table 10. The validity test of the scale

| Items | CVI | CVR | Kappa statistics |
|--|------|------|------------------|
| Frequency of urgency | 1.00 | 1.00 | 1.00 |
| Frequency of nocturia | 1.00 | 1.00 | 1.00 |
| Frequency of leakage | 1.00 | 1.00 | 1.00 |
| Volume of urine leakage | 1.00 | 1.00 | 1.00 |
| Frequency of urination | 1.00 | 1.00 | 1.00 |
| Frequency of dysuria | 1.00 | 1.00 | 1.00 |
| Urination delay time | 1.00 | 1.00 | 1.00 |
| Frequency of drip after urination | 1.00 | 1.00 | 1.00 |
| Residual urine volume | 1.00 | 1.00 | 1.00 |
| Frequency of incomplete urination | 1.00 | 1.00 | 1.00 |
| Defecation frequency | 1.00 | 1.00 | 1.00 |
| Defecation time | 1.00 | 1.00 | 1.00 |
| Frequency of tenesmus | 1.00 | 1.00 | 1.00 |
| Frequency of fecal incontinence | 1.00 | 1.00 | 1.00 |
| Frequency of constipation | 1.00 | 1.00 | 1.00 |
| Frequency of tension and anxiety | 1.00 | 1.00 | 1.00 |
| Frequency of feeling depressed and lack of interest | 1.00 | 1.00 | 1.00 |
| Urination pain frequency | 0.89 | 0.78 | 0.89 |
| Frequency of pain during bladder filling | 1.00 | 1.00 | 1.00 |
| Sleep time | 1.00 | 1.00 | 1.00 |
| Drugs promote sleep frequency | 1.00 | 1.00 | 1.00 |
| External factors affect sleep frequency | 1.00 | 1.00 | 1.00 |
| Erection confidence intensity (male) | 1.00 | 1.00 | 1.00 |
| Frequency of difficulty in erectile maintenance (male) | 1.00 | 1.00 | 1.00 |
| Sexual satisfaction (male) | 1.00 | 1.00 | 1.00 |
| Sexual desire level (female) | 1.00 | 1.00 | 1.00 |
| Sexual life satisfaction (female) | 1.00 | 1.00 | 1.00 |
| Frequency of sexual pain (female) | 1.00 | 1.00 | 1.00 |

Abbreviations: CVI: Content validity index; CVR: Content validity ratio.

such experiences), as well as a decline in quality of life. In our cohort, most patients reported anxiety (71.89%) and depression (73.51%) symptoms within the past two weeks. The assessment of anxiety symptoms has been incorporated

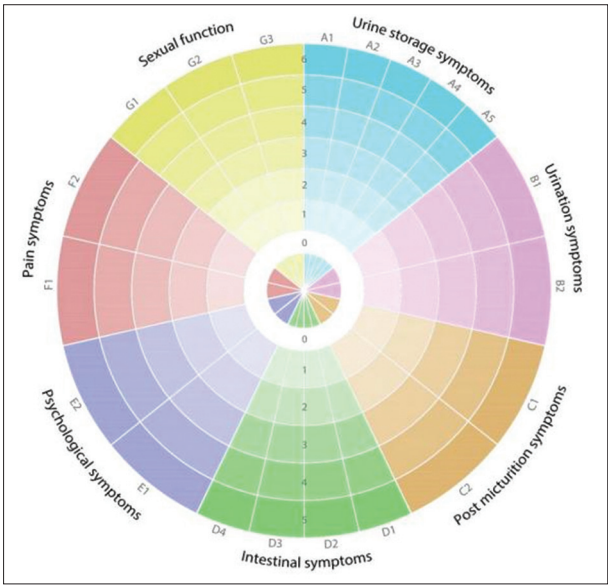


Figure 1. The severity of symptoms across seven domains for the patient. A higher score indicates more severe symptoms, which are represented on the radar chart by increased blocks and color intensity.

into the SCI-NLUTDS, reflecting the patients’ current state of anxiety and depression.

