

Observational study of sleep-related disorders in Italian patients with Parkinson's disease: usefulness of the Italian version of Parkinson's disease sleep scale

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Abstract Sleep disturbances are common in patients with Parkinson's disease (PD). We aimed to evaluate prevalence and severity of nighttime sleep disturbances in Italian PD patients and to validate the Italian version of the Parkinson's disease sleep scale. A total of 221 PD patients and 57 healthy controls participated in a cross-sectional study with retest. PDSS, Epworth Sleepiness Scale (ESS), Hamilton Depression Rating Scale, Unified Parkinson's Disease Rating Scale (UPDRS), and Hoehn and Yahr staging were applied. PDSS total and individual items scores from patients were significantly lower than those in controls. Internal consistency of PDSS scale was satisfactory and intraclass correlation coefficient for test–retest reliability was 0.96 for total PDSS score. A significant negative correlation was found between total PDSS and ESS scores, and between total PDSS and HDRS scores. PDSS scores were also related to UPDRS sections II, III and IV, and H&Y stage. PDSS and ESS scores were not related to

levodopa equivalent dose. Daytime sleepiness, depressive symptoms and disease severity correlate with sleep disturbances in Italian PD patients. The PDSS is a valid and reliable tool to evaluate sleep disturbances in Italian patients.

Keywords Parkinson's disease · Sleep disturbances · PDSS · ESS

Introduction

Sleep disturbances are common in Parkinson's disease (PD), with a prevalence ranging from 60 to 90% of patients, with both impairment of nighttime sleep and excessive daytime sleepiness [1].

Many factors have been implicated including the use of dopaminergic therapy [2], coexisting depression [3], and more importantly the underlying disease itself [4–6]. Sleep disorders in PD appear to arise from a combination of neurochemical and neurodegenerative changes in central sleep regulatory centres [7–9].

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Antiparkinsonian medications may affect sleep since they act on motor and non-motor symptoms, including akinesia, nighttime pain and spasms, nycturia, dystonia upon awakening, and undesirable psychotic-like effects such as hallucinations [10]. On the other hand, increased daytime sleepiness has been associated to antiparkinsonian drug burden [11, 12], although this relationship remains controversial.

Appropriate assessment of sleep problems in PD could contribute to better patient management. The Parkinson's disease sleep scale (PDSS), a visual analogue scale of 15 items, has been developed as a specific clinical tool for assessment of sleep disorders in PD [13]. This scale has been recently recommended for evaluating overall sleep impairment as a screening tool and as a measure of severity by the Sleep Scale Task Force of the Movement Disorder Society [14]. The Task Force recognized that this scale has not been designed for, and is not sufficient to screen for specific sleep disorders in PD such as RLS and RSD [14].

This study was intended to evaluate prevalence and severity of nighttime sleep disturbances in Italian PD patients, and to validate the Italian version of the PDSS.

Patients and methods

This was a multi-center, observational, cross-sectional study with retest. Patients affected by PD and healthy controls were enrolled in seven Italian centres over 16 months. Translation of the original PDSS to Italian language was carried out by two independent professional translators; the translation was examined at a consensus meeting, back-translated and approved at a second consensus meeting. Italian version of the PDSS may be found in Supplementary material.

Inclusion criteria for patients and controls were as follows: age ranging between 40 and 80 years, and Mini-Mental State Examination (MMSE) [15] score ≥ 24 . Patients had to have a diagnosis of idiopathic PD according to the United Kingdom PD Society Brain Bank Criteria [16] and disease stage 1–4 on Hoehn & Yahr Modified Scale [17]. Exclusion criteria were as follows: presence of dementia, treatment with sedative or hypnotic medications, severe systemic diseases that might impede adequate assessment of PD and any other kind of inability to understand and complete self-assessment questionnaires. The study was approved by the Ethics Committees of participating centres. Prior to assessments, all subjects signed an informed consent.

In order to evaluate the relationship between sleep disorder and dopaminergic treatment, the daily levodopa equivalent dose was calculated for each patient [18].

