Validation of the Dutch-Language Version of the Neurogenic Bowel Dysfunction Score in Patients With Multiple Sclerosis

Tess van Doorn, MD; Ilse M. Groenendijk, MD, PhD; Jeroen R. Scheepe, MD, PhD; Bertil F.M. Blok, MD, PhD

Background: Neurogenic bowel dysfunction (NBD), like fecal incontinence and constipation, is a common symptom of disease in patients with multiple sclerosis (MS). The NBD score is a validated symptom-based questionnaire consisting of 10 multiple-choice questions. The aim of this study was to validate the Dutch version of the NBD score in patients with MS, creating an objective measuring tool of bowel dysfunction.

Methods: Translation and validation of the NBD score was performed according to standardized guidelines. Adult patients with MS visiting a urology department completed a set of questionnaires (test): the NBD score, the Fecal Incontinence Quality of Life scale (FIQL), the Fecal Incontinence Severity Index (FISI), and the EQ-5D 3-Level questionnaire (EQ-5D-3L). After 1 to 2 weeks, the questionnaires were completed again (retest). A control group recruited at a general practitioner's practice completed the questionnaires once. Data were analyzed for measurement properties.

Results: Sixty-one patients and 50 controls were included. Content validity was adequate, internal consistency was moderate (Cronbach α = 0.57 and 0.41), and reproducibility was excellent (interclass correlation coefficient = 0.78). Criterion validity was confirmed; the NBD score correlated moderately/strongly with the FIQL, FISI, and EQ-5D-3L. The NBD scores in the patient group were significantly higher than those in the control group, demonstrating good construct validity.

Conclusions: The Dutch version of the NBD score showed moderate to good validity and good reliability for assessment of NBD in patients with MS. *Int J MS Care. 2022;24(2):67-73. doi:10.7224/1537-2073.2020-105*

Neurogenic bowel dysfunction (NBD) is one of the most debilitating symptoms of multiple sclerosis (MS), negatively affecting patients' quality of life. Bowel dysfunction is rated as the third most bothersome symptom by patients, after fatigue and impaired mobility, and it has a significant effect on their psychosocial and physical life and overall illness.[1] The prevalence is high: 29% to 43% of patients with MS experience constipation and more than 50% experience fecal incontinence.[2] The causes of NBD are multifactorial. Fecal incontinence can be caused by, eg, loss of voluntary control of defecation due to lesions in the frontal lobe. Constipation can be caused by, eg, prolonged colonic transit due to loss of supraspinal modulation.[1] Nonneurologic factors causing constipation include anticholinergic (bladder management) or opiate (pain management) intake and impaired mobility.[3] In women, damage to the anal sphincter and its innervation due to pregnancy and vaginal delivery can lead to fecal incontinence.[4] As MS progresses and involvement of the spinal cord is present, bowel symptoms tend to worsen.[1] Because patients may be reluctant to mention these problems, caregivers working with patients with MS must be aware of these symptoms and assess NBD in every patient, regardless of the course of MS.[1,5]

From the Department of Urology, Erasmus Medical Center, Rotterdam, the Netherlands (TvD, IMG, JRS, BFMB). Correspondence: Tess van Doorn, MD, Department of Urology, Erasmus Medical Center, Dr Molewaterplein 40, 3015 GD Rotterdam, the Netherlands; email: t.vandoorn.1@erasmusmc.nl

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At present, 2 questionnaires on fecal incontinence are available in the Dutch language: translated versions of the Fecal Incontinence Quality of Life scale (FIQL) and the Fecal Incontinence Severity Index (FISI).[6] Both questionnaires have been validated for nonneurogenic patients and assess the impact of fecal incontinence on quality of life solely, rather than measuring NBD. The NBD score is a symptom-based questionnaire that covers both constipation and fecal incontinence.[7] It was developed for patients with spinal cord injury, but because the pathophysiology and symptoms of NBD in spinal cord injury and MS are similar, it is thought to be suitable for patients with MS.[8]

The aim of this study was to validate a Dutch-language version of the NBD score in patients with MS to ensure that bowel dysfunction can be assessed and evaluated objectively. Recently, our group published validation studies of questionnaires on bladder function and sexual function in neurogenic patients.[9,10] The ultimate goal is to generate a comprehensive pelvic function data set to enable patients and their professional caregivers to explore and monitor symptoms objectively and correlate measurements to nonurogenital symptoms over time. The Dutch-language NBD score will complete this data set.

