Development and Validity Testing of a Morning Stiffness Assessment Scale for Patients with Rheumatoid Arthritis

HyunSoo Oh ▼ SuHyang Bang ▼ BoAe Im ▼ SiWon Lee ▼ WhaSook Seo

Morning stiffness is known to exert a significant impact on functional ability, quality of life, and employment status. There is an increasing need for a valid, reliable tool to comprehensively assess morning stiffness. The purpose of this study was to develop and verify a Morning Stiffness Assessment Scale. Items were developed on the basis of a framework of the conceptual attributes of morning stiffness. Validity and reliability tests were conducted on the devised scale. Eighty-five patients with rheumatoid arthritis were included to verify the devised scale. A 10-item Morning Stiffness Assessment Scale was developed. Its content and construct validities were well supported. The scale was found to have good reliability. The devised scale is simple and brief, but it provides a more comprehensive means of evaluation for morning stiffness. We believe this scale offers a clinically useful means of properly assessing morning stiffness and has potential utility for evaluating the effects of morning stiffness treatments.

Introduction

Rheumatoid arthritis (RA) is a chronic autoimmune disorder that primarily affects joints and has a reported prevalence of 0.4%–1.3% in the U.S. population (Helmick et al., 2008; Oh et al., 2019; Sacks et al., 2010). Although the effects of RA are multidimensional and include physical, psychosocial, and cognitive symptoms, the most common symptoms are pain and stiffness (Phillips & Dow, 2012; Schlaeger et al., 2018). The clinical symptoms of RA have been demonstrated to follow circadian rhythm (Halls et al., 2015; Sierakowski & Cutolo, 2011), and stiffness is most severe during early mornings, that is, morning stiffness (MS) (Mok et al., 2016).

Morning stiffness has been reported to significantly impact functional ability, quality of life, and employment status in RA patients (Minnock et al., 2018; Nikiphorou et al., 2012; Young et al., 2002). In addition, it is known to be associated with early retirement during the early disease course of RA and thus imposes financial losses and burdens on patients and their families (Nikiphorou et al., 2012; Young et al., 2002). Morning stiffness has also been noted to be an important RA symptom because it is an indicator of disease activity that can discriminate between remission and relapse of RA (Orbai et al., 2015). Accordingly, routine assessment of MS has been recommended for RA patients (Mok et al., 2016).

Morning stiffness is one of seven RA classification criteria established in 1987 but was excluded from the 2010 update because no reliable measures of MS existed (van Tyul et al., 2014). Traditionally, MS has been assessed using one question about its duration in minutes/hours or its intensity on a visual analog scale, a numerical rating scale (NRS), or a 4- or 5-point Likert scale (Halls et al., 2015). Furthermore, MS duration and intensity have been shown to be unreliably correlated (Rhind et al., 1987). Accordingly, a valid, reliable tool that can assess MS comprehensively is needed. To devise such a tool, it is essential that the conceptual framework of MS, which remains inadequately defined, be understood (Bacci et al., 2017; Halls et al., 2015; Mok et al., 2016; Orbai et al., 2014).

Background

Although the pathophysiological mechanism responsible for MS has not been elucidated, RA symptoms, including MS, have been demonstrated to follow circadian rhythm (Cutolo et al., 2005; Gibbs & Ray, 2013; Straub & Cutolo, 2007). Studies indicate that clinical circadian rhythms of RA symptoms are related to (1) changes in the nocturnal secretions of hormones caused by altered function of the

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hypothalamic–pituitary–adrenocortical axis and the pineal gland, resulting in reduced corticosteroid and increased melatonin production during night; and (2) a nocturnal increase in proinflammatory cytokine levels. Corticosteroid is a strong endogenous anti-inflammatory agent, and melatonin is an immunostimulatory hormone. Proinflammatory cytokine levels peak during night and early morning when plasma cortisol levels are low and melatonin levels are high, which may explain why symptom severity is greatest in the early morning (Cutolo et al., 2005; Gibbs & Ray, 2013; Straub & Cutolo, 2007).

Patients with RA experience MS-related functional disability more than three times a week, which causes difficulties in activities of daily living (ADL) and adversely affects quality of life (da Silva et al., 2011; Mattila et al., 2014). Furthermore, MS-associated functional disability leads to poor work performance due to late arrival at work or sick leave (Mattila et al., 2014). Thus, MS appears to exert multidimensional influences on the lives of RA patients. The Asia Pacific Morning Stiffness in Rheumatoid Arthritis Expert Panel, which consists of eight rheumatologists, agreed on 10 consensus points for MS (Mok et al., 2016). According to the statements made, MS is a common problem of RA, lasts for at least an hour, and may be more prevalent in patients with recently diagnosed disease. In addition, the panel stated that MS has marked impact on patient quality of life and is not necessarily correlated with DAS28 (Disease Activity Score 28) scores. It was also emphasized that patient-reported outcomes are probably the most effective way to evaluate MS and that MS should be routinely assessed in RA patients (Mok et al., 2016).