On the first visit each subject was asked for the presence of sleep disturbance and then evaluated for cognitive state, depressive symptoms, daytime sleepiness and nighttime sleep quality by means of MMSE [15], Hamilton Depression Rating Scale (HDRS) [19], ESS [20], and PDSS [13]. PD patients were also evaluated by means of Unified PD Rating Scale (UPDRS). Moreover, caregivers were asked for the presence of “sudden, jerky and repetitive leg movements” and “dream-enacting behaviors including talking, punching, kicking, yelling” experienced by the patient while asleep, that could resemble PLMS and RSD, respectively. To evaluate test–retest reliability, all patients and controls completed PDSS one week after the first evaluation, under standardised conditions with the same neurologist administering the scale on each occasion.

All the collected data were analysed by means of descriptive statistics. The same descriptive statistics were also calculated in the group of patients split in two classes according to a cut-off value for HDRS (HDRS < 17 and HDRS ≥ 17) and ESS scales (ESS < 12 and ESS ≥ 12).

Internal consistency of the PDSS scale was evaluated using Cronbach's α coefficients (criterion value ≥ 0.70) and item-total corrected correlations (criterion value ≥ 0.30). Acceptability was explored by closeness of means to medians (arbitrary limit 10% of the maximum possible score), the ranges of scores, the skewness (limits between -1 and $+1$), and the floor and ceiling effect (maximum acceptable for both, 15%). Test–retest reliability was assessed using the intraclass correlation coefficient (ICC). ICC values ≥ 0.70 were considered satisfactory. Precision was determined by calculating standard error of the measurement (SEM). To assess the sensitivity of the scale in distinguishing between patients and healthy controls, the total and single item scores of the PDSS were compared by using unpaired *t* test. The concurrent validity of the scale was evaluated analyzing the relation of PDSS with ESS and UPDRS. Correlations between ESS and PDSS scores and age, disease duration, Hoehn & Yahr staging, and type of treatment were examined. Correlation between PDSS total score or single PDSS items scores and levodopa equivalent dose was assessed by means of Spearman coefficients. A stepwise regression model was applied to evaluate the effect of all examined variables on the PDSS and ESS total scores in PD patients. In order to identify general characteristics of sleep disorders pointed out by the PDSS scale (construct validity), a factor analysis model and a cluster analysis model were applied to each item.

The opportunity to consider the two questions for the caregiver as additional items of PDSS scale was evaluated. PDSS, ESS, HDRS, and UPDRS total scores were analysed, according to the presence/absence of possible PLMS and RSD as reported by the caregivers at baseline. To validate the two questions for the caregiver, scores of PDSS items evaluating nocturnal restlessness (items 4 and

5) and nocturnal psychosis (items 6 and 7) were compared between patients with possible PLMS and RSD and the remaining patients.

Results

We enrolled 221 PD patients (132 M, 89 F; age 66.3 ± 8.9 years) and 57 healthy controls (31 M, 26 F; age 64.5 ± 9.5 years).

Sleep disorders were reported by 48% of patients and 19% of controls. PD mean duration was 6.5 ± 4.8 years (range 1 month–32 years), and modified H&Y mean stage was 2.3 ± 0.8 . Thirty-two percent of the patients were in the initial phase, 39% of patients were in the stable phase and 29% in the complicated phase. Ninety-four percent of patients were treated with antiparkinsonian drugs: 86.8% of them took dopaminergic agonists, 92.7% were on levodopa, 12.2% on amantadine. Mean levodopa equivalent dose was 621 ± 365 mg/day.

MMSE scores were similar in PD patients (28.7 ± 2.9) and healthy controls (29.5 ± 1.9). According to HDRS, patients' mood was significantly worse than healthy subjects' (mean score 9.6 ± 5.6 vs. 3 ± 3.7 ; $p < 0.002$). Ten percent of PD patients suffered from severe depression (HDRS total score ≥ 17).

Figure 1 shows profiles of mean PDSS scores per item in PD patients and healthy controls at baseline. Table in Supplementary material section shows the differences in total and individual scores of PDSS between PD patients and healthy controls at baseline. Sleep quality was worse in