SD in SCI-NLUTD patients involves reduced libido, genital discomfort, and altered orgasm responses.⁴ It is linked to both neurological injury and urinary symptoms, significantly impacting quality of life. Previous studies showed that nearly half of patients with cauda equina syndrome experienced SD, and SCI often led to complications, such as SD, due to shared innervation between genital organs and the bladder.²³ Chronic pain, spasms, autonomic dysreflexia, and bladder/bowel dysfunction further exacerbate SD.²⁴ Psychological factors, such as anxiety and depression, also contribute to SD.²⁵ Research highlights that female SCI patients experience reduced sexual function across domains such as inhibition, self-worth, and satisfaction.²⁶ This underscores the profound impact of SCI-NLUTD on sexual health.

Intestinal dysfunction significantly impacts the quality of life in SCI-NLUTD patients, affecting physical and mental health.²⁷ SCI disrupts the autonomic control of the gastrointestinal tract, leading to issues like constipation,

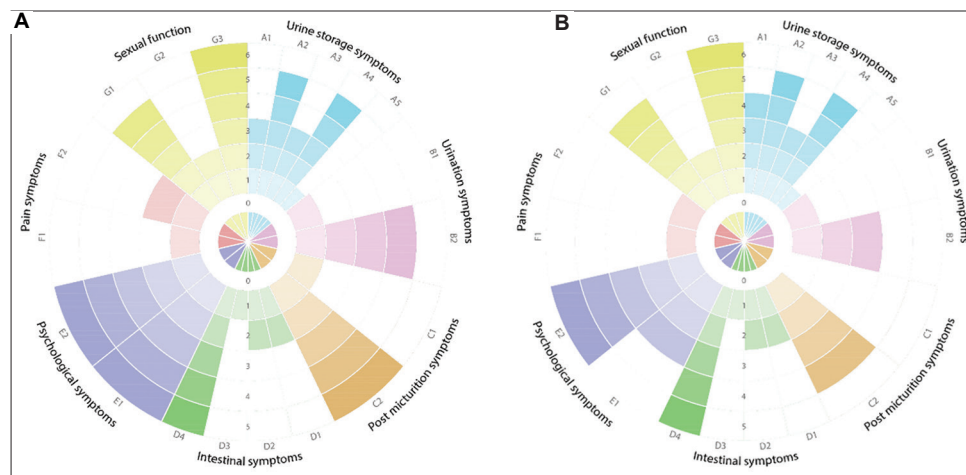


Figure 2. Symptom evolution in a spinal cord injury patient with neurogenic lower urinary tract dysfunction monitored by radar chart assessment. (A) Multi-domain symptoms' severity at baseline evaluation, revealing prominent psychological manifestations with minimal pain-related symptoms. (B) Significant improvement in voiding symptoms, post-micturition symptoms, and psychological domains after the intervention period.

reduced colonic motility, and altered mucosal secretion.²⁸ Constipation is prevalent, often requiring interventions, such as rectal stimulation or suppositories, while fecal incontinence decreases over time.²⁹ Due to poor internal consistency, fecal incontinence frequency was excluded from the SCI-NLUTDS. Intestinal problems hinder daily activities and social integration. The SCI-NLUTDS comprehensively assesses these issues, providing granular insights into patients' gastrointestinal dysfunction.

Pain is common among patients with SCI-NLUTD. Research by Modirian *et al.*³⁰ indicated that patients with pelvic pain among those with SCI had the highest levels of pain, which significantly affected their quality of life. Kolodziej *et al.*³¹ pointed out that, after gynecological surgeries, pain was a key factor affecting quality of life, in addition to bladder and bowel symptoms. This study further observed that 49.73% of SCI-NLUTD patients experienced pain and discomfort during urination, and 42.16% of patients complained of lower abdominal pain. These symptoms may be caused by urinary tract infections or constipation. Therefore, a comprehensive assessment of pain symptoms is crucial, and pain-related items were included in the SCI-NLUTDS.

With respect to sleep quality, patients with SCI or NLUTD face a substantially higher risk of sleep disorders, including sleep-related breathing disorders, with an incidence three to four times higher than in the general population. Consequently, this leads to poor sleep quality, intermittent hypoxemia, sleep fragmentation, and nocturnal hypertension among patients.³² Exploratory factor analysis revealed inconsistent loadings among the sleep items. Removing these items improved the internal consistency of the remaining domains. Therefore, to comprehensively and effectively assess the overall quality of life of SCI-NLUTD patients, sleep-related items were to be excluded from the questionnaire. However, the

complete removal of sleep-related items may compromise the comprehensiveness of the scale. Therefore, we plan to develop an independent standardized sleep assessment module in subsequent studies as a supplementary tool to the core scale, enabling comprehensive evaluation of patients' sleep disorders.

