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Validation of the Korean Version of the 12-Item Multiple Sclerosis Walking Scale and Application to Neuromyelitis Optica Spectrum Disorder

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Background and Purpose Gait problems are a primary complaint in patients with multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD). The 12-item Multiple Sclerosis Walking Scale (MSWS-12) is a patient-reported measure assessing the impact of MS on the walking ability. We aimed to adapt and validate the Korean version of the MSWS-12 for the Korean population with MS and NMOSD.

Methods Thirty-four MS and 35 NMOSD patients were recruited. The MSWS-12 questionnaire was translated into the Korean language and evaluated for its validity and reliability in these patients.

Results The MS and NMOSD patients had mean ages of 35.9 and 42.1 years, respectively, median disease durations of 5.6 and 7.2 years, median Expanded Disability Status Scale (EDSS) scores of 2.75 (range, 0−6.5) and 3.5 (range, 0−7.5), and median baseline MSWS-12 total scores of 25 [interquartile range (IQR), 2.60−53.65] and 25 (IQR, 7.29−50.00). The baseline MSWS-12 total score in the patients with MS showed strong correlations with scores for the EDSS, timed 25-foot walk (T25FW), Multiple Sclerosis Impact Scale-29 (MSIS-29) physical dimension, and 36-item Short-Form Health Survey (SF-36) physical component summary (PCS), with Spearman's correlation coefficients (ρ) of 0.922, 0.756, 0.933, and -0.874, respectively. In patients with NMOSD, the baseline MSWS-12 total score showed strong correlations with scores for the EDSS, MSIS-29 physical dimension, and SF-36 PCS (ρ=0.769, 0.910, and -0.852, respectively), and moderate correlations with scores for the T25FW and Fatigue Severity Scale-9 (ρ=0.597 and 0.630, respectively).

Conclusions The Korean version of the MSWS-12 appears to be a valid and reliable scale that can be used for Korean patients with MS. The MSWS-12 can also be applied to patients with NMOSD.

Key Words multiple sclerosis, neuromyelitis optica spectrum disorder, Multiple Sclerosis Walking Scale-12, Korean, reliability, validity.

INTRODUCTION

Multiple sclerosis (MS) is an inflammatory, demyelinating disease of the central nervous system (CNS), and can be a progressive, disabling condition that affects a wide range of body systems, including motor, sensory, and cognitive systems. Neuromyelitis optica spectrum disorder (NMOSD), another idiopathic inflammatory syndrome of the CNS, can cause severe relapses and consequent serious disability.

Walking is a key component of physical functioning that plays a key role in the ability to perform the activities of daily living in patients with MS,[1] and hence impairments in walking ability are of great concern for these patients.[2,3] It is important to be able to confidently

measure walking disabilities in patients with MS because they may eventually require assistance while walking.[4] Gait problems are one of the most-common complaints in patients with NMOSD. Since individual attacks are usually more severe and recovery is often less complete in NMOSD than in MS,[5] assessments of gait problems are even more important in patients with NMOSD than in patients with MS.

The Expanded Disability Status Scale (EDSS) is a well-established clinical measure of disability in MS that assesses disability based on the maximum walking distance and the need for a walking aid within the middle range of 4.0−7.0.[6] However, the EDSS may be limited by intra- and interrater variabilities and has low sensitivity to changes in the assessed walking disabilities.[7,8]

The 12-item Multiple Sclerosis Walking Scale (MSWS-12) is a commonly adopted patient-reported outcome measure used to assess the extent to which MS impacts the walking ability,[9] and it is currently the only qualitative, patient-based test that specifically measures walking disabilities. The MSWS-12 is easy to administer in a clinical setting for measuring walking difficulties in daily life, and it has been translated into various languages and validated as a useful tool in MS.[10-14] However, the MSWS-12 has not been validated for Korean MS patients, and moreover its applicability has not been evaluated for patients with NMOSD. The aim of this study was to adapt and validate a Korean version of the MSWS-12 for the Korean population with MS and NMOSD.

