The Multiple Sclerosis Intimacy and Sexuality Questionnaire (MSISQ-15): Validation of the Dutch version in patients with multiple sclerosis and spinal cord injury

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Aims: The Multiple Sclerosis Intimacy and Sexuality Questionnaire (MSISQ-15) evaluates symptoms of sexual dysfunction in patients with multiple sclerosis (MS). The objective of this study was to provide and validate a Dutch version of the MSISQ-15 in patients with neurological disease such as MS and spinal cord injury (SCI).

Methods: The linguistic validation process of the original English MSISQ-15 into Dutch was performed according to standardized guidelines. Sexually active patients with MS or spinal cord disorders, including SCI and cauda equine syndrome, who visited a tertiary urology center or a rehabilitation center completed the MSISQ-15, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) in women, or International Index of Erection Function (IIEF-15) in men at baseline (test) and 2 weeks later (retest). A reference group recruited from a general medical practice completed the questionnaires once. Data were analyzed for measurement properties.

Results: Fifty-three patients with MS, 49 patients with spinal cord disorder, and 50 references were included. Content validity was adequate. Internal consistency (Cronbach's alpha >0.8) and reproducibility (intraclass correlation coefficient >0.8) of the MSISQ-15 were excellent. Patients' MSISQ-15 scores were correlated with severity of symptoms of sexual dysfunction measured by PISQ-12 or IIEF-15 and confirmed positive rating for criterion validity. MSISQ-15 scores in patients were higher than in references (on a scale of 15-75: 38.9 ± 11.4 vs 21.1 ± 5.4; P < 0.001), indicating good construct validity.

Abbreviations: ASIA, American Spinal Injury Association; EQ-VAS EQ, visual-analogue scale; ICC, intraclass correlation coefficient; IIEF, international index of erection function; LOA, limits of agreement; MS, multiple sclerosis; MSISQ, multiple sclerosis intimacy and sexuality questionnaire; PISQ, prolapse/urinary incontinence sexual questionnaire; PRO, patient reported outcome; SCI, spinal cord injury; SD, sexual dysfunction.

[Correction added on 3 September, 2018, after first online publication: A correction has been made in affiliation.]

John Heesakkers led the peer-review process as the Associate Editor responsible for the paper.

No direct or indirect commercial incentive associated with publishing this manuscript. Study received local ethics committee approval (MEC-2016-370).
Conclusions: The Dutch MSISQ-15 is a reliable and valid measure to evaluate symptoms of sexual dysfunction in patients with MS or with SCI.

KEYWORDS  
neurogenic, quality of life, surveys and questionnaires, urinary bladder, validation studies

1 INTRODUCTION

Living with neurological diseases such as multiple sclerosis (MS) or spinal cord injury (SCI) might have significant consequences for a person’s sexual function and quality of life. Sexual function can be assessed with patient-reported outcome (PRO) measures, usually a questionnaire. This also allows evaluating change over time.

The Multiple Sclerosis Intimacy and Sexuality Questionnaire (MSISQ) evaluates symptoms of sexual dysfunction (SD) in MS patients, divided in three dimensions. Categorized as primary SD are symptoms as a result of neurologic changes that directly influence sexual function, such as impaired genital sensation, erectile dysfunction, orgasm dysfunction, decreased vaginal lubrication, and loss or reduction of libido. Secondary SD includes symptoms that arise from MS and indirectly influence sexual function, such as muscle tightness, spasticity, bladder and bowel dysfunction, pain, or discomfort in non-genital areas of the body. Tertiary SD refers to the psychological, emotional, social, and cultural aspects of MS that impact sexual function. The original version of the MSISQ was in English and consisted of 19 items and has been translated and validated in the Persian and Portuguese languages. A re-evaluation in a larger English cohort resulted in a validated 15 item version. At this moment, no validated Dutch PRO measure is available to assess SD in patients with a neurological disease. Although the MSISQ-15 was developed for patients with MS, the similarity between the SD symptoms of patients with MS and those with SCI, as well as the similarity in treatment, suggests that the instrument might work well in both populations. This study is designed to provide a validated Dutch version of the MSISQ-15 in patients with neurological diseases.

