

# Validity of the medical outcomes study sleep scale in patients with painful diabetic peripheral neuropathy in Korea

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## ABSTRACT

**Aims/Introduction:** Sleep disturbances caused by painful diabetic neuropathy (PDN) might have substantial impacts on the multifaceted aspects of PDN, including quality of life. There are no convincing data on the validation or reliability of sleep problem measurements in patients with PDN in Korea. This large population-based cross-sectional study examined psychometric properties of the Medical Outcomes Study (MOS) Sleep Scale in patients with PDN in Korea.

**Materials and Methods:** Measurements of patient-reported outcomes (Brief Pain Inventory-short form, MOS Sleep Scale and EuroQoL Health [EQ-5D]) were documented. PDN was diagnosed if the average daily pain intensity was  $\geq 4$  based on the visual analog scale or if patients were taking medication for their current pain.

**Results:** There were 577 patients with PDN (41.6% with diabetic peripheral neuropathy). The internal consistency of reliability for the MOS Sleep Scale was 0.80 as measured by Cronbach's alpha. The extent to which multiple items in a dimension were intercorrelated and formed a dimension measuring the same underlying concept (Pearson's correlation coefficient) ranged from 0.24 to 0.71 (all  $P < 0.001$ ). Each item of the MOS Sleep Scale was significantly correlated with the average pain score and the pain interference score (Pearson's correlation coefficients ranged from 0.20 to 0.28 and from 0.29 to 0.40, respectively; all  $P < 0.001$ ). The correlations between the EQ-5D index and the MOS Sleep Scale ranged from  $-0.27$  to  $-0.31$  (all  $P < 0.001$ ).

**Conclusions:** The MOS Sleep Scale showed good reliability in the evaluation of PDN in Korean type 2 diabetic patients. (J Diabetes Invest, doi: 10.1111/jdi.12066, 2013)

**KEY WORDS:** Diabetic neuropathies, Pain, Sleep

## INTRODUCTION

Diabetic peripheral neuropathy (DPN) is the most common long-term complication of diabetes, and is a risk factor for foot ulceration and lower extremity amputation. It was reported that 63.8% of type 2 diabetic patients experience some degree of pain<sup>1</sup>. Chronic painful diabetic peripheral neuropathy (PDN) can cause symptoms that persist for many years and severely impairs the quality of life<sup>1,2</sup>. Patients with PDN reported that the pain caused substantial disruptions in sleep and the enjoyment of life, as well as moderate interference in recreational

activities, normal work, mobility, general activity, social activities and mood<sup>3</sup>, with PDN patients having greater impairment than non-diabetic controls<sup>2</sup>.

Sleep disturbances are well established as being associated with depression, anxiety, impaired social functioning, hospitalization, chronic medical conditions and mortality<sup>4,5</sup>. Patients with painful DPN reported impaired sleep relative to the general population and other chronic diseases<sup>6</sup>. In contrast, links between sleep and metabolic control were established, and chronic sleep impairment might represent a novel risk factor for type 2 diabetes mellitus, potentially influencing the progression of this condition<sup>7,8</sup>. Thus, sleep problems caused by PDN might have substantial impacts on the multifaceted aspects of this disease, including quality of life.

The measurement of a patient's experiences of pain and sleep through validated instruments before the use of medical equipment could provide important information. There are a number of sleep questionnaires that are designed to measure the quality of sleep or the impact of sleep problems on daily function and quality of life in patients with PDN<sup>9</sup>. A 12-item self-report sleep measure was developed in the Medical

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Received 11 October 2012; revised 5 December 2012; accepted 26 December 2012

Outcomes Study (MOS) to provide a concise assessment of important dimensions of sleep, including initiation, maintenance, respiratory problems, quantity, perceived adequacy and somnolence<sup>10</sup>. However, there are no convincing data on the validation or reliability of these measurements in PDN patients in Korea. The aim of the present study was to examine psychometric properties of the MOS Sleep Scale in patients with PDN based on a large population-based cross-sectional study in Korea.

