French version of the short form of the Neurogenic Bladder Symptom Score: Cross-cultural adaptation and validation

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Abstract

Introduction: This study aimed to empirically validate a French version of the Neurogenic Bladder Symptoms Score-Short From (NBSS-SF), a psychometric multidimensional tool to assess lower urinary tract symptoms (LUTS) for patients with a neurological condition.
Methods: One hundred and five participants with multiple sclerosis or spinal cord injury prospectively completed the questionnaire at baseline and 7–14 days later. The α coefficient of Cronbach (internal consistency) and the intraclass correlation coefficient (ICC) (test-retest reliability) were calculated.
Results: The internal consistency for the overall questionnaire was high (Cronbach's α coefficients from 0.79), while coefficients for each subscale were variable (urinary incontinence 0.91; storage and voiding 0.69; consequences 0.25). For test-retest reliability, 88/105 (84%) patients filled and sent back their questionnaire 10 days (±3.6 days) after baseline version. ICC was 0.90 for the total score and was 0.73 for the urinary incontinence subdomain, 0.79 for storage and voiding, and 0.75 for consequences.
Conclusions: The psychometric qualities of the French version of the NBSS-SF are well-supported, thus providing a valid tool to measure bladder symptoms across three different domains in patients with neurogenic bladder.

Introduction

Globally, lower urinary tract symptoms (LUTS) are frequent and related to various etiologies. In patients with neurological disorders, such as spinal cord injury (SCI), cauda equina syndrome, spina bifida, or multiple sclerosis (MS), urinary disorders are very common, and symptoms depends on the level of the neurological lesion.[1]

Neurogenic bladder may be responsible for upper urinary tract complications, such as urinary tract infection (UTI) or renal failure.[2] It can also decrease quality of life[3] and have an important socio-economic impact.[4]

To investigate LUTS, different tools or questionnaires are available. In recent years, new ways to assess symptoms, satisfaction, and quality of life have been developed and validated. These tools, corresponding to patient-reported outcomes (PROs), allow direct evaluation of patients' point of view without clinician judgement. Initially developed in oncology, these assessment tools have recently taken on a more widespread role in general urology. Indeed, in the absence of risk factors for complications, PROs are appropriate for assessing symptoms such as overactive bladder or urinary incontinence, and could help in therapeutic management.[5] Furthermore, questionnaires are now widely used in clinical trials to assess treatment efficacy as a more objective way than by simple patient declaration.

Welk et al developed and validated a questionnaire in 2013 specifically designed for a neurogenic population and allowing a multimodal assessment of LUTS[6] — the Neurogenic Bladder Symptom Score (NBSS). The NBSS is composed of 24 items and explores three domains: urinary incontinence, bladder storage and voiding, and consequences. In addition, NBSS includes two additional questions related to bladder management and quality of life.[7] In 2020, Welk et al developed a short version of NBSS (NBSS-SF) composed of 10 items exploring the three same domains as the NBSS original long version.[8]

The NBSS has already been translated into Portuguese (Brazil),[9] Turkish,[10] and Greek.[11] In addition to direct translation, cross-cultural adaptation of existing questionnaires is important to improve accurate evaluation. This step should consider language specificity, allowing better understanding of the translated version by the targeted population without changing the meaning of the questions. Some questionnaires, such as Qualiveen[12] or Urinary Symptoms Profile (USP),[13] are available in French to assess quality of life *related* to neurogenic LUTS; however, there is no French-validated, multidimensional questionnaire specifically assessing neurogenic LUTS.[13]

NBSS-SF has the advantage of exploring three different domains important for patients suffering from LUTS. In addition to symptoms (urinary incontinence, bladder storage, and voiding) and quality of life assessment, the consequences domain comprises two questions exploring UTIs and treatment efficiency for LUTS.

The objective of our study was to validate the French version and the cross-cultural adaptation of the NBSS-SF.

Methods

We conducted a prospective study between June and October 2020 in our neurourology clinic. According to the international guidelines for cross-cultural adaptation of self-reported measures,[14,15] we first obtained written authorization from the NBSS author.