METHODS

This study was approved by the Institutional Review Board of the National Cancer Center, Korea (approval no: NCC2019-0254), and was performed in accordance with the Declaration of Helsinki.

Patients

Patients with MS and NMOSD were recruited between December 2015 and March 2019 at the National Cancer Center, Korea. The inclusion criteria were a confirmed MS diagnosis according to the McDonald criteria 2010[15] or an NMOSD diagnosis according to 2015 criteria,[16] being older than 18 years, being able to walk with or without the use of support devices, and an EDSS score ranging from 0 to 7.5. Patients suffering from an exacerbation within 30 days prior to the assessment, unstable medical conditions, apparent cognitive dysfunction, or other systemic chronic illnesses were excluded from the study.

Korean translation

The MSWS-12 questionnaire was translated from the original English version using the same procedures as we previously used to produce the Korean versions of the Multiple Sclerosis Impact Scale-29 (MSIS-29) and the Multiple Sclerosis International Quality of Life (MusiQoL).[17] The original English version of the MSWS-12 was converted into Korean by two bilingual translators, and the initially produced Korean version was then back-translated into English by a bilingual physician. The original and back-translated English versions were compared for consistency by detecting the presence of ambiguous or inadequate items, and then the final Korean version was confirmed (Supplementary Table 1 in the online only Data Supplement).

Administration of the tests

The patients with MS or NMOSD completed the MSWS-12 questionnaire at an interval of 14 days in order to determine the test–retest reliability. An experienced neurologist (J.W.H.) evaluated patients using the following measures: 1) sociodemographic data, 2) type of MS, 3) the EDSS,[6] 4) EDSS functional system scores of visual function, 5) the Korean version of the Fatigue Severity Scale-9 (FSS-9),[18] with a total score of ≥36 indicating the presence of fatigue,[19] 6) the Korean version of the Patient Health Questionnaire-9 (PHQ-9),[20] with a total score of ≥10 indicating the presence of moderate depression, 7) the Korean version of the MSIS-29, which measured the physical (20 items) and psychological (9 items) impacts of MS, with lower scores indicating better quality of life,[17,21] and 8) the Korean version of the 36-item Short-Form Health Survey (SF-36), which provided a subjective summary of how individuals perceived their health.[22] The SF-36 includes the following eight dimensions, involving physical and mental components: [general health perception (GH, 5 items), physical functioning (PF, 10 items), role limitations due to physical problems (RP, 4 items), bodily pain (BP, 2 items), energy/vitality (VT, 4 items), social functioning (SF, 2 items), role limitations due to emotional problems (RE, 3 items), and mental health (MH, 5 items)]. The scores were transformed to a scale from 0 to 100 for each dimension and used for evaluating correlations. Lower scores represented a better function/outcome, with the exception of the SF-36 questionnaire. Lastly, a timed 25-foot walk (T25FW) was performed twice, and average values were correlated with the MSWS-12 scores.

Statistical analysis

The patient characteristics and transformed dimension scores from the questionnaires were summarized as mean±standard deviation values or as medians with ranges or interquartile ranges. The scores for each dimension from all questionnaires were summed or transformed to scales ranging from 0 to

100 based on scoring guidelines. The correlations between the total scores on the MSWS-12 and the sociodemographic variables were assessed using Spearman's correlation coefficient. The validity of the MSWS-12 was assessed based on the four criteria listed below. All statistical analyses were performed using R version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria).