Morning stiffness has been consistently reported to be significantly correlated with other RA symptoms such as pain and functional disability, but findings on its correlation with disease activity are inconsistent (Khan et al., 2009; Yazici et al., 2004). Because disease activity has been considered to be an indicator of inflammatory status as it is based on assessments of swollen joints and inflammatory markers, its correlation with MS was presumed to be significant, but empirical evidence does not support this point of view.

Because RA symptoms often involve cycles of relapse and remission, inflammatory condition needs to be accurately assessed for efficient treatment planning in clinical practice (Mok et al., 2016). Inflammatory conditions are commonly evaluated using serum inflammatory markers (C-reactive protein or erythrocyte sedimentation rate) or disease activity measures (DAS28, Crohn's Disease Activity Index, or Simple Disease Activity Index) (Bacci et al., 2017). Although some studies have shown that disease activity may not be necessarily correlated with MS (Khan et al., 2009; Yazici et al., 2004), many RA patients describe MS as an indicator of disease worsening (relapse) or improvement (remission) (Orbai et al., 2015). Therefore, it seems that both disease activity and MS need to be assessed to evaluate inflammatory conditions in RA patients (Soubrier et al., 2006).

Traditionally, MS has been assessed using a one-item question on MS duration or intensity (Bacci et al., 2017). However, because MS is a complicated and multidimensional symptom with many aspects (e.g., duration, location, timing, intensity, and impact) (Orbai et al., 2015), intuitively, responses to a single question would appear to be incapable of reflecting MS status. However, no comprehensive MS measure has been developed on the basis of a systematic conceptualization of MS, which we believe is probably due to the lack of a conceptual framework for MS (Halls et al., 2015; Orbai et al., 2014).

Aims

The present study was conducted to develop and verify a Morning Stiffness Assessment Scale (MSAS). The specific aims of this study were (1) to develop a comprehensive scale to assess MS based on theoretical conceptualization of MS, (2) to determine the content and construct validities of the devised MSAS, and (3) to test the reliability of the devised MSAS.

Methods

Study Design

A nonexperimental, descriptive, correlational study design was adopted to examine the construct validity and reliability of the devised scale.

Item Development

In a study conducted to understand the meaning of MS from the perspectives of RA patients, five themes were identified (Halls et al., 2015): part of having RA, local/widespread, linked to behavior and environment, highly variable, and impact on daily life. According to their statements, RA patients identify MS as a natural result of RA and consider it to affect only joints or the whole body. Patients with RA often recognize that MS is related to behavioral and environmental factors, including movement, medication, and weather, and that it exhibits marked intra- and interpatient variability in terms of time, duration, and intensity. We considered that these patient-perceived characteristics of MS should be incorporated into the developed MSAS.

Halls et al. (2015) emphasized that the overall impact of MS on daily living should be considered to understand MS in RA patients. It appears that consideration of the multidimensional impact of MS from the perspectives of RA patients may be prerequisite for the meaningful assessment of MS. Similarly, Mok et al. (2016) concluded the most effective way to measure MS was to assess patient-reported outcomes, such as psychological well-being, quality of life, and work performance (da Silva et al., 2011; Westhoff et al., 2008). These impacts of MS were also taken into account for inclusion in the MSAS.

Summarizing, we considered a comprehensive MSAS should include items related to (1) the characteristics of MS including traditional MS indices (duration and intensity), local/widespread, linked to behavior and environment, and variability; and (2) the multidimensional impact of MS on patient-reported outcomes (pain, ADL, work performance, psychological well-being, and quality of life). A framework (see Figure 1)