Step 1: Translation and back-translation

With the author's agreement, two independent bilingual translators (fluent in English and native French) created a French version of the NBSS-SF. Both versions were combined and disagreement in wording or item redaction were resolved. The next step was the back-translation with native English translators. Among the two translators, one of them had no medical experience and the other was a general practitioner. Both were native English speakers fluent in French.

Next, a bilingual expert committee, composed of urologists and neurourologists, compared the different versions to create a pre-final version of the questionnaire. Cross-cultural equivalence with analysis of the semantic, idiomatic, conceptual, and empirical equivalence of the source was validated by the expert committee.[14]

Step 2: Pilot study

We conducted a pilot study with 30 subjects, during which, acceptability and understanding were evaluated by the following questions: "Do you think this question is acceptable to explore your symptoms?" and "Do you understand the question?" Participants had to rate the two parameters for each translated item on a three-point Likert scale (A=perfectly; B=good; C=poor). Comprehension and acceptance were considered good if they answered A or B. All comments were collected to incorporate into the final version after validation by a panel of experts.

Step 3: Validation study

A validation study was performed to determine the psychometric properties of the questionnaire. To perform the validation, patients in our department between September and October 2020 who were over 18 years old were consecutively included. They had to be able to read and understand French to complete the questionnaire. We used the same inclusion criteria as Welk et al[8] and we included patients with neurogenic bladder. Exclusion criteria were recent urological surgery, recent UTI, or a treatment modification during the study.

We calculated the Cronbach's α coefficient,[16] a measure of internal consistency (reliability) ranging from 0–1, with a coefficient greater than 0.7 considered very good.[17] The NBSS-SF is composed of two items covering quality of life and bladder management and eight items covering the three subdomains (items 3, 4, 5 for urinary incontinence, items 6, 7, 8 for storage and voiding, and two items covering consequences). The calculation of total score was similar to the initial version of NBSS (i.e., a total score ranging from 0–28). We calculated a Cronbach's α coefficient for each subscale and a coefficient for the whole questionnaire.

For test-retest reliability, we used the intraclass correlation coefficient (ICC).[18] An ICC greater than 0.7 was considered a good test-retest reproducibility.[17] Patients completed the final version of the questionnaire and had to mail the second questionnaire within 7–14 days. As this second questionnaire was completed at home, all patients were followed up by telephone to avoid missing data.

Correlations were computed between NBSS-SF scores obtained overall and for each domain on two different occasions, separated by a 7–14-day interval.

As recommended in literature,[19] the estimates for the sample size was based on minimal requirement of at least 10 patients per question. As NBSS-SF was composed of 10 items, we included a minimum of 100 patients. Written consent was obtained. The study was approved by the ethics committee (RCB ID NO.: 2018-A01644-51).

Statistical analysis

All statistics analyses were performed with RStudio (Version 1.2.5033, RStudio: Integrated Development for R. RStudio, Inc., Boston, MA, U.S.).

Results

Pilot study

A total of 30 patients were included for this step. Understanding and acceptance were good or very good for 93% (28/30). After data collection, only two wordings in item redaction were modified; "penile condom" and "diapers" were adapted in the French translation for a better understanding and improved cross-cultural adaptation. After these minor modifications, all items were reviewed by the expert committee and validated for the pre-final version.

Validation study

One hundred and six patients were included in the validation study from September 2020 to October 2020. Population characteristics are described in Table 1. One patient was excluded due to treatment modification during the study, leaving a total of 105 patients, 59 of whom were women (56%); the mean age was 53 years. Patients presented with various neurological disorders: 58 (55%) had MS, 17 (16%) had a SCI, and 30 (29%) had other neurological conditions, such as Parkinson's disease, spina bifida, or cauda equina syndrome (Table 1). Bladder management and urinary treatments are described in Table 1, with a majority (n=69, 66%) performing clean intermittent self-catheterization (CISC) either exclusively (54/105) or in association with spontaneous voiding (15/105). Other urinary treatments were antimuscarinics (42%) and intradetrusor injections of onabotulinum toxin (45%). Twenty-nine patients (28%) had a combination of at least two medications of different therapeutic classes (Table 1).

