Validation of the Korean Migraine-Specific Quality of Life Questionnaire Version 2.1 in Episodic and Chronic Migraine

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Aims: To evaluate the validity of the Korean Migraine-Specific Quality of Life Questionnaire version 2.1 (K-MSQ v 2.1) in patients with episodic migraine (EM) or chronic migraine (CM). **Methods:** Subjects were recruited from a headache clinic and completed several self-report instruments, including the K-MSQ v 2.1, the Migraine Disability Assessment Scale (MIDAS), the Headache Impact Test-6 (HIT-6), the Migraine-Specific Quality of Life (MSQoL), the Patient Health Questionnaire-9 (PHQ-9), and the Generalized Anxiety Disorder-7 (GAD-7). Some of the subjects were assessed 4 weeks later and underwent the K-MSQ v 2.1 to examine test-retest reproducibility. Internal consistency and test-retest reproducibility were assessed to determine reliability. Construct validity was also assessed. Internal consistency (Cronbach's α) and test-retest reproducibility (intraclass correlation coefficients) were assessed to determine reliability. Pearson correlations were used to determine the validity. **Results:** For the 180 eligible patients, the value of Cronbach's α for the three dimensions of the K-MSQ v. 2.1 (Role Function-Restrictive, Role Function-Preventive, and Emotional Function) were 0.954, 0.909, and 0.898, respectively, indicating excellent internal consistency. The intraclass correlation coefficients between baseline and the 4-week retest showed reliable reproducibility. The scores of the three dimensions for the K-MSQ v. 2.1 were well correlated with scores for the MIDAS, the HIT-6, the MSQoL, the PHQ-9, and the GAD-7. Internal consistency and construct validity showed similar tendencies in patients with EM and those with CM. **Conclusion:** The K-MSQ v 2.1 is a reliable and valid screening tool for evaluating QoL in patients with EM and CM. *J Oral Facial Pain Headache 2017; 31:251–256. doi: 10.11607/ofph.1769*

Keywords: *chronic migraine, migraine, MSQ, quality of life, validation*

Migraine is the sixth highest cause of disability worldwide and represents an enormous burden to patients and society.[1–3] Migraine is subdivided based on headache frequency into episodic migraine (EM) or chronic migraine (CM). Although EM and CM are considered part of a spectrum of migraine disorders, CM is a distinct disorder in terms of its demographic and clinical characteristics and its treatment response compared with EM. In addition, patients with CM are significantly more disabled and have greater impairments to their quality of life (QoL) than those with EM.[4]

Measuring QoL is key for assessing the burden of disease,[5,6] and an improvement in QoL is a major goal during the treatment of patients with migraine. Patients with migraine have demonstrated significantly impaired QoL compared with control subjects.[7,8] The impact of migraine on QoL cannot be assessed by evaluating only the frequency and severity of headache attacks.[9] Patient-reported outcome instruments are recognized as important tools for assessing the impact of disease on QoL and for evaluating changes in disease-related disability and QoL in clinical practice.[5,10] In research on headache disorders, international guidelines recommend the use of disease-specific instruments to quantify the potential benefits of treatment.[11]

The 16-item Migraine-Specific Quality of Life Questionnaire version 1.0 (MSQ v 1.0) has been developed[12] and is widely used as a

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migraine-specific instrument in research on health-related quality of life (HRQoL). It examines the impact of migraine on the HRQoL of patients over the previous 4 weeks across three dimensions: Role Function-Restrictive (RR), Role Function-Preventive (RP), and Emotional Function (EF). Subsequently, the revised 16-item MSQ v 2.0 and 14-item MSQ v 2.1 were developed.[13,14] A US hospital-based study and a multi-country, web-based survey have revealed evidence for the high internal consistency and good reliability and validity of the MSQ v 2.1 in patients with EM and CM.[14,15] The MSQ v 2.1 has also been validated in patients with CM who took prophylactic treatment and had a history of medication overuse.[16–18] In addition, it has been used to evaluate the effects of psychiatric comorbidities and preventive medication on QoL.[19,20] To date, there has not yet been a validation study in the Korean population. Therefore, the aim of this study was to evaluate the validity of the Korean MSQ v 2.1 (K-MSQ v 2.1) in patients with EM or CM.