Internal validity and reliability

The item internal consistency (IIC) was used to assess the correlations among items. The IIC shows how each item is correlated with the sum of the remaining items in one dimension. An IIC value of at least 0.4 has been recommended for indicating adequate consistency.[23] The internal consistency reliability was measured using Cronbach's alpha coefficients, and was considered to be high if the coefficient exceeded 0.7 for group comparisons.[24]

Floor and ceiling effects

A floor or ceiling effect was considered to be present if more than 15% of patients displayed the lowest or highest possible score, respectively.[25]

Reproducibility

Reproducibility was measured by the test–retest intraclass correlation coefficient (ICC), which was calculated using the baseline and follow-up responses. ICCs exceeding 0.80 were considered to be indicative of high reproducibility.[26]

External validity

The external validity of the MSWS-12 was determined by examining the correlations of its baseline scores with the EDSS, T25FW, MSIS-29, SF-36, FSS-9, and PHQ-9 scores using Spearman's correlation coefficients (ρ). For the SF-36, the eight average dimension scores and the physical component summary (PCS) and mental component summary (MCS)—which have positive weights on physical and mental dimensions, respectively—were also calculated. A high external validity was indicated by the ρ exceeding 0.5.[27]

RESULTS

Thirty-four patients with MS (19 males and 15 females) and 35 patients with NMOSD (6 males and 29 females) were recruited. The MS and NMOSD patients were aged 35.9±9.3 and 42.1±12.4 years, respectively. They had median disease durations of 5.6 years (range, 2 months to 20.7 years) and 7.2 years (range, 8 months to 20.2 years), and median EDSS scores of 2.75 (range, 0–6.5) and 3.5 (range, 0–7.5), respectively. The median values for the visual functional system scores were 0 in both groups (range, 0–4). The median baseline total score on the MSWS-12 was 25 (IQR, 2.60–53.65) in the MS patients and 25 (IQR, 7.29–50.00) in the NMOSD patients (Table 1). The MS classification determined that 32 (94.1%) patients had relapsing-remitting multiple sclerosis (RRMS), 1 (2.9%) had secondary progressive multiple sclerosis (SPMS), and 1 (2.9%) had primary progressive multiple sclerosis (PPMS). One of the MS patients used a cane and one used a four-wheel walking frame. Two of the NMOSD patients were unable to take more than a few steps and were essentially restricted to wheelchairs for transport.

The MSWS-12 scores of the MS and NMOSD patients were not correlated with age, sex, or disease duration.

Internal validity and reliability

In the patients with MS, the IIC ranged between 0.732 and 0.955 at baseline and between 0.709 and 0.948 at the follow-up; the corresponding values in the patients with NMOSD were 0.751–0.932 and 0.789–0.954, respectively. These results confirm the internal validity of the MSWS-12 questionnaire. The high internal consistency reliability of the MSWS-12 was verified by Cronbach's alpha coefficients of 0.976 and 0.972 for the baseline and follow-up assessments, respectively, in the patients with MS, and 0.978 and 0.980 in those with NMOSD.

Floor and ceiling effects

Eight (23.5%) of the patients with MS scored at the lower limit (raw score 12 points) and one (2.9%) scored at the upper limit (raw score 60 points) for the test and retest, suggesting the existence of floor effects among the MS patients in our cohort. Five (14.3%) of the patients with NMOSD scored at the lower limit, and three (8.6%) and two (5.7%) scored at the upper limit in the test and retest, respectively. Considering the individual questions, a majority of patients showed the lowest score (1 point) on item 8 [23 (67.6%) MS patients and 27 (77.1%) NMOSD patients] and item 9 [25 (73.5%) MS patients and 25 (71.4%) NMOSD patients] at the baseline evaluation.

Reproducibility

The reproducibility of the MSWS-12 was excellent in both the MS patients (ICC=0.910) and NMOSD (ICC=0.940) patients.