## METHODS

### Study Population

Patients with type 2 diabetes from 40 hospitals across Korea were enrolled in the present multicenter, cross-sectional, observational study from December 2009 to June 2010. The main characteristics of the study design were published elsewhere<sup>11</sup>. Initially, 4,000 eligible patients were consecutively enrolled from outpatient departments of multicenters during the study period. Of these, 1,388 (33.5%) patients had DPN based on the diagnostic criteria of a previously reported study<sup>11</sup>. PDN was diagnosed if the average daily pain intensity was  $\geq 4$  (moderate or more pain) using the visual analog scale (VAS) or if patients were taking medication for their current pain. Diabetic complications were categorized and defined as definite criteria according to a previous study<sup>11</sup>. Each patient received written information about the study and all participants gave informed consent. The study was approved by the local ethics committees of each of the 40 hospitals.

### Patient-Reported Outcome Measures

The patients completed patient-reported outcome measures questionnaires. This included the Brief Pain Inventory (BPI)-short form, MOS Sleep Scale and EuroQol Health (EQ-5D). All of these measures were completed during clinic visits.

#### BPI-Short Form

The BPI is a patient-completed numeric rating scale that assesses the severity of pain (severity scale), its impact on daily functioning (interference scale) and other aspects of pain (e.g., location of pain, relief from medication)<sup>12</sup>. The modified short form used in the present study includes the four-item pain severity scale (worst, least, average and current pain) and the seven-item pain interference scale (general activity, mood, walking ability, normal work, relationships with other people, sleep and enjoyment of life). Each BPI item uses a 0–10 numeric rating scale anchored at 0 for 'no pain' and 10 for 'pain as bad as you can imagine' for severity, and 'does not interfere' to 'completely interferes' for interference. The 'average pain score' was defined using the scale rating average pain. The 'pain interference score' was defined using the scale that pain has interfered with sleep during the previous 24 h. Support for the reliability and validity of the USA English version has been reported in patients with painful DPN<sup>13</sup>.

#### MOS Six-Item Sleep Scale

The MOS Sleep Scale was applied to patients to assess their quality of sleep. Results supported the construction of six subscales based on the 12 items in the MOS Sleep Scale. A shorter version of the MOS Sleep Scale of the index was also developed based on considerations of item content and item-total correlations. This six-item version was used in the present study (Appendix S1). Participants were asked to recall sleep quality during the previous 4 weeks. The MOS Sleep Scale yields several dimensions of sleep, including initiation, maintenance, adequacy, somnolence and respiratory impairments. Participants were asked to respond on a six-scale score, ranging from 'none of the time' to 'all of the time'. Item responses were assigned scores using conventional scoring rules, with higher scores indicating a greater severity of sleep disturbance. A sleep problem index (SPI), using the sum of all six sleep items, was also scored to provide a measure of overall sleep quality. Support for the reliability and validity of the German, Polish and USA English versions has been reported in patients with painful DPN<sup>14</sup>.

#### EQ-5D

The impact of PDN on patient quality of life was assessed using the EQ-5D. The EQ-5D has a five-item standardized health profile measure<sup>15,16</sup>. Each item reflects one dimension of quality of life (motility, self-care, usual activities, pain/discomfort and anxiety/depression) coded at one of three levels. The recall period was 'today.' The scores from the five domains can be used to calculate a single preference-based index score. In addition, the EQ-5D contains a VAS that asks the patients to rate their current health state from 0 to 100, where 0 represents the worst imaginable health state and 100 represents the best imaginable health state. The reliability and validity has been established for a number of disease entities.

#### Statistical Analysis

All data are expressed as mean  $\pm$  standard deviation (SD), unless stated otherwise. The internal consistency of reliability was assessed by Cronbach's coefficient alpha computed for the derived factors from the factor analysis, using the criterion of an alpha coefficient of  $\geq 0.7$  for acceptable reliability. In addition, internal consistency of reliability was evaluated using inter-correlations between each item of the MOS Sleep Scale. Construct validity of the MOS Sleep Scale was evaluated by examining the statistical relationships between the MOS Sleep Scale and the average pain score, the pain interference score, and EQ-5D. Pearson correlation coefficients were used to evaluate these relationships. The statistical package SAS for Windows (SAS Institute, Cary, NC, USA) was used for the analyses. A *P*-value  $< 0.05$  was considered statistically significant.