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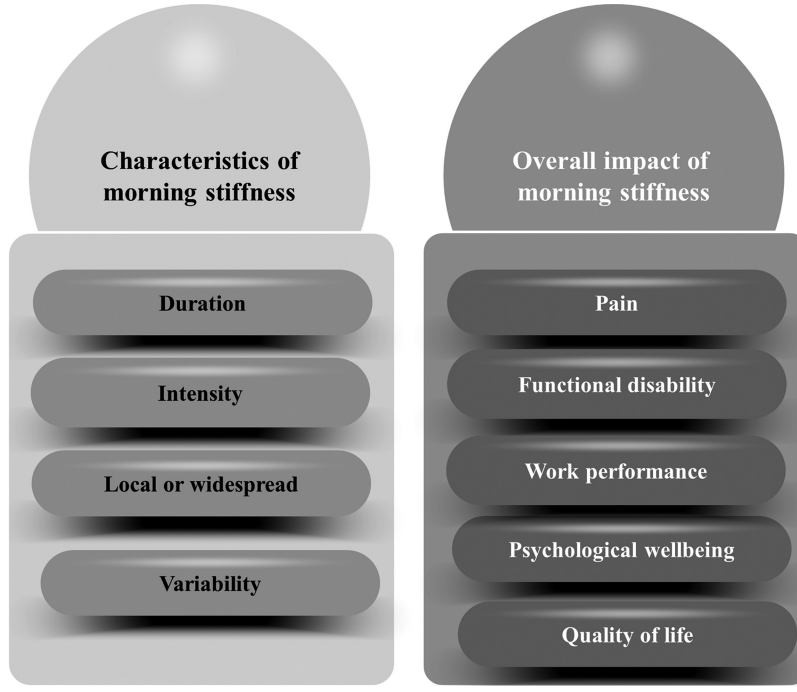

Figure 1. Framework for item development of the Morning Stiffness Assessment Scale.

was then devised for item development, and 13 items were devised (see Table 1).

Responses to most items (11 items) were rated using a 4-point Likert scale: "strongly agree," "agree to some extent," "disagree to some extent," and "not agree at all." However, responses to the item on MS intensity were "very stiff," "somewhat stiff," "almost no stiffness," and "no stiffness" and responses to the item on MS duration were "within 10 minutes of awaking," "within 30 minutes of awaking," "more than 60 minutes of awaking," "within 3 hours of awaking," and "almost all day."

A pretest survey was administered to 10 conveniently selected RA patients being treated in a rheumatology outpatient clinic. Only patients who agreed to participate in this pretest survey after being informed of the study purpose were selected. The pretest survey was administered to ensure that items were understandable and the time taken to complete the assessment was acceptable. The result obtained indicated that all 13 items of the devised scale were understandable, that the provisional 13-item MSAS had no obvious problems, and that it required at most 5 minutes to complete.

Table 1. The 13 Items Developed on the Basis of the Theoretical Framework of Morning Stiffness

Characteristics of morning stiffness	
Intensity	1. How much stiffness do you experience after waking up in the morning? 2. I have difficulties moving my body for a while after waking due to morning stiffness.
Duration	3. How long does morning stiffness last after waking up?
Variability	4. The intensity of my morning stiffness differs every day. 5. It is difficult to predict the intensity of stiffness the next morning.
Local or widespread (time and sites)	6. My morning stiffness affects only one or two joints. 7. My morning stiffness occurs only during an inflammation or exacerbation period.
Overall impact of morning stiffness	
Impact on pain	8. Morning stiffness causes more pain.
Impact on activities of daily living	9. I have difficulties performing daily activities, such as tooth brushing or face washing, due to morning stiffness.
Impact on work/job	10. I have difficulties performing house work or going to work due to stiffness in the morning. 11. I am unable to work and stay in bed all morning due to morning stiffness.
Impact on psychological health	12. I am depressed due to morning stiffness.
Impact on quality of life	13. Morning stiffness lowers my quality of life.

Note. Items were originally developed in Korean (translated into English for publication purpose).

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The MSAS was originally developed in Korean, and its validity and reliability were tested with a sample comprising Korean patients in the present study. For publication purpose and the global use of MSAS, this tool was translated into English by the corresponding author of the present study. A professional native English-speaking proofreader reviewed the translated items to ensure accuracy. Furthermore, two nursing professors with experience in related research fields confirmed whether individual items of the translated scale had the same meaning as the original items in Korean.

Study Participants

Eighty-five RA patients were recruited by convenience sampling. All participants were outpatients, being treated at a rheumatology outpatient clinic at a university hospital in Incheon (South Korea). Only patients who satisfied the following criteria were recruited: (1) rheumatologist-diagnosed RA based on diagnostic test results; (2) an age of 19 years or older; (3) able to understand and complete questionnaires; and (4) the provision of consent after being informed of the study purposes and procedures.

According to power analysis conducted using the G*power 3.1 (Faul et al., 2009), the minimum sample size required was 68 (regression analysis, $\alpha = .05$, effect size = 0.12, $\alpha = .05$, power $(1 - \beta) = .80$, number of predictors = 1). Effect size (0.12) was calculated on the basis of Mattila et al.'s study (2014). Eighty-five participants were enrolled to account for an expected loss of approximately 20% due to missing data or erratic responses. The missing data rule used was that if 10% or more data were missing, then the data of that patient were excluded from the study. However, all 85 participants were included as there were no exclusions. This sample size appeared to be sufficient for factor analysis based on common rules of thumb regarding minimum sample size, that is, five to 10 participants should be included per item, and as the present study involved consideration of 13 items (13×5–$10 = 65$–130 participants).

