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Validation of a Korean Version of the Insomnia Severity Index

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Background and Purpose The purposes of this study were to standardize and validate a Korean version of the Insomnia Severity Index (ISI-K), and to evaluate its clinical usefulness.

Methods We translated the ISI into Korean and then translated it back into English to check its accuracy. The 614 patients with sleep disorders who were enrolled in this study comprised 169 with primary insomnia, 133 with comorbid insomnia, and 312 with obstructive sleep apnea. All subjects underwent one night of polysomnography (PSG) and completed the Korean versions of both the Pittsburgh Sleep Quality Index (PSQI-K) and the Epworth Sleepiness Scale, as well as the ISI-K. The ISI-K was compared to these sleep scales and various PSG sleep parameters.

Results The internal consistency the ISI-K total score was confirmed by a Cronbach's alpha of 0.92, and the item-to-total-score correlations (item-total correlations) ranged from 0.65 to 0.84, suggesting adequate reliability. The correlation between the ISI-K total score and PSQI-K was 0.84, which suggested adequate convergent validity. Low-to-moderate correlations were obtained between the ISI-K total score and PSG-defined sleep parameters: 0.22 for sleep onset latency, 0.38 for wake after sleep onset, and 0.46 for sleep efficiency. A cutoff score of 15.5 on the ISI-K was optimal for discriminating patients with insomnia. The test-retest scores over a 4-week interval with 34 subjects yielded a correlation coefficient of 0.86, suggesting excellent temporal stability.

Conclusions The findings of this study show that the ISI-K is a reliable and valid instrument for assessing the severity of insomnia in a Korean population. **J Clin Neurol 2014;10(3):210-215**

Key Words sleep, insomnia, reliability, validity.

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Introduction

Insomnia is one of the most common sleep disorders, with prevalence rates in general populations reportedly ranging from 12.8% to 38.3%,[1-3] including 22.8% in Koreans.[4] Insomnia can cause impairment of several daytime cognitive functions (e.g., attention, concentration, and memory)[5] that can lower efficiency at work[6,7] and increase the risks of injuries and traffic collisions[6,8] and of falls in older adults.[9] Insomnia is also a prevalent complaint in clinical practice that can present with several other comorbid medical or psychiatric disorders.[10] When left untreated, insomnia may aggravate or increase other conditions or delay recovery.[11-13] It is therefore necessary to recognize insomnia early and initiate the appropriate treatment.

Polysomnography (PSG) is regarded as a reliable method for obtaining objective information on several sleep parameters. However, it is expensive and is not recommended for routine screening for insomnia. On the other hand, the Korean version of the Pittsburgh Sleep Quality Index (PSQI-K)[14] and the Korean version of the Epworth Sleepiness Scale (KESS)[15] are reliable and valid instruments for subjectively assessing sleep quality, sleep disturbances, and daytime sleepiness, but neither of these instruments is specifically designed for assessing insomnia.

The Insomnia Severity Index (ISI) is a brief self-report ques-

tionnaire that measures the patient's perception of insomnia severity.[16] The ISI has been validated for several age groups from adolescence[17] to the elderly,[18] and is reported to be a useful assessment instrument for individuals with psychiatric diseases,[19,20] cancer,[21] and other clinical diseases.[16,22,23] The ISI has been translated into several languages, including Chinese,[24] Hindi,[25] Spanish,[26] and Arabic,[27] with these language versions demonstrating adequate psychometric properties. However, there is no standardization for Korean. The purposes of the present study were to develop a Korean version of the ISI (ISI-K) using standard translation procedures, and to verify its validity and reliability as a screening measure of insomnia in a Korean population.