The Cronbach's α coefficient for the overall questionnaire was 0.79. The Cronbach's α for each subscale was 0.91 for urinary incontinence, 0.69 for storage and voiding, and 0.25 for consequences (Table 2).

In our study, 88/105 (84%) patients sent back their second questionnaire 7–14 days after the first completion of the first NBSS-SF. Reasons for missing data were incomplete questionnaires for two patients and no answer from 15 patients despite multiple reminders. The non-responders did not differ from the responders (Table 3). The mean time between the initial questionnaire and the re-test questionnaire was 10 days (±3.6 days). The test-retest reliability was 0.90 for the total score. Concerning reliability of the different subdomains, ICC was 0.73 for urinary incontinence, 0.79 for storage and voiding, and 0.75 for consequences (Table 4). Mean time to complete the questionnaire was 3.1 minutes (±1.1 minute). The mean total score of NBSS-SF was 9/28 (±5.2).

Table 1. Patient demographics at baseline (n=105)

Demographic characteristics	
Gender, n (%)	
Male	46 (44)
Female	59 (56)
Mean age, years (SD)	53 (14.7)
Injury, n (%)	
Multiple sclerosis	58 (55)
Spinal cord injury	17 (16)
Other neurological conditions (Parkinson, spina bifida, cauda equina syndrome, conus medullaris syndrome, etc.)	30 (29)
Bladder management, n (%)	
Spontaneous voiding (SV)	34 (32)
Exclusive intermittent catheterization (IC)	54 (51)
Mixed: IC and SV	15 (14)
Urostomy bag or indwelling urinary catheter	2 (2)
Urinary treatment, n (%)	
No treatment	20 (19)
Antimuscarinic	44 (42)
Alpha-blocker	13 (12)
Posterior tibial nerve stimulation	10 (9.5)
Detrusor botulinum toxin	47 (45)
Urethral sphincter botulinum toxin	3 (3)
Enterocystoplasty	2 (2)
2 treatments or more (different therapeutic classes)	29 (28)

SD: standard deviation.

Table 2. Internal consistency of French NBSS-SF

NBSS	Internal consistency (Cronbach's α) n=105	Cronbach's α coefficient by Welk and al n=230
Overall score	0.79	0.76
Subdomains		
Incontinence	0.91	0.86
Storage and voiding	0.69	0.71
Consequences	0.25	0.43

NBSS: Neurogenic Bladder Symptoms Score-Short From.

Discussion

The psychometric properties of this French version of the NBSS-SF are overall similar to those of the original English version. Cross-cultural adaptation shows good comprehension and acceptance results. In the methodological process, translation and back-translation by independent translators did not produce any issues except for two minor items: the translation of "diapers" and "penile condom" did not correspond to correct wording in French. These two terms were responsible for poor comprehension by patients during the pilot study and, therefore, the wording was changed and validated by the expert committee, improving comprehension of the translated questionnaire. The revised version was used in the final validation step.

Concerning psychometric properties, internal consistency and test-retest correlations of the French version were similar to the initial version,[8] with total Cronbach's α of 0.79 and ICC of 0.90, respectively. As suggested by Welk and al,[8] internal consistency for the consequences domain was very low (Cronbach's α=0.25). This result could have many explanations, including the study population.

In the original validation study of NBSS-SF,[8] results were presented with three different cohorts. For each cohort, the consequences domain had the worst results, with low or very low Cronbach's α coefficient. In this study, cohort 1 included MS (59%) and SCI (35%) patients. Our cohort was quite similar, but bladder management was different. Only 20% of patients were performing CISC in the original study, whereas more than 50% of our population was performing it. This proportion is comparable with cohort 2 (51% performing CISC) in the original validation study. For both cohorts (1

Table 3. Population characteristic between responder and non-responder for test-retest reliability