Data Collection Procedure

Data collection was performed after obtaining approval from the human research committee at our university (INHAUH 2018-05-033), the director of the Rheumatology Department, and the president of the university hospital where data were collected. All data were obtained by medical record review and using a self-reporting questionnaire by participants who read questions and selected responses without assistance, in a quiet conference room at the rheumatology outpatient center. For elderly individuals with presbyopia-associated reading difficulties, questionnaires were read by a data collector. Because subjects responded directly to the questionnaire, we believe this process was not subject to bias. The average time taken to complete the whole questionnaire package was approximately 15 minutes.

Data were collected between March and July 2019 by three coauthors (second, third, and fourth authors) who were graduate nursing students with robust clinical (5–20 years) and research experiences in RA. They practiced presenting the devised MSAS to RA patients before data collection. Practice sessions were conducted simultaneously for the three data collectors to reduce individual bias. Because items were provided with definite answers, no response-associated difficulties were experienced by patients during data collection.

Data on demographic (age, gender, marital status, and educational background), health-related (smoking, alcohol consumption, and exercise), and major variables (MS, pain, functional disability, and quality of life) were obtained using a self-report questionnaire. Data on disease-related characteristics (duration of RA from diagnosis and medications taken for RA) were obtained by medical record review.

Levels of pain, functional disability, and quality of life were assessed to determine nomological validity, a form of construct validity. Nomological validity can be supported by confirming that relationships between concepts or variables are consistent with empirical evidence or theories. In the case of MS, it has been consistently reported to be significantly related to degree of pain, functional disability, and quality of life in previous studies or related literature (da Silva et al., 2011; Khan et al., 2009; Phillips & Dow, 2012; Westhoff et al., 2008; Yazici et al., 2004). Accordingly, we examined whether MSAS scores were significantly related to degree of pain, functional disability, or quality of life to verify construct validity of the MSAS.

Measurements

Pain level was measured using an NRS, with responses ranging from "no pain" (scored as 0) to "maximum pain" (scored as 10). Despite being a single-item scale, the NRS has been widely used because of its good validity and reliability (Krebset al., 2007).

Degree of functional disability was evaluated using the Modified Health Assessment Questionnaire (MHAQ) (Uhlig et al., 2006), which is a short version of the Stanford Health Assessment Questionnaire (HAQ, 22 items), and was originally developed to assess functional disability in RA patients. In the present study, the MHAQ was translated into Korean by the first author who is fluent in English and Korean. The Korean version of the MHAQ was then back-translated into English by the corresponding author who is also fluent in both languages. The translators and other authors compared the back-translated version with the original. No inconsistencies were found. The MHAQ is an eight-item questionnaire, and responses are rated using a 4-point Likert scale ("without any difficulty," "with some difficulty," "with much difficulty," and "unable to do"). Higher scores indicate more severe functional disability. The HAQ has been demonstrated to be a highly valid and reliable tool (Johnson et al., 2005), and the MHAQ is also generally accepted to be a valid (based on the high correlation exhibited by MHAQ and HAQ scores, $r = .88$) and reliable tool (Cronbach $\alpha = 0.85$) (Uhlig et al., 2006). In the present study, the Cronbach α for the MHAQ was 0.91.

Quality of life was assessed using the eight-item Health-Related Quality of Life Instrument (HINT-8), which was developed for use in the Korea National

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Health and Nutrition Examination Survey (Lee et al., 2014). Items are evaluated using a 4-point Likert scale and consist of climbing stairs, endurance of pain, vitality, working, depression, memory, sleep, and happiness. HINT-8 scores were calculated using the formula provided by its developers. The total scores range from 0.105 to 1, and higher scores indicate higher levels of quality of life. Construct validity of the HINT-8 was verified by the group comparison method or convergent, discriminant, and criterion validity tests. Test–retest reliability was shown to be good or excellent, depending on items, and its interrater correlation was also high (.85). In the present study, test–retest reliability of the HINT-8 was 0.85 ($\rho = 0.85$).

Data Analysis

Statistical analysis was performed using SPSS 19.0/PC (IBM-Data Solution, Seoul, South Korea). General and disease-related characteristics were subjected to descriptive analysis. Content validity was determined on the basis of Content Validity Index (CVI), and construct validity was evaluated by using exploratory factor analysis and regression analysis. In addition, internal consistency coefficients (Cronbach α) were computed to evaluate the reliability of the MSAS.

Ethical Consideration

All study participants were informed beforehand about study purposes and procedures. Study participants were assured that their medical records would be reviewed, and they had the right not to participate and to withdraw from the study without prejudice at any stage. In addition, they were also assured that their personal information would remain confidential and that data would be published as means and ranges. Written informed consent was obtained from all study participants.