External validity

The baseline MSWS-12 total score for the patients with MS was strongly correlated with scores for the EDSS and T25FW (ρ=0.922 and 0.756, respectively), but not with those for the PHQ-9 and FSS-9 (ρ=0.426 and 0.280) (Table 2). In the patients with NMOSD, the baseline MSWS-12 total score showed

Table 1. Characteristics of MS and NMOSD patients

Patient characteristic	MS (*n*=34)	NMOSD (*n*=35)
Sex, males:females	19:15	6:29
Age, years	35.9±9.3	42.1±12.4
Disease duration, years	5.60 (0.17–20.70)	7.20 (0.67–20.20)
EDSS score	2.75 (0.00–6.50)	3.50 (0.00–7.50)
EDSS visual functional score	0 0 [24], 1 [5], 2 [4], 3 [0], 4 [1]	0 0 [19], 1 [4], 2 [4], 3 [6], 4 [2]
T25FW, s	5.25 (4.00–34.30)	5.95 (3.80–13.60)
Mobile by oneself	34 (100%)	33 (94.3%)
Mobile without using support devices	32 (94.1%)	32 (91.4%)
MSWS-12 baseline total score	25.00 [2.60–53.65]	25.00 [7.29–50.00]
MSWS-12 follow-up total score	21.88 [2.08–46.88]	20.83 [5.21–42.71]
MSIS-29 score		
Physical (one response missing)	15.00 [5.00–31.25]	11.25 [6.25–33.75]
Psychological	25.00 [13.89–46.53]	30.56 [8.33–56.94]
SF-36 score		
Average of the eight dimensions	61.48 [32.27–77.52]	62.38 [37.81–74.91]
Physical component summary	42.62 [34.64–51.49]	42.46 [33.90–48.14]
Mental component summary	42.40 [31.26–51.09]	44.31 [34.82–50.17]
GH	47.00 [32.75–55.75]	47.00 [33.50–57.00]
PF	77.50 [50.00–93.75]	75.00 [55.00–90.00]
RP	62.50 [0.00–100.00]	50.00 [0.00–100.00]
BP	74.00 [47.00–84.00]	62.00 [51.00–74.00]
VT	42.50 [30.00–55.00]	45.00 [35.00–55.00]
SF	62.50 [40.62–75.00]	62.50 [50.00–75.00]
RE	100.00 [0.00–100.00]	100.00 [0.00–100.00]
MH	54.00 [45.00–72.00]	60.00 [50.00–72.00]
FSS-9 total score (five responses missing)	36.00 [22.00–47.00]	34.00 [21.75–47.00]
PHQ-9 total score	5.00 [3.00–11.75]	7.00 [2.50–11.50]

Data are *n*, *n* (%), median [*n*], mean±standard deviation, median (range), or median [interquartile range] values.
BP: bodily pain, EDSS: Expanded Disability Status Scale, FSS-9: Fatigue Severity Scale-9, GH: general health perception, MH: mental health, MS: multiple sclerosis, MSIS-29: Multiple Sclerosis Impact Scale-29, MSWS-12: 12-item Multiple Sclerosis Walking Scale, NMOSD: neuromyelitis optica spectrum disorder, PF: physical functioning, PHQ-9: Patient Health Questionnaire-9, RE: role limitation due to emotional problems, RP: role limitations due to physical problems, SF: social functioning, SF-36: 36-item Short-Form Health Survey, T25FW: timed 25-foot walk, VT: energy/vitality.

a strong correlation with the EDSS score (ρ=0.769) and a moderate correlation with scores for the T25FW (ρ=0.597) and FSS-9 (ρ=0.630). When compared with each dimension of the MSIS-29, the physical dimension score (ρ=0.933) showed a much stronger correlation with the MSWS-12 score than with the psychological dimension score (ρ=0.528) in the MS patients. Similar results were obtained in the patients with NMOSD (ρ=0.910 and 0.743, respectively). Among the SF-36 dimension scores, the PCS calculated with positive weights on five physical dimensions (ρ=-0.874) showed a strong correlation with the baseline MSWS-12 score, whereas the MCS calculated with positive weights on four mental dimensions (ρ=-0.306) was not correlated in the MS patients. In detail, the baseline MSWS-12 score was correlated with the scores for PF (ρ=-0.940), RP (ρ=-0.636), BP (ρ=-0.746), SF (ρ=-0.695), and the average of the eight dimensions (ρ=-0.678). In the patients with NMOSD, the PCS (ρ=-0.852) also showed a strong correlation with the baseline MSWS-12 score, whereas the MCS (ρ=-0.371) did not. In detail, the baseline MSWS-12 score was correlated with the scores for PF (ρ=-0.935), BP (ρ=-0.766), SF (ρ=-0.684), and the average of the eight dimensions (ρ=-0.759).