Methods

Translation of the ISI into Korean

The ISI comprises seven items that evaluate difficulty falling asleep and staying asleep, problems waking up too early, satisfaction with current sleep patterns, interference with daily functions, noticeability of impairment attributed to sleep problems, and distress caused by the sleep problem. Each of the ISI items is rated on a scale of 0−4; the total score ranges from 0 to 28, with a higher score indicating greater insomnia severity. The total ISI scores are divided into four subcategories: 0−7, no clinically significant insomnia; 8−14, subthreshold insomnia; 15−21, moderate insomnia; and 22−28, severe insomnia. A cutoff score of 15 has been used as the threshold for clinically significant insomnia, and a score below 8 has been used to define remission after treatment (i.e., no longer meets the criteria for insomnia).[28]

Linguistic validation was achieved by having two sleep specialists translate the original ISI questionnaire into Korean; the Korean version was then translated back into English by one sleep specialist and one linguist, both of whom were fluent in Korean and English. Comparison of the original ISI with the final back-translated version was performed by individuals who were fluent in both languages and who were not involved in the research study. The final ISI-K was obtained after completion of these standard procedures.

Subjects

A sample of patients was sequentially selected from those who visited a regional sleep center between August 2009 and May 2012; all participants were older than 18 years, and all met the criteria for one or more of the following disorders: primary insomnia, comorbid insomnia, or obstructive sleep apnea (OSA). The Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision is used to diagnose primary insomniacs, the primary complaint of which is difficulty initiating or maintaining sleep, or nonrestorative sleep, for at least 1 month.[29] Comorbid insomniacs meet the criteria of primary insomniacs, but are also diagnosed as simultaneously having another disease, such as a psychiatric disorder or medical disorder. Such comorbid disorders were diagnosed through an interview using sleep questionnaires. OSA was diagnosed for those with a Respiratory Disturbance Index greater than 5, based on the second edition of the International Classification of Sleep Disorders.[30]

All subjects completed the ISI-K, KESS,[15] second edition of the Beck Depression Inventory,[31] and PSQI-K,[14] and submitted to overnight PSG. In order to examine test-retest reliability, 34 subjects were randomly selected to undergo a retest at a 4-week interval without treatment. The required sample size was calculated using the G-power 3.1.3 program based on an effect size of dz=0.5, an error probability of 0.05, and a statistical power of 0.80.

The PSQI-K and PSG were used as a subjective and an objective gold standard, respectively. The PSQI is a widely used measure of sleep quality[32] and has been used in previous studies as a convergent measure with ISI in other language versions.[24,26,27] PSG was used as the primary diagnosis tool for other sleep disorders, and as a complementary instrument for the evaluation of insomnia, although it is not indicated for the routine evaluation of this condition.[33,34]

The study and all procedures were approved by the institutional review board of a regional university hospital in Korea.

Statistical analysis

The data analyses were performed using SPSS version 18.0 (SPSS Inc., Chicago, IL, USA). The data are presented as mean±SD values, and $p<0.05$ was considered indicative of statistical significance. Descriptive statistics were used for examining the demographic data, test-retest reliability was examined with a paired-samples *t*-test, and internal consistency was examined with Cronbach's alpha coefficient. The correlations between ISI-K, KESS, and PSQI-K scores and various sleep parameters from PSG [sleep onset latency (SOL), wake after sleep onset (WASO), and sleep efficiency] were examined using Pearson's correlation coefficient. In addition, the receiver operating characteristic (ROC) curve was used to determine the optimal cutoff score based on its sensitivity and specificity; a perfect medical test would have 100% sensitivity and 100% specificity, corresponding to the upper left-hand corner (0, 1) on the ROC curve.[35-37] The discriminative ability of the test across the full range of cutoffs was reflected by the area under the curve (AUC).[35] A perfect test would have an AUC of 1.0; a commonly applied rule of thumb is that a test with an AUC greater than 0.9 has high accuracy, while 0.7−0.9 indicates moderate accuracy, 0.5−0.7 indicates low accuracy, and 0.5 is considered a chance result.[38,39]

