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ORIGINAL ARTICLE

Validation of the Korean Version of the Scale for Outcomes in Parkinson's Disease-Autonomic

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JMD
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ABSTRACT

Objective Autonomic symptoms are commonly observed in patients with Parkinson's disease (PD) and often limit the activities of daily living. The Scale for Outcomes in Parkinson's disease-Autonomic (SCOPA-AUT) was developed to evaluate and quantify autonomic symptoms in PD. The goal of this study was to translate the original SCOPA-AUT, which was written in English, into Korean and to evaluate its reliability and validity for Korean PD patients.

Methods For the translation, the following processes were performed: forward translation, backward translation, expert review, pretest of the pre-final version and development of the final Korean version of SCOPA-AUT (K-SCOPA-AUT). In total, 127 patients with PD from 31 movement disorder clinics of university-affiliated hospitals in Korea were enrolled in this study. All patients were assessed using the K-SCOPA-AUT and other motor, non-motor, and quality of life scores. Test-retest reliability for the K-SCOPA-AUT was assessed over a time interval of 10–14 days.

Results The internal consistency and reliability of the K-SCOPA-AUT was 0.727 as measured by the mean Cronbach's α-coefficient. The test-retest correlation reliability was 0.859 by the Guttman split-half coefficient. The total K-SCOPA-AUT score showed a positive correlation with other non-motor symptoms [the Korean version of non-motor symptom scale (K-NMSS)], activities of daily living (Unified Parkinson's Disease Rating Scale part II) and quality of life [the Korean version of Parkinson's Disease Quality of Life 39 (K-PDQ39)].

Conclusion The K-SCOPA-AUT had good reliability and validity for the assessment of autonomic dysfunction in Korean PD patients. Autonomic symptom severities were associated with many other motor and non-motor impairments and influenced quality of life.

Key Words Autonomic; Parkinson's disease; Korean version; Scale for Outcomes in Parkinson's disease-Autonomic.

Autonomic dysfunctions are commonly observed in Parkinson's disease (PD), and some of these abnormalities are associated with debilitating complications.[1-3] Some autonomic manifestations appear before the motor symptoms[4-7] and are more prevalent as the disease progresses. They influence quality of life and treatment modality.[8,9]

The Scale for Outcomes in Parkinson's disease-Autonomic (SCOPA-AUT)[10] is a patient-reported questionnaire for the focused assessment of autonomic dysfunction in PD. It has been widely translated and validated in PD since its development in 2004 by Visser et al.,[10] and is composed of 25 items including five individual aspects: gastrointestinal (GI; 7 items), urinary (6 items), cardiovascular (3 items), thermoregulatory (4 items), pupillomotor (1 item), and sexual (2 items for men and 2 items for women) functions.

There is a lack of reliable questionnaires to assess the full spectrum of autonomic dysfunction in Korean patients with PD. In the present study, we translated the SCOPA-AUT into Korean and assessed the acceptability, reliability and validity of the Korean version of SCOPA-AUT (K-SCOPA-AUT) for use in Korean patients with PD. We also investigated the association between autonomic symptom severities and other Parkinsonian motor, non-motor, and quality of life scores.

MATERIALS & METHODS

Study participants

The Institutional Review Board at each participating hospital approved this study, and written informed consent was obtained from each study subject. The study was conducted as one of validating processes for assessing motor and nonmotor functions (SCOPAs, sleep scales, etc.) in Korean patients with PD by researcher group of Korean Movement Disorder Society.

All subjects were enrolled from 31 movement disorder clinics of university-affiliated hospitals in Korea. The inclusion criteria included consecutive Korean PD patients who met the diagnostic criteria of the United Kingdom Parkinson Disease Society Brain Bank[11] and were on stable doses of anti-Parkinson medications for at least 4 weeks prior to the study. The exclusion criteria were as follows: PD patients who 1) had neurological abnormalities related to atypical PD, 2) had secondary causes of PD such as drugs or structural brain lesions, 3) were taking antipsychotic medications including anti-depressants or

had a history of psychiatric diseases, or 4) had severe cognitive impairment [Korean version of Mini-Mental State Examination (K-MMSE) < 20].[12]

Translation

For the translation of the English version of the SCOPA-AUT[10] into Korean, the following processes were performed: forward translation and backward translation, expert committee review, pretest of the pre-final version and development of the final Korean version.