Materials and Methods

Subjects

This study included patients with migraine who visited a headache clinic at Kyungpook National University Hospital from April 2015. Patients were aged between 15 and 65 years and were newly diagnosed at a headache clinic or previously diagnosed with migraine but had not taken triptans, preventive medications, or psychiatric medications within the last month. This study was performed as a part of a hospital-based study that investigated the impact of migraine on psychiatric and psychosocial problems; thus, if patients were already taking triptans, preventive medications, or psychiatric medications that could confound the relationship between migraine and psychiatric or psychosocial problems due to the influence of the psychotropic agents, these patients were excluded from this study. Patients were diagnosed according to the International Classification of Headache Disorders third edition (ICHD-III) beta version by a trained neurologist (S.P. Park).[21] Patients with intellectual disability or severe medical, neurologic, or psychiatric disorders preventing them from understanding the self-report questionnaires were excluded. Patients with probable migraine and who refused study participation were also excluded.

Study Design

This cross-sectional study was approved by the Institutional Review Board of Kyungpook National University Hospital, and all subjects gave written informed consent. Demographic, social, and clinical information of the subjects was collected at enrollment. The sociodemographic variables were age, gender, education, place of residence, employment, household income, and marital status (ie, married vs unmarried, divorced, or bereaved). The clinical variables were age at onset, disease duration, type of migraine, migraine chronicity (EM or CM), family history, accompanying symptoms (ie, nausea and/or vomiting, photophobia, phonophobia, or osmophobia), and family history.

Eligible subjects conducted several self-report questionnaires, including the K-MSQ v 2.1, the Migraine Disability Assessment Scale (MIDAS),[22] the Headache Impact Test-6 (HIT-6),[23] the Migraine-Specific Quality of Life (MSQoL),[24] the Patient Health Questionnaire-9 (PHQ-9),[25] and the Generalized Anxiety Disorder-7 (GAD-7).[26] A total of 121 subjects were assessed 4 weeks later and underwent the K-MSQ v 2.1 to examine test-retest reliability.

Linguistic Validation of K-MSQ

The original English version was translated into Korean, then back to English from the Korean version. A native English speaker compared the two versions and concluded that they were identical. Thereafter, 20 Korean patients with migraine completed the questionnaire to evaluate problems in comprehension. No further adaptations were required.

Questionnaires

K-MSQ v 2.1

Patients completed the Korean version of the MSQ v 2.1 for validation. The MSQ v 2.1 measures the impact of migraine on QoL over the previous 4 weeks across three dimensions: RR, RP, and EF.[13] It consists of 14 questions: 7 in the RR dimension, 4 in the RP dimension, and 3 in the EF dimension. The MSQ v 2.1 has shown reliability and validity to evaluate QoL.[14] Each question is rated on a 6-point scale from 1 to 6. The dimension scores are summed and rescaled to give a total score between 0 and 100. Higher scores on the MSQ indicate a better state of QoL.

MIDAS

The Korean version of the MIDAS was used to evaluate disability during the previous 3 months.[22] The MIDAS includes 5 items and evaluates the impact of migraine on performance in activities at work, school, or home. Cronbach's α was 0.75.

HIT-6

The HIT-6 measures a wider spectrum of headache-related burden.[27] The HIT-6 includes six items, each of which is answered using a 5-point Likert scale (6 = never, 8 = rarely, 10 = sometimes, 11 = very often, 13 = always). The total score can range from 36 to 78, with larger scores indicating a greater impact.[28] The Korean version of the HIT-6 has been validated, and Cronbach's α was 0.85.[23]

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MSQoL

The MSQoL is a useful tool to evaluate QoL.[29] The MSQoL consists of 25 items, each of which is rated on a 4-point scale from 1 to 4. The total scores can range from 25 to 100. Higher scores indicate a better state of QoL. The Korean version of the MSQoL has been validated and Cronbach's α was 0.93.[24]

PHQ-9

The PHQ-9 was designed for diagnosis of major depressive disorder (MDD) over the previous 2 weeks.[30] It includes 9 items, each of which is rated on a 4-point scale from 0 to 3.[31] The overall score can range from 0 to 27, and a cut-off score of 7 indicates MDD.[25] The PHQ-9 can be downloaded for free on the PHQ website (http://www.phqscreeners.com/). The Korean version of the PHQ-9 has been validated in patients with migraine, and Cronbach's α was 0.89.[25]