Table 1. Demographic and clinical characteristics of the subjects

	Insomnia		OSA	Total
	Primary (*n*=169)	Comorbid (*n*=133)	(*n*=312)	(*n*=614)
Age (years)	55.5±11.6	52.3±13.5	45.5±13.5	49.8±13.7
Female, n (%)	104 (61.2)	86 (64.7)	44 (14.1)	234 (38.0)
BMI (kg/m^2)	23.3±2.8	23.0±4.0	26.0±5.3	24.6±4.7
PSG				
SOL (min)	34.0±48.7	34.2±51.4	12.0±22.0	22.9±39.8
WASO (min)	147.8±75.4	112.0±76.5	68.1±59.2	99.6±76.0
SE (%)	59.3±20.6	68.3±21.9	82.3±13.9	72.9±20.5
N1 (%TST)	18.2±11.9	16.4±12.3	10.7±6.3	14.7±10.7
N2 (%TST)	46.5±12.0	51.8±35.5	42.8±10.2	46.5±21.0
N3 (%TST)	19.2±12.3	17.2±14.2	24.3±8.7	20.7±12.0
REM (%TST)	15.5±9.1	18.9±9.8	13.2±11.7	15.1±10.9
RDI	1.7±3.2	1.6±3.4	29.6±21.8	15.9±21.0
Arousal index, total	9.9±6.2	10.4±5.8	28.5±19.9	19.5±17.4
O_2 saturation	96.4±1.2	96.6±1.2	94.9±2.4	95.7±2.1
KESS score	3.3±3.9	5.0±4.6	8.2±4.0	6.2±4.6
PSQI-K score	15.4±2.8	14.5±3.4	7.4±3.3	11.1±4.9
ISI-K score	22.8±4.3	22.2±4.9	10.4±5.6	16.4±7.9

Data are mean±SD or *n* (%) values.
BMI: body mass index, ISI-K: Korean version of the Insomnia Severity Index, KESS: Korean version of the Epworth Sleepiness Scale, N1: stage 1, N2: stage 2, N3: slow-wave sleep, PSG: polysomnography, PSQI-K: Korean version of the Pittsburg Sleep Quality Index, RDI: Respiratory Disturbance Index, REM: rapid eye movement, SE: sleep efficiency, SOL: sleep onset latency, TST: total sleep time, WASO: wake after sleep onset.

Results

Demographic characteristics

The entire sample comprised 614 patients with sleep disorders, including 169 with primary insomnia, 133 with comorbid insomnia, and 312 with OSA. The age was 49.8±13.7 years. The gender ratios (i.e., percentage of women) in the primary insomnia, comorbid insomnia, and OSA groups were 61.2%, 64.7%, and 14.1%, respectively. The sleep efficiency, SOL, WASO, and KESS, PSQI-K, and ISI-K scores were 72.9±20.5%, 22.9±39.8 min, 99.6±76.0 min, 6.2±4.6, 11.1±4.9, and 16.4±7.9, respectively. The other demographic and clinical characteristics of the subjects are listed in Table 1.

Reliability of the ISI-K

Cronbach's alpha of the ISI-K was 0.92, which indicated a high internal consistency, and did not change substantially even after deleting any of the items on the scale. The item-total correlations ranged from 0.65 to 0.84, suggesting good homogeneity of the items for measuring the severity of insomnia (Table 2). The test-retest correlation was 0.86 for the total score (p<0.001), and ranged from 0.43 to 0.85 (Table 3) for the seven components.

Table 2. Item-total correlations and Cronbach's alpha for the ISI-K (*n*=614)

Item	Corrected item-total correlation	Cronbach's alpha if item deleted
Initial	0.80	0.90
Middle	0.84	0.90
Terminal	0.74	0.91
Distress	0.80	0.91
Interference	0.74	0.91
Noticeability	0.65	0.92
Satisfaction	0.77	0.90
Cronbach's alpha	0.92	

ISI-K: Korean version of the Insomnia Severity Index.

Validity of the ISI-K

There was a strong positive correlation between the total ISI-K score and other subjective sleep assessment tools, and the PSQI-K score (r=0.84, p<0.01), suggesting that patients with more severe perceived insomnia also reported worse sleep quality; and a weak negative correlation with the KESS score (r=-0.29, p<0.01), indicating that those with more severe insomnia reported less daytime sleepiness (Table 4).

