

ARTICLE The Neurogenic Bowel Dysfunction score (NBD) is not suitable for patients with multiple sclerosis

Gabriel Miget^{1,2^{IZI}}, Eliane Tan^{1,2}, Martina Pericolini^{1,2,3}, Camille Chesnel^{1,2}, Rebecca Haddad^{1,2}, Nicolas Turmel^{1,2}, Gérard Amarenco^{1,2} and Claire Hentzen^{1,2}

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STUDY DESIGN: Retrospective cohort study.

OBJECTIVE: Bowel and anorectal dysfunctions are common in patients with multiple sclerosis (pwMS). The use of validated questionnaires is recommended in the initial assessment and patient's follow-up. The Neurogenic Bowel Dysfunction (NBD) score is the most used questionnaire but has been developed in spinal cord injured patients and has never been validated in other neurological diseases. We aimed to assess NBD's relevance in pwMS.

SETTINGS: Monocentric study in a tertiary neuro-urology department.

METHODS: A retrospective study in pwMS consulting for the first time in our department, that fulfilled the NBD questionnaire between 2010 and 2021 was performed. Qualitative and quantitative answers for each question were analyzed. Content validity and internal consistency were evaluated.

RESULTS: One hundred thirty-five pwMS (mean age 47.1, 58% of women) fulfilled the NBD questionnaire. Mean NBD score was 6.0 (SD 6.1) and 75% of patients had a score <9. Content validity analysis revealed 4 items not appropriate, 1 item with irrelevant calibration, and omission of some treatment widely used in pwMS. Internal consistency was appreciated with Cronbach's alpha = 0.48 IC 95% [0.31; 0.6].

CONCLUSION: NBD questionnaire lacks content validity and presents a weak internal consistency in pwMS. A specific questionnaire is therefore required in pwMS to optimize bowel management and follow-up.

Spinal Cord (2022) 60:1130-1135; https://doi.org/10.1038/s41393-022-00837-3

INTRODUCTION

Multiple sclerosis (MS) is an autoimmune central nervous system disorder characterized by demyelination and central neurologic damage. MS is the first cause of disability in young adults and affects 2.5 million people in the world [1]. Bowel and anorectal dysfunction are common in patients with multiple sclerosis (pwMS). Indeed, 35 to 54% [2] of pwMS suffer from chronic constipation and 29 to 51% fecal incontinence [3]. Often less described than lower urinary tract symptoms, bowel symptoms have a major impact on quality of life and their psycho-social and professional consequences are well established [2, 4]. Moreover, bowel and anorectal disorders alter neurogenic bladder functioning, leading to difficulties to manage overactive bladder and/or urinary retention in the context of a real "cross-talk" due to mutual innervation and proximity of spinal and cortical control centers [5].

The assessment of bowel and anorectal disorders is based primarily on clinical data with history taking, clinical evaluation (fecal impaction) and consideration of their impact on quality of life. As usual, the use of specific and validated questionnaires is recommended because of their accuracy, exhaustiveness, reproducibility and ability to quantify disorders in all dimensions, thus allowing appropriate therapeutic strategies. However, there is no validated symptom questionnaire specific to bowel and anorectal disorders in PwMS. The Neurogenic Bowel Dysfunction (NBD) score was developed by Krogh et al. [6] in 2005 and only validated in patients with spinal cord injury (SCI) in different languages but not in French. This score consists of ten questions, the score of which varies, depending on the question, between 0 and 13. The minimum overall score is 0 and the maximum score is 47. The total score is used to classify the subjects into four distinct groups according to the severity of the bowel problems: a score between 0 and 6 corresponds to "very minor" severity, a score between 7 and 9, "minor severity", a score between 10 and 13, "moderate" severity and a score over 14 "severe" severity.