2 MATERIALS AND METHODS

This prospective validation study was approved by the Institutional Ethics Committee (MEC-2016-370) and conducted at a tertiary urology center and at a rehabilitation center.

2.1 Study populations and study design

2.1.1 Patient group

Adults with MS or SCI or cauda equina syndrome were eligible for inclusion if they spoke Dutch fluently. Exclusion criteria consisted of dementia, mental retardation, active malignant tumors, and no sexual activity during the last 6 months. All potential eligible patients were informed about the study and invited to participate by the treating physician during a regular outpatient visit between July 2016 and January 2018. After written informed consent patients were asked to complete the questionnaires during the inclusion visit (test) and 2 weeks later at home (retest). Clinical characteristics of included patients were retrieved from their medical files.

2.1.2 Reference group

The reference group was invited from one general practitioner’s practice in January and February 2017. Exclusion criteria consisted of Dutch language difficulties, neurourolological dysfunction, dementia, mental retardation, and no sexual activity during the last 6 months. Since patients visiting the general practitioner might have less severe health issues, we considered these patients as proper reference group. They provided written informed consent and completed the questionnaires once.

2.2 Questionnaires

The questionnaire set consisted of the MSISQ-15, the EQ visual-analogue scale (EQ-VAS), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), and International Index of Erection Function (IIEF-15).

- The MSISQ-15 is a self-report measure that evaluates the influence of MS symptoms on sexual activity and satisfaction over the preceding 6 months. It is a valid and reliable short version of the MSISQ-19 and consists of 15 items. The MSISQ-15 is divided in three dimensions to allow focus on the specific domain of sexual concerns; primary SD (items 8, 12, 13, 14, 15),
2.4 | Measurement properties

The following measurement properties were used to validate the questionnaire:

2.4.1 | Content validity

The content validity examines the extent to which the items of the questionnaire measure the concepts of interest in the target population. Researchers subjectively assessed the correspondence between the questionnaire items and the clinical symptoms. During the linguistic validation, content validity was assessed from interviews with patients.12

2.4.2 | Internal consistency

The internal consistency is the correlation between the different items in the questionnaire and demonstrates if the items measure the same underlying construct. A Cronbach's alpha was calculated for the total score and three domains of the MSISQ-15. A Cronbach's alpha between 0.70 and 0.95 was considered to reflect adequate internal consistency.12

2.4.3 | Reproducibility

The reproducibility is the degree to which scores on a questionnaire are corresponding in repeated measurements in stable persons. This was determined by reliability and agreement. The degree to which patients can be differentiated from each other, despite the measurement error, reflects the reliability. The reliability was calculated using the intraclass correlation coefficient (ICC) for agreement, where ICC scores over 0.70 are acceptable.12,13 The agreement concerns the measurement error, that is, the similarity in scores rated on separate occasions. Differences within the limits of agreement (LOA) can be interpreted as measurement error. The LOA were calculated as the mean change in scores of repeated measurements ±1.96 × standard deviation of the changes.13,14

2.4.4 | Criterion validity

The extent to which questionnaire scores relate to a gold standard refers to the criterion validity.12 For the MSISQ-15 no perfect gold standard exists. In the absence of a gold standard the Dutch PISQ-12 and the Dutch IIEF-15 were used for women and men, respectively. Pearson's correlation coefficient was determined (range −1 to 1); when values are close to the extremes indicate either a more negative or positive correlation.12

2.4.5 | Construct validity

The construct validity refers to the extent to which hypotheses about the scores of the questionnaire relate to other measures.
Construct validity is considered adequate when at least 75% of the results of the predefined hypotheses are in accordance.\textsuperscript{12}

The predefined hypotheses were as follows:
1. The reference group will have lower MSISQ-15 scores than the patient group.
2. Female patients with lower PISQ-12 scores will have higher MSISQ-15 scores.
3. Male patients with lower IIEF-15 scores will have higher MSISQ-15 scores.
4. Patients who score higher on the EQ-VAS will have lower MSISQ-15 scores.