DISCUSSION

This study examined the validity of the Korean version of the MSWS-12 in patients with MS and applied it to patients with NMOSD. To the best of our knowledge, this is 1) the first report on the development of a Korean version of the MSWS-12 and 2) the first attempt to apply the MSWS-12 to NMOSD patients, regardless of language. The scores for the Korean version of the MSWS-12 were consistent and reli-

Table 2. External validity of the MSWS-12 in MS and NMOSD patients, as assessed using Spearman's correlations with other scales and variables

Scale/variable	MS		NMOSD	
	Baseline	Follow-up	Baseline	Follow-up
EDSS	0.922	0.868	0.769	0.694
T25FW				
Average	0.771	0.741	0.689	0.632
Trial 1	0.756	0.729	0.597	0.515
Trial 2	0.800	0.775	0.749	0.712
MSIS-29				
Physical	0.933	0.933	0.910	0.826
Psychological	0.528	0.606	0.743	0.583
SF-36				
Average of the eight dimensions	-0.678	-0.748	-0.759	-0.648
Physical component summary	-0.874	-0.910	-0.852	-0.761
Mental component summary	-0.306	-0.404	-0.371	-0.247
GH	-0.448	-0.578	-0.439	-0.234
PF	-0.940	-0.905	-0.935	-0.893
RP	-0.636	-0.705	-0.578	-0.493
BP	-0.746	-0.760	-0.766	-0.675
VT	-0.290	-0.419	-0.493	-0.392
SF	-0.695	-0.715	-0.684	-0.565
RE	-0.542	-0.602	-0.459	-0.366
MH	-0.351	-0.442	-0.518	-0.378
FSS-9	0.280	0.352	0.630	0.380
PHQ-9	0.426	0.483	0.561	0.468

BP: bodily pain, EDSS: Expanded Disability Status Scale, FSS-9: Fatigue Severity Scale-9, GH: general health perception, MH: mental health, MS: multiple sclerosis, MSIS-29: Multiple Sclerosis Impact Scale-29, MSWS-12: 12-item Multiple Sclerosis Walking Scale, NMOSD: neuromyelitis optica spectrum disorder, PF: physical functioning, PHQ-9: Patient Health Questionnaire-9, RE: role limitation due to emotional problems, RP: role limitations due to physical problems, SF: social functioning, SF-36: 36-item Short-Form Health Survey, T25FW: timed 25-foot walk, VT: energy/vitality.

able, and were correlated with the various subjective and objective tests applied in this study, suggesting that it could be a useful measure of the subjective walking ability in patients with NMOSD as well as those with MS.

Among the demographic factors, age and disease duration in the patients with MS were not correlated with the MSWS-12 scores, which contrasts with the findings of a previous study.[12] This discrepancy could be related to either the small number of patients included in our study or, considering that most of the patients showed relatively low EDSS scores that were not correlated with age or disease duration in our MS cohort, to specific characteristics of our cohort. These results were similar in the patients with NMOSD. Individual myelitis attacks can be severe in NMOSD, and complete recovery might not occur, especially during the initial phase of the disease before appropriate treatment is started. There appeared to be poor consistency between the MSWS-12 scores and disease duration.

