

SCIENTIFIC INVESTIGATIONS

## Health-Related Quality of Life Among Drug-Naïve Patients with Narcolepsy with Cataplexy, Narcolepsy Without Cataplexy, and Idiopathic Hypersomnia Without Long Sleep Time

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**Objective:** To evaluate the health-related quality life (HRQOL) of drug-naïve patients with narcolepsy with cataplexy (NA with CA), narcolepsy without cataplexy (NA without CA) and idiopathic hypersomnia without long sleep time (IHS without LST), and to explore the factors influencing the HRQOL. Factors associated with the occurrence of automobile accidents are also discussed.

**Methods:** A total of 137 consecutive drug naïve patients who met the criteria of the 2nd edition of the *International Classification of Sleep Disorders* (NA with CA, n = 28; NA without CA, n = 27; IHS without LST, n = 82) were enrolled. The patients were asked to fill out questionnaires, including the SF-36, Epworth Sleepiness Scale (ESS), sociodemographic variables, and items regarding driving habits and the experiences related to automobile accidents.

**Results:** All 3 diagnostic groups had significantly lower scores in most SF-36 domains compared with Japanese normative data. Significant differences among the 3 diagnostic groups were not observed. Specific factors in SF-36 domains were not found with multiple linear regres-

sion analyses, while disease duration was positively correlated with mental health among all subjects. Among the patients reporting driving habits, ESS score ( $\geq 16$ ) was positively associated with the experience of automobile accidents.

**Conclusions:** Our results indicated that HRQOL decreases in drug-naïve patients with hypersomnia, but neither disease category nor severity of the disorder appears as an associated factor. Increased severity of hypersomnia, however, was thought to play an important role in the occurrence of automobile accidents.

**Keywords:** Narcolepsy, idiopathic hypersomnia without long sleep time, health-related quality of life, SF-36, automobile accidents

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Hypersomnia, a complaint of excessive daytime sleep or sleepiness, affects 9% to 17% of the general population,<sup>1-4</sup> with an impact on the functions of daily life. Some previous studies provided the data suggesting that patients with narcolepsy suffer from severe limitations and difficulties in everyday life activities (school, job, interpersonal relationships, and social activities).<sup>5,6</sup> Studies using the 36-item short form (SF-36) showed that health-related quality of life (HRQOL) among patients with hypersomnias of central origin, especially narcolepsy, decreases in comparison to the general population.<sup>7-11</sup>

In the 2nd edition of the *International Classification of Sleep Disorders* (ICSD-2),<sup>12</sup> narcolepsy was classified into 2 categories focusing on the existence of cataplexy (i.e., narcolepsy with cataplexy [NA with CA] and without cataplexy [NA without CA]). Idiopathic hypersomnia without long sleep time

(IHS without LST), also known as NREM narcolepsy or essential hypersomnia, manifesting hypersomnolence similar to narcolepsy without REM sleep abnormality, was also classified as an independent category. Most studies related to HRQOL in patients with hypersomnia have been done on narcoleptic patients with and without psychostimulant medication, and no study has been conducted focusing on untreated patients in the above 3 diagnostic groups<sup>7-11</sup> Moreover, conclusive information about the association between clinical backgrounds and the impairment of HRQOL in these drug-naïve patients has not been obtained.

Excessive daytime sleepiness (EDS) while driving or performing other activities that require constant alertness is dangerous. Narcolepsy has marked effects on daytime performance and has been associated with an increased risk of automobile accidents, as well as accidents on the job and at home.<sup>13,14</sup> However, a relationship between the subjective severity of sleepiness and the occurrence of automobile accidents in the drug-naïve patients has not been elucidated.

The aims of the present study were as follows: (1) to evaluate HRQOL of drug-naïve patients with NA with CA, NA without

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CA, and IHS without LST; (2) to explore the factors influencing HRQOL; and (3) to clarify the association between clinical background factors including severity of sleepiness and occurrence of automobile accidents.