2.4.6 \textbf{Floor and ceiling effects}

If more than 15% of the respondents would achieve the lowest or highest possible score, floor or ceiling effects are considered.\textsuperscript{12} The floor and ceiling effects were assessed for the total and domain scores at baseline in the patient and reference groups.

2.5 \textbf{Statistical methods}

Based on the guidelines for validation of questionnaires,\textsuperscript{12} we aimed at a sample size of 50 MS patients, 50 SCI patients, and 50 control persons. Statistical analysis was performed using SPSS version 24.0 (IBM Corp., Armonk, NY). Continuous data are presented as mean and standard deviation. Categorical data are presented as counts and percentages. Differences between the patient and reference groups or within the patient group, were tested with the Student's \textit{t}-tests for continuous variables and chi-squared tests for categorical variables. Statistical significance was defined as \textit{P}-value <0.05.

3 \textbf{RESULTS}

A total of 106 patients were included in the study. Three patients were excluded from the analysis because they did not return the second questionnaire. One patient did not fully complete the questionnaires and was excluded. Of the 102 included patients who completed both questionnaires, 49 were female and 53 male. Fifty-three patients had MS, of whom 36 (68%) relapsing-remitting MS, 6 (11%) primary progressive MS, 8 (15%) secondary progressive MS, and of 3 (6%) the type of MS was unknown. Forty-three patients had an SCI and 6 a cauda equina syndrome. The SCI patients were classified by the American Spinal Injury Association (ASIA) impairment scale\textsuperscript{15} as follows: 21 (49%) patients ASIA A, 7 (16%) patients as ASIA B, 4 (9%) patients as ASIA C, 8 (19%) patients ASIA D, 1 (2%) patient ASIA E, and in 2 (5%) patients the grade was unknown. The level of SCI was cervical in 13 (30%), thoracic in 26 (61%), and lumbar in 4 (9%). The reference group consisted of 50 adults, of whom 29 were female and 21 male. Table 1 shows the characteristics of the patient and reference groups.

3.1 \textbf{Content validity}

During the linguistic validation process 12 MS and 8 SCI patients judged the content validity to be adequate. The majority confirmed the importance of all questions to assess the broad range of problems in sexual function with their neurological condition. Further, they found the Dutch version clear, understandable, and easy to complete. No adjustments were necessary.

3.2 \textbf{Internal consistency}

The MSISQ-15 showed a good internal consistency with Cronbach's alpha's of >0.8 for test and retest in MS patients, SCI patients, and total patient group (Table 2). The internal consistencies for the domains were adequate with Cronbach's alpha's of >0.7 in the total patient group and MS patients. In the SCI patients, the primary domain showed a moderate internal consistency with a Cronbach's alpha of 0.53 (test) and 0.55 (retest). The internal consistency for the secondary and tertiary domains was good.

3.3 \textbf{Reproducibility}

The average test-retest period was 20.3 ± 13.8 days, 30.2 ± 25.7 days, 25.1 ± 20.9 days for MS patients, SCI patients, and total patient group, respectively. The ICCs for agreement for the total MSISQ-15 and the three domains in MS patients, SCI patients, and total patient group were all higher than 0.7, indicating an adequate reliability (Table 3). Table 3 lists the LOA ranges of the total MSISQ-15 and the domains.

3.4 \textbf{Criterion validity}

A significant relationship was found between the total score of MSISQ-15 and the total score of PISQ-12 in females of the patient group (test: \textit{r} = −0.682; retest: \textit{r} = −0.649, Table 4). In the male study population, the patient group showed a significant relationship between the total score of MSISQ-15 and the total score of IIEF-15 (test: \textit{r} = −0.446; retest: \textit{r} = −0.405, Table 4).
### 3.5 Construct validity

All predefined hypotheses were confirmed:

1. The reference group did indeed have lower MSISQ-15 scores than the patient group (Table 1).

2 and 3. Female patients with lower PISQ-12 scores and male patients with lower IIEF-15 indeed had higher MSISQ-15 scores (criterion validity).