First, two independent bilingual translators translated the English version of the SCOPA-AUT into Korean, literally. A panel consisting of five authors (SB Koh, JS Kim, TB Ahn, SM Cheon, and SJ Kim) reviewed the translations to confirm a single forward translation. Another bilingual translator translated the Korean version draft of the SCOPA-AUT back into English. Second, discrepancies between the English version of the SCOPA-AUT and the Korean version of the SCOPA-AUT were evaluated by the panel. Third, interviews with four PD patients were conducted to test the interpretation of the translation. Through these processes, the final version of the K-SCOPA-AUT was obtained (Supplementary in the online-only Data Supplement).

Acceptability, reliability, and validity

The movement disorder specialists (all authors) conducted the following battery of standard assessment measures: a standard demographic and clinical characteristics form, levodopa equivalent dosage (LED),[13] modified Hoehn and Yahr (H&Y) score, Unified Parkinson's Disease Rating Scales (UPDRS) parts I, II, and III, K-MMSE, the Korean version of the Montreal Cognitive Assessment (MoCA-K),[14] the Korean version of the Montgomery-Asberg Depression Rating Scale (K-MADRS),[15] the Korean version of the Parkinson's Disease Quality of Life 39 (K-PDQ39)[16] and the Korean version of the Non-Motor Symptoms Scale (K-NMSS).[17] For the test-retest reliability, scales and/or questionnaires were completed twice, in separate situations, with a sufficient time interval of 10–14 days to minimize memory or practice effects.

Statistical analysis

Reliability was tested for both the internal consistency and stability of measures. Internal consistency was analyzed by Cronbach's α-coefficient.[18] The criterion value for Cronbach's α-coefficient was ≥ 0.70. Test-retest reliability was assessed by the Guttman split-half coefficient. Spearman's rank correlation coefficients were used to identify associations of the K-SCOPA-AUT score with other variables. SPSS 19.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

RESULTS

A total of 127 patients (males 64, females 63) were enrolled in this study. The demographic data are summarized in Table 1. The mean age was 66.6 ± 8.9 years, and the mean disease duration was 46.2 ± 46.5 months. Based on the modified H&Y score, there were 17 (13.4%) patients at stage 1, 58 (45.6%) at stage 2, 50 (39.3%) at stage 3, and 2 (1.6%) at stage 4 and 5, respectively. The LED was 384.3 ± 401.1 mg, and 41 (32.3%) patients were drug-naïve.

Table 2 shows the score in each domain and the total score from the K-SCOPA-AUT. The mean total sum of the K-SCOPA-AUT was 12.5 ± 8.2 (mean± SD) and ranged from 0 to 40. Four patients received a score of 0.

Cronbach's α-coefficient for the K-SCOPA-AUT was 0.727. All of the K-SCOPA-AUT items showed Cronbach's α coefficients of ≥ 0.70 except item 8 (Cronbach's α-coefficient = 0.695). The correlations between four of the five domains, except the sex-

Table 1. Demographic data of study subjects

Variables	
Age (years)	66.6 ± 8.9 (40–85)
No. of men (%)	64 (50.4)
Disease duration (months)	46.2 ± 46.5 (1–252)
LED (mg)	384.3 ± 401.1 (0–1,895)
H&Y	2.2 ± 0.7
UPDRS	
Part I	1.9 ± 1.9
Part II	7.5 ± 5.7
Part III	19.8 ± 10.9
K-MMSE	27.7 ± 2.2 (20–30)
MoCA-K	23.1 ± 4.2 (11–30)
K-NMSS	34.5 ± 26.0 (0–122)
K-MADRS	9.8 ± 8.8 (0–40)
K-PDQ39	31.7 ± 27.0 (0–122)

Data are shown as the mean ± standard deviation (range) or number (%). LED: levodopa equivalent dosage, H&Y: Hoehn and Yahr, UPDRS: Unified Parkinson's Disease Rating Scale, K-MMSE: Korean version of Mini-Mental State Examination, MoCA-K: Korean version of Montreal Cognitive Assessment, K-NMSS: Korean version of Non-Motor Symptoms Scale, K-MADRS: Korean version of Montgomery-Asberg Depression Rating Scale, K-PDQ39: Korean version of Parkinson's Disease Quality of Life 39.