## METHODS

The present study was approved by the local ethics committee of the Japan Somnology Center. Informed consent was obtained from all the patients who participated in the study.

### Participants

Among patients  $\geq 20$  years who visited the outpatient clinic of the Japan Somnology Center seeking medical assistance, 137 consecutive drug-naïve patients with a diagnosis of NA with CA ( $n = 28$ ), NA without CA ( $n = 27$ ), or IHS without LST ( $n = 82$ ) who met the criteria of ICDSD-2<sup>12</sup> were enrolled between May 2003 and October 2004. Because of an insufficient number of patients, IHS with LST was not targeted in the present study. All subjects with NA without CA and IHS without LST underwent overnight polysomnography followed by a standard multiple sleep latency test (MSLT).<sup>15</sup> Among the subjects with NA with CA, 7 did not undergo MSLT, but each had a history of typical cataplexy and clear sleep onset REM periods during overnight polysomnography. The 21 remaining subjects with NA with CA and all the subjects with NA without CA had  $\geq 2$  SOREMP and  $< 8$  min mean sleep latency on MSLT. All subjects with IHS without LST showed  $\leq 8$  min of mean sleep latency and 0-1 SOREMP on MSLT. Diagnoses were made according to the above criteria by at least 2 board-certified sleep disorder expert psychiatrists. Patients with comorbidities of other sleep disorders (e.g., obstructive sleep apnea syndrome, periodic limb movement disorder, circadian rhythm sleep disorders), psychiatric disorders (including mood disorders) and other major medical illnesses, and patients taking sedatives habitually were completely excluded from this study.

### Measures

The participants were asked to fill out a questionnaire that included an instrument assessing dimensions of HRQOL, an instrument evaluating subjective sleepiness, questions regarding sociodemographic variables, and items regarding driving habits and the experiences of automobile accidents. Additional clinical information including demographic variables was also obtained from the participants' medical records.

### Medical Outcomes Study Short Form-36 Version 1.2

HRQOL was assessed by using the Japanese version of the Short Form-36 health survey questionnaire (SF-36, Ver. 1.2), a self-administered questionnaire that has been widely used and validated on Japanese general population.<sup>16-18</sup> The questionnaire comprises 36 questions divided into the following 8 domains representing different aspects of HRQOL.

1. *Physical functioning (PF)*, the subject's ability to deal with the physical requirement of life, such as attending to personal needs, walking, and flexibility.

2. *Role limitations due to physical problems (RP)*, the extent to which physical capabilities limit activity.
3. *Role limitations due to emotional problems (RE)* the extent, if any, to which emotional factors interfere with work or other activities.
4. *Social functioning (SF)*, the extent to which physical health or emotional problems have interfered with family, friends, and other social interactions during the previous 4 weeks.
5. *Mental health (MH)*, feelings of anxiety and depression.
6. *Energy/vitality (VT)*, feelings of pep, energy, and fatigue.
7. *Bodily pain (BP)*, perceived amount of pain experienced during the previous 4 weeks and the extent to which that pain interfered with normal work activities.
8. *General health perceptions (GH)*, general health in terms of personal perception.

### Epworth Sleepiness Scale

Subjective sleepiness was assessed at the time of the first visit, using the Epworth Sleepiness Scale (ESS),<sup>19</sup> a widely accepted self-completion questionnaire, previously validated on both the Japanese general population and patients with hypersomnia.<sup>20</sup> Participants were asked about the possibility of falling asleep in 8 specific situations that are commonly encountered in daily life (0 = would never doze; 3 = high chance of dozing). The ESS score is the sum of 8 item-scores and can range from 0 to 24.<sup>19</sup> The severity of subjective sleepiness was defined by the ESS score: normal (ESS score  $< 11$ ), mild ( $\geq 11$ ,  $< 16$ ) and severe ( $\geq 16$ ).<sup>21-23</sup>

### Sociodemographic Variables, Automobile Accidents, and Clinical Information

Sociodemographic variables included marital status, numbers of family members in the household, educational status, and occupation. Questions about driver's license, driving habit, and the experience of automobile accidents were embedded: "Have you ever been involved in automobile accidents or near-miss incidents while driving during the last 5 years?" Clinical information including age, gender, age at onset of hypersomnia, and length of its morbidity was also obtained.