GAD-7

The GAD-7 was designed for diagnosis of GAD over the past 2 weeks.[32] It includes 7 items, each of which is rated on a 4-point scale from 0 to 3. The overall score can range from 0 to 21 and a cut-off score of 5 indicates generalized anxiety disorder (GAD). The GAD-7 can be downloaded for free on the Patient Health Questionnaire website (www.phqscreeners.com). The Korean version of the GAD-7 has been validated in patients with migraine, and Cronbach's α was 0.92.[26]

Statistical Analyses

Statistical Package for the Social Sciences (SPSS version 21.0) was used for data analysis. Descriptive statistics are presented as counts, percentages, means, and standard deviations (SD). Cronbach's α was computed to ascertain internal consistency and was recalculated to identify change of Cronbach's α after items were removed. The intraclass correlation coefficient (ICC) was used to examine test-retest reproducibility. An ICC of < 0.6 is considered unreliable, between 0.6 and 0.8 moderately reliable, and ≥ 0.8 highly reliable.[33] Pearson correlations were used to determine the validity of the MSQ. The level of statistical significance was set at $P < .05$.

Table 1 Sociodemographic, Clinical, and Psychometric Characteristics of Eligible Subjects (n = 180)

Characteristics	Mean ± SD (range) or n (%)
Age (y)	39.3 ± 12.8 (15–64)
Gender (female)	156 (86.7)
Education (y)	12.8 ± 2.9 (5–20)
Place of residence (city)	150 (83.3)
Employment (yes)	100 (55.6)
Household income (at least US $2,800/mo)	122 (67.8)
Married without divorce or bereavement	108 (60.0)
Age at onset (y)	29.7 ± 12.1 (7–59)
Disease duration (y)	9.6 ± 8.4 (0–37)
Type of migraine	
Migraine with aura	11 (6.1)
Migraine without aura	169 (93.9)
Migraine chronicity	
Episodic migraine	81 (45.0)
Chronic migraine	99 (55.0)
Family history of migraine	112 (62.2)
Associated symptoms	
Nausea and/or vomiting	151 (83.9)
Photophobia	86 (47.8)
Phonophobia	106 (58.9)
Osmophobia	89 (49.4)
MIDAS (d)	30.6 ± 36.2 (0–190)
HIT-6 score	59.1 ± 8.2 (36–78)
MSQoL score	67.5 ± 15.7 (28–99)
PHQ-9 score	6.4 ± 5.8 (0–27)
GAD-7 score	4.7 ± 4.6 (0–21)
K-MSQ score	
Role function-restrictive	53.1 ± 24.5 (0–100)
Role function-preventive	65.3 ± 24.3 (0–100)
Emotional function	70.3 ± 25.8 (0–100)

VAS = visual analog scale; MIDAS = Migraine Disability Assessment Scale; HIT-6 = Headache Impact Test-6; MSQoL = Migraine-Specific Quality of Life; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7; K-MSQ = Korean Migraine-Specific Quality of Life Questionnaire Version 2.1.

Table 2 Reliability of the K-MSQ v 2.1 Using Cronbach's α

Dimension	No. of items	Overall (n = 180)	EM (n = 81)	CM (n = 99)
Role function-restrictive	7	0.954	0.957	0.950
Role function-preventive	4	0.909	0.913	0.906
Emotional function	3	0.898	0.867	0.916

K-MSQ v. 2.1 = Korean Migraine-Specific Quality of Life Questionnaire Version 2.1; EM = episodic migraine; CM = chronic migraine.

Results

A total of 225 patients with migraine visited the clinic consecutively during the study. Of these patients, 45 were excluded for the following reasons: refusal to complete the questionnaires (n = 22), probable migraine (n = 8), mental retardation (n = 3), illiteracy (n = 4), or older than 65 years of age (n = 8). Subsequently, 180 patients completed the study. The invited subjects underwent the K-MSQ v 2.1 without experiencing difficulty comprehending and replying to the questions. Sociodemographic, clinical, and psychometric characteristics of the participants are listed in Table 1. The majority of patients were female (86.7%). A total of 11 patients (6.1%) experienced migraine with aura, and 99 patients (55%) had CM.