Results

Descriptive Statistics of Subject Characteristics and Major Variables

Mean participant age was 62.18 years (SD = 10.56): younger than 60 years 42.4% (n = 36) and 60 years or older 57.6% (n = 49). Of the 85 participants, 71 (81.6%) were female and 14 (16.1%) were male (see Table 2). Eight participants (9.2%) were current smokers (the mean number of cigarettes per day was 16.00, SD = 11.10), and the mean duration of smoking was 351.00 (SD = 120.98) months. Eighteen (20.7%) participants were found to consume alcohol, and the mean frequency of alcohol consumption was 1.54 (SD = 1.47) times per week. To evaluate exercise-related habits, regularity, frequency, and types of exercise were assessed. Forty-six (54.1%) participants were found to perform regular exercise, mostly walking, at a frequency of 3.39 (SD = 1.76) times per week and for the mean duration of 64.28 (SD = 57.10) minutes every time (see Table 2).

Mean disease duration after diagnosis was 135.82 (SD = 119.35) months. All participants were found to currently take RA medications, and the mean duration of medication taking was 126.07 (SD = 100.58) months. The mean duration of stiffness each morning was 215.53 (SD = 39.27) minutes. Mean scores were as follows: pain 4.33/10 (SD = 2.80), MS 22.19/40 (SD = 8.49), functional disability 13.14/32 (SD = 5.05), and quality of life 0.63/1 (SD = 0.15) (see Table 2), inferring moderate levels of pain, MS, and quality of life and a mild level of functional disability based on descriptive comparisons of the mean and total scores.

Table 2. Descriptive Statistics of Demographic, Disease-Related, and Major Variables (N= 85)

Variables/Categories	n (%)/Mean ± SD
Age (years)	62.18 ± 10.56
Age group	
<60 years	36 (42.4)
≥60 years	49 (57.6)
Gender	
Male	14 (16.1)
Female	71 (81.6)
Smoking	
No	77 (90.6)
Yes	8 (9.4)
Smoking duration (months)	351.00 ± 120.98
Numbers of cigarette per day	16.00 ± 11.10
Alcohol consumption	
No	67 (78.8)
Yes	18 (21.2)
Frequencies of alcohol consumption per week	1.54 ± 1.47
Exercise	
No	39 (45.9)
Yes	46 (54.1)
Numbers of exercise per week	3.39 ± 1.76
Duration of exercise each time (minutes)	64.28 ± 57.10
Duration of rheumatoid arthritis after diagnosis (months)	135.82 ± 119.35
Rheumatoid arthritis medication	
No	0 (0.0)
Yes	85 (100.0)
Duration of taking rheumatoid arthritis medication (months)	126.07 ± 100.58
Duration of morning stiffness each time (minutes)	215.53 ± 39.27
Pain score	4.33 ± 2.80 (0–10)
Morning stiffness score	22.19 ± 8.49 (1–40)
Functional disability score	13.14 ± 5.05 (1–32)
Quality-of-life score	0.63 ± 0.15 (0.105–1)

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Content Validity Testing

Content validity of the initial 13-item MSAS was assessed by an expert panel composed of four rheumatologists, three nursing professors with experience in developing assessment tools, and three nurses with more than 5 years of clinical rheumatology experience. The expert panel evaluated whether the 13 items were suitable for assessing MS using a 3-point scale: (1) very suitable, (2) suitable, or (3) not suitable. The CVI (sum of the number of items with an expert score of 1 or 2 divided by the total number of items) was computed. Items with a CVI score of 0.80 or more were considered to have good content validity. All the 13 items were included because their CVI scores were above 0.8. However, the expert panel suggested that two items needed modification because of ambiguous wording. On the basis of detailed feedback from the expert panel, these two items were refined: Item 1 was changed from "How severe is the stiffness you experience after waking up in the morning?" to "How much stiffness do you experience after waking up in the morning?" and Item 5 was changed from "I can predict the intensity of stiffness the next morning" to "It is difficult to predict the intensity of stiffness the next morning." Content validity testing resulted in the development of the 13-item initial version of the MSAS.

Construct Validity Testing

Construct validity was evaluated by using exploratory factor analysis and regression analysis (for nomological validity testing).

Exploratory Factor Analysis

Exploratory factor analysis was conducted to establish construct validity of the MSAS. Before performing factor analysis, the Kaiser–Meyer–Olkin (KMO) test was conducted to evaluate sampling adequacy. In addition, Bartlett's sphericity test was conducted to confirm whether the correlation matrix was diagonal, which indicates no correlation. In general, a KMO value of more than 0.60–0.80 is required for factor analysis (Kang, 2013). In terms of Bartlett's sphericity test, a significant result ($p < .05$) indicates that the correlation matrix was a diagonal correlation matrix. We found a KMO value of 0.86 and Bartlett's sphericity $\chi^2 = 426.04$, $p < .001$ (see Table 3), that is, factorable.