### Statistical Analysis

Demographic, sociodemographic and clinical variables were compared among three diagnostic groups (NA with CA, NA without CA, and IHS without LST). One-way analysis of variance (ANOVA) was used for the comparison of the continuous variables among the 3 diagnostic groups, and the chi-squared test was employed for categorical variables.

The scores of 8 subscales of the SF-36 were converted into Japanese norm-based score according to their gender and age (standardized  $t$  score transformation with a mean of  $50 \pm 10$ ).<sup>18</sup> Scores below 50 indicate that health status is below average compared to the general Japanese population. This method enables comparison of the magnitude of impact among the 8 subscales, which reflects the recommendation of Japanese Manual of SF-36.<sup>18</sup> The scores of all subjects were compared with those

**Table 1**—Descriptive Variables Including Main Demographic and Clinical Features and Prevalence of Automobile Accidents in Each Diagnostic Group

characteristics	Overall	NA with CA	NA without CA	IHS without LST	p value
Number of participants	137	28	27	82	
Gender (%)					
Male	48.2	35.7	37.0	56.1	n.s.
Female	51.8	64.3	63.0	49.3	
Age (years)					
Mean ± SD	31.2 ± 9.2	33.2 ± 13.0	28.6 ± 8.6	31.4 ± 7.6	n.s.
Median (range)	28 (20-61)	28.5 (21-61)	26 (20-57)	29 (21-59)	
Age at onset (years)					
Mean ± SD	18.6 ± 6.7	18.8 ± 7.0	17.8 ± 4.2	18.8 ± 7.2	n.s.
Median (range)	18 (8-55)	18 (10-38)	18 (11-27)	17 (8-55)	
Disease duration (years)					
Mean ± SD	12.6 ± 8.5	14.4 ± 12.3	11.0 ± 8.7	12.5 ± 6.6	n.s.
Median (range)	11 (1-50)	11.5 (2-50)	8.5 (2-39)	12 (1-29)	
Marital status (%)					
Married	26.3	17.9	11.1	34.1	0.033
Not married	73.7	82.1	88.9	65.9	
Number of family members (%)					
≥ 1	60.6	75.0	40.7	62.2	n.s.
0	32.8	21.4	48.1	31.7	
missing	6.6	3.6	11.1	6.1	
Education (%)					
Junior high school	17.5	25.0	25.9	12.2	n.s.
Vocational school	19.0	14.3	18.5	20.7	
College or higher	59.1	57.1	55.6	61.0	
missing	4.4	3.6	0	6.1	
Occupation (%)					
Employed (full time)	64.7	60.7	55.6	68.3	n.s.
Employed (part time)	11.0	14.3	22.2	6.1	
Housewives	7.4	10.7	7.4	6.1	
Students	15.4	14.3	11.1	17.1	
missing	1.5	0	3.7	2.4	
Mean sleep latency on MSLT (Mean ± SD)	3.1 ± 2.1 (n = 130)	1.7 ± 1.6 (n = 21)	2.6 ± 2.7 (n = 27)	3.6 ± 1.8 <sup>a</sup> (n = 82)	< 0.001
ESS score					
Mean ± SD	14.8 ± 3.3	16.9 ± 2.8	14.5 ± 2.7 <sup>b</sup>	14.1 ± 3.3 <sup>c</sup>	< 0.001
0-10 (%)	9.5	0.0	7.4	13.4	
11-15 (%)	46.0	32.1	55.6	47.6	0.037
16-24 (%)	44.5	67.9	37.0	39.0	
N of having driving licence and driving habit	80	16	14	50	
Trouble while driving (%)					
automobile accidents or near-miss incidents	55.0	75.0	50.0	50.0	n.s.