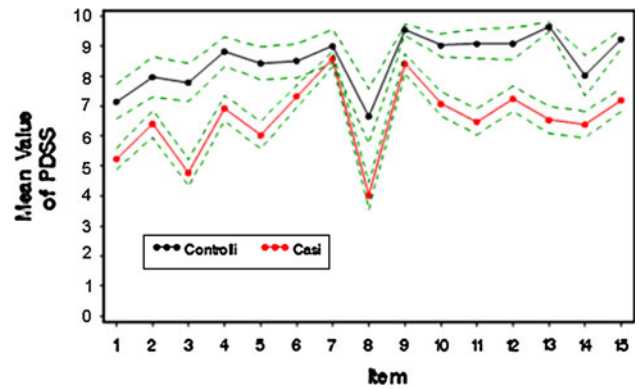


Fig. 1 PDSS profiles of mean scores per item in PD patients and healthy controls

patients than in healthy controls: mean total score was 98.3 ± 27.1 in PD patients and 127.9 ± 16.3 in controls ($p < 0.0001$). The patients scored about 2 points lower than healthy controls in individual items, and total score difference amounted to approximately 30 points at both visits. PD patients had significantly lower scores than controls in all items of the PDSS. At the second assessment we observed similar significant differences between PD patients and controls in total and individual item scores (data not shown).

PDSS total score was significantly lower in PD patients reporting sleep disorders (89.2 ± 28.4) as compared to other PD patients (113.7 ± 22.5 ; $p < 0.0001$).

Item profiles were similar between the two groups, with item 8 (getting up at night to pass urine) scores being the lowest in each group (Fig. 1).

Validation-related statistics are shown in Table 1. Internal consistency of PDSS scale was verified.

Table 1 Validation-related statistics in PD patients

	Cronbach's α	Item-total correlation	ICC	SEM	Skewness	Floor effect (%)	Ceiling effect (%)
PDSS total score	0.86		0.96	1.8	-0.44	0	0
Item 1	0.85	0.65	0.93	0.18	-0.18	0	0
Item 2	0.86	0.41	0.94	0.22	-0.64	0.9	2.3
Item 3	0.86	0.53	0.88	0.22	0.14	0.45	0.2
Item 4	0.85	0.57	0.92	0.21	-0.85	0.45	7.2
Item 5	0.85	0.64	0.86	0.23	-0.38	0.9	5.4
Item 6	0.85	0.55	0.88	0.18	-0.98	0	6.3
Item 7	0.86	0.46	0.74	0.13	-2.4	0	9
Item 8	0.87	0.22	0.87	0.22	0.5	0.9	2.3
Item 9	0.86	0.34	0.82	0.16	-2.18	0	9.9
Item 10	0.85	0.65	0.89	0.2	-0.86	0	8.6
Item 11	0.85	0.58	0.91	0.21	-0.52	0	8.1
Item 12	0.86	0.51	0.82	0.21	-1.09	0.45	7.7
Item 13	0.86	0.39	0.95	0.23	-0.66	0.45	5.9
Item 14	0.85	0.64	0.88	0.22	-0.56	0	1.8
Item 15	0.86	0.55	0.91	0.19	-0.88	0.45	7.7

Cronbach's α coefficient value (0.86) indicated highly positive correlations between the items. Item-total corrected correlation showed significant coefficients for all items. The less correlated item was the eighth (getting up at night to pass urine, $r = 0.22$).

Regarding test-retest reliability, the ICC was 0.96 for the total score, which is satisfactory. The ICC for single items ranged from 0.74 (item 7) to 0.95 (item 13) (Table 2). SEM ranged from 0.13 (item 7) to 0.23 (item 5 and 13) and was 1.8 for PDSS total score at both first and second assessment. Acceptability was good according to all considered criteria. The total PDSS score was free of floor or ceiling effect and the skewness value was -0.44 .

Negative correlation was found between total PDSS and ESS scores, for both patient and healthy subject groups, at baseline (Table 2) and after one week (data not shown). PDSS scores were approximately 26% lower in patients with relevant daytime sleepiness ($ESS \geq 12$) than in other PD patients. All items of the PDSS showed a significant negative correlation with ESS score in PD patients, with the exception of items 2 (falling asleep), 11 (painful cramps) and 13 (tremor on waking) (Table 2). Item 15 of the PDSS showed the greatest correlation coefficient with the total ESS score ($r = -0.61$, $p < 0.0001$).

PDSS total score was correlated to PD severity measures: significant inverse correlation was found between PDSS total score and UPDRS-II and III scores ($r = -0.37$, $p < 0.0001$ and $r = -0.26$, $p = 0.0001$). PDSS total score

was inversely related to UPDRS-IV score ($r = -0.39$; $p < 0.0001$). PDSS total score was related to H&Y score ($r = -0.27$; $p < 0.0001$).