Methods

Study Design and Study Population

Study Design

This prospective cohort validation study was conducted in the Urology Department of Erasmus Medical Center, Rotterdam, the Netherlands, and at a participating general practitioner's (GP's) office. Ethical approval was obtained from the institutional medical ethics review board.

Study Population

Adult (≥ 18 years of age) patients with MS visiting the Urology Department between June 2018 and July 2019 were invited to participate in this study. The following exclusion criteria were applied: dementia, difficulty reading and/or understanding the Dutch language, bowel stoma, active bowel tumors, and inflammatory bowel disease. Participants signed an informed consent form before the study began. They were asked to complete a set of questionnaires at baseline and again 7 to 14 days afterward, which were handed out on paper and returned by postal service. Questionnaires that were returned more than 35 days after the first set were excluded. Patient and disease characteristics were retrieved from the medical records.

Control Group

Patients who visited the participating GP's office in Rotterdam in September and October 2018 were asked to participate as the control group. This control group was chosen because these patients visiting their GP are overall not very diseased and form a good representation of the overall population.

Patients were eligible for the study if they were 18 years or older and had no difficulty reading or understanding the Dutch language. Exclusion criteria were similar to those of the patient group. In addition, patients were asked about bowel symptoms, and if they noted any symptoms, they were not included in the control group. All the participants signed an informed consent form. Patients in the control group completed the same set of questionnaires as the study population, but only once.

Questionnaires

The set of questionnaires consisted of the following 4 items.

NBD Score

The NBD score is a symptom-based questionnaire that covers constipation and fecal incontinence.[7] Developed for patients with spinal cord injury, the questionnaire consists of 10 weighted multiple-choice questions. Some minor linguistic adjustments have been made since the original publication, and a scale question was added on general satisfaction of the current bowel management.[11] The latter is supposed to give the physician insight into the possible needs of the patient. Because this question was not included, and, therefore, not validated, in the original questionnaire, it was omitted from the current validation study. Overall scores are divided into 4 groups; higher scores represent more severe bowel dysfunction (0-6, very minor; 7-9, minor; 10-13, moderate; and ≥14, severe). The Dutch-language version can be found in **Figure S1**, which is published in the online version of this article at IJMSC.org.

Fecal Incontinence Quality of Life Scale

The FIQL is a questionnaire that measures the severity of incontinence for gas, mucus, and liquid and solid stool by scoring its frequency.[6,12] Answer options are as follows: never, 1 to 3 times a month, once a week, 2 or more times a week, once a day, and 2 or more times a day. This questionnaire has

two rating options, one for specialists and one for patients. In this study, patient-specific ratings were used.

Fecal Incontinence Severity Index

The FISI is a severity score for patients with fecal incontinence, a Dutch-language version of which has already been validated.[6,13] This questionnaire covers 4 aspects of fecal incontinence: gas, mucus, liquid stool, and solid stool, to be scored by the degree of occurrence, ranging from never to 2 or more times a day. Similar to the FIQL, this questionnaire has 2 different rating options, one for specialists and 1 for patients. In this study, patient-specific ratings were used.

EQ-5D 3-Level Questionnaire

The EQ-5D 3-Level questionnaire (EQ-5D-3L) is a widespread instrument to measure health-related quality of life. It covers 5 dimensions contributing to health-related quality of life: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, to be scored in 3 levels: no problems, some problems, and extreme problems. This questionnaire also includes a visual analogue scale with which the patient can self-rate his or her health state from best imaginable health state to worst imaginable health state.

Linguistic Validation

For the cross-cultural adaptation of the English-language NBD score into the Dutch language, standardized guidelines on linguistic validation were followed.[14] Three professional native Dutch-speaking translators performed the forward translation separately, and consensus was reached during a meeting with one of the investigators (T.v.D.). After small adjustments to text rather than context, the final version was approved by 2 urologists (J.R.S. and B.F.M.B.). To complete the translation procedure, a native English speaker performed the backward translation.

Measurement Properties

Content Validity

Content validity was assessed during face-to-face interviews with 17 patients who were asked to give their opinion on the clarity of the questions. Assessment by the researchers (T.v.D., J.R.S., and B.F.M.B.) was performed during the linguistic validation process, focusing on the questionnaire items and the correlation to the known clinical symptoms.