NA, narcolepsy; CA, cataplexy; IHS, idiopathic hypersomnia; LST, long sleep time; MSLT, multiple sleep latency test; ESS, Epworth Sleepiness Scale; n.s. not significant. a) versus NA with CA,  $p < 0.001$ , Scheffe's test. b) versus NA with CA,  $p = 0.017$ , Scheffe's test. c) versus NA with CA,  $p < 0.001$ , Scheffe's test.

of the national normative scores among each diagnostic group by using Welch's test. Multiple linear regression analyses were performed to identify the factors associated with HRQOL as measured by the SF-36 scores among each diagnostic group. Gender (female/male), age, disease duration, and the ESS score were set as the independent variables.

After evaluating the rates of the patients with experiences of automobile accidents or near-miss incidents, multiple logistic regression analyses were performed to explore the factors associated with the occurrence of these accidents or near-miss incidents among the subject patients. The dependent variable was the experience of the occurrence of these accidents or near-

miss incidents, which were dichotomized for analysis (accident or near-miss incident / none). The independent variables were gender, age, disease duration, the diagnostic group, and the ESS score (normal / mild / severe).

Multiple linear regression analysis was performed to clarify the contribution of single covariates, including the experience of automobile accidents or near-miss incidents, to the SF-36 scales score among the subject patients having usual driving habits. Gender, age, disease duration, the diagnostic group, ESS score, and the experience of automobile accidents or near-miss incidents were set as the independent variables. Four participants who did not have a driver's license, 49 without usual driving habits, 2

**Table 2**—SF-36 Profiles of the Patients with Hypersomnia by Diagnostic Groups in Comparisons with National-Norm Scores

no. Subscale	overall n = 137		NA with CA n = 28		NA without CA n = 27		IHS without LST n = 82	
	Scale Scores§	p value†	Scale Scores§	p value†	Scale Scores§	p value†	Scale Scores§	p value†
PF	51.2 (8.4)	0.023	53.4 (6.1)	0.008	51.4 (5.7)	n.s.	50.5 (9.7)	n.s.
RP	36.1 (24.5)	< 0.001	38.7 (23.6)	0.020	33.0 (28.4)	0.004	36.2 (23.6)	< 0.001
BP	51.0 (11.1)	n.s.	53.9 (9.1)	0.036	53.0 (9.7)	n.s.	49.4 (12.0)	n.s.
GH	47.3 (10.8)	0.004	47.9 (8.2)	n.s.	49.0 (12.6)	n.s.	46.5 (10.9)	0.009
VT	43.8 (9.7)	< 0.001	45.7 (9.4)	0.026	44.0 (9.6)	0.003	43.1 (9.9)	< 0.001
SF	43.9 (12.6)	< 0.001	43.1 (12.0)	0.006	45.3 (12.7)	n.s.	43.7 (12.9)	< 0.001
RE	36.5 (22.6)	< 0.001	39.9 (25.6)	n.s.	33.4 (22.3)	0.001	36.4 (21.7)	< 0.001
MH	44.6 (10.6)	< 0.001	45.3 (11.6)	0.046	45.3 (11.1)	0.034	44.2 (10.1)	< 0.001

NA, narcolepsy; CA, cataplexy; IHS, idiopathic hypersomnia; LST, long sleep time. PF, physical health; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role emotional; MH, mental health; and n.s., not significant. §; Scale scores are made according to norm-based scoring (standardized t score transformation with a mean of  $50 \pm 10$ ), and parenthesis indicate standard deviation. †; vs national-norm scores.

who did not answer the question about the experience of accidents, and 2 who did not answer the item about a driver's license were excluded from the analysis about the accidents. As a result, 80 current drivers were included in the accident analyses.

