



# Innovative multidisciplinary tool for screening bowel and bladder symptoms in multiple sclerosis

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## Abstract

**Introduction** Bowel and bladder symptoms are frequent in people with Multiple Sclerosis (PwMS) and early diagnosis and treatment become crucial to improve their quality of life (QoL). The study aims to design a multidisciplinary questionnaire for screening bladder and bowel symptoms in PwMS.

**Materials and methods** The Bowel and Bladder Symptoms Screening in Multiple Sclerosis (BBSS-MS) questionnaire for screening bowel and bladder symptoms was designed in Italian following a three-steps process. In the first step, a dedicated board of experts identified a pool of items, which will be analysed for content, clarity, and consistency during the second step. During the third step, the relevance of each item was evaluated through a two-round process following the Delphi method. For each round of the Delphi method, medians, the 25th and 75th percentiles, and the IQR of the score for each statement were calculated. Stata 16.1 software was used to conduct all analyses.

**Results** The Board identified 22 items to include in the BBSS-MS, based on existing questionnaire and clinical expertise. After discussing about the comprehensibility and clarity of items, the first version of the BBSS-MS composed of 22 items was proposed. Following, a Panel of 44 experts scored the relevance of each question and all the questions reached the score to be included in the questionnaire. The final 21-item version of the BBSS-MS was proposed.

**Discussion and conclusion** To our knowledge, the BBSS-MS represents the first self-reported hybrid questionnaire for screening bladder and bowel symptoms in an Italian MS population.

**Keywords** Bowel dysfunction · Bladder dysfunction · Screening · Multiple sclerosis · Questionnaire · Delphi method

## Introduction

Multiple sclerosis (MS) is an autoimmune-mediated neurodegenerative disease of the central nervous system characterized by inflammatory demyelination with axonal transection

[1] and it is a primary cause of lower urinary tract (LUT) and bowel dysfunctions.

On average, LUT symptoms (LUTS) are reported about ten years after the MS diagnosis. However, in one out of ten people with MS (PwMS), LUTS may be present at the time of the initial MS manifestation [2]. Due to the progressive nature of MS, the prevalence of LUTS and dysfunction increases over time, leading to almost all PwMS having LUTS ten years after symptoms started, especially related to storage and voiding [3]. Storage (caused by overactive bladder, OAB) symptoms include urinary urgency, increased daytime frequency, nocturia (night-time frequency), and incontinence. In contrast, voiding symptoms include urinary hesitancy, weak and interrupted stream, straining to urinate, double voiding, and sensation of incomplete bladder emptying after voiding [4]. The severity of OAB symptoms is associated with a worsening of information processing speed and an increase in depression and anxiety [5]. In PwMS with

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LUTS, urologic quality of life (QoL) is mainly affected by storage urinary symptoms [6].

As a consequence of MS, neurogenic bowel dysfunction (NBD) is a prevalent and debilitating symptom and appears to be associated with the presence of bladder dysfunction, high level of disability, and long disease duration [7]. NBD in MS includes both constipation and faecal incontinence symptoms arising from complex pathophysiology including slow gut transit, pelvic floor dyssynergia and anorectal hypo-sensitivity [8]. The estimated prevalence of NBD in MS varies between 39%–73% depending on the studied population, which makes accurate quantification challenging [7]. Specifically, constipation is reported in 17–94% of MS cases, while faecal incontinence is reported in 1–69% [9]. PwMS ranked bowel problems as the third most bothersome symptom after fatigue and issues with mobility [10]. This is not surprising, given the embarrassing nature of bowel symptoms and the need to plan activities of daily living (ADLs) around bowel care, which may affect a person's approach to social interactions [11]. These factors, amongst the other associated physical challenges, may lead to a negative impact on psychological and emotional health [12].

Despite the high incidence of these symptoms and their interference with QoL and the performance of ADLs [13], only one-third of PwMS with bladder and bowel dysfunction report these symptoms to their neurologist. PwMS are often reluctant to talk about bladder and bowel disorders for several reasons, e.g. due to embarrassment, back seat to other clinical issues, acceptance of relation to the chronic nature of MS, and lack of awareness of available healthcare system [14]. Despite the high prevalence of bladder, bowel and sexual dysfunction symptoms, which are known to have negative effects on QoL, the majority of PwMS report that their healthcare providers did not investigate these symptoms [15]. This may happen for several reasons: bladder and bowel symptoms are not the focus of attention and dialogue (e.g., EDSS—Expanded Disability Status Scale—considers motor, sensory, and visual functions, but only a generic item on sphincter functions), limited knowledge (about PwMS and HCPs—Health Care Professional) of bladder and bowel management and reluctance to be involved, lack of adequate diagnostic tools (bladder/urodynamic scanner) and assessment tools in neurological units, lack of clear link between bladder and bowel dysfunction treatment services. Thus, there is a tendency to underestimate and under-diagnose these symptoms [14]. This aspect represents a problem in symptoms management in PwMS because these dysfunctions can lead to further medical complications. These problems require specialized treatments, sometimes hospitalization, and can in turn worsen the MS symptoms [16]. Therefore, diagnosis and treatment become crucial in managing of the symptoms of PwMS. Specifically, the priorities in long-term diagnosis and treatment can be summarized as

protecting the upper urinary tract, achieving bladder and bowel continence, and improving the overall QoL.