PDSS total score was found to be significantly correlated to depression in both groups ($r = -0.57$, $p < 0.01$ for patients and $r = -0.53$, $p < 0.01$ for healthy subjects). PDSS total score was significantly lower (67 ± 25.1) in patients with $HDRS \geq 17$ ($n = 21$) than in patients with $HDRS < 17$ ($n = 200$; 101.5 ± 25.2 ; $p < 0.001$).

No correlation was found between levodopa equivalent dose and PDSS total and single item scores in PD patients.

Possible PLMS were reported by the caregivers in 36% of PD patients versus 12% of healthy controls ($p < 0.001$) while possible RSDA was reported by the caregivers in 27% of PD patients versus 1.7% of healthy controls ($p < 0.001$). Patients with possible PLMS as reported by the caregiver scored about 24 points less than other PD patients on PDSS (83.7 ± 25.4 vs. 107.4 ± 23.1 ; $p < 0.0001$). As regards UPDRS-II, mean score was 13.6 ± 7.5 in PD patients with possible PLMS as compared to 10.8 ± 6.4 in patients without ($p = 0.005$). The presence of possible PLMS was not related to UPDRS-III, MMSE and HDRS scores. Patients with possible PLMS as reported by the caregiver presented significantly lower scores than PD patients without possible PLMS at item 4 (5.4 ± 3.3 vs. 7.4 ± 3 ; $p = 0.0018$) and item 5 (4.2 ± 3.1 vs. 6.7 ± 3.2 ; $p < 0.001$) of the PDSS.

PD patients with possible RSDA as reported by the caregiver (27% of PD patients) scored about 16 points less than patients without RSDA on PDSS (86.8 ± 26.2 vs. 102.9 ± 25.5 ; $p < 0.0001$). As regards UPDRS-II, mean score moved from 14.5 ± 8.9 in patients with possible RSDA to 10.8 ± 5.7 in patients without ($p < 0.0001$), while UPDRS-III score moved from 27.5 ± 13.1 to 23.5 ± 10.8 ($p = 0.026$). PD patients with possible RSDA as reported by the caregiver presented significantly lower scores than PD patients without possible RSDA at item 6 (6 ± 3.1 vs. 8 ± 2.2 ; $p < 0.0001$) and item 7 (7.9 ± 2.3 vs. 8.9 ± 1.5 ; $p < 0.001$) of the PDSS.

By regression analysis, we found that presence of motor complications ($p = 0.005$) and caregiver's report of PLMS ($p < 0.0001$) were significant predictors of PDSS, with R^2 of 0.22, while female sex ($p = 0.0008$) and afternoon naps ($p = 0.04$) were significant predictors of ESS, with R^2 of 0.12.

Factor and cluster analysis showed the multidimensional structure of the scale (construct validity). In factor analysis for the patient group, 5 factors were identified, explaining 67% of variance. Factor 1 was related to overall quality of night sleep, including item 1, item 2, item 3, and item 5. Factor 2 was related to nocturnal motor symptoms, including item 4, item 10, item 11, item 12 and item 14. Factor 3 was related in part to nocturnal psychosis,

Table 2 Correlations between PDSS total and individual items scores and ESS total score in PD patients and healthy controls at baseline

PDSS	Patients		Healthy controls	
	<i>R</i>	<i>p</i> value	<i>r</i>	<i>p</i> value
Total score	-0.34	<0.0001*	-0.29	0.0455*
Item 1	-0.18	0.0055*	-0.26	0.0749
Item 2	-0.03	0.5984	-0.03	0.8236
Item 3	-0.26	<0.0001*	-0.09	0.5088
Item 4	-0.15	0.0194*	-0.11	0.4356
Item 5	-0.16	0.0138*	-0.16	0.2536
Item 6	-0.20	0.0019*	-0.25	0.0844
Item 7	-0.20	0.0027*	-0.02	0.8549
Item 8	-0.30	<0.0001*	-0.41	0.004*
Item 9	-0.15	0.0213*	-0.04	0.7613
Item 10	-0.19	0.0037*	-0.14	0.325
Item 11	-0.11	0.0785	-0.18	0.2038
Item 12	-0.16	0.0146*	-0.21	0.1476
Item 13	-0.08	0.211	-0.08	0.5774
Item 14	-0.25	0.0002*	-0.18	0.2097
Item 15	-0.61	<0.0001*	-0.15	0.3106

* $p < 0.05$

including items 6 and 7, and in part to nycturia (item 9) and daytime dozing (item 15). Factor 4 and factor 5 included only one item each one, related to tremor on waking (item 13) and urine incontinence (item 8).