5. Study limitations

A potential limitation of our study is that the data were derived primarily from a Chinese population, which may limit their generalizability to other ethnic groups. Therefore, further work is warranted to assess the reliability and validity of the questionnaire in international patient populations. Secondly, the radar chart utilized in this scale has not yet undergone systematic validation by clinicians. Future studies should employ standardized questionnaires and interviews to quantitatively and qualitatively evaluate the radar chart's ease of use, learning curve, and interpretability.

6. Conclusion

This new instrument provides an intuitive, valid, and reliable method for assessing patients with NLUTD and monitoring their symptoms during follow-up. The SCI-NLUTDS demonstrated good internal consistency, construct validity, and test-retest reliability in the target population.

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Conflict of interest

The authors declare they have no competing interests.

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Ethics approval and consent to participate

This study involving human participants was reviewed and approved by the Research Ethics Committee of Qilu Hospital, Shandong University (Approval No. KLYY-202209-036). The committee specifically approved the procedure for the participation of human subjects described in this study. Written informed consent was obtained from all participating human subjects or their legal guardians before enrollment in the study. All methods were carried out in accordance with relevant guidelines and regulations, including the principles of the 1964 Helsinki Declaration and its later amendments.

Consent for publication

All participants (or their legal guardians for incapacitated patients) provided written informed consent for the publication of anonymized research data. The consent forms explicitly stated that individual data would be de-identified and analyzed in aggregate form, with no personally identifiable information disclosed in any publications.

Data availability statement

The original datasets are not publicly available due to patient privacy restrictions, but are available from the corresponding author on reasonable request. De-identified data supporting the scale validation will be shared on approval of a methodologically sound proposal.

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Appendix

Spinal Cord Injury-induced Neurogenic Bladder Questionnaire

Name: _____

Age: _____

1. Over the past 7 days, how frequently have you experienced a sudden, compelling desire to urinate that was difficult to defer (urgency)?
 - Never (1 point)
 - Less than once a week (2 points)
 - Once or more per week (3 points)
 - About once a day (4 points)
 - 2–4 times per day (5 points)
 - 5 or more times per day (6 points)
2. Over the past 7 days, how many times did you typically get up at night to urinate?
 - None (1 point)
 - Once (2 points)
 - Twice (3 points)
 - Three times (4 points)
 - Four times or more (5 points)
3. Over the past 7 days, how often have you experienced urinary leakage (including leakage around catheter or stoma)?
 - No leakage (1 point)
 - Less than once per week (2 points)
 - Once or more per week (3 points)
 - 1–2 times per day (4 points)
 - More than 2 times per day (5 points)
4. Over the past 7 days, what was the typical amount of urinary leakage (including leakage around catheter or stoma)?
 - None (no urinary leakage) (1 point)
 - Very small amount (2 points)
 - Small amount (clothes/pad feel damp) (3 points)
 - Moderate amount (clothes/pad feel wet) (4 points)
 - Large amount (clothes/pad are soaked) (5 points)
5. Over the past 7 days, what was your typical daytime urinary frequency?
 - 6 times or less (1 point)
 - 7–10 times (2 points)
 - 11–14 times (3 points)
 - 15–19 times (4 points)
 - 20 times or more (5 points)
6. Over the past 7 days, how often have you experienced a weak or slow urinary stream when urinating?
 - Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Always (5 points)
7. Over the past 7 days, how long did you typically have to wait before you could start urinating?
 - Never had to wait (1 point)
 - A few seconds (<30 s) (2 points)
 - 30 s to 1 min (3 points)
 - 1 to 2 min (4 points)
 - More than 2 min (5 points)
8. Over the past 7 days, how often have you experienced dribbling after you finished urinating?
 - Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Always (5 points)
9. What is your typical post-void residual urine volume (measured by ultrasound or during intermittent catheterization)?
 - 0–10 mL (1 point)
 - 10–50 mL (2 points)
 - 50–100 mL (3 points)
 - 100–500 mL (4 points)
 - More than 500 mL (5 points)
10. Over the past 7 days, how often have you had a sensation of not emptying your bladder completely after you finished urinating?
 - Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Always (5 points)
11. Over the past 4 weeks, how would you rate your confidence in getting and maintaining an erection? (For male patients)
 - None (6 points)
 - Very low (5 points)
 - Low (4 points)
 - Moderate (3 points)
 - High (2 points)
 - Very high (1 point)
12. Over the past 4 weeks, how difficult was it to maintain your erection to complete sexual intercourse? (For male patients)
 - Did not attempt sexual intercourse (6 points)
 - Extremely difficult (5 points)
 - Very difficult (4 points)