In SCI population, psychometric properties of the NBD score are excellent and therefore this tool can be used to better specify fecal incontinence and constipation. Nevertheless, this tool is very often used in clinical practice despite the absence of specific language validation, as well as in research, in various neurogenic populations (e.g., PwMS, Parkinson disease, stroke) despite the absence of validation in these specific populations. Moreover, even if the type of anorectal and bowel symptoms are similar in MS and SCI populations in terms of symptoms (incontinence and

¹GRC 01, GREEN Groupe de Recherche Clinique en Neuro-Urologie, AP-HP, Hôpital Tenon, Sorbonne Université, 75020 Paris, France. ²Department of Neuro-urology, Tenon Hospital, AP-HP, 4, Rue de la Chine, 75020 Paris, France. ³Urology Department, Policlinico Tor Vergata, Università Degli Studi di Roma "Tor Vergata", 00133 Rome, Italy. ^{Semenil:} gabriel.miget@aphp.fr

Received: 20 January 2022 Revised: 4 July 2022 Accepted: 4 July 2022 Published online: 20 July 2022

constipation), on the one hand the consequences of these symptoms are different (for example, there is a risk of dysautonomia in SCI that is not observed in PwMS) and on the other hand, the relative importance of symptoms is very different in clinical practice depending on the cause of the neurogenic dysfunction.

In the absence of specific validation of the NBD questionnaire in MS, despite the lack of specific validation in French, given its common use, we aimed to evaluate its relevance in PwMS.

MATERIALS AND METHODS

The reporting of this study adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

We performed a retrospective and monocentric study in a neuro-urology department of a French university hospital.

Patients consulting for the first time in our department, aged over 18 with MS diagnosed on the 2010 McDonald's criteria and then on the 2017 revised McDonald's criteria who filled the NBD questionnaire between 2010 and 2021 were included. Patients with a significant cognitive disorder (mini mental state evaluation \leq 24) or not able to read or understand French were not included.

The following data were collected retrospectively from the medical files of the patients: demographic characteristics (age, sex, body mass index), the disease course and duration of MS, and the results of the following symptom questionnaires were collected: urinary symptom profile [7] and the Patient Global Impression of Severity scale (PGI-S) for bowel disorders whose use is validated in French [8], after having been initially validated in female stress urinary incontinence [9] or in urinary disorders related to benign prostatic hypertrophy [10]. This score is a 1-item questionnaire that ask an individual subject to rate the severity of a specific condition. It has four response possibilities (absent, mild, moderate, severe). Prévinaire et al. [8] showed in a French study concerning NBD in a neurological population (SCI, PwMS, Stroke) an association between the PGI-S and the NBD score. we sought a correlation between the PGI-S and the categorial NBD score.

To assess the relevance of using the NBD score in pwMS, we described and analyzed the distribution of specific responses to each item. We analyzed the content validity by assessing the content of each item and the associated responses to discuss their relevance. For those whose relevance was questionable, we also compared the observed responses to the content of the medical and nursing files.

Then, we performed internal consistency analyses using Cronbach's alpha coefficient calculation and a comparison of the NBD score with the PGI-S score.

Statistical analyses were performed using a significance level of 5%, with "RStudio Team (2020). RStudio: Integrated Development for R. RStudio, Inc., Boston, MA URL http://www.rstudio.com/".

Means, percentage, and standard deviation (SD) were used to describe the population. Results of the NBD was presented by mean, median and quartiles.

Internal consistency was appreciated with Cronbach's alpha and the 95confidence interval was calculated with the bootstrap method. Link between NBD and PGI-S scale was evaluated by a Person's correlation given the number of ex-aequos on the PGI not allowing for a Spearman correlation. A *p* value <0.05 was considered statistically significant.

The study was approved by a local ethics committee. Protocol and data collection were conducted in accordance with the ethical standards of the national research committee and with the Declaration of Helsinki. Data were collected and analyzed without any identifying information and the study was performed in accordance with European regulation no. 2016/ 679, known as the general regulation on data protection.

RESULTS

A total of 135 patients (mean age 47.1, SD 13) fulfilled the NBD score and were included in the study. Seventy-nine were women, the mean EDSS score was 4.9 (SD 1.8) and 54% had a relapsing-remitting course of MS. The general characteristics of the population are given in Table 1.

The mean NBD score was 6.0 (SD = 6.1) and 75% of patients had a score <9 as illustrated in Fig. 1A. In our study population, The NBD values ranged from 0 to a maximum of 32. After conversion

Table 1. Characteristics of the included population.