Communality coefficients (an indication of variable usefulness) were then examined. Three items in the initial 13-item MSAS were found to have low communalities (a factor loading of ≤0.40, which is a commonly used cutoff; Kang, 2013): Item 4 "The intensity of my morning stiffness differs every day"; Item 5 "It is difficult to predict the intensity of stiffness the next morning"; and Item 7 "My morning stiffness occurs only during an inflammation or exacerbation period." Accordingly, exploratory factor analysis was conducted on the remaining 10 items with factor loadings of 0.4 or more.

In this study, exploratory factor analysis of the final 10-item MSAS yielded two components with eigenvalues greater than 1. The total variance explained by these two components was 62.5% and thus because the communality value of the fraction of variance needs to be 0.60 or more (Kim, 2005), the 10-item MSAS appeared to be acceptable in terms of its explanatory power. Five items loaded onto Component 1 (51.0% variance) and five loaded onto Component 2 (11.5% variance). According to the framework developed for item development in the present study (see Figure 1), there were two conceptual attributes of MS, that is, "characteristics of MS" and "overall impact of MS." This corresponds with the findings of exploratory factor analysis that derived two components (see Table 3).

The item with highest loading onto Component 1 was "I am unable to work and stay in bed all morning due to morning stiffness," which assesses impact on ADL. Other items loaded onto Component 1 were "I am depressed due to morning stiffness," "Morning stiffness lowers my quality of life," "I have difficulties performing house work or going to work due to stiffness in the morning," and "I have difficulties performing daily activities, such as tooth brushing or face washing, due to morning stiffness." The items loaded onto Component 1 appeared to assess multidimensional impact of MS,

Table 3. Construct Validity Test: Exploratory Factor Analysis

Items of Morning Stiffness Assessment Scale	Factors	
	I	II
11. I am unable to work and stay in bed all morning due to morning stiffness	0.83	0.12
12. I am depressed due to morning stiffness.	0.81	0.18
13. Morning stiffness lowers my quality of life.	0.80	0.26
10. I have difficulties performing house work or going to work due to stiffness in the morning.	0.73	0.35
9. I have difficulties performing daily activities, such as tooth brushing or face washing, due to morning stiffness	0.68	0.30
3. How long does morning stiffness last after waking up?	0.04	0.77
1. How much stiffness do you experience after waking up in the morning?	0.28	0.71
6. My morning stiffness affects only one or two joints	0.23	0.68
8. Morning stiffness causes more pain.	0.50	0.64
2. I have difficulties moving my body for a while after waking up due to morning stiffness	0.52	0.60
Cumulated variance (%)	51.0%	62.5%
Kaiser–Meyer–Olkin = 0.86; Bartlett test of sphericity: $\chi^2 = 426.04$; $p < .001$		

Note. Items were developed in Korean (translated into English for publication purpose). Responses for Items 2 and 4–13: (1) not agree at all; (2) disagree to some extent; (3) agree to some extent; and (4) strongly agree. Responses for Item 1: (1) no stiffness; (2) almost no stiffness; (3) somewhat stiff; and (4) very stiff. Responses for Item 3: (1) within 10 minutes of awaking; (2) within 30 minutes of awaking; (3) more than 60 minutes of awaking; (4) within 3 hours of awaking; and (5) almost all day. The authors permit free use of this scale for clinical, research, and educational purposes.

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Table 4. Construct Validity Test: Nomological Validity Test

	Correlational Matrix Between Morning Stiffness and Other Major Variables			
	r (*p*)			
Variables	Morning Stiffness	Pain	Disability	Quality of Life
Morning stiffness	1.00			
Pain	.68 (<.001)	1.00		
Functional disability	.61 (<.001)	.55 (<.001)	1.00	
Quality of life	−.54 (<.001)	−.38 (<.001)	−.54 (<.001)	1.00
	Regression Analysis for Quality of Life			
Variables	R^2	*F* (*p*)	β	*t* (*p*)
Pain			−.08	−0.61 (.543)
Functional disability	.37	15.61 (<.001)	−.35	−3.07 (.003)
Morning stiffness			−.38	−2.92 (.005)

corresponding to the overall impact of MS in the framework devised for item development.

The item with highest loading onto Component 2 was "How long does morning stiffness last after waking up?" In addition, four items ("How much stiffness do you experience after waking up in the morning?"; "My morning stiffness affects only one or two joints"; "Morning stiffness causes more pain"; and "I have difficulties moving my body for a while after waking up due to morning stiffness") were loaded onto Component 2. The items loaded onto Component 2 appeared to assess characteristics of MS, corresponding to the characteristics of MS in the framework devised for item development.