Given the progressive nature of MS, PwMS with LUTS and bowel dysfunctions require regular long-term follow-up and symptoms management, requiring a multidisciplinary approach [17]. Healthcare providers should systematically investigate these symptoms in clinical practice and perform a thorough and complete examination [18]. Proactive screening should also be extended to young PwMS with mild disability, considering that moderate to severe constipation has been reported as an early symptom, or even prodrome of MS [15].

Routine screening of bladder and bowel dysfunction in PwMS may allow for early identification and management of these disabling symptoms. It is important to consider timely and tailored management of these symptoms to prevent further worsening and impact on QoL.

In recent years, several screening tools for sphincter problems have been presented, particularly for urinary dysfunction [17, 19–21], however, it has been suggested that no tools have been effective in identifying LUTS in presumably asymptomatic people [22].

This study aims to design an easy-to-use hybrid questionnaire tool to identify and evaluate bladder and bowel symptoms in PwMS in a preventive and specific way through a multidisciplinary approach.

## Materials and methods

The Bowel and Bladder Symptoms Screening in Multiple Sclerosis (BBSS-MS) questionnaire for identification of bladder and bowel symptoms was designed in Italian following a three-step process [23]. In the first step, potential questionnaire items were identified. A literature review of the existing questionnaires for assessment of bowel and bladder dysfunctions in PwMS revealed a gross list of items. A small board of 29 experts (nurses, neurologists, urologists, physiatrists, physiotherapists, gastroenterologists, and colorectologists) identified a potentially useful set of items to form the new hybrid questionnaire.

The second step covered a technical analysis of the questionnaire, considering the aspects of content, clarity, and consistency of the items. The clarity of the items was discussed and adjusted with a small group of PwMS according to MULTI-ACT guidelines [24].

The third step of the process aimed to evaluate the individual items. This step was carried out following the Delphi method to reach a consensus among a panel of 44 clinical experts including neurologists, urologists, gastroenterologists, neuro-urologists, physicians in rehabilitation medicine, physical therapists, and nurses. The Delphi method is widely utilized in research studies and its validity for

questionnaire development has been described elsewhere [25]. Through a series of rounds, the items of the questionnaire were presented to the panel in order to obtain a certain level of consensus. In the first round, a survey composed of statements, which were the selected items and an additional question about the items' order, was presented to the panel. The panel was asked to score the level of importance of the statements on a 7-point scale (e.g., no agreement = 1; high agreement = 7). A web-based method allowed each expert to answer without interacting with others thereby maintaining anonymity. At the end of the first round, the 25th and 75th percentiles (75thp-25thp; interquartile range, IQR) of each statement were calculated. In the second round, panellists were asked to score the same statements considering the IQR of each question (which represents the range in which 50% of responses are included) as an index of their colleagues' responses. Those who responded outside the IQR in the second round were asked to motivate the score. In case of comments about the non-clarity of the items, the panel discussed how to rephrase.

At the end of the second round, the median value and the 25th and 75th percentiles of each statement were calculated. Before the submission to the panel, the following rule had been decided: the question remains in the hybrid questionnaire if at least 75% of respondents score 4 or more. For each round of the Delphi method, medians, the 25th and 75th percentiles, and the IQR of the score for each statement were calculated. Stata 16.1 software was used to conduct all analyses.

## Results

Based on a literature review and evaluation by a board of clinical experts, 22 items were identified and included in the new hybrid questionnaire. Specifically, items of the Actionable Bladder Symptom Screening Tool (ABSST) [26], items of the International Prostate Symptom Score (IPSS) [27], full Wexner Constipation and Wexner Incontinence questionnaires [28], and additional  $n = 23$  items were proposed by the board based on their clinical expertise and experience.

The second step consisted of four meetings among experts and PwMS to discuss the comprehensibility and clarity of items. At the end of the step, a first 22-item version of BBSS-MS was proposed.

Following this, the final list of items was defined using a Delphi method. For the first round of the consensus, a survey composed of the 22 selected items and an additional question about the items order were submitted to the panel of experts, they were asked to assess the importance of each question. Forty-four experts responded to the survey; the 25th and 75th percentiles of each statement were calculated (see Table 1). In the second round, 40 panellists participated.