## RESULTS

The descriptive variables for the main demographic and clinical features of the patients in each diagnostic group are shown in Table 1. Of 137 participants, 51.8% were female. The age range was 20 years to 61 years, with a median of 28 years. Demographic and clinical variables did not differ statistically among the 3 diagnostic groups except for marital status, the mean sleep latency on MSLT, and the ESS scores. Residual analysis revealed that the rates of married patients were significantly higher in IHS without LST ( $p < 0.01$ ), and were significantly lower in NA without CA ( $p < 0.05$ ). ANOVA showed that the mean sleep latency on MSLT differed significantly among the 3 diagnostic groups ( $F_{2,127} = 8.44$ ,  $p < 0.001$ ). Scheffe's post hoc test revealed that the mean sleep latency in the NA with CA group was significantly shorter than that of IHS without LST ( $p = 0.001$ ). ANOVA also showed that the ESS scores differed significantly among the 3 diagnostic groups ( $F_{2,134} = 7.53$ ,  $p < 0.001$ ). Scheffe's post hoc test revealed that the ESS scores in the NA with CA group were significantly higher than that of the other 2 groups (NA with CA vs. NA without CA,  $p = 0.012$ ; NA with CA vs. IHS without LST,  $p < 0.001$ ). Residual analysis revealed that the rates of patients with ESS scores between 16 from 24 were significantly higher in NA with CA ( $p < 0.01$ ).

### Comparison of Short Form-36 with Normative Data

As a total group, the patients had significantly lower SF-36 scores in all domains except PF and BP scales than age- and gender-matched Japanese normative data.

Although the scores of all 8 subscales of the SF-36 did not differ statistically among the 3 diagnostic groups, RP, VT, and MH were significantly lower in all these diagnostic groups than normative data. The SF was significantly lower in both the patients with NA with CA and IHS without LST; RE was significantly lower in both the patients with NA without CA and IHS without LST; and GH was significantly lower in the patients

with IHS without LST. In contrast, PF and BP were significantly higher in the patient group with NA with CA in comparison to normative data (Table 2).

### Factors Influencing the HRQOL

Multiple linear regression analyses showed that only disease duration was positively correlated with the ME among the total subjects ( $\beta = 0.248$ ,  $p = 0.048$ ,  $R^2 = 0.037$ ). In patients with NA with CA, a negative association between the RP and ESS scores was found in multiple linear regression analyses ( $\beta = -0.504$ ,  $p = 0.024$ ,  $R^2 = 0.225$ ). In patients with NA without CA, MH was positively associated with disease duration and being male ( $\beta = 0.960$ ,  $p = 0.007$ ,  $\beta = -0.404$ ,  $p = 0.017$ , respectively,  $R^2 = 0.551$ ) (Table 3).

### Automobile Accident Rates and Factors Associated with Automobile Accidents

Of the 80 current drivers, 44 patients (55.0%) had experienced at least one accident or near-miss incident during the preceding 5 years (Table 1). Table 4 shows the results of the logistic regression analysis. Only ESS scores were significantly associated with increased experience of automobile accident or near-miss incident (severe; OR = 14.63, 95% CI: 1.97 to 108.67). However, the experience of automobile accidents or near-miss incidents was not associated with any SF-36 scale scores among the subject current drivers with hypersomnia.