Internal Consistency

Internal consistency can be assessed to determine whether items in a questionnaire are correlated and to demonstrate whether these questions measure the same underlying concept. Cronbach α was measured for the total score because the NBD score has no subscales. An outcome between 0.70 and 0.95 was considered sufficient, confirming good internal consistency.[15]

Reproducibility

To determine the reproducibility of a questionnaire, the degree of similarity of answers needs to be measured at multiple time points in a clinically stable person. The test-retest period was 1 to 2 weeks, following the recommendations of Terwee et al.[15] This period is long enough to prevent recall bias but short enough to prevent clinical imbalance in patients. The interclass correlation coefficient is calculated to determine agreement of the repeated measurements of test and retest of the total NBD score. An outcome greater than 0.70 is considered adequate. The limits of agreement are calculated as the mean ± SD change in scores of repeated measures.[16,17]

Criterion Validity

Criterion validity can be determined by measuring the correlation between the NBD score and a gold standard. Because a gold standard for the NBD score does not exist, we considered the FIQL, FISI, and EQ-5D-3L to be suitable proxies. In the case of linear association, the correlation of the NBD score with the used questionnaires is measured using the Pearson correlation coefficient (range, –1 to 1). If there is no linear association, the Spearman correlation coefficient (range, –1 to 1) is used.

Construct Validity

To determine construct validity, the following predefined hypotheses were tested: (1) The NBD scores of the controls will be lower than those of the patients; (2) Patients with lower FIQL scores will have higher NBD scores; (3) Patients with higher FISI scores will have higher NBD scores; and (4) Patients with lower EQ-5D-3L scores will have

Table 1. Participant Characteristics and Baseline Scores

Characteristic	Patient group (n = 61[a])	Control group (n = 50[a])	*P* value
Age, y	51.8 ± 12.4	38.4 ± 14.4	<.001[b]
Sex			.370[c]
Female	43 (70.5)	39 (78)	
Male	18 (29.5)	11 (22)	
Duration of disease, y	13.6 ± 8.4	NA	
Multiple sclerosis course			
Relapsing-remitting	32 (52.5)		
Primary progressive	8 (13.1)	NA	
Secondary progressive	18 (29.4)		
Unknown	3 (4.9)		
Mobility			
Fully ambulatory	30 (49.2)		
Limited walking	21 (34.4)	NA	
Wheelchair bound	6 (9.8)		
Unknown	4 (6.6)		
Estimated EDSS score (n = 55)	4.7 ± 1.8		
Baseline scores			
NBD score	5.78 ± 5.26 (n = 54)	1.81 ± 3.67 (n = 47)	<.001[b]
NBD general satisfaction score	6.20 ± 2.03 (n = 49)	7.61 ± 1.62 (n = 49)	<.001[b]
FIQL total score	3.49 ± 0.62	3.99 ± 0.16	<.001[b]
Domain 1: lifestyle	3.63 ± 0.58	3.92 ± 0.23	.002[b]
Domain 2: coping/behavior	3.28 ± 0.77	3.94 ± 0.19	<.001[b]
Domain 3: depression/self-perception	3.625± 0.61	4.12 ± 0.20	<.001[b]
Domain 4: embarrassment	3.49 ± 0.62	3.98 ± 0.10	<.001[b]
FISI total score	21.65 ± 13.21 (n = 57)	18.50 ± 13.59	.228[b]
EQ-5D-3L index score	0.63 ± 0.25	0.92 ± 0.15	<.001[b]
EQ-5D-3L VAS score	66.85 ± 14.38 (n = 55)	75.92 ± 15.11 (n = 38)	.004[b]

EDSS, Expanded Disability Status Scale; EQ-5D-3L, EQ-5D 3-Level questionnaire; FIQL, Fecal Incontinence Quality of Life scale; FISI, Fecal Incontinence Severity Index; NA, not applicable; NBD, neurogenic bowel dysfunction; VAS, visual analogue scale.
Note: Data are given as mean ± SD or number (percentage) unless otherwise indicated.
[a]Except as stated otherwise.
[b]T test.
[c]$\chi 2$ test.

higher NBD scores. Construct validity is considered adequate when 75% or greater is confirmed.[15]

Floor and Ceiling Effects

If 15% or more of all respondents, both patients and controls, achieve the lowest or highest score possible on a questionnaire, floor and ceiling effects are considered.[15] These effects were assessed for the total NBD score at baseline in both groups.