4. In the patient group a significant correlation was found between the MSISQ-15 score and the EQ-VAS (Table 4). This confirmed the hypothesis: “patients who score higher on the EQ-VAS will have lower MSISQ-15 scores.”

### 3.6 Floor and ceiling effects

In the patient group, no floor effects were seen for the total score, primary domain, and secondary domain (Table 5). Floor effects were seen in the tertiary domain (19% of the patients). Ceiling effects were absent in the patient group.

In the reference group, floor effects were found in all the domains (24-46%). Six (12%) reference persons had the

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**TABLE 1** Demographic and clinical characteristics presented as mean ± standard deviation or numbers (%)

|                      | MS, N = 53a | SCI, N = 49a | P-value | Patient group, N = 102a | Reference group, N = 50a | P-value |
|----------------------|-------------|-------------|---------|--------------------------|---------------------------|---------|
| Age, yrs             | 46.0 ± 10.1 | 41.3 ± 11.9 | 0.034b  | 43.7 ± 11.2              | 40.4 ± 15.2               | 0.135b  |
| Gender               |             |             |         |                          |                           |         |
| Male                 | 12 (22.6)   | 41 (83.7)   | <0.001c | 53 (52.0)                | 21 (42.0)                 | 0.248c  |
| Female               | 41 (77.4)   | 8 (16.3)    |         | 49 (48.0)                | 29 (58.0)                 |         |
| Time since diagnosis of neurogenic disease, yrs | 10.1 ± 7.5 | 13.1 ± 11.7 | 0.125b  | 11.5 ± 9.8               | –             | –       |
| Mobility             |             |             |         |                          |                           |         |
| Fully ambulatory     | 17 (32.1)   | 8 (16.3)    | <0.001c | 25 (24.5)                | –             | –       |
| Limited walking      | 31 (58.5)   | 9 (18.4)    |         | 40 (39.2)                |                           |         |
| Wheelchair bound     | 5 (9.4)     | 32 (65.3)   |         | 37 (36.3)                |                           |         |

**TABLE 2** Cronbach's alpha reflects the internal consistency for the MSISQ-15 total and subscale scores

|                      | MS, N = 53 | SCI, N = 49 | Total patient group, N = 102 |
|----------------------|------------|------------|-----------------------------|
| MSISQ-15 total score | 0.90       | 0.82       | 0.87                        |
| MSISQ-15 domains     |            |            |                             |
| Primary              | 0.79       | 0.53       | 0.70                        |
| Secondary            | 0.76       | 0.79       | 0.77                        |
| Tertiary             | 0.89       | 0.89       | 0.89                        |
lowest possible total score. No ceiling effects were found in the reference group.

4 | DISCUSSION

After linguistic validation of the original English MSISQ-15 into the Dutch language, we validated its use for patients with MS and spinal cord disorders such as SCI and cauda equina syndrome. The measurement properties showed this Dutch version of the MSISQ-15 to be valid, reliable, and consistent. This enables physicians to assess the influence of symptoms of neurological disease on sexual activity and satisfaction in patients in clinical practice and in research settings.

The quality of PRO measures for sexual function in neurological patients was assessed in a recently published systematic review.3 Strong evidence was found only for the MSISQ-15/-19 for patients with MS. PRO measures for patients with SCI showed mostly poor to fair quality and re-evaluation of all measurement properties was advised.3 In view of this we chose to validate the Dutch MSISQ-15 not only in patients with MS, but also in patients with SCI and cauda equina syndrome. In all these three conditions, interruption of the spinal cord or the pelvic autonomic nerves interferes with genital engorgement, erections, ejaculation, and climax.1,16 Besides the similarity between the influence of symptoms on sexual function, the similarity in treatment suggests that the instrument might work well in those populations.