## RESULTS

### Patient Characteristics

It was found that 1,388 (33.5%) patients had DPN based on the diagnostic criteria of a previously reported study<sup>11</sup>. Of these, 577

**Table 1** | Clinical and demographic characteristics of patients with painful diabetic neuropathy

Clinical parameters	Mean $\pm$ SD
Age (years)	63.6 $\pm$ 10.6
Female	344 (59.6)
Duration of diabetes (years)	13.1 $\pm$ 8.1
BMI (kg/m <sup>2</sup> )	25.0 $\pm$ 3.7
Fasting plasma glucose (mg/dL)	147.0 $\pm$ 64.7
HbA <sub>1c</sub> (%)	7.9 $\pm$ 1.7
Hypertension†	397 (68.8)
Dyslipidemia†	298 (51.7)
Diabetic retinopathy†	217 (37.6)
Diabetic nephropathy†	157 (27.2)
Average pain score‡	3.5 $\pm$ 2.5
Pain interference score‡	3.0 $\pm$ 3.5
Sleep problem index§	186.9 $\pm$ 141.8
MOS Sleep Scale	
MOS-1	45.2 $\pm$ 37.0
MOS-2	8.7 $\pm$ 21.0
MOS-3	38.0 $\pm$ 38.7
MOS-4	36.9 $\pm$ 36.4
MOS-5	19.3 $\pm$ 27.5
MOS-6	38.7 $\pm$ 36.7

Data are expressed as mean  $\pm$  standard deviation for continuous variables and as frequency (%) for categorical variables ( $n = 577$ ). MOS-1, sleep adequacy; MOS-2, respiratory problem during sleep; MOS-3, sleep initiation problem; MOS-4, sleep maintenance problem; MOS-5, somnolence; MOS-6, sleep adequacy. BMI, body mass index; HbA<sub>1c</sub>, glycated hemoglobin; PDN, painful diabetic neuropathy. †Defined as definite diagnostic criteria in reference<sup>11</sup>. ‡Derived from the Brief Pain Inventory-short form. §Derived from the Medical Outcomes Study (MOS) Sleep Scale.

patients (41.6%) with PDN were included for analysis in the present study. The demographic and clinical characteristics of the study population are shown in Table 1. This analysis included 233 males and 344 females with a mean age of 63.6  $\pm$  10.6 years. The mean duration of diabetes was 13.1  $\pm$  8.1 years. The incidences of diabetic retinopathy and nephropathy were 37.6 and 27.2%, respectively. The average pain score and the pain interference score were 3.5  $\pm$  2.5 and 3.0  $\pm$  3.5, respectively, as derived from the BPI-short form. A mean SPI of 186.9  $\pm$  141.8 was calculated from the sum of all items in the MOS Sleep Scale.

The internal consistency of reliability reached 0.80 for the MOS Sleep Scale when measured by Cronbach's alpha. Cronbach's alpha ranged from 0.74 to 0.81 for the multi-item dimensions if any single item was deleted (Table 2). The extent to which multiple items in a dimension were intercorrelated and formed a dimension measuring the same underlying concept (Pearson's correlation coefficient) ranged from 0.24 to 0.71 (all  $P < 0.001$ ; Table 3 and Appendix S2).

The construct validity of the MOS Sleep Scale was evaluated by correlations with the average pain score and the pain interference score (Table 4 and Appendix S2). Each item of the

**Table 2** | Cronbach's coefficient alpha of the Medical Outcomes Study Sleep Scale

MOS Sleep Scale	Correlation with total	Cronbach's alpha if item removed
MOS-1	0.65	0.74
MOS-2	0.35	0.81
MOS-3	0.62	0.75
MOS-4	0.64	0.75
MOS-5	0.40	0.80
MOS-6	0.66	0.74

Medical Outcomes Study (MOS)-1, sleep adequacy; MOS-2, respiratory problem during sleep; MOS-3, sleep initiation problem; MOS-4, sleep maintenance problem; MOS-5, somnolence; MOS-6, sleep adequacy.

**Table 3** | Pearson's correlation coefficients between items of the Medical Outcomes Study Sleep Scale

	MOS-1	MOS-2	MOS-3	MOS-4	MOS-5	MOS-6
MOS-1	–	0.24*	0.49*	0.47*	0.28*	0.71*
MOS-2	0.24*	–	0.26*	0.28*	0.28*	0.25*
MOS-3	0.49*	0.26*	–	0.61*	0.29*	0.47*
MOS-4	0.47*	0.28*	0.61*	–	0.35*	0.48*
MOS-5	0.28*	0.28*	0.29*	0.35*	–	0.31*
MOS-6	0.71*	0.25*	0.47*	0.48*	0.31*	–

\* $P < 0.001$ . Medical Outcomes Study (MOS)-1, sleep adequacy; MOS-2, respiratory problem during sleep; MOS-3, sleep initiation problem; MOS-4, sleep maintenance problem; MOS-5, somnolence; MOS-6, sleep adequacy.