	Mean (SD)	Count (%)
Gender		
Women		79 (58.5)
Men		56 (41.5)
Age (years)	47.1 (13.0)	
BMI (kg/m ²)	23.05 (5.1)	
EDSS	4.9 (1.8)	
Type of MS		
RR		74 (54.8)
SPMS		30 (22.2)
PPMS		25 (18.5)
Missing		6 (4.4)
Time of the disease (years)	13.8 (10.3)	
PGI severity	2.23 (1.0)	
Normal		41 (30.4)
Mild		27 (20.0)
Moderate		42 (31.1)
Severe		15 (11.1)
Missing		10 (7.4)
USP score		
Overactive bladder (/21)	8.11 (4.0)	
Stress incontinence (/9)	1.87 (2.9)	
Voiding dysfunction (/9)	2.67 (2.5)	

BMI body mass index, *EDSS* expanded disability status scale, *RR* relapsingremitting, *SPMS* secondary-progressive multiple sclerosis, *PPMS* primaryprogressive multiple sclerosis, *PGI* Patient Global Impression severity score, *USP* Urinary Symptom Profile score.

of the total score to the categorical NBD severity score, 63% had very minor NBD, 13.3% had minor NBD, 12.6% had moderate NBD and 11.1% had severe NBD. No correlation was found between the time of disease and NBD score. The distribution of subjects according to the different scores is depicted in Fig. 1B. The qualitative analysis of the distribution of the total score shows a positive non-Gaussian but asymmetric distribution. Shapiro–Wilk's normality test confirms this observation, p < 0.001.

The distribution of responses for each item of the questionnaire is described in Fig. 2, with asymmetric distribution in seven items. Among these, five in particular caught our attention.

In question 2 "Time used for each defecation" (Fig. 2B), 120 subjects (88.9%) answered "less than 30 min" while 14 (10.4%) responded that they needed more time. Only one patient (0.7%) reported a time >60 min. This patient performed trans anal irrigations (TAI) to treat constipation. Two other subjects also used this treatment but reported a defecation time under 30 min.

In question 3 (Fig. 2C) "Uneasiness, headaches or perspiration during defecation", 121 subjects (89.6%) answered negatively compared to 14 patients (10.4%) reporting these symptoms. There is therefore an asymmetry in favor of the absence of these symptoms. The same results were observed for questions 4 (Fig. 2D) "Regular use of tablets against constipation" and 8 (Fig. 2H) "Medication against fecal incontinence". In the 4th question, 14 (10.4%) subjects answer "yes" but none of them received oral tablets for constipation.

Also, regarding the "incontinence treatments" (question 8), on the 15 subjects who answered "yes" (11.11%), only two subjects were treated with Loperamide. Lastly, for question 10 (Fig. 2J), only ten subjects (7.4%) reported perianal skin disorders.



Fig. 1 Distribution of the total score. The median score is indicated in red. A Statistical distribution of the NBD total score. B Qualitative description of the number of subjects according to the score.



Fig. 2 Distribution of answers for each question of the Neurogenic Bowel Dysfunction score.

These observations highlight the question of content and face validity of this questionnaire, in our study population of PwMS.

Internal consistency was appreciated with Cronbach's alpha = 0.48 IC 95% [0.31; 0.6].

A moderate correlation was found between the NBD score and the PGI-S score ($\rho = 0.57$ IC 95% [0.44; 0.68]; p < 0.001). This correlation between the categorized NBD score and the PGI-S can be seen in a qualitative representation in Fig. 3.



Fig. 3 Qualitative representation of the poor correlation between the categorial NBD score and the PGI-S (Patient Global Impression of Severity).

DISCUSSION

The qualitative review the NBD score of pwMS and internal consistency of this questionnaire reveals that its use is not inappropriate in this population. Indeed, our study showed that the score structure and calibration, the content validity and the internal consistency are not supporting its use in MS population.

Concerning the content validity, some items are miscalibrated, inappropriate or even incomplete, particularly with the omission of certain therapeutic possibilities that may impact, influence, or even testify to the severity of the NBD.