With the exception of Item 8, all items and their matched components in the factor analysis findings corresponded with the framework developed for item development (see Figure 1), supporting construct validity of the final version of the MSAS. Item 8 ("Morning stiffness causes more pain") was shown to be associated with "overall impact of MS" in the framework but found to be included in "characteristics of MS" in the factor analysis. After careful consideration, we decided to classify this item into "characteristics of MS" as found in factor analysis because we devised this item to assess whether MS has a clinical feature of aggravating other symptoms.

Nomological Validity

Nomological validity is a form of construct validity and examines whether structural relationships among variables are consistent with empirical evidence or theories (Spiro & Weitz 1990). In RA patients, MS has been consistently reported to be significantly related to pain, functional disability, and quality of life (da Silva et al., 2011; Khan et al., 2009; Phillips & Dow, 2012; Westhoff et al., 2008; Yazici et al., 2004). Therefore, correlations between MSAS scores and degree of pain, functional disability, or quality of life were examined. Our findings indicated that MSAS scores were significantly correlated with degree of pain ($r = .68$, $p < .001$), functional disability ($r = .61$, $p < .001$), and quality of life ($r = .54$, $p < .001$; see Table 4) and thus supported the nomological validity of the MSAS.

Because pain and functional disability also have been reported to be major influencers of quality of life in RA patients (Uhm et al., 2012), additional regression analysis was conducted to determine whether MS was significantly correlated with quality of life in a model that included three predictors (MS, pain, and functional disability). Our findings indicated that MS remained a significant variable in terms of explaining quality of life even in the presence of two other predictors (i.e., pain and functional disability) ($\beta = -.38$, $t = -2.92$, $p = .005$; see Table 4).

Reliability Testing

In this study, the Cronbach α of the MSAS was 0.89 and that of the two subscales was 0.80 for "characteristics of MS" and 0.87 for "overall impact of MS," indicating good reliability despite the small number of items (see Table 5).

Discussion

Morning stiffness is the most common symptom of RA (Phillips & Dow, 2012), but due to a lack of valid and reliable measures for MS, it was excluded from the most recently issued RA classification criteria (van Tyul et al., 2014). Nevertheless, MS is still considered to be a clinically significant indicator of disease aggravation or improvement (Orbai et al., 2014, 2015) and to affect quality of life (Orbai et al., 2015). Accordingly, we conducted this study to develop a comprehensive scale to assess MS based on a theoretical conceptualization of MS from the patient perspective and to verify the validity and reliability of the developed MSAS.

For item development, a framework of the conceptual attributes of MS was devised on the basis of empirical evidence in the present study (da Silva et al., 2011; Halls et al., 2015; Mok et al., 2016; Orbai et al., 2015; Westhoff et al., 2008). According to the framework, MS attributes were classified into two dimensions, namely, "characteristics of MS" and "overall impact of MS." On the basis of this framework, items addressing duration, intensity, local/widespread, and variability of MS were considered

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Table 5. Reliability of the Morning Stiffness Assessment Scale and Its Two Subscales

Scale/Subscales	Value
Total score	Cronbach α = 0.89
"Characteristics of MS" component score	Cronbach α = 0.80
"Overall impact of MS" component score	Cronbach α = 0.87

Note. MS = morning stiffness.

Table 6. Morning Stiffness Assessment Scale

Subscales	Items
Characteristics of morning stiffness	How much stiffness do you experience after waking up in the morning? I have difficulties moving my body for a while after waking up due to morning stiffness. How long does morning stiffness last after waking up? My morning stiffness affects only one or two joints. Morning stiffness causes more pain.
Overall impact of morning stiffness	I have difficulties performing daily activities, such as, tooth brushing or face washing, due to morning stiffness. I have difficulties performing house work or going to work due to stiffness in the morning. I am unable to work and stay in bed all morning due to morning stiffness. I am depressed due to morning stiffness. Morning stiffness lowers my quality of life.

to be "characteristics of MS" and items addressing impact of MS on other RA symptoms, such as pain or functional disability, work performance, psychological well-being, and quality of life, were considered "overall impact of MS." Thirteen items were devised.

However, three items (two items addressing MS variability and one item addressing local/widespread nature of MS) were found to have low communality coefficients (a measure of the extent of communality an item has with other items). As a rule of thumb, communality coefficients lower than 0.40 need to be excluded (Kang, 2013). In terms of MS variability, it has been reported that RA patients perceive MS to be highly variable in terms of timing, duration, and intensity (Halls et al., 2015; Orbai et al., 2015). Accordingly, two items were included to assess MS variability in the initial 13-item MSAS but were finally excluded because of low communality. In addition, although many RA patients described MS as an indicator of inflammation (Orbai et al., 2015), the associated item was excluded for low communality. Ten items were then included in the final version of the MSAS. Further investigation may need to determine the usefulness of the three excluded items in the assessment of MS. The final MSAS appears in Table 6.