The reliability of the K-MSQ v 2.1 is demonstrated in Table 2. Cronbach's α values indicated excellent

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Table 3 Corrected Item-Total Correlations and Cronbach's α When an Item is Deleted from the K-MSQ

Dimension and item	Corrected item-total correlation	Cronbach's α with an item deleted
Role function-restrictive		
Item 1	0.756*	0.953*
Item 2	0.817*	0.948*
Item 3	0.888*	0.942*
Item 4	0.920*	0.940*
Item 5	0.898*	0.941*
Item 6	0.867*	0.944*
Item 7	0.747*	0.954*
Role function-preventive		
Item 8	0.775*	0.888*
Item 9	0.775*	0.889*
Item 10	0.778*	0.887*
Item 11	0.847*	0.862*
Emotional function		
Item 12	0.744*	0.902*
Item 13	0.858*	0.804*
Item 14	0.796*	0.856*

Data are presented as Pearson correlation coefficient.
*P value < .001.

Table 4 Intraclass Correlation Coefficients (ICCs) When the K-MSQ v. 2.1 was Conducted in 121 Patients with Migraine at Baseline and 4 Weeks Later

Dimension	Baseline (mean ± SD)	4 weeks later (mean ± SD)	ICCs	95% CI
Role function-restrictive	48.9 ± 25.0	74.3 ± 23.3	0.685*	0.549–0.780
Role function-preventive	61.8 ± 25.5	83.9 ± 19.8	0.694*	0.562–0.786
Emotional function	66.6 ± 26.8	82.8 ± 21.2	0.680*	0.541–0.776

K-MSQ = Korean Migraine-Specific Quality of Life Questionnaire Version 2.1;
95% CI = confidence interval.
*P value < .001.

Table 5 Construct Validity of the K-MSQ v 2.1

	Overall (n = 180)	EM (n = 81)	CM (n = 99)
Variable	*r*	*r*	*r*
Role function-restrictive			
MIDAS	−0.529**	−0.452**	−0.570**
HIT-6	−0.759**	−0.756**	−0.750**
MSQoL	0.576**	0.540**	0.584**
PHQ-9	−0.415**	−0.320*	−0.448**
GAD-7	-0.304**	−0.311*	−0.272*
Role function-preventive			
MIDAS	−0.470**	−0.433**	−0.534**
HIT-6	−0.604**	−0.623**	−0.616**
MSQoL	0.496**	0.558**	0.463**
PHQ-9	−0.302**	−0.256*	−0.356**
GAD-7	−0.202*	−0.265*	−0.176
Emotional function			
MIDAS	−0.464**	−0.381**	−0.487**
HIT-6	−0.618**	−0.605**	−0.621**
MSQoL	0.757**	0.726**	0.776**
PHQ-9	−0.447**	−0.353*	−0.473**
GAD-7	−0.333**	−0.337*	−0.308*

K-MSQ = Korean Migraine-Specific Quality of Life Questionnaire Version 2.1; EM = episodic migraine; CM = chronic migraine; MIDAS = Migraine Disability Assessment Scale; HIT-6 = Headache Impact Test-6; MSQoL = Migraine-Specific Quality of Life; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7.
Data are presented as Pearson correlation coefficient.
*P value < .05; **P value < .001.

internal consistency for the patients overall and across migraine frequency groups. The RR dimension was more reliable than the other dimensions. The correlations between each item and the dimension score are shown in Table 3. The scores from all of the items were well correlated with the RR, RP, and EF scores.

The test-retest reliability of the K-MSQ v 2.1 was examined in 121 patients who were tested 4 weeks later. The ICCs between the results at baseline and at the 4-week follow-up are listed in Table 4. All ICCs of the three dimensions had moderate reliability.

The validity for each dimension of the K-MSQ v 2.1 is described in Table 5. The scores of the three dimensions of the K-MSQ v 2.1 in the overall patient sample were negatively correlated with the scores of the MIDAS, the HIT-6, the PHQ-9, and the GAD-7, and positively correlated with the score of the MSQoL. Similar tendencies were observed in patients with EM and CM. The K-MSQ v 2.1 showed a higher correlation with tools examining migraine-related disability or QoL than tools examining mood or anxiety.