JMD
J Mov Disord 2017;10(1):29-34

women domain, and the total K-SCOPA-AUT score were statistically significant [Spearman's rank correlation coefficient, (*r*S) = 0.298–0.641, all were $p < 0.05$] (Table 3). The test-retest reliability (The Guttman split half-coefficient) of the total K-SCOPA-AUT was 0.859, and each domain was between 0.666 and 0.906 (Table 3).

The total K-SCOPA-AUT score was 12.5 ± 8.2 (range, 0–40) out of a possible maximum of 69. The total K-SCOPA-AUT score was not related to increasing age and LED; however, it was weakly to moderately associated with motor severity scales (H&Y score, UPDRS part I, II, and III) and moderately to strongly associated with other non-motor symptoms (K-NMSS, K-MADRS) (Table 4). The total K-SCOPA-AUT score was negatively correlated with both the K-MMSE and MoCA-K scores (Table 4). The total K-SCOPA-AUT score was significantly and positively correlated with the PDQ-39 score.

In sub-domain analysis, the GI domain score was especially positively correlated with a wide range of motor and non-motor severity scores (H&Y score, UPDRS, K-NMSS, K-MADRS, and K-PDQ39) (Table 4). The urinary domain and cardiovascular domain scores were also positively related to H&Y score, UPDRS part II, K-NMSS, K-MADRS, and K-PDQ39 (Table 4). The thermoregulatory and pupillomotor domain scores were associated with increasing depression score (K-MADRS). The sex-women domain was not correlated with any of the demographic or disease characteristics data.

Table 2. Total and each domain scores of the Korean version of the Scale for Outcomes in Parkinson's disease-Autonomic (K-SCOPA-AUT)

K-SCOPA-AUT domains	Mean ± SD	Median (range)
Gastrointestinal	2.9 ± 3.0	2 (0–13)
Urinary	6.3 ± 4.6	5 (0–18)
Cardiovascular	1.0 ± 1.4	0 (0–7)
Thermoregulatory	0.9 ±1.4	0 (0–6)
Pupillomotor	0.4 ± 0.8	0 (0–3)
Sex (men)	0.9 ± 1.7	0 (0–6)
Sex (women)	0.4 ± 1.3	0 (0–6)
Total score	12.5 ± 8.2	11 (0–40)

Table 3. Test-retest reliability (Gutmann Split Half-coefficient) of the Korean version of the Scale for Outcomes in Parkinson's disease-Autonomic (K-SCOPA-AUT) domains and correlations between each domain score and the total K-SCOPA-AUT score.

K-SCOPA-AUT domains	Guttman Split Half-coefficient	Spearman's rank correlation	
		*r*S	*p* value
Gastrointestinal	0.883	0.641	< 0.001
Urinary	0.797	0.861	< 0.001
Cardiovascular	0.822	0.380	< 0.001
Thermoregulatory	0.666	0.325	< 0.001
Pupillomotor	0.720	0.324	< 0.001
Sex-men	0.906	0.298	0.001
Sex-women	0.884	0.127	0.243
Total K-SCOPA-AUT scores	0.859	-	-

DISCUSSION

Several researchers have suggested that the most common non-motor symptoms of PD are autonomic and that autonomic dysfunction is correlated with poor health-related quality of life.[1-7] A scale to evaluate and qualify the severity of autonomic symptoms is very important for the management of PD patients. This specialized scale assessing the full spectrum of autonomic symptoms has been translated and validated in many languages; however, this questionnaire has not yet been validated in Korean. Therefore, we translated the English version of the SCOPA-AUT[10] into Korean and evaluated its reliability and validity for use in Korean patients with PD.

Table 4. Correlation between the Korean version of the Scale for Outcomes in Parkinson's disease-Autonomic (SCOPA-AUT) scores and clinical features

SCOPA-AUT domains	Age	Disease duration	LED	H&Y	UPDRS part I	UPDRS part II	UPDRS part III	K-MMSE	K-NMSS	K-MADRS	K-PDQ39
Gastrointestinal	0.133	0.225*	0.233†	0.339†	0.357†	0.310†	0.153	-0.126	0.414†	0.250†	0.393†
Urinary	0.112	0.156	0.069	0.220*	0.301†	0.375†	0.143	-0.156	0.621†	0.358†	0.483†
Cardiovascular	-0.072	-0.055	0.026	0.192*	0.161	0.213*	0.141	-0.102	0.234†	0.302†	0.324†
Thermoregulatory	-0.091	0.148	0.049	0.044	0.091	0.138	0.116	0.003	0.153	0.214*	0.226*
Pupillomotor	-0.144	0.029	-0.049	-0.002	0.212*	0.133	0.058	0.032	0.154	0.228†	0.154
Sex-men	-0.285†	0.011	0.206*	0.068	0.015	0.185	0.108	0.064	0.096	-0.036	0.007
Sex-women	-0.117	0.107	0.020	-0.141	0.052	0.031	-0.121	-0.122	-0.091	-0.011	-0.106
Total	0.037	0.215*	0.171	0.312†	0.324†	0.446†	0.193*	-0.178*	0.640†	0.387†	0.527†

