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Title: Reliability of the Japanese version of the Scales for Outcomes in Parkinson's Disease-Autonomic questionnaire

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## Abstract

**Objective:** The Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-AUT) questionnaire was used to assess autonomic dysfunction in patients with neurological disorders. The aim of this study was to evaluate the reliability of the Japanese version of the SCOPA-AUT.

**Methods:** We translated the SCOPA-AUT from English to Japanese. Thirty-one patients with diseases involving autonomic symptoms completed the form twice. The reliability was assessed by Cronbach's coefficient alphas and intraclass correlation coefficients (ICCs).

**Results:** The average (standard deviation, SD) total scores of the first and second assessments of the SCOPA-AUT were 15.7 (SD, 7.1) and 13.6 (SD, 6.5), respectively. The Cronbach's coefficient alphas were globally high, but the ICCs were moderately high. The valid response rates for the questions about sexual dysfunction were 36.7% in men and 26.6% in women.

**Conclusions:** The Japanese version of the SCOPA-AUT had high internal consistency. However, the questions about sexual dysfunction showed less valid response rates.

## Introduction

Some neurological disorders involve autonomic dysfunction. Reliable objective scales of these diseases have not been developed for use in clinical trials. The Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-AUT) questionnaire was developed for assessing autonomic dysfunction in patients with Parkinson's disease (PD) [1]. It consists of 25 items (gastrointestinal dysfunction, urinary dysfunction, cardiovascular dysfunction, thermoregulatory dysfunction, pupillomotor dysfunction, sexual dysfunction for men, and sexual dysfunction for women), and patients choose the applicable options on the form. Each item is scored from 0 (no symptoms) to 3 (severe), and the total score ranges from 0 to 69 for both men and women. The English and Portuguese versions of the SCOPA-AUT have been validated [2], but the Japanese version of the SCOPA-AUT has not been published nor tested for its reliability. The SCOPA-AUT can be applied to patients with various neurological disorders because it has recently been used to assess non-PD patients, such as those with multiple system atrophy (MSA) and Huntington's disease [3][4]. Thus, we prepared the Japanese version of the SCOPA-AUT. The purpose of this study was to confirm its reliability in patients with diverse neurological disorders.

## Materials and Methods

We conducted this prospective, single-institution, observational study with hospitalized patients and outpatients of the Department of Neurology of Hokkaido University Hospital between October 2012 and November 2012. All study patients had been diagnosed with some kind of neurological

disorder that was accompanied by autonomic dysfunction. We set the target sample size as “31 patients.” This was because the intraclass correlation coefficients in the two evaluations were expected to be  $\sim 0.85$  at 95% confidence interval, which had an accuracy of 0.2 in 31 persons. Previous studies about SCOPA-AUT were conducted in a larger population; however, the validation study of Scale for the Assessment and Rating of Ataxia (SARA) was performed in a smaller group (n=27), and the validity was confirmed [5]. This study was approved by the institutional review board of Hokkaido University Hospital. Prior to the study, written informed consents were obtained from all participants. Those who disagreed to participate in the study or who had severe cognitive impairment making no sense of questionnaires were excluded.

The SCOPA-AUT was translated by native Japanese speakers from English to Japanese. The Japanese version of the SCOPA-AUT was translated back into English by native English speakers. The back translation was compared to the English version and then modified. The final translation was established as the Japanese version of the SCOPA-AUT. We obtained permission to use the questionnaire from the SCOPA research group in the Netherlands.

At first, patients or their family (if a patient could not write because of upper limb disturbance) chose the appropriate options on the Japanese version of the SCOPA-AUT, and they completed the form again 1 to 4 weeks later. Two trials were performed at the neurology ward or clinic.

The amassed data were subjected to linkable anonymizing. Statistical analyses were then performed.

## Statistical analysis

JMP® Pro 10.0.0 (SAS Institute Inc., Cary, NC, USA) was used for the statistical analysis. The total score and every particular item on the SCOPA-AUT were analyzed with Cronbach's coefficient alphas and intraclass correlation coefficients (ICCs). The items were considered to have high internal consistency if the Cronbach's coefficient alphas were more than 0.8. The ICCs were interpreted to be in conformity to the reference as slight (0.000 to 0.200), fair (0.201 to 0.400), moderate (0.401 to 0.600), substantial (0.601 to 0.800), or almost perfect (0.801 to 1.000) [6]. The mean values are presented with standard deviations (SD).

## Results

Thirty-two patients were enrolled, but 1 patient was excluded because of a schedule conflict. The demographics of the 31 study patients (male/female, 15/16) are shown in Supplementary Table. The mean age was  $64.8 \pm 12.9$  years (range, 30 to 82 years). The study patients included 9 with MSA, 8 with PD, 5 with myelopathy, and 9 with other diseases. Patients showing severe autonomic dysfunction that significantly affected their activity of daily living and cognitive impairment were not included.