The correlations between ISI-K and PSG parameters were as follows: there was a weak positive correlation between item 1 of the ISI-K (difficulty falling asleep) and SOL (r=0.22, p< 0.01), a moderate positive correlation between item 2 of the

Table 3. Item-total correlations and Cronbach's alpha for the test-retest reliability of the ISI-K (*n*=34)

Item	Test score	Retest score	*r*	*p*
Initial	1.6±1.3	1.4±1.3	0.77	<0.001
Middle	1.8±1.3	1.6±1.3	0.68	<0.001
Terminal	1.4±1.3	1.3±1.3	0.73	<0.001
Distress	2.7±1.0	2.5±1.1	0.77	<0.001
Interference	1.9±1.2	1.5±0.9	0.51	0.002
Noticeability	1.9±1.4	1.7±1.1	0.43	0.010
Satisfaction	2.0±1.5	1.8±1.4	0.85	<0.001
Total score	13.6±7.7	12.1±6.7	0.86	<0.001

Data are mean±SD values.
ISI-K: Korean version of the Insomnia Severity Index.

Table 4. Correlations between ISI-K, PSQI-K, and KESS scores, and PSG data (*n*=614)

ISI-K	PSQI-K	KESS	PSG		
			SOL	WASO	SE
Initial			0.29*		
Middle				0.38*	
Total score	0.84*	–0.29*	0.22*	0.40*	–0.46*

*Correlation is significant at the 0.01 level (two-tailed).
ISI-K: Korean version of the Insomnia Severity Index, KESS: Korean version of the Epworth Sleepiness Scale, PSG: polysomnography, PSQI-K: Korean version of the Pittsburg Sleep Quality Index, SE: sleep efficiency, SOL: sleep onset latency, WASO: wake after sleep onset.

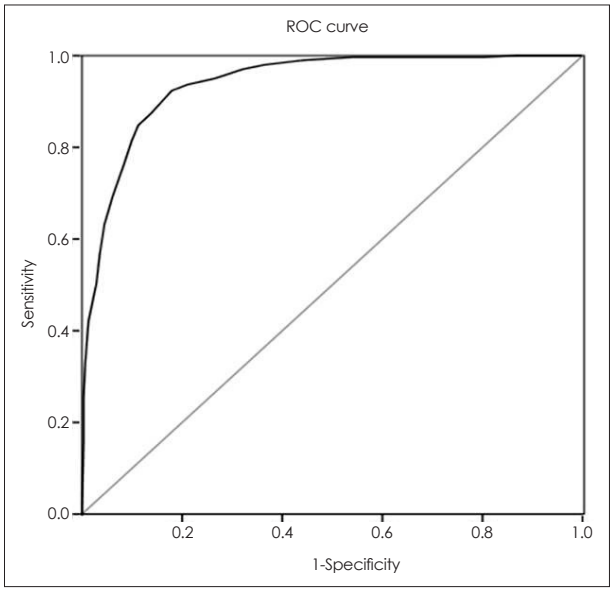

Fig. 1. Receiver operating characteristics (ROC) curve for the Korean version of the Insomnia Severity Index.

ISI-K (difficulty staying asleep) and WASO (r=0.38, p<0.01), and a moderate negative correlation between the total score of the ISI-K and sleep efficiency (r=-0.46, p<0.01) (Table 4).

The ROC curve was used to evaluate the sensitivity and specificity of the ISI-K (Fig. 1). An AUC of 0.93 (95% confidence interval=0.92−0.95) was obtained. The sensitivity and specificity values corresponding to various ISI-K cutoff scores for discriminating between patients with and without insomnia are presented in Table 5. A cutoff score of 15.5 had a sensitivity of 0.92 and specificity of 0.82.

Discussion

The findings of this study show that the ISI-K measures the severity of insomnia similarly to the original ISI.[16] There was a high degree of internal consistency, with the Cronbach's alpha of 0.92 exceeding the usually accepted value of 0.70.[40] The item-total correlations ranged from 0.65 to 0.84, thus also exceeding the usual accepted value of 0.30.[41] The value of Cronbach's alpha was higher than 0.74, which was first established for examining the validation of clinical tests,[16] and similar to those achieved by the Arabic[27] and Hindi[25] versions of the ISI (0.92 and 0.91, respectively). However, the item-total correlations of the current research were more stable than those of the Arabic[27] and Hindi[25] versions (0.49−0.92 and 0.56−0.87, respectively). For the test-retest reliability, the total score changed from 13.6±7.7 to 12.1±6.7 over the 4-week interval. The correlation coefficient for the test-retest total scores was high, at 0.86.