*Spearman's rank correlation test, $p<0.05$, †Spearman's rank correlation test, $p<0.001$. H&Y: Hoehn and Yahr stage score, K-MADRS: Korean version of Montgomery-Asberg Depression Rating Scale, K-MMSE: Korean version of Mini-Mental Status Examination, K-NMSS: Korean version of Non-Motor Symptoms Scales, LED: levodopa equivalent dosage, K-PDQ39: Korean version of Parkinson's Disease Quality of Life 39, UPDRS: Unified Parkinson's Disease Rating Scale.

The internal consistency and reliability of the K-SCOPA-AUT was 0.727 by Cronbach's α-coefficient, and the test-retest correlation reliability of the total K-SCOPA-AUT was 0.859 measured by the Guttman Split Half-coefficient, which are both considered to indicate acceptable reliability. However, in the sub-analysis of each item and the domain scores, Cronbach's α-coefficient of item 8 (0.695) and the Guttman split half-coefficient of the thermoregulatory domain (0.666) lacked an acceptable range.

Previous studies have suggested the existence of correlations between the total SCOPA-AUT score and increasing age,[19,20] disease severity,[19] disease duration,[20] and dopaminergic medication dosage;[10,19] however, the correlations were not consistent among the studies. In this study, the total SCOPA-AUT score was not significantly associated with increasing age and levodopa dosage, but it was significantly associated with motor severity scales (H&Y, UPDRS part I, II, and III). The mean total SCOPA-AUT score measured in this study population (12.5 ± 8.2) was lower than the reported scores (> 20) of previous reports.[10,20] A possible explanation is that our PD patients had milder disease severity, shorter disease duration and were taking lower doses of levodopa compared with the other studies. Furthermore, a considerable number (32.3%) of drug-naïve PD patients were enrolled in this study. Therefore, the SCOPA-AUT results in this study may represent autonomic features of PD patients with mild to moderate severity. As expected, the total SCOPA-AUT score was related to non-motor scales (K-NMSS and K-MADRS) and the quality of life scale (K-PDQ-39).

In the sub-score analysis, the GI domain score was positively correlated with disease duration, LED, and a wide range of motor and non-motor severity scores (H&Y, UPDRS part I, II, III, K-NMSS, and K-MADRS), as well as the quality of life score (K-PDQ39). The urinary domain and cardiovascular domain scores were also positively correlated with H&Y, UPDRS part II, K-NMSS, K-MADRS, and K-PDQ39. The thermoregulatory and pupillomotor domain scores were positively correlated with the depression score (K-MADRS). Sexual items in women were not correlated with any of the demographic, disease severity, other autonomic domain scores or total K-SCOPA-AUT score. A total of 61.9% female patients left the sexual items blank or scored 'not applicable' on the sexual items (question 24 and 25), but they all answered properly in the other K-SCOPA-AUT items. This is consistent with other preceding studies.[10,19,20] The discrepancy may be associated with a reluctant attitude about sexual dysfunctions due to ethical and cultural backgrounds, leading patients to withhold this information from a physician. A high rate (29.7%) of missing values or scores of 'not applicable' were also found in men for sexual items, which was again consistent with previous studies. The total K-SCOPA-AUT score, the GI domain sub-score, and the urinary domain sub-score were moderately to strongly correlated with the K-NMSS score, which indicated that these scores could be used with the K-NMSS to detect autonomic symptoms in PD patients as well.

In conclusion, the K-SCOPA-AUT is a reliable and valid assessment tool for evaluating the autonomic features of Korean PD patients. Autonomic symptom severities measured by the K-SCOPA-AUT were associated with many other motor and non-motor impairments and influenced quality of life.

Supplementary Materials

The online-only Data Supplement is available with this article at https://doi.org/10.14802/jmd.16057.

Conflicts of Interest

The authors have no financial conflicts of interest.

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