The MSWS-12 total score was at the lower limit in 23.5% and 14.3% of the MS and NMOSD patients, respectively, suggesting that floor effects could be present for patients with MS; however, floor and ceiling effects should always be considered in the relevant context. The percentage of lower-limit scores was remarkably high in both patient groups for items 8 and 9, which are yes-or-no questions related to the use of mobility supports indoors and outdoors, respectively. It is understandable that most of our patients did not have severe disability, given that the median EDSS scores were 2.75 and 3.5 for the MS and NMOSD patients, respectively. The patients who showed lower-limit scores on the MSWS-12 had EDSS scores ranging from 0 to 3.5. Given that patients with EDSS scores lower than 3.5 are considered to be fully ambulatory, those patients might not have obvious walking difficulties even though other disabilities such as visual or upper extremity dysfunction can slightly impair the gait.

The MSWS-12 score was strongly correlated with both the total score and the physical dimension score of the MSIS-29. Considering that the physical dimension of the MSIS-29 includes various physical conditions, such as hand/arm motion, social isolation, and bladder/bowel dysfunction, as well as gait problems,[21] those correlations suggest that gait problems are related to various physical problems encountered

during daily life. The MSWS-12 score was correlated with the psychological dimension score on the MSIS-29 in both the MS and NMOSD patients as well, although with weaker correlations. These findings suggest that the subjective disability in walking as measured by the MSWS-12 could be related to psychological problems.

These relationships were confirmed by correlations with the SF-36, which is a measure of the self-perception of various aspects of the health-related quality of life, and was previously validated in patients with MS.[28] The MSWS-12 score was correlated with the average of the eight dimension scores and the SF-36 PCS score but not with the SF-36 MCS score, although there was a moderate correlation with the social functioning item in MCS. Among PCS items, the questions that were more specific for physical function and disability (e.g., PF, RP, and BP) showed stronger correlations in the MS and NMOSD patients.

The MSWS-12 score was also strongly correlated with performance in the T25FW, which is an objective and specific assessment of walking disability on a flat ground, thereby verifying that the MSWS-12 represents a good measure for the walking ability in patients with MS and NMOSD. The MSWS-12 measures different aspects of walking, such as running and climbing stairs, in contrast to objective walking measures, and it has been suggested to be more responsive to changes than either the EDSS or T25FW.[29] Additional studies with long-term follow-ups are needed to confirm the usefulness of the MSWS-12 as a marker for disability progression in MS and NMOSD patients.

The correlations of the MSWS-12 score with psychological measures such as FSS-9 and PHQ-9 were relatively weak compared to physical measures in both the MS and NMOSD patients, which is similar to the findings of previous studies,[29] despite the FSS-9 and PHQ-9 previously being validated in patients with MS.[19,30] Considering that these measures are parameters for fatigue and depression, respectively, the direct correlations of FSS-9 and PHQ-9 scores with walking ability might be weaker than for physical measures.

This study was subject to some limitations, such as the small number of patients, the relatively slight disability of the included patients (which was probably related to the floor effects found in the MSWS-12 scores), the high proportion of RRMS patients compared with SPMS and PPMS patients, and the uneven distribution of the disabilities. The effects of visual functional system scores on the MSWS-12 were not evaluated because a large majority of the patients had no or only slight visual disability, and the highest scores were 4 in both groups, suggesting that visual disabilities did not exert severe effects on the walking abilities.

In conclusion, this study has successfully validated the Korean version of MSWS-12, which appears to be a valid and reliable scale for assessing patients with MS. The MSWS-12 can also be applied to patients with NMOSD. The MSWS-12 is currently the only qualitative, patient-based test that specifically measures walking disabilities. In contrast to the available objective walking measures, the MSWS-12 subjectively measures different aspects of walking and has been suggested to be more responsive to changes than are EDSS and T25FW scores.[9] Future longitudinal studies examining changes in walking disabilities as MS and NMOSD progress might be valuable.

Supplementary Materials

The online-only Data Supplement is available with this article at https://doi.org/10.3988/jcn.2020.16.2.270.

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Conflicts of Interest

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