Table 1 shows the statistical parameters of the SCOPA-AUT Japanese version. The mean total scores for the first and second assessments were  $15.677 \pm 7.091$  ( $n = 69$ ; range, 6–31) and  $13.580 \pm 6.534$  ( $n = 69$ ; range, 3–29), respectively. The ICC of the total SCOPA-AUT score was 0.644, and the Cronbach's coefficient alpha was 0.877. Cronbach's coefficient alphas of all of the items were more

than 0.8. Total invalid answers were '45' in the first assessment and '53' in the second assessment. '45' meant 3 blank answers + 42 'use catheter' and 'not applicable', and '53' meant 6 blank answers + 47 'use catheter' and 'not applicable'. These invalid answers were not included in the total score. The participants could choose the option "use catheter" in items 8 to 13 and "not applicable" in items 22 to 25. In the 4 questions about sexual dysfunction, items 22 to 25, there were 62 replies in total, and 20 responses in the first assessment and 19 responses in the second assessment were valid. The valid response rates for the questions about sexual dysfunction were 31.5% in total, 36.7% in the men, and 26.6% in the women. The patients who chose "not applicable" were older than the patients providing valid responses, but this difference was not statistically significant (former: 67.6-year-old males and 68.4-year-old females vs. the latter: 58.1-year-old males and 60.3-year-old females).

For the ICC, items 7, 15, 22, 23, and 25 were evaluated as almost perfect. The total score and items 2, 4, 8, 9, 11, 13, 14, and 19 were substantial, items 1, 3, 6, 10, and 12 were moderate, items 5, 18, 20, and 21 were fair, and item 17 was slight. In items 16 and 24, ICCs could not be calculated because none of the participants had symptoms, and, thus, they had zero scores.

There was a significant correlation between each item and the domain. In addition, each domain was positively correlated with the total score. The ICCs were high for the following, as shown in Table 1: sexual dysfunction in women (items 24 and 25), sexual dysfunction in men (items 22 and 23), cardiovascular dysfunction (items 14 to 16), gastrointestinal dysfunction (items 1 to 7), pupillomotor dysfunction (item 19), urinary dysfunction (items 8 to 13), and thermoregulatory

dysfunction (items 17, 18, 20, and 21). The Cronbach's coefficients were high in all of the domains.

## Discussion

This study, which included patients with various neurological disorders, had similar results as those of previous reports of patients with PD. Although the SCOPA-AUT was developed to estimate autonomic dysfunctions in PD patients, it can provide useful data for patients with other neurological diseases.

The SCOPA-AUT has been reported to be helpful for evaluating Asian patients with PD [7]. This study showed that the SCOPA-AUT was useful not only in Asian patients with PD, but also in Asian patients with other neurological disorders.

The Cronbach's coefficient alphas were more than 0.8 for the total score and for all items, suggesting high internal consistency. Cronbach's coefficient alphas of the total score were almost equal before and after excluding the items which had low valid response rates (item 22, 23, 24 and 25). It meant these 4 items, indeed, had no large effect on SCOPA-AUT overall. However, most of the ICCs were moderate, and the test-retest reliability of the Japanese version of the SCOPA-AUT was substantial. This result was considered equal to those of previous studies (ICCs: 0.71 to 0.87) [1][2]. The questions about thermoregulatory dysfunction showed low ICCs, suggesting that the participants' feelings of temperature varied because this study was conducted when the seasons changed.

The small number of valid response for items 22, 23, and 25 may have influenced the high ICCs.

However, the low ICCs may reflect the inclusion of patients with different diseases compared to those examined in previous studies. The earlier study on the use of the SCOPA-AUT in patients with MSA [3] was more heterogeneous than those studies that included only patients with PD. Thus, the SCOPA-AUT may be suitable for screening nonhomogeneous diseases, such as MSA.

The average total scores of this study were 13.580 and 15.677 for the first and second assessment, respectively. This was lower than those of previous reports (18.8–23.0). Item 16 shows all zeros, indicating that no one fell unconscious in the previous 6 months. This suggested that our study group consisted of patients with less severe dysautonomia. The lower average score in this study compared to those for the English or Portuguese versions suggests the same thing.

There were not many invalid answers, except for questions about sexual dysfunction. This tendency was compatible with previous reports. In this study, there were 0.4–0.8% missing answers, and there were 5.9–6.6% invalid answers for all of the items, which was similar to a previous study (0.8–1.0%) [3]. Invalid answers accounted for more than two-thirds of the questions about sexual dysfunction. The Portuguese version showed “not applicable” data for 56.9% of the women and 10.6% of the men [2]. In the original version, there were 13% missing data, and “not applicable” accounted for 50% [1]. The most feasible reasons for the many invalid responses were presumed to be the lack of a partner and a sense of shame [2]. This study also suggested this because the mean age of the patients with invalid responses was older than those with valid answers. Alternatively, this may imply that the Japanese are more reserved. A more appropriate approach for evaluating sexual dysfunction needs to be developed.

