French version of the short form of 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 a neurogenic bladder.

Introduction

Lower urinary tract symptoms (LUTS) are frequent in worldwide population, 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. In these conditions, LUTS can occur from the beginning of neurological disease (SCI, MS) or during its progression (MS).

Neurogenic bladder may be responsible for upper urinary tract complications such as urinary tract infection or renal failure.² It can also decrease quality of life³ and have an important socio-economic impact.⁴

To investigate LUTS, different tools or questionnaires are available. In the last years, a new way to assess symptoms, satisfaction or quality of life has been developed and new tools have been specifically validated. These tools, corresponding in Patient Reported Outcomes (PRO) allow to directly evaluate patients point of view without clinicians' judgement. Initially developed in oncology, they recently take a wide part of management in urology. Indeed, in the absence of risk factors of complications, PRO are appropriated for assessing symptoms such as overactive bladder or urinary incontinence and could help in therapeutic management. These questionnaires are now widely used in clinical trial to assess treatment efficacy as a more objective way that simple patient declaration.

Welk and al developed and validated a new questionnaire in 2013 to allow a multimodal assessment of LUTS specifically designed for a neurogenic population. The Neurogenic Bladder Symptom Score (NBSS) is composed of 24 items and explores 3 domains (urinary incontinence, bladder storage and voiding, consequences). In addition, NBSS includes two additional questions related to bladder management and quality of life. In 2020, Welk and al. developed a short version of NBSS (NBSS-SF), composed of 10 items exploring the 3 same domains as the NBSS original long version.

The NBSS has already been translated in Brazilian, Portuguese, ⁹ Turkish ¹⁰ and Greek ¹¹ languages. Cross cultural adaptation of existing questionnaire is important for clinicians, to improve accurate evaluation of specific or generic domains. This step should carefully takes into account language specificity, allowing a perfect comprehension of the translated version by the targeted population, without changing the meaning of the questionnaire. Some questionnaires are available in French to assess quality of life related to neurogenic LUTS such as Qualiveen ¹² or bladder symptoms (Urinary Symptoms Profile (USP))¹³ However, there is no French-validated multidimensional questionnaire specifically assessing neurogenic LUTS, the USP questionnaire being a generic tool.¹³

NBSS-SF has the advantage to explore 3 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 2 questions exploring urinary tract infections and treatment efficiency for LUTS. Thus, this questionnaire allows a multidimensional overview of patients suffering from LUTS. A French version of NBSS-SF should also facilitate clinical research and international collaboration due to growing up utilization of NBSS-SF in urology and the large number of available validated translation.

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

Methods

We conducted a prospective study between June and October 2020 in our neuro-urology 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 to maintain a better understanding. Next step was the back-translation with native English translators. Among the 2 translators, one of them had no medical experience and the other one was a general practitioner. Both were native English speakers and perfectly fluent in French language.

Then, a bilingual expert committee, composed by urologists and neuro-urologists, 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 and pre-final versions of the NBSS-SF have been validated by the expert committee. ¹⁴

Step 2: Pilot study

We conducted a pilot study with 30 subjects. During this pilot study, 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?". Participant had to rate the two parameters for each translated item with a 3 level Likert scale (A: perfectly; B: good; C: poor). Comprehension and acceptation were considered as good if they answered A or B. All difficulties and remarks were collected to incorporate these comments in the final version after validation by a panel of experts.

Step 3: Validation study

To perform validation study, we used the same inclusion criteria than Welk and al. [8] and we included patients with neurogenic bladder. Patients over 18 were consecutively included in our department between September and October 2020. They had to read and understand French to fulfill the questionnaire. Exclusion criteria were recent urological surgery, recent urinary tract infection, or a treatment modification during the study.

Validation study was performed to determine the psychometric properties of the questionnaire.

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 as very good. 17 The NBSS-short form is composed of 2 first items (covering quality of life and bladder management) and 8 items covering 3 subdomains (items 3, 4, 5 for urinary incontinence, items 6, 7, 8

for storage and voiding) and finally 2 items covering the consequences. The calculation of total score was similar to initial version of NBSS (i.e., quality of life /4; incontinence /12; storage and voiding symptoms /9; consequences /7, total score ranging from 0 to 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 is considered as a good test-retest reproducibility. ¹⁷ Patients completed the final version of the questionnaire and they had to mail the second questionnaire within 7 to 14 days. As this second questionnaire was completed at home, all patients were called 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 litterature¹⁹, the estimates for the sample size was based on minimal requirement of at least 10 patients per question. As NBSS-SF was composed by 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 analyzes were performed with RStudio (Version 1.2.5033, RStudio: Integrated Development for R. RStudio, Inc., Boston).

Results

Pilot study

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

Validation study

One hundred and six patients were included from September 2020 to October 2020. Population characteristics is described in Table 1. One patient was excluded due to treatment modification during the study. In total, 105 patients were included with 59 women (56%) and mean age was 53 years. Patients were between the ages of and years (median). They presented 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 intra-detrusor 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' α coefficient for the overall questionnaire was 0.79. The Cronbach' α for each subscale was respectively 0.91 (urinary incontinence), 0.69 (storage and voiding) and 0.25 (Consequences) (Table 2).