Statistical Methods

Based on guidelines on validation of questionnaires, a sample size of 50 patients and 50 controls was considered adequate.[15] Statistical analysis was performed using SPSS Statistics for Windows, Version 25.0 (IBM Corp). Continuous data are reported as mean ± SD and categorical data as numbers or percentages. Possible differences between the patient and control groups were tested with the χ^2 test for categorical variables and the *t* test for continuous variables. A $P < .05$ was considered statistically significant.

Results

Participants were included between June 2018 and July 2019, with 66 patients signing an informed consent form. Three patients were excluded because the questionnaires were not completely filled in, one because the patient only signed the informed consent, and one because the period between completing both sets of questionnaires exceeded 35 days. Ten patients did not return the second set of questionnaires and were not included in the retest analysis;

Table 2. Criterion Validity Tested by Spearman and Pearson Correlation Coefficients

NBD total score	FIQL score		FISI score		EQ-5D-3L index score	
	Correlation Coefficient	*P* value	Correlation Coefficient	*P* value	Correlation Coefficient	*P* value
Test	–0.565[a]	<.001	0.285[a]	.005	–0.479[a]	<.001
Retest	–0.535[a]	<.001	0.373[b]	.013	–0.298[a]	.047

EQ-5D-3L, EQ-5D 3-Level questionnaire; FIQL, Fecal Incontinence Quality of Life scale; FISI, Fecal Incontinence Severity Index; NBD, neurogenic bowel dysfunction.
[a]Spearman correlation coefficient.
[b]Pearson correlation coefficient.

this analysis was performed with the remaining 51 patients.

Fifty persons visiting the participating GP in September or October 2018 completed the set of questionnaires. These controls were statistically significantly younger than the study patients. There was no statistically significant difference in sex distribution between the groups. All baseline total scores differed statistically significantly between patients and controls, except for the FISI (**Table 1**).

Content Validity

Seventeen patients were involved in the linguistic validation process. The questions were found to be relevant, clear, and easy to answer. A few patients needed some clarification on the question concerning digital evacuation of stool because they were not familiar with this phenomenon. Content validity was confirmed; adjustments were not necessary.

Internal Consistency

If one or more questions were left unanswered, total NBD scores could not be calculated. This was the case for 6 patients, all but one of whom did not fill in the same questions at test and retest. Questions left unanswered were on digital evacuation of stool and frequency of fecal incontinence. Regarding the question on involuntary defecation, patients stated that an answer option of "never" was missing and for that reason left open. Internal consistency was determined to be moderate to low for the total NBD score. Cronbach α was 0.57 for the test and 0.41 for the retest.

Reproducibility

The mean ± SD time between completing the first and second sets of questionnaires was 14.6 ± 7.1 days. The mean ± SD change in total NBD score at the time of test and retest was 0.93 ± 3.30. Reliability was found to be adequate, with an interclass correlation coefficient of 0.78 for the total score of the questionnaire. The limits of agreement of the total scores ranged from –5.54 to 7.40.

Criterion Validity

Criterion validity was measured using the Pearson or Spearman correlation coefficient. Significant correlations were found between total NBD score and total scores on the FIQL, FISI, and EQ-5D-3L. These correlations ranged from weak to moderate (**Table 2**).

Construct Validity

All 4 predefined hypotheses were confirmed, evidencing good construct validity. Controls had statistically significantly lower NBD scores than patients (Table 1). Patients who scored lower on the FIQL/EQ-5D-3L or higher on the FISI had statistically significantly higher NBD scores (**Table 2**).

Floor and Ceiling Effects

Floor and ceilings effects were not present in the patient group; 6 patients (11.1%) had the lowest score possible and none had the highest score possible. In the control group, floor effects were seen; 51.1% had the lowest score (0) possible, indicating no bowel symptoms. Ceiling effects were not seen in the control group; none scored the highest score possible.

Discussion

The aim of this study was to translate and validate the Dutch NBD score in patients with MS. We showed that the NBD score is a valid and reliable

tool to objectively measure and explore bowel symptoms in this patient population, which enables professional caregivers to follow these symptoms over time or researchers to use it for research purposes.

The control group was recruited at a GP's office located in a multicultural neighborhood. Most older people visiting the GP had difficulties reading the Dutch language, which might have led to selection bias. Moreover, the mean age of controls was significantly lower than that of patients. We assume that this has had a negligible effect; the mean of both patients and controls were middle-aged adults, and the total NBD scores differed significantly between the 2 groups, which is the only measurement in the validation process involving controls.