**Table 4** | Pearson's correlation coefficient between the Medical Outcomes Study Sleep Scale and the average pain score and pain interference score

	MOS-1	MOS-2	MOS-3	MOS-4	MOS-5	MOS-6	SPI†
Average pain score‡	0.21*	0.28*	0.28*	0.28*	0.22*	0.20*	0.34*
Pain interference score‡	0.40*	0.33*	0.39*	0.36*	0.29*	0.35*	0.50*

\* $P < 0.001$ . †Derived from the Medical Outcomes Study (MOS) Sleep Scale. ‡Derived from the Brief Pain Inventory-short form. MOS-1, sleep adequacy; MOS-2, respiratory problem during sleep; MOS-3, sleep initiation problem; MOS-4, sleep maintenance problem; MOS-5, somnolence; MOS-6, sleep adequacy. SPI, sleep problem index.

MOS Sleep Scale was significantly correlated with the average pain score and the pain interference score (Pearson's correlation coefficients ranged from 0.20 to 0.28 and from 0.29 to 0.40, respectively, all  $P < 0.001$ ). Correlations of  $\geq 0.40$  were found between the SPI of the MOS Sleep Scale and the pain interference score, and between the 'sleep adequacy' score of the MOS

**Table 5** | Pearson's correlation coefficients between the Medical Outcomes Study Sleep Scale and EuroQoL Health

	MOS-1	MOS-2	MOS-3	MOS-4	MOS-5	MOS-6	SPI†
ED-5Q	-0.27*	-0.31*	-0.29*	-0.30*	-0.27*	-0.28*	-0.40*
VAS‡	-0.29*	-0.27*	-0.25*	-0.25*	0.27*	-0.31*	-0.38*

\* $P < 0.001$ . †Derived from the Medical Outcomes Study (MOS) Sleep Scale. ‡Derived from EuroQoL Health (EQ-5D). MOS-1, sleep adequacy; MOS-2, respiratory problem during sleep; MOS-3, sleep initiation problem; MOS-4, sleep maintenance problem; MOS-5, somnolence; MOS-6, sleep adequacy. SPI, sleep problem index; VAS, visual analog scale.

Sleep Scale and the pain interference score. Correlations ranging between 0.30 and 0.40 were found between the pain interference score and 'respiratory problem during sleep,' 'sleep initiation problem,' 'sleep maintenance problem,' and 'sleep adequacy' scores of the MOS Sleep Scale, and between the SPI of the MOS Sleep Scale and the average pain score. The highest correlation (0.50) was found between the SPI and the pain interference score. The correlations between the EQ-5D index and the MOS Sleep Scale ranged from  $-0.27$  to  $-0.31$  (all  $P < 0.001$ ; Table 5).

## DISCUSSION

In the present study, we assessed the psychometric properties of the MOS Sleep Scale in patients with PDN based on a large population-based cross-sectional study in Korea. The MOS Sleep Scale was found to have acceptable reliability between type 2 diabetic patients with PDN. There was a moderate correlation with the pain interference score on the seven items of the MOS Sleep Scale, but relatively weak correlations with the average pain score and EQ-5D outcomes.

Preliminary support for the MOS Sleep Scale was provided in a developmental sample of 3,445 individuals with chronic illness who participated in the cross-sectional phase of the MOS<sup>10</sup>. In the preceding time, this instrument has proven its usefulness in evaluating the associations between sleep disturbance and various parameters in chronic illnesses, such as congestive heart failure, depression and chronic obstructive pulmonary disease<sup>17–19</sup>. This measurement also showed good psychometric properties in patients with PDN in a population-based clinical trial carried out in several countries<sup>14</sup>. These earlier studies were carried out mostly with Caucasians in Western countries. The present study is the first to report on the validation of the MOS Sleep Scale in patients with PDN based on a large nationwide-study in Korea, and provides additional information regarding the reliability and validity of this instrument among patients with PDN.