In our study, 88/105 (84%) patients sent back their questionnaire 7 to 14 days after the first completion of NBSS-SF. Reasons for missing data were incomplete questionnaires for 2 patients and no answer from 15 patients despite multiple reminders. The non-responders did not differ from the responders (Table 3). The 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 sub-domains, ICC was 0.73 for Urinary incontinence, 0.79 for Storage and voiding and 0.75 for consequences (Table 4). Time to fulfill the questionnaire was 3.1 minutes (+/-1.1min). Total score of NBSS-SF was 9/28 (+/-5.2).

Discussion

The psychometric properties of this French version of NBSS-SF are overall similar to those of the original English version. Cross cultural adaptation shows good comprehension and acceptation results. In the methodological process, translation and back translation by independent translators did not provide any difficulties except for 2 items. These items, related to the translation of "diapers" and "penile condom", did not correspond to correct wording in French language and need to be adapted. These two terms were responsible for a poor comprehension by patients during the pilot study and wording has been changed and validated by the expert committee to improve language, and thus comprehension of the translated questionnaire. This version was used in the final validation step with a large number of patients.

Concerning psychometric properties, internal consistency and test-retest correlations were similar to the initial version 8 with respectively total Cronbach's α at 0.79 (Table 2) and ICC at 0.90 (Table 3). As suggested by Welk and al. 8 , internal consistency for the "consequences" domain was very low (Cronbach's $\alpha=0.25$). This result could be explained by many reasons.

First one is the population study. In the validation study of NBSS-SF,⁸ results were presented with three different cohorts. For each cohort, consequences domain has the worst results with low or very low Cronbach's alpha coefficient (respectively 0,43; 0,33 and 0,68). In this study⁸, cohort 1 was composed by 59% of MS and 35% of SCI. Our cohort is quite similar, but bladder management is different. There was only 20% of patients performing CISC in the original study whereas it represents more than 50% in our population. This proportion is comparable with cohort 2 (51% performing CISC). For both cohorts (1 and 2), the "consequences" domain had the lowest score for internal consistency (respectively 0.43 and 0.33). In neurogenic bladder, CISC, exclusively or in addition to other urinary management (onabotulinum toxin or antimuscarinics) are 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 "conse-

quences" domain and quality of life subscales. Urinary treatment and management are responsible for a significant impact in daily life for neurological population. In 2018, Myers and al. ²¹ reported that SCI patients had better satisfaction when performing CISC than indwelling catheter. In this study, assessment of urinary disorder impact was performed with NBSS and the SCI QoL Difficulties. ²² As described in validation study of SCI QoL difficulties, there is a lot of determinants in "consequences" and "quality of life" domains. It was one of the limitations in validation of NBSS SF study ⁸ and Welk and al. suggested to perform the full version of NBSS ⁷ to better explore this subscale. Indeed, even if the information provided by this subscale may be useful in clinical practice, it is not sufficient to have a complete evaluation of "consequences". It seems to be very difficult to assess this wide domain with only one or 2 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.

However, 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 3 subscales of NBSS-SF allow to assess "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 USP¹⁴ or IPSS,²⁵ but these tools do not assess specifically the "consequences" domain. This domain allows a more comprehensive assessment and consideration of potential complications due to insufficient, ineffective, or inappropriate treatments. This balance in treatment assessment is difficult to explore and allows both patient perspective (Patient reported Outcome Measure (PROM)) and medical considerations (e.g. urinary tract infection).

Even if NBSS-SF is very useful, because of its simplicity and rapidity to fulfill (3min), it is probably not sufficient to assess all the consequences and quality of life impact. As shown in validation study by Welk and al.⁸, this subscale is poorly correlated to the Qualiveen questionnaire, but remained significant.

On the other hand, test-retest reliability was very good (ICC = 0.9) for total score and each subscale. This psychometric property is very important for the use of the NBSS-SF in research study but as the validation study suggests⁸, the long form is more accurate in exploring each domain. Indeed, NBSS 7 shows a good correlation coefficient with the validated questionnaire for each domain.

One of the strengths of the NBSS-SF is its population of interest. Indeed, 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 a neurological condition, especially for SCI population. NBSS-SF should be used for further research in neurogenic bladder population.

Conclusions

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

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Figures and Tables

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	30 (29)		
syndrome, conus medullaris syndrome, etc.)			
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 Storage and voiding Consequences	0.91 0.69 0.25	0.86 0.71 0.43		

NBSS: Neurogenic Bladder Symptoms Score-Short From.

Table 3. Population characteristic between responder and non-responder for test- retest reliability				
Tetest Tenashity	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. ‡Welsch test.

Table 4. Reproducibility of French NBSS-SF				
NBSS	Test-retest (intra- class correlation coefficient) n=88	Intraclass correlation coefficient by Welk and al n=120		
Overall score	0.9	0.84		
Subdomains Incontinence Storage and voiding Consequences	0.73 0.79 0.75	0.80 0.80 0.86		

NBSS: Neurogenic Bladder Symptoms Score-Short From.