The present results suggest that the ISI-K exhibits good convergent/discriminant validity with other subjective sleep-related instruments measuring sleep quality (PSQI-K) and sleepiness (KESS). The ESS has been used widely to assess the propensity for daytime sleepiness, especially among patients with OSA.[15,42] Daytime sleepiness may be a consequence of inadequate sleep, but it is not a common complaint of patients with insomnia. There have been reports of patients with insomnia tending to have slightly elevated ESS scores (mostly among patients with comorbid OSA), but such elevations are not necessarily predictive of insomnia.[43] The present study found a correlation between the ISI-K and KESS, which may be due to some of the insomnia patients also having OSA. OSA patients achieved higher scores on the KESS and lower scores on the ISI-K, while insomnia patients tended to exhib-

Table 5. Sensitivity and specificity for various cutoff scores of the ISI-K

Cutoff score	Sensitivity	Specificity
5.50	0.99	0.19
6.50	0.99	0.25
7.50	0.99	0.31
8.50	0.99	0.39
9.50	0.99	0.45
10.50	0.99	0.55
11.50	0.98	0.63
12.50	0.97	0.67
13.50	0.95	0.73
14.50	0.93	0.78
15.50	0.92	0.82
16.50	0.87	0.86
17.50	0.84	0.88
18.50	0.81	0.90
19.50	0.76	0.91
20.50	0.69	0.93
21.50	0.63	0.95
22.50	0.56	0.96
23.50	0.50	0.97
24.50	0.42	0.98
25.50	0.32	0.99
26.50	0.25	0.99
27.50	0.16	0.99

ISI-K: Korean version of the Insomnia Severity Index.

it the opposite result. These results can be interpreted as showing that more severe insomnia can cause lower sleep quality, but that the severity of insomnia will not increase the severity of excessive daytime sleepiness.

We also used the PSG data as an objective measure of sleep; the ISI-K score exhibited a low-to-moderate correlation with various PSG parameters. The coefficient for the correlation between "difficulty falling asleep" on the ISI-K and SOL of the PSG was 0.29, which was lower than that found in the original research (0.45),[16] but similar to that found in research into insomnia among cancer patients (0.26).[21] The coefficient for the correlation between "difficulty staying asleep" on the ISI-K and WASO of the PSG was 0.38, which was a higher than that found in the original ISI study (0.16)[16] and in the aforementioned study on cancer patients (0.07).[21] The correlation between the total score of the ISI-K and sleep efficiency from the PSG (coefficient=-0.46) was stronger than that reported in the original ISI study (coefficient=-0.09).[16] Although the correlations between the ISI-K and PSG data were not especially strong in our study, they were statistically significant, and indicate the presence of adequate convergent validity.[16]

The ROC curve was used to evaluate the sensitivity and specificity of the ISI-K. The analysis showed that a cutoff score of 15.5 had a sensitivity and specificity of 0.92 and 0.81, respectively, and is similar to the optimal cutoff score found in the original study (15.0).[19] Thus, the ISI-K can be considered as a first-line tool for screening insomnia patients in Korean.

Our study was subject to some limitations. First, it was conducted at a regional sleep center in Korea and so was limited to community patients; however, since the questions of the ISI-K did not have local characteristics, there were no regional differences and hence the ISI-K did not need to be changed. Second, we did not include any healthy controls without sleep problems, and additional studies that include such participants are needed. Third, we did not strictly assess for the presence of comorbid disorders, such as psychiatric disorders.

In conclusion, within the limitations of this study, the ISI-K can be considered a valid and reliable tool for assessing the severity of insomnia in Koreans. In addition, it is useful as a simple screening tool to identify patients who suffer from insomnia.

Conflicts of Interest

The authors have no financial conflicts of interest.

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