The limitations of this study were as follows: (i) a control group consisting of individuals without any autonomic dysfunction or neurological disorder was not included in this analysis, (ii) severe cognitive impairment were excluded, but mild cognitive impairment may be included because accurate cognitive function tests such as Mini-Mental State Examination were not evaluated, and (iii) analyses based on each disease were not conducted. These two aspects must be explored in detail while conducting a more stringent validation study.

## Conclusions

The Japanese version of the SCOPA-AUT had high internal consistency, and it may be applied to patients with various neurological disorders other than PD. It is preferable that the SCOPA-AUT is used for screening nonhomogenous groups, as in this study. However, it is difficult to get a high response rate to questions about sexual dysfunction.

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Table 1. Statistical parameters of the Japanese version of the Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-AUT) questionnaire.

Item	First assessment			Second assessment			ICC	Cronbach's coefficient alpha
	Mean	SD	Missing answers	Mean	SD	Missing answers		
1 Swallowing/choking	0.677	0.832	0	0.581	0.620	0	0.550	0.888
2 Sialorrea	0.321	0.541	0	0.321	0.541	0	0.667	0.890
3 Dysphagia	0.387	0.715	0	0.226	0.425	0	0.591	0.887
4 Abdominal fullness	0.500	0.731	1	0.677	0.909	0	0.611	0.888
5 Constipation	1.548	1.060	0	1.355	1.018	0	0.341	0.889
6 Straining for defecation	1.452	1.207	0	1.194	1.046	0	0.550	0.888
7 Fecal incontinence	0.194	0.601	0	0.194	0.601	0	0.911	0.891
8 Urinary urgency	0.800	0.805	1	0.600	0.724	1	0.653	0.888
9 Urinary incontinence	0.742	0.855	0	0.552	0.632	2	0.740	0.886
10 Incomplete emptying	0.645	0.950	0	0.467	0.571	1	0.597	0.889
11 Weak stream of urine	1.129	0.957	0	1.167	0.910	1	0.677	0.886
12 Urinary frequency	1.032	0.912	0	0.900	0.662	1	0.428	0.886
13 Nocturia	1.710	0.902	0	1.621	0.942	2	0.653	0.891
14 Lightheadedness (standing up)	1.000	1.095	0	0.742	0.815	0	0.663	0.888
15 Lightheadedness (standing for some time)	0.774	0.921	0	0.633	0.809	1	0.803	0.888
16 Syncope	0.000	0.000	0	0.000	0.000	0	*	0.896
17 Hyperhidrosis (day)	0.452	0.723	0	0.548	0.810	0	0.199	0.891
18 Hyperhidrosis (night)	0.433	0.728	1	0.323	0.653	0	0.369	0.892
19 Oversensitive to bright light	0.419	0.620	0	0.355	0.551	0	0.624	0.890

20 Cold intolerance	0.387	0.615	0	0.267	0.521	1	0.392	0.896
21 Heat intolerance	0.484	0.677	0	0.516	0.769	0	0.222	0.890
22 Erection problem	1.571	1.134	8	1.667	1.211	9	0.942	0.883
23 Ejaculation problem	1.600	1.517	10	2.000	1.414	11	1.000	0.884
24 Vaginal lubrication	0.000	0.000	12	0.000	0.000	11	*	0.896
25 Problems with orgasm	0.250	0.500	12	0.250	0.500	12	1.000	0.888
<b>Total</b>	<b>15.677</b>	<b>7.208</b>	<b>45</b>	<b>13.580</b>	<b>6.642</b>	<b>53</b>	<b>0.644</b>	<b>0.877</b>
Gastrointestinal	5.065	3.463	1	4.548	3.139	0	0.625	0.882
Urinary	6.032	3.755	1	5.065	3.010	8	0.494	0.883
Cardiovascular	1.774	1.944	0	1.355	1.539	1	0.800	0.887
Thermo	1.742	1.483	0	1.645	1.836	1	0.089	0.888
Pupillomotor	0.419	0.620	1	0.355	0.551	0	0.624	0.890
Sexual function, male	2.714	2.563	18	3.000	2.683	20	0.988	0.883
Sexual function, female	0.250	0.500	24	0.200	0.447	23	1.000	0.888

Items 22 and 23 were intended only for men, and items 24 and 25 were intended only for women.

Abbreviations: SD, standard deviation, ICC: intraclass coefficient.

\*The ICCs of items 16 and 24 could not be calculated because their variances were zero.

Supplementary Table. Demographic data of the patients.

Characteristic	Outcome
Patients, n	31
Gender, male/female, n	15/16
Age, years, mean $\pm$ SD	64.8 $\pm$ 13.1
Disease, n	
Multiple system atrophy	9
Parkinson's disease	8
Myelopathy	5
Other parkinsonism	3
Multiple sclerosis	3
Myelitis	1
Spinocerebellar degeneration	1
Pure autonomic failure	1