As mentioned in the Results section, some participants left questions unanswered or needed explanation. Difficulty understanding questions was also reported in the translation and validation study to Arabic by Mallek et al.[18] A possible explanation is that the NBD score was developed for patients with spinal cord injury. Although the NBD symptoms in spinal cord injury can be similar to those in MS, symptoms become more severe in MS as the disease progresses and the number of lesions increases.[8,19] In earlier stages of the disease, symptoms of NBD might not be present or recognized. In future use of the NBD score, the terminology should be clearly explained before the questionnaire is completed.

Internal consistency was assessed to determine whether the items in the questionnaire are correlated to each other. The calculated Cronbach α was moderate for the test (0.57) and relatively low for the retest (0.41), indicating moderate internal consistency. Erdem et al[20] found a comparable Cronbach α (0.547). A possible explanation for the moderate to low internal consistency is that the NBD score covers both fecal incontinence and constipation. In addition, the number of questions is limited, and subscales are not provided. Still, guidelines on measurements in medicine state that low internal consistency is not problematic if the construct measured is evident because this measure alone does not establish the validity of a questionnaire.[21] We, therefore, suggest that the moderate internal consistency is acceptable.

All predefined hypotheses were confirmed, indicating good construct validity. Although the FISI total scores did not statistically significantly differ between controls and patients, higher NBD scores showed statistically significantly higher FISI scores in patients.

Patients with MS visiting the outpatient clinic of the Urology Department were asked to participate in this study, regardless of experiencing symptoms of fecal incontinence or constipation. The total NBD scores were low, although statistically significantly higher than those in the control group, indicating very minor overall bowel dysfunction in both the patient and control groups (0-6 points is very minor). It is known that NBD worsens as the disease progresses.[8,19] Most participants in the patient group were in the relapsing-remitting course of the disease, in which symptoms, including bowel symptoms, can be absent or mild between exacerbations. A slightly positive correlation was found between total NBD scores and the estimated Expanded Disability Status Scale score; thus, higher Expanded Disability Status Scale scores indicate higher NBD scores (correlation coefficient = 0.18, $P = .22$).

This study has several limitations. It was not possible to measure responsiveness and interpretability of the NBD score because most patients were not starting or changing treatment for bowel problems. Another limitation is that patients were included regardless of any bowel symptoms. Although internal consistency was moderate, all other measurements in the validation process showed statistically significant differences between patients and controls, showing adequate validity and reliability of the NBD score.

To date there is no gold standard questionnaire available for the validation process. Therefore, we used the FISI and FIQL, which both cover fecal incontinence solely. Because all measurements correlated significantly between the NBD score and the FISI and FIQL scores, we assume that the use of these proxy gold standard questionnaires was adequate.

PRACTICE POINTS

- Patients are reluctant to report bowel dysfunction. The neurogenic bowel dysfunction (NBD) score can help explore these underexposed, but debilitating, symptoms and optimize treatment.
- The Dutch-language version of the NBD score is a valid and reliable questionnaire to explore and examine NBD in patients with MS. Caregivers can use this tool to measure effects of treatment in a semiobjective manner in clinical practice.

The strengths of this validation study are that it was performed according to standardized guidelines and that it is the first validation study of the NBD score in patients with MS. Although Mallek et al[18] included 8 patients with MS in their validation process, this group of patients was not analyzed separately. The prevalence of NBD is high in patients with MS and has a great effect on quality of life. In a previous study, almost half of the patients stated having adjusted their lives to their bowel regimen, negatively affecting social life and relationships.[22] Naturally, patients may be reluctant to mention bowel dysfunction. The NBD score can help explore underexposed symptoms objectively and open up the conversation between patient and physician.

Validation of the Dutch-language version of the NBD score contributes to construction a complete data set for the evaluation of urogenital symptoms in neurogenic patients. Recently, our group validated the Qualiveen Short Form on bladder symptoms[10] and the Multiple Sclerosis Intimacy and Sexuality Questionnaire on sexual dysfunction.[9] The NBD score completes this pelvic function data set, which will be made available for all professional caregivers involved.

In conclusion, the Dutch-language version of the NBD score is a valid and reliable questionnaire to explore and examine NBD in patients with MS. It can be used to measure effects of treatments in an objective manner in clinical practice and in research. □

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