Discussion

The K-MSQ v 2.1 was easily comprehended by patients and its internal consistency reliability was excellent, comparable to that of the original version and higher than that reported by the Italian and Persian versions.[14,15,18,34] The ICC values indicated an excellent test-retest reliability between consecutive visits in all dimensions, which was higher than that of the US and in Persian studies.[14,34] Each dimension of the K-MSQ v. 2.1

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has construct validity as confirmed by the correlations with the MIDAS score, the HIT-6 score, the MSQoL score, the PHQ-9 score, and the GAD-7 score in enrolled subjects.

Several disease-specific HRQoL instruments have been developed for the assessment of patients with migraine. The MSQoL is used to assess the effects of migraine on QoL over the long term for a nonspecified time period and includes a 25-item questionnaire.[29] The 24-hour Migraine-Specific Quality of Life Questionnaire (MQoLQ) is a 15-item, self-administered questionnaire designed to measure the short-term impact of migraine on QoL within 24 hours after having taken migraine medication and within the first 24 hours of a migraine attack.[35] In contrast to the MSQoL and MQoLQ, the 16-item MSQ v 1.0 was developed to evaluate the long-term impact of migraine on HRQoL over a specified time period (ie, the previous 4 weeks).[12] It is composed of three dimensions: RR, PR, and EF. The RR and RP dimensions assess whether normal activities are limited or interrupted by migraine, and the EF dimension measures the emotional effects of migraine. The items vary in the number of substantive response categories. To reduce wording ambiguity and standardize response categories, the revised 16-item MSQ v 2.0 was developed,[13] and subsequently the revised 14-item MSQ (v 2.1) was developed for easier administration.[14]

Previous studies have shown the construct validity of the MSQ v 2.1 in different populations and patient groups.[14,15,18,34] In the US study, the MSQ v 2.1 score was significantly correlated with the MIDAS, the HIT-6, and depression and anxiety scores.[15] The Italian study showed that the RR and RP dimensions of the MSQ v 2.1 were more strongly correlated than the EF dimension with MIDAS score, while the depression score correlated better with the EF dimension than with the RR and RP dimensions.[18] Other studies revealed that the three dimensions of the MSQ v 2.1 had significant correlations with the Medical Outcomes Study 36-Item Short Form Health Survey score.[14,34] In the current study, the MIDAS, the HIT-6, and the MSQoL were used to evaluate the construct validity of the K-MSQ v 2.1. In addition, depression and anxiety were assessed by the PHQ-9 and GAD-7, which are useful screening tools to evaluate psychiatric problems in patients with migraine.[25,26] All correlations were statistically significant, supporting the construct validity of the K-MSQ v 2.1.

Psychiatric problems have been commonly reported in patients with migraine, affecting the frequency and intensity of migraine attacks.[36,37] Disability and QoL impairments in patients with migraine are greater when migraine is associated with either depression or anxiety.[38] In addition, depressive symptoms have been identified as the strongest predictor of QoL in patients with migraine.[39] Previous studies have shown that the MSQ v 2.1 score was correlated with depression and anxiety symptoms.[15,18] Consistent with previous studies, the K-MSQ v 2.1 score in the present study was negatively correlated with depression and anxiety. Among the three dimensions, the MSQ-EF score was more strongly correlated with the PHQ-9 and GAD-7 scores than with the RR and RP scores, which is similar to the findings of a previous study.[18]

Some limitations of the present study need to be considered. The study included subjects referred to a single specialty clinic, which might narrow the sample population to patients with relatively more severe migraine. In addition, the sample size of the study was small. Due to this limitation, further studies should be conducted using a larger sample of patients with migraine that also includes patients who are not referred to specialists.

Conclusions

This is the first study to evaluate the reliability and validity of the K-MSQ v 2.1 in Korean patients with EM and CM. The study showed that the K-MSQ v 2.1 can be reliably applied as a screening measure of QoL in patients with migraine. In a busy clinical setting, the brevity of the K-MSQ v 2.1 gives it the potential to quickly and efficiently evaluate QoL in patients with migraine.

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