One item appears to be miscalibrated based on the analysis of response patterns. In the first question, the possibility of responding of a time needed to exonerate of more than 60 min (1 subject in our study, performing enemas) does not seem appropriate. Indeed, this defecation duration is rarely observed in clinical practice in PwMS [11] as compared to the population of patients with SCI. An additional cut-off between 0 and 30 min could allow the identification of patients reporting defecation difficulties, a common symptom in MS. It is true that TAI may last up to 1 h, but the question is not evoked in this way and the use of TAI is not explicitly evaluated.

Four other questions do not appear to be appropriate for PwMS regarding their content. Question 3, regarding the presence or absence of autonomic symptoms during defecation efforts is controversial. While it has been shown that autonomic dysregulation can be encountered in MS [12] with only few case reports of autonomous hyperreflexia [13, 14], these symptoms are not usual in PwMS. Indeed, these autonomic dysreflexia is usually observed in SCI population [15]. Analysis of the responses to questions 4 and 8 compared to the patient file provided unexpected results. In question 4, 10.3% of subjects responded positively about taking oral treatment (tablets) while the analysis of their medical file showed the absence of such treatment currently available in our country (Bisacodyl (Dulcolax®), Pyridostigmine Bromide (Mestinon®) or Prucalopride (Resolor®). This raises the problem of understanding this question but also of the frequency of selfmedication in this type of symptoms. Same observation can be made regarding guestion 8. The content of this item is an issue: there is no drug treatment for the management of anal incontinence, except for the use (currently in clinical trials) of botulinum toxin in the very specific context of rectal hyperactivity which have not yet been studied in MS [16–18]. This suggests obvious difficulties in understanding this item, especially since of the 15 patients who answered "yes", only 2 were treated with Loperamide which can provide a benefit in matters of continence even in the absence of diarrhea.

Concerning question 10 and the presence of perianal skin disorders, this item seems perfectly appropriate in SCI, which is prone to pressure ulcers, especially considering the severity of motor disorders and the frequency of sensory disorders, which are less often encountered in terms of severity in PwMS, except at an advanced stage of the disease.

As previously mentioned, it is also important to consider that many treatments used in the current management of neurogenic bowel disorders are not mentioned [2]. Conservative management such as diet and fluid advices, toilet training, recommended in first line of care and often self-initiated before any medical advice, or behavioral adaptations [11, 19], could also be included in the list of items. Indeed, in the same way as laxative treatments, these therapeutic approaches have proven to be beneficial in the management of bowel disorders in PwMS. Moreover, rectal suppositories, especially the potassium tartrate suppository (Eductyl®) is frequently used because of its effectiveness on distal constipation (used by 28.1% of patients in our study). Although its efficacy has been little documented in the literature, there is some evidence of symptoms improvement with its use in current practice [20, 21]. Concerning the TAI already discussed above, their efficacy and safety of use has already been shown in the literature with well-designed studies [22-24]. Thus, this treatment is recommended by scientific societies and should be considered in the evaluation of NBD in PwMS as well as laxatives [2, 25, 26].

Concerning internal consistency, Cronbach's alpha was 0.48 Cl 95% [0.31; 0.6], a value indicating a low internal consistency of this questionnaire in our MS population, far from the objectives between 0.70 and 0.80 usually recommended [27]. Despite a significant correlation between the NBD score and the PGI-S score, this correlation remains moderate [28]. This could be explained on the one hand by the characteristics of the population included in

our study but also by a poor calibration both in terms of content and understanding of the NBD questionnaire items in our population.

The qualitative and quantitative analysis of the distribution of the responses showed a low median = 5 (1st quartile = 1.0-3rd quartile = 9.0), with 75% of subjects with a score below 9 out of a maximum of 47. These results reflect the poor calibration of the score for our population of pwMS.