## DISCUSSION

Several studies have revealed that physical and mental components of HRQOL is decreased among the patients with insomnia<sup>24-27</sup> and among those with sleep apnea.<sup>28-30</sup> However, only a few studies have reported on HROQL of drug-naïve patients with hypersomnia, with comparison to the general population by diagnostic groups.<sup>9,10</sup> Vignatelli et al. found that drug-naïve patients with narcolepsy (newly diagnosed narcolepsy group) showed significantly lower scores in all subscales of SF-36 except for BP, when compared with scores of the general Italian population. Beusterien et al. also assessed SF-36 in a group of patients positive for narcolepsy based on the criteria of the 1st edition of *ICSD*

**Table 3**—Multiple Linear Regression Analyses: Contribution of Single Co-Variates to the SF-36 Scales Score by Diagnostic Groups

	NA with CA		NA without CA		IHS without LST	
	Standardized $\beta$	p value	Standardized $\beta$	p value	Standardized $\beta$	p value
<b>PF</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	—	—	—
<b>RP</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	-0.504	0.024	—	—	—	—
R <sup>2</sup>	—	0.225	—	—	—	—
<b>BP</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	—	—	—
<b>GH</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	—	—	—
<b>VT</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	—	—	—
<b>SF</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	—	—	—
<b>RE</b>						
gender	—	—	—	—	—	—
age	—	—	—	—	—	—
disease duration	—	—	—	—	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	—	—	—
<b>MH</b>						
gender	—	—	-0.404	0.017	—	—
age	—	—	—	—	—	—
disease duration	—	—	0.960	0.007	—	—
ESS	—	—	—	—	—	—
R <sup>2</sup>	—	—	—	0.551	—	—

NA, narcolepsy; CA, cataplexy; IHS, idiopathic hypersomnia; LST, long sleep time; ESS, Epworth Sleepiness Scale. PF, physical health; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role emotional; and MH, mental health. Standardized  $\beta$ , Standardized regression coefficient. R<sup>2</sup>, Coefficient of determination.

at baseline without medication in a clinical trial of modafinil, and showed that RP, VT, SF, and RE were significantly impaired in this group compared to the general US population. However, these studies did not focus on diagnostic categories (particularly the presence or absence of cataplexy in narcolepsy and idiopathic hypersomnia with or without long sleep time). The present study is the first to compare the HRQOL of consecutive drug-naïve

patients with hypersomnias of central origin—divided into NA with CA, NA without CA, and IHS without LST—with national normative data, and to investigate the factors influencing the HRQOL in each diagnostic group.

In the present study, drug-naïve patients within the categories of hypersomnias of central origin, showed all domains of HRQOL to be significantly poorer than those of the Japanese population norm

**Table 4**—Correlation Between the Descriptive Variables and the Involvement of Automobile Accidents or Near-Miss Incidents Among the Subject Patients Having Usual Driving Habits, as Assessed by Logistic Regression Analysis

	Crude			Adjusted		
	OR	95%CI	p value	OR	95%CI	p value
gender						
male						
female	0.88	0.36-2.17	n.s.	0.64	0.22-1.90	n.s.
age						
for every increase of one year	1.03	0.97-1.08	n.s.	1.01	0.92-1.10	n.s.
disease duration						
for every increase of one year	1.04	0.98-1.10	n.s.	1.03	0.95-1.13	n.s.
diagnosis						
IHS without LST						
NA with CA	3.00	0.85-10.58	n.s.	1.74	0.40-7.57	n.s.
NA without CA	1.00	0.31-3.27	n.s.	1.00	0.27-3.69	n.s.
ESS score						
0 - 10						
11 - 15	4.25	0.76-23.81	n.s.	4.68	0.66-33.06	n.s.
16 -24	12.06	2.12-68.54	0.005	14.63	1.97-108.67	0.009

OR, odds ratio; 95% CI, 95% confidence interval. NA, narcolepsy; CA, cataplexy; IHS, idiopathic hypersomnia; LST, long sleep time; ESS, Epworth Sleepiness Scale. n = 80

except for PF and BP. Interestingly, the present study showed that the HRQOL profile did not differ statistically among the 3 diagnostic groups, although patients with NA with CA presented more severe sleepiness than the other groups, demonstrated on both ESS score and mean sleep latency on MSLT. The severity of subjective sleepiness was significantly associated with RP only in the group of patients with NA with CA, but was not associated with any HRQOL domains in the total patient group. These findings suggest that the severity of subjective sleepiness does not act as a main factor for the decrease of HRQOL. The HRQOL profile of the group of NA with CA decreased in a fashion similar to that of the NA without CA group. Vignatelli et al. demonstrated that cataplexy did not show any correlation with SF-36 scales among patients with narcolepsy. These findings might indicate that the presence of cataplexy is unlikely to have an impact on the HRQOL among narcolepsy groups.