All the questions reached the score to be included in the questionnaire with a high level of agreement, except for item 5 and item 9 which reached a low level of agreement. All responders allocated the maximum score to item 1 and 95% to items 2, 3, 4 and 10. A score  $\geq 6$  was assigned by the total of responders to items 11, 12 and 14 by 95% of the panellists to items 6, 7, 8, 13, 21, 22, by 75% to items 15, 19, 23, and by 65% to item 16. The 95% of the panellists scored  $\geq 5$  to item 18, whereas 99% and 98% of the responders assigned a score  $\geq 4$  to item 5 and item 9, respectively (Supplementary materials—ANNEX A). In the second round, panellists answered outside the IQR in 12 items explaining their choice. In particular, items 2 and 5 were rephrased after panellists' suggestions, and items 6, 8, 9, 10, 13 and 22 were also suggested to be rephrased, however, after discussion in the board, they decided not to follow the panellist suggestion for these items. Finally, some panellists proposed to delete items 15, 17, 18 and 21 from the questionnaire, however, the board decided to delete only item 18. In conclusion, 21 items characterized the final version of BBSS-MS (Supplementary Materials—ANNEX B).

## Discussion

Awareness of bladder and bowel symptoms for PwMS and their implications on daily life are fundamental for improving self-management of MS and initiating discussions with HCPs about these pertinent symptoms. It is clear from the literature that tools designed to detect bladder and bowel symptoms are scarce, which leads to a risk of underestimation or underdiagnosis [29]. This hybrid questionnaire, called BBSS-MS, has been developed with expert advisors and in consultation with PwMS. To our knowledge, it represents the first attempt to create a self-reported questionnaire for checking bladder and bowel symptoms in an Italian study population of PwMS. The questionnaire uses language that is appropriate for PwMS and covers all aspects of bladder and bowel disorders. Moreover, it has the potential to be highly user-friendly, concise, and straightforward. Consequently, the questionnaire could direct the attention of HCPs toward symptoms that may not be adequately explored during routine clinical assessments. There are other notable characteristics of the questionnaire: 1) The tool could improve the care pathways of PwMS from both the perspective of the individual with the disease and HCPs; 2) The tool could potentially be useful for other neurological conditions. The BBSS-MS could help with not only checking for bladder and bowel symptoms but also in monitoring the MS progression. The next step will be a validation of the BBSS-MS, conducting a multicentre trial to ensure a formal validation study within the Italian MS population.

**Table 1** Statements scores for round 1 and round 2 of the Delphi process

Statements	Round 1				Round 2			
	Median	25° p	75° p	IQR	Median	25° p	75° p	IQR
1	7	7	7	0	7	7	7	0
2	7	6.5	7	0.5	7	7	7	0
3	7	6	7	1	7	6	7	1
4	7	7	7	0	7	7	7	0
5	6	4	7	3	6	4	7	3
6	7	5.5	7	1.5	7	6	7	1
7	7	5.5	7	1.5	7	6	7	1
8	6	5.5	7	1.5	7	6	7	1
9	6	4	7	3	6	4	7	3
10	7	7	7	0	7	7	7	0
11	7	6	7	1	7	6	7	1
12	7	6	7	1	7	6	7	1
13	7	6	7	1	7	6	7	1
14	7	6	7	1	7	6	7	1
15	7	5	7	2	7	5.5	7	1.5
16	6	4	7	3	6	5	7	2
17	6	4.5	7	2.5	6	5	7	2
18	6	5	7	2	6	5	7	2
19	6	5	7	2	7	6	7	1
20	6	5	7	2	6	5	7	2
21	7	6	7	1	7	6	7	1
22	7	6	7	1	7	6	7	1
23	7	6	7	1	7	6	7	1

## Conclusion

This study is the result of the panel's real interest in creating a hybrid questionnaire on bladder and bowel dysfunction, which is easy to administer and interpret, the Bowel and Bladder Symptoms Screening in MS (BBSS-MS). The outcome of this work may help neurologists and HCPs in performing a complete evaluation of PwMS, both during the first visit and follow-up visits. This tool can help capture symptoms that may be hidden either due to embarrassment in describing them to the HCPs, or due to lack of knowledge of the link with MS. It is crucial to define the specific assessment and monitor the symptoms within a certain timeline and reduce the possibility of secondary damage with consequent worsening of the general clinical condition.

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**Author contributions** All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Giampaolo Brichetto, Margherita Monti Bragadin, Sara Rinaldi, Stefania Musco and Gianfranco Lamberti. The first draft of the manuscript was written by Giampaolo Brichetto, Margherita Monti Bragadin, Erica Grange, Sara Rinaldi. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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## Declarations

**Ethical statement** This article does not contain any studies with human participants performed by any of the authors.

**Conflict of interest** AISM members have indirect conflict of interest with Coloplast.

Coloplast confirms that the manuscript has been read and approved by all named authors.

Coloplast full responsibility for the work being reported.

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