The internal consistency of MOS Sleep Scale reliability showed good results measured by Cronbach's alpha in the present study. The measurement by the MOS Sleep Scale exceeded Nunnally's threshold of acceptable reliability (i.e.,  $\geq 0.7$ ), providing support for its use in the assessment of sleep disturbance in patients with PDN<sup>20</sup>. Deletion of a single item reduced or subtly increased (only in MOS-2) Cronbach's alpha,

which suggests that all six items of this instrument might be retained. The internal consistency of reliability assessed by intercorrelations between each item of the MOS Sleep Scale was also acceptable for all items. In particular, the close correlation between two items of 'sleep adequacy' with the same dimension supports good reliability ( $r = 0.71$ ).

Correlations between the MOS Sleep Scale and the average pain score, and between the pain interference score and the EQ-5D index provided evidence for construct validity. Measurements that were conceptually related to the MOS Sleep Scale, including the average pain score, the pain interference score and EQ-5D, correlated well with all items of the MOS Sleep Scale for the present study population. This shows the relationship between sleep and other elements of quality of life in patients with PDN, and is consistent with previous studies showing that sleep disturbance has an impact not only on physical functioning, but also on mental and social functioning, in DPN patients<sup>2,4,14</sup>. All of the relationships in the present study were in the expected directions; as sleep scores increased, so did the average pain and pain interference scores, whereas the quality of life decreased. It was suggested that the pain score and the pain interference score of the BPI-short form correlated well with the MOS Sleep Scale, providing good evidence that this measurement is representative of the construct of sleep disturbance caused by pain.

The MOS Six-Item Sleep Scale of the present study is a brief, self-administered assessment with five theoretical dimensions and six items to measure key aspects of sleep, such as adequacy, disturbance and somnolence, in general or clinical populations. This instrument is a brief survey that takes approximately 1–2 min to complete. Thus, its design should allow clinicians to easily apply this instrument to patients with PDN in clinical practice. In addition, the results showed the reliability and validity of the translated Korean version of the MOS Sleep Scale, and supported the cross-cultural validity of the different language versions of the MOS Sleep Scale.

The results of the present study are subject to some limitations. First, the cross-sectional design of the present study did not permit exploration of causal relationships between sleep disturbance and pain. In addition, we could not apply some tests, such as the test–retest reliability and responsiveness to changes in clinical status (e.g., pain scores), because only a single assessment and not multiple assessments were made. Nevertheless, the strength of the present study is that our results are based on the largest available data set in Korea. Other limitations of this study were related to the secondary analysis of the observational design of the original study. Furthermore, because a validated tool for clinical diagnosis of PDN was not used in this study, it is not clear if patients were rating pain of different etiology. In addition, it is not known what effects concurrent medications have on sleep scale measurements. However, consistency between sleep scales and other variables could be independent of interpatient variation. Furthermore, the study enrolled 577 patients, which was a respectable sample size. The

MOS Sleep Scale was compared with measures of pain and quality of life, but not sleep, in this study. Thus, it does not provide empirical evidence to support the interpretation of the MOS Sleep Scale in the context specific sleep outcomes in the population studied. Finally, although the present study is a valuable contribution to the reliability of the MOS Sleep Scale in this study population, further detailed assessment is required to confirm its content validity.

In conclusion, the present study provides evidence of the good reliability and validity of the MOS Sleep Scale in patients with PDN in Korea. The MOS Sleep Scale is relatively simple and can be easily applied in daily practice. Therefore, the MOS Sleep Scale can be used to assess sleep disturbance caused by pain in patients with PDN. The easy and appropriate assessment of sleep disturbance using this instrument might help us to improve the quality of life in diabetic patients. Further studies are required to examine the MOS Sleep Scale's test-retest reliability and responsiveness to any intervention for PDN using clinical trials or other repeated measure designs.

## ACKNOWLEDGEMENTS

All authors declare that they have no conflicts of interest. This study was sponsored by Pfizer Pharmaceuticals Korea Ltd. and supported by the Priority Research Centers Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology (2010-0020224). We fully acknowledge the participating investigators in Korea and steering members of the Korean Diabetic Neuropathy Study Group. We especially thank Professor Ki Jun Song (Department of biostatistics, Yonsei University College of Medicine, Korea) for carrying out the statistical analysis.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

- Appendix S1** | Medical Outcomes Study Six-Item Sleep Scale
- Appendix S2** | Scatter plots between variables