In cluster analysis for the patient group, the same conclusions could be drawn, with the difference that the five clusters explained 63% of total variance. Each cluster was related to the same characteristics of sleep disorders as previous factors with few differences (item 4 in this analysis was included in cluster 2 related to nocturnal motor symptoms).

Discussion

Our study showed that the Italian version of the PDSS can be used in routine clinical practice and research. PDSS was able to distinguish between PD patients and controls. Individual items showed good discriminatory power between PD patients and healthy controls. PD patients showed more severe sleep disorders than healthy controls. PDSS was proven time stable and internally consistent in both patient and control groups. Similarly, its internal consistency and test–retest reliability were highly satisfactory. The SEM of PDSS was 1.8 for both the crossover and longitudinal assessments, indicating that the Italian version of PDSS is very precise for both crossover and longitudinal studies. Factor analysis showed the multidimensional structure of the scale, with five factors explaining 67% of variance. Finally, PDSS was able to discriminate between patients with and without reported sleep disturbances. The overall profile of the 15 items was similar to previous reports from England, Spain and Japan [13, 21–23]. The mean total PDSS score found in our large sample of PD patients was similar to that reported by Chaudhuri et al. (101.1) [13], Martinez-Martin et al. (96.9) [21], and Abe et al. (99) [22], and lower than those found by Suzuki et al. (112.8) [23], and Wang et al. (118.4) [24]. This discrepancy may reflect different composition of the samples among these studies or inter-country differences in sleep disturbances among PD patients.

PDSS score was found negatively correlated to ESS score, indicating a relationship between falling asleep during the day and bad quality of night sleep. As found in previous studies [13, 24], poor scores on item 15 (related to daytime naps) of the PDSS were strongly related with excessive daytime sleepiness measured with the ESS, thus supporting criterion validity of the Italian version of PDSS. PDSS scores were negatively correlated to UPDRS section II, III and IV scores, indicating that bad quality of night sleep was related to daily living activities, poor motor function, and the presence of fluctuations and dyskinesia. Regression analysis showed that the presence of PLMS as

reported by caregiver and motor complications were significant, although weak, regressors. Motor complications have been reported to be significant determinants of sleep disorders also in Japanese and Spanish PD patients [21–23], suggesting that nocturnal motor symptoms are relevant in determining bad sleep quality in PD patients.

The original version of PDSS does not directly address RSD and PLMS, which occur frequently in PD. We tried to add two questions for the caregivers that possibly allow for identification of RSD and PLMS. The report of possible RSD and PLMS had good discriminatory power between PD patients and healthy controls and was associated with worse sleep quality as indicated by PDSS total scores. Moreover patients with possible PLMS had significantly worse scores on PDSS items evaluating nocturnal restlessness (items 4 and 5) and patients with possible RSD had significantly worse scores on PDSS item evaluating nocturnal psychosis (items 6 and 7), suggesting that these questions could be considered as additional items of the PDSS.

A PDSS worse performance was significantly related also to a worse HDRS score. A correlation between total PDSS scores and measures of anxiety and depression was reported in previous studies [21, 24], and PDSS score has been recently identified as significant determinant of depression in PD patients [25].

We found no correlation between PDSS score and levodopa equivalent dose. Only one of the previous studies assessing levodopa equivalent dose found a significant negative correlation with PDSS total score [24], while the majority of previous studies are concordant with our findings [21, 23, 26].

Limitations of the study are related to characteristics of the samples, particularly regarding the small number of healthy controls and the exclusion of individuals on sedatives or sleeping medication that might have influenced our results. While our data were in course of analysis, a revised version of the PDSS (PDSS-2) has been proposed and validated in a sample of 113 PD patients from Germany, Austria and England [27]. If the validity and clinical usefulness of this new scale will be confirmed by other studies, it would be worthwhile to validate it in the Italian population.

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