In our results, only disease duration was positively correlated with the MH among the total subjects. When multiple linear regression analyses were conducted in each diagnostic category, this tendency was significant in patients with NA without CA. This finding is in line with the previous report in which disease duration positively influenced the RP and the RE among drug-naïve patients with narcolepsy.<sup>9</sup> Considering that the illness remains stable for several years in the majority of patients with narcolepsy,<sup>31</sup> prolongation of morbidity might bring patients certain kinds of coping skills to manage disadvantage with the disorder.

The present study could not find common factors responsible for the decrease of SF-36 domains among 3 diagnostic groups, even in SF-36 scale scores which showed clearly lower values than that of the general population. We speculate that the decrease of HRQOL could be attributed to psychological, social, and environmental factors, such as lifestyle or social support rather than subjective sleepiness.

Several studies have reported on the risk of automobile accidents in patients with narcolepsy or idiopathic hypersomnia.<sup>14,32,33</sup> In the present study, 55% of current drivers had at least one automobile accident or near-miss incident in the last 5 years. This finding is comparable to a study reported by Aldrich et al. in

which 20% to 49% of current drivers with hypersomnia including narcolepsy or idiopathic hypersomnia had accidents, and 54% to 74% had near-miss incidents due to sleepiness.<sup>33</sup> Early diagnosis and treatment of patients with hypersomnias of central origin is important in prevention of automobile accidents. In the present study, multiple logistic analyses revealed that severe EDS was an independent factor for the experience of accidents while driving. Further studies are needed to determine whether effective treatment of hypersomnia reduces the occurrence of automobile accidents among the patients of this category.

In our results, the experience of automobile accidents or near-miss incidents was not associated with any SF-36 scale scores among the current drivers with hypersomnia. This finding might indicate that accidents and/or near-miss incidents themselves do not act as a associated factor for the deterioration of HRQOL among the participants with hypersomnia. However, it is possible that automobile accidents of our patients were not sufficiently serious to cause persistent damage to physiological and/or mental function of the participants. In addition, we should consider the possibility that those who died in an accident or those who had serious handicaps due to injuries in crashes were not included in the present study.

In conclusion, the present study demonstrated impairment in the mental component but not the physical component of the HRQOL among drug-naïve patients with hypersomnias of central origin. The impact on the magnitude of impairment of HRQOL was not different among the disease categories. The aggravation of the severity of subjective sleepiness was significantly associated with the increased risk of automobile accidents. Our findings strongly support the necessity of early treatment of patients with hypersomnia. Further prospective study on larger samples should be done to establish the strategies for both improving HRQOL and preventing automobile accidents among the patients of this category.

#### ABBREVIATIONS

HRQOL	health-related quality of life
SF-36	36-item short form health survey

ICSD-2	2nd edition of the <i>International Classification of Sleep Disorders</i>
NA with CA	narcolepsy with cataplexy
NA without CA	narcolepsy without cataplexy
IHS without LST	idiopathic hypersomnia without long sleep time
MLST	multiple sleep latency test
SOREMP	sleep onset rapid eye movement period
ESS	Epworth Sleepiness Scale
ANOVA	analysis of variance
PF	physical functioning
RP	role limitations due to physical problems
RE	role limitations due to emotional problems
SF	social functioning
MH	mental health
VT	energy/vitality
BP	bodily pain
GH	general health perceptions

### DISCLOSURE STATEMENT

This was not an industry supported study. The authors have indicated no financial conflicts of interest.

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