	Responder (n=88)	Non responder (n=17)	p
Gender, n (%)			0.60†
Male	40 (45.5)	7 (41.2)	
Female	48 (54.5)	10 (58.8)	
Age, years (SD)	53 (14.6)	52 (15.9)	0.78‡
Injury, n (%)			1†
Multiple sclerosis	48 (54.5)	10 (58.8)	
Spinal cord injury	13 (14.8)	4 (23.5)	
Other	27 (30.7)	3 (17.7)	
Bladder management, n (%)			0.25†
Spontaneous voiding (SV)	28 (31.8)	5 (29.4)	
Exclusive intermittent catheterization (IC)	47 (53.4)	7 (41.2)	
Mixed (IC + SV)	12 (13.7)	4 (23.5)	
Urostomy bag or indwelling urinary catheter	1 (1.1)	1 (5.9)	
Urinary treatment, n (%)			
No treatment	15 (17)	5 (29.4)	
Antimuscarinics	39 (44.3)	5 (29.4)	
Alpha-blocker	12 (13.6)	1 (5.9)	
Posterior tibial nerve stimulation	10 (11.4)	0	
Detrusor botulinum toxin	38 (43.2)	9 (52.9)	
Urethral sphincter botulinum toxin	2 (2.3)	1 (5.9)	
Enterocystoplasty	2 (2.3)	0	
2 treatments or more (different therapeutic classes)	24 (27.3)	5 (29.4)	

†Fischer's test. ‡Welch test.

Table 4. Reproducibility of French NBSS-SF

NBSS	Test-retest (intraclass correlation coefficient) n=88	Intraclass correlation coefficient by Welk and al n=120
Overall score	0.9	0.84
Subdomains		
Incontinence	0.73	0.80
Storage and voiding	0.79	0.80
Consequences	0.75	0.86

NBSS: Neurogenic Bladder Symptoms Score-Short From.

and 2), the consequences domain had the lowest score for internal consistency (0.43 and 0.33, respectively).

In neurogenic bladder, CISC, exclusively or in addition to other urinary management (onabotulinum toxin or antimuscarinics) is widely known to improve quality of life and decrease the risk of long-term complications.[20] The significant proportion of patients treated by CISC in our population study could be a reason for low internal consistency in the consequences domain and quality of life subscales.

Urinary treatment and management can significantly impact daily life for those with neurological conditions. In 2018, Myers and al reported that SCI patients had better satisfaction when performing CISC than with an indwelling catheter;[21] this study assessed urinary disorder impact with NBSS and the SCI QoL Difficulties assessment tool.[22] As described in the validation study of SCI QoL Difficulties, there are several determinants in the consequences and quality of life domains; this was one of the limitations in the validation of the original NBSS-SF. Even if the information provided by the consequences subscale may be useful in clinical practice, it is very difficult to assess this wide domain with only two questions. In the neurogenic population, the impact of urinary disorders is well-known in terms of degradation of quality of life or socio-economic burden,[1,23,24] and a specific assessment is probably more accurate than a reduced (multidimensional) approach that may lead to reduced information.

That said, our French validation of the NBSS-SF will be helpful for clinical and research purposes (including international collaboration) because of its multidimensional evaluation of urinary symptoms in the neurogenic population. The three subscales of NBSS-SF allow assessment of "positive" symptoms (incontinence, voiding or storage symptoms) but also a "negative" domain (consequences). Other tools or questionnaires have been validated and are now used in French, such as USP[14] or the International Prostate Symptom Score (IPSS),[25] but these tools do not specifically assess the consequences domain. This domain allows a more comprehensive assessment and consideration of potential complications due to insufficient, ineffective, or inappropriate treatments.

Another one of the strengths of the NBSS-SF is its population of interest. In clinical practice or research, it can be applied to patients suffering from LUTS due to a neurological condition. Many other questionnaires are specific to one neurological condition, such as SCI,[26] but the NBSS-SF can be used for further research in the neurogenic bladder population.

Conclusions

The French version of the NBSS-SF reports similar psychometric properties as the initial version developed by Welk et al. Total score for Cronbach's α and reproducibility are good (0.79) and very good (0.9), respectively. The availability of this instrument in French will facilitate the assessment and management of PROs in francophone clinics and research settings; however, for clinical practice, the quality-of-life subdomain should be assessed by a complementary instrument due to its low psychometric properties.

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This paper has been peer-reviewed.

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