Construct validity was examined using exploratory factor analysis and nomological validity testing. Exploratory factor analysis yielded two components, and the total variance explained by these two components was 62.5%, which is acceptable in terms of explanatory power. Most items and their matched components in the factor analysis findings corresponded with the framework developed for item development (see Figure 1), confirming the construct validity of the MSAS. The explanatory power of items of the "overall impact of MS" component was higher than that of the "characteristics of MS" component, which signified the importance of assessing MS impact on patient-reported outcomes, as has been emphasized in previous studies (Mok et al., 2016; Orbai et al. 2015).

Morning stiffness is a well-known symptom to influence quality of life in RA patients (da Silva et al., 2011; Mattila et al., 2014; Westhoff et al., 2008) and has also been reported to be significantly correlated with pain and functional ability (Halls et al., 2015; Khan, et al., 2009; Mok et al., 2016; Yazici et al., 2004). Actually, some RA patients find it difficult to differentiate MS and pain or functional disability (Halls et al., 2015). Accordingly, we conducted nomological validity testing by examining whether there were significant correlations between MSAS scores and degrees of pain, functional disability, or quality of life as shown in empirical evidence (da Silva et al., 2011; Khan et al., 2009; Phillips & Dow, 2012; Westhoff et al., 2008; Yazici et al., 2004). Our findings well supported the nomological validity of the MSAS. Furthermore, our findings indicated that MS was significantly correlated with quality of life in a model that included two other predictors (pain and functional disability), which further supported the nomological validity of the MSAS. The Cronbach α of the MSAS was 0.89, which was satisfactory, and those of subscale were also satisfactory, indicating good reliability of the MSAS.

With respect to study limitations, because the validity and reliability of the MSAS were tested on a relatively small number of RA patients (n = 85) recruited at one university hospital, our findings are limited in terms of generalizability. Large-scale, multicenter studies are required to confirm the validity and reliability of the MSAS. In addition, the MSAS still needs further verification and refinement to be a standardized instrument for assessing MS.

Nursing Implications

The 10-item MSAS devised in the present study is a simple and brief assessment scale but provides more comprehensive evaluations because it was developed on the basis of multidimensional attributes of MS from patients' perspectives. Therefore, we believe that this scale offers a clinically useful means of properly assessing MS and recommends that orthopaedic nurses use this scale routinely to properly monitor the conditions of RA patient in an outpatient clinic setting as well as in an acute hospital setting. We also expect that this scale will be beneficial by helping orthopaedic nurses and other health professionals to understand MS and by improving communication between RA patients and health professionals. Furthermore,

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this scale can be useful for evaluating the effects of MS treatment and thus enhancing the clinical outcomes of MS treatments.

Conclusion

In the present study, the 10 items of the devised MSAS were developed on the basis of a framework of the conceptual attributes of MS and their validity and reliability were found to be well supported. Exploratory factor analysis on these 10 items corresponded with the framework for MS devised during item development stage, which supported construct validity. Exploratory factor analysis showed the MSAS was composed of two components (i.e., characteristics of MS and overall impact of MS) and that these two components had acceptable total variance, which indicated adequate explanatory power. Furthermore, MSAS scores were significantly correlated with pain, functional disability, and quality-of-life scores and found to significantly explain quality of life even in the presence of two other predictors (i.e., pain and functional disability), which verified nomological validity. In addition, it was demonstrated that the MSAS had high internal consistency, indicating good reliability.

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ERRATUM

Effect of Nonelastic Compression With an Adjustable Wrap After Total Knee Arthroplasty: Erratum.

The lead author of an article that appeared in the November/December 2020 issue of *Orthopaedic Nursing* reported an error in Table 3, page 381, and apologizes for this error. In the first table column, the outcome measurements are described (Total leg volume, Circumference infrapatellar, Circumference midpatellar, and Circumference suprapatellar) for the control group and the treatment group. In the last two outcome measurements (midpatellar and suprapatellar) the word "control" is used for both groups, whereas it should have read "treatment group" for the second row. The outcomes are correct. Please see a corrected version of this table at the following link: http://links.lww.com/ONJ/A16.

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Hendrickx, A. A., Krijnen, W. P., Bimmel, R., van der Schans, C. P., & Damstra, R. J. (2020). Effect of nonelastic compression with an adjustable wrap after total knee arthroplasty. *Orthopaedic Nursing, 39*(6), 377–383.

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