The good internal consistency of the Dutch MSISQ-15 with Cronbach’s alpha’s ranging from 0.82 to 0.91 for (re)test and patient (sub)groups (Table 2) is comparable with that of the original MSISQ-15 (total Cronbach’s $\alpha = 0.92$, primary domain $\alpha = 0.87$, secondary domain $\alpha = 0.82$, tertiary domain $\alpha = 0.91$).5 The Cronbach’s alpha’s of all subdomains were adequate, except for the primary domain in the spinal cord disorder group (0.53-0.55). The original design of the primary domain focuses on “MS-related-neurologic changes” that may directly affect sexual feeling or response. In the spinal cord disorder group a moderate correlation of the items in the primary domain was found. This could have been caused by the specific well-known problems in SCI patients such as dissociation between desire, erection, ejaculation, and orgasm.16 Another explanation for the moderate correlation could be the more severe disease-related disability in patients with a spinal cord disorder. However, during the face-to-face interviews (linguistic validation process) the SCI patients did not mention any irrelevant or missing items. Overall, the internal consistency of the total MSISQ-15 score remains good.

The reproducibility for the Dutch MSISQ-15 in terms of test-retest scores was excellent. The mean change between
test and retest was ± 0.31 points, demonstrating adequate agreement. We found an ICC for agreement of 0.88 for the 15 items of the Dutch translation of the MSISQ-15, indicating good reliability. Comparison with other studies was not possible, a test-retest was neither performed in the original MSISQ-15 study nor in the MSISQ-19 study.

Patients and references were good distinguishable as shown by the confirmation of predefined hypotheses, confirming discriminative ability and therewith good criterion validity. Furthermore, confirming its use to specifically deal with sexual problems faced by patients with neurological disease.

No ceiling effects were found in patients or references. As expected, floor effects were present in all domains in the reference group (24-42%). Still, only 6 (12%) references had the lowest possible MSISQ-15 total score. Remarkable is the floor effect of the tertiary domain in the patient group (19%). The tertiary domain items measure the psychological aspects of SD. Possible explanations for a lowest score are the duration or acceptance of living with a neurological disease and having a stable relationship. This could lead to a reduced reliability and could have effects on the responsiveness. Still the reliability was found to be good (ICC tertiary domain 0.85, Table 3).

Analyzing the responsiveness and interpretability of the MSISQ-15 was not possible because of the short follow-up. Another limitation of our study was the lack of a golden standard. In the absence of a validated Dutch measure of sexual function in neuro-urological patients, we used the PISQ-12 in women and the IIEF-15 in men. Additionally, the IIEF-15 assesses erectile dysfunction over the last month in contrast to the last 6 months of the MSISQ-15. Lastly, treating physicians were asked to recruit all consecutive patients meeting the inclusion criteria, but we do not know what proportion actually participated and what were the reasons for non-participation.

One of the strengths of our study was the use of standardized measurement properties to evaluate the reliability and validity of the MSISQ-15, proposed by Terwee et al. Furthermore, our study design also allowed testing the MSISQ-15 in patients with spinal cord disorders. The results support the usability of the measure in this population, except when using the primary domain as subscale on itself. In general, MSISQ-15 outcomes may support the patient and physician to discuss SD. We recommend the Dutch physicians to use this measure in both research and clinical practice to evaluate SD in patients with MS and spinal cord disorders. Providing that the result of the primary domain in patients with spinal cord disorders should be cautiously handled because of the moderate internal consistency. To assess the urogenital function in neuro-urological patients we advise to use the MSISQ-15 combined with the SF-Qualiveen. The SF-Qualiveen is a questionnaire validated in Dutch to evaluate the urinary-specific quality of life in MS or SCI patients.

### 5 CONCLUSIONS

In conclusion, this Dutch version of MSISQ-15 was tested following well-established guidelines on measurement properties and showed good validity and reliability. The MSISQ-15 allows us to evaluate SD in patients with MS and spinal cord disorders in both research and clinical practice.
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CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

AUTHORS' CONTRIBUTIONS

Study design: TN, JS, LH, TS, BB; Data collection: TN, JS, TS, BB; Data analysis and interpretation: TN, LH; Manuscript writing: TN; Critical review of the final script: JS, LH, TS, BB; Data collection: TN, JS, LH, TS, BB; Final approval of the version published: all authors.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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