- Difficult (3 points)
 - Slightly difficult (2 points)
 - Not difficult at all (1 point)
13. Over the past 4 weeks, how frequently have you felt satisfied with your overall sex life? (For male patients)
- Did not attempt sexual intercourse (6 points)
 - Almost never or never (5 points)
 - Less than half the time (4 points)
 - About half the time (3 points)
 - More than half the time (2 points)
 - Almost always or always (1 point)
14. Over the past 4 weeks, how would you rate your level of sexual desire? (For female patients)
- None (6 points)
 - Very low (5 points)
 - Low (4 points)
 - Moderate (3 points)
 - High (2 points)
 - Very high (1 point)
15. Over the past 4 weeks, how satisfied have you been with your overall sex life? (For female patients)
- Did not attempt sexual intercourse (6 points)
 - Very dissatisfied (5 points)
 - Somewhat dissatisfied (4 points)
 - Equally satisfied and dissatisfied (3 points)
 - Moderately satisfied (2 points)
 - Very satisfied (1 point)
16. Over the past 4 weeks, how often did you feel pain or discomfort during sexual intercourse? (For female patients)
- Did not attempt sexual intercourse (6 points)
 - Almost always or always (5 points)
 - Most of the time (more than half the time) (4 points)
 - Sometimes (about half the time) (3 points)
 - Occasionally (less than half the time) (2 points)
 - Almost never or never (1 point)
17. Over the past 4 weeks, what was your average frequency of defecation?
- More than twice per day (1 point)
 - Once to twice per 1–2 days (2 points)
 - 1 to 3 times per week (3 points)
 - Less than once per week (4 points)
 - Less than once per month (5 points)
18. Over the past 4 weeks, how much time did you typically spend on defecation each time (in minutes)?
- <5 min (1 point)
 - 5–10 min (2 points)
 - 10–20 min (3 points)
 - 20–30 min (4 points)
 - 30 min (5 points)
19. Over the past 4 weeks, how often did you experience a sensation of incomplete evacuation after defecation (i.e., tenesmus)?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)
20. Over the past 4 weeks, how often have you experienced fecal incontinence (inability to control bowel movements)?
- Never (1 point)
 - ≤ 1 time/month (2 points)
 - <1 time/week (3 points)
 - <1 time/day (4 points)
 - ≥ 1 time/day (5 points)
21. Over the past 4 weeks, how often have you experienced constipation?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)
22. Over the past 2 weeks, how often have you felt nervous, anxious, or on edge?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)
23. Over the past 2 weeks, how often have you felt down, depressed, or uninterested in things?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)
24. Over the past 7 days, how often did urination or catheter use cause pain or discomfort?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)
25. Over the past 7 days, how often did you feel lower abdominal pain when your bladder was full?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)

26. Over the past 4 weeks, what was your average actual sleep time at night?
- >7 h (1 point)
 - 5–6 h (2 points)
 - 3–4 h (3 points)
 - 1–2 h (4 points)
 - Near-total nighttime sleeplessness (5 points)
27. Over the past 4 weeks, how often did you need to use medication to help you sleep?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)
28. Over the past 4 weeks, how often did your sleep get affected by factors such as nocturia, pain, or discomfort?
- Never (1 point)
 - Less than half the time (2 points)
 - About half the time (3 points)
 - More than half the time (4 points)
 - Every time (5 points)