The reading of recent data in the literature reinforces this idea, with the NBD score in the general population of pwMS often being low, supporting the idea of a poor calibration for pwMS [29, 30]. Indeed, two recent well-conducted prospective studies on anorectal disorders in pwMS showed on the one hand a low prevalence of anorectal disorders in this specific population with 17.3% of subjects reporting anorectal disorders [29], but above all a low NBD score of 4.54 (SD = 6.38) [29] and 3.8 (SD = 5.5) [30]. Moreover, in these two studies, a very large proportion of subjects had a NBD score <10, in 82.6% of the subjects in the study by Carotenuto et al. and 85.5% of the subjects in the study by Bisecco et al. The NBD score was statistically associated with the age of the subjects, the duration of the disease and the EDSS. The differences between our work and those of Alvino et al. concerning the total NBD score and the proportion of the categorical score can be explained by a higher average age in our study, as well as a higher EDSS and a longer course of the disease in our population. Besides, Bisecco et al. found results on the categorical score similar to those presented in our study in their subgroup analysis on the EDSS with a cut-off of EDSS = 4. Although our study was carried out in a tertiary center and therefore with a recruitment of subjects probably presenting a more severe impairment concerning their pelvi-perineal disorders than the global pwMS population, the comparison of the results of the NBD score between our study and the two studies of Carotenuto et al. and Bisseco et al. supports our observations.

Of course, our study has some limitations beyond the absence of specific validation in French. The retrospective design does not allow us to evaluate certain psychometric aspects of the questionnaire. Difficulty with comprehension of the questions could obviously be reminiscent of the potential cognitive disorders frequently observed in MS population, and not common in the SCI population in which the NBD questionnaire has been validated. However, we tried to limit the possible effect of cognitive impairment by excluding any subject with MMSE score <24. In addition, it was not possible to perform a test-rest reliability analysis which is part of the psychometric evaluation of symptom scores [27].

Because anorectal disorders are among the most disabling symptoms in PwMS, sometimes reported as the third most embarrassing symptom after motor disorders and fatigue [31], it is therefore necessary to assess them accurately. The NBD score is the main questionnaire related to bowel disorders used in neurological populations. Although it has been validated in English and has obvious qualities in the spinal cord injured population with rigorous psychometric validation [6], it's use in PwMS seems to be inappropriate. Our study reveals the need of a specific questionnaire to quantify severity and impact of bowel symptoms in pwMS to guarantee an accurate evaluation, but also to conduct research studies on bowel disorders management with an appropriate tool. A similar assessment of the NBD questionnaire validity in other neurological diseases such as parkinsonian syndromes might be useful, as constipation is a frequent complaint in this population. In PwMS, patients could present very specific symptoms, due to the neurogenic characteristics of bowel symptoms and location of the demyelination. For instance, PwMS with spinal lesions may experience dyssynergic constipation, and a localized demyelination lesion in the conus medullaris can lead to various clinical presentation, combining fecal incontinence with distal constipation. Also, cerebral lesions are

linked with fecal urgency and incontinence. A specific tool is needed in PwMS to characterize symptoms, follow the effectiveness of treatments, and evaluate their impact on the quality of life.

CONCLUSION

Symptoms questionnaires are a simple way to improve patients assessment and guide management, as well as assess treatment efficacy in clinical practice or trials.

The use of the NBD questionnaire in the evaluation of bowel and anorectal disorders does not seem to be appropriate in pwMS. In contrast to its use in spinal cord injured patients, in pwMS the NBD questionnaire lacks content validity and presents a weak internal consistency. Thus, development and validation of a specific tool to assess bowel disorders is required in this population.

DATA AVAILABILITY

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

GM participated in the development of the study design and objectives. He was responsible for data extraction and data input, performed the statistical analysis, and was responsible for writing the manuscript, submitting it, and proofreading it. He validated the final version. ET participated in the writing of the manuscript. MP participated in the writing of the manuscript. CC participated in the development of the study design and objectives, in the writing and proofreading of the manuscript. NT participated in the writing analyses. RH participated in the writing of the manuscript. NT participated in the writing of the manuscript. NT participated in the writing of the manuscript. NT participated in the writing of the manuscript and provided feedback on the report. CH participated in the development of the study design and objectives, in the writing of the exult participated in the report.

FUNDING

ET reports a grant from ARSEP Foundation (foundation pour l'aide à la recherche sur la sclérose en plaques). The others author(s) received no financial support for the research, authorship and/or publication of this article.

COMPETING INTERESTS

The author(s) declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: ET reports a grant from ARSEP foundation (foundation pour l'aide à la recherche sur la sclérose en plaques). None of the other authors reported no competing interests.

ADDITIONAL INFORMATION

Correspondence and requests for materials should be addressed to Gabriel Miget.

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