A pilot study on a specific measure for sleep disorders in Parkinson's disease: SCOPA-Sleep

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A PILOT STUDY ON A SPECIFIC MEASURE FOR SLEEP DISORDERS IN PARKINSON'S DISEASE: SCOPA-SLEEP

Summary. Introduction. *There is a high prevalence of sleep disorders in Parkinson's disease (PD).* Aims. *To assess some basic metric attributes of the SCOPA-Sleep scale, a measure for PD patients; secondary objective: to check the impact caused by the sleep disorder on the health-related quality of life (HRQoL) of patients and their caregivers.* Subjects and methods. *68 PD patients and their main caregivers; measures: Hoehn and Yahr staging, SCOPA-Motor, Clinical Impression of Severity Index (CISI-PD), PDSS, Hospital Anxiety and Depression Scale, SCOPA-Psychosocial, and EuroQoL. Carers filled in a PDSS questionnaire about patient sleep and HRQoL measures (SF-36, EuroQoL). SCOPA-Sleep acceptability, scaling assumptions, internal consistency, construct validity and precision were determined.* Results. *SCOPA-Sleep acceptability and scaling assumptions resulted satisfactory, although the nocturnal sleep subescale (SC-Ns) showed a mild ceiling effect (22.1%) and a defective convergent validity was found for daytime sleepiness (SC-Ds) item 6. Internal consistency also was satisfactory for both scales (alpha = 0.84 and 0.75, respectively). The correlation between SC-Ns and PDSS was high (r_S = –0.70), as it was between SC-Ns and PDSS questionnaire by caregiver (r_S = –0.53). The corresponding coefficients with the SC-Ds gained lower values (r_S = –0.41 y –0.50). Standard error of measurement was 1.45 for the SC-Ns and 1.76 for the SC-Ds. Both, patient and caregiver HRQoL showed a loose association with the sleep measures.* Conclusion. *SCOPA-Sleep is a feasible, consistent, and useful scale for assessment of sleep disorder in PD patients. A weak association between sleep disorder and HRQoL was found. [REV NEUROL 2006; 43: 577-83]*

Key words. *Assessment. CISI-PD. Health-related quality of life. Parkinson's disease. Parkinson's Disease Rating Scale. SCOPA-Sleep. Sleep disorder.*

INTRODUCTION

While clinical manifestations of Parkinson's disease (PD) typically include motor disorders, such as tremor, rigidity, hypokinesia, and gait disturbances, there is also a wide variety of 'non-motor' symptoms, to which increasing attention is being paid. Some noteworthy non-motor symptoms are neuropsychiatric disturbances, sleep disorders, gastrointestinal and autonomic manifestations, sensory symptoms, and a miscellany that includes fatigue, visual troubles, seborrhea, and weight loss [1].

Yet, despite the huge impact these symptoms have on patients' overall health and quality of life, they are frequently overlooked. Indeed, this is so even in the specialized setting, where health professionals tend to be more attentive to the motor aspects of the disease [2,3].

One of the reasons for this situation has been the absence of simple, valid measurement instruments for systematic application in daily practice and clinical research. The availability of such instruments would enable the magnitude of the alterations and the effect of therapies to be quantified. The problem posed by this deficit will soon be resolved, however: specific scales for some of these dysfunctions are already available [4-7] and there are several initiatives under way aimed at designing a unified scale for non-motor symptoms [1,8,9].

A very frequent problem in PD is upset sleep, which includes insomnia (difficulty falling or staying asleep at night), parasomnias –such as REM (rapid-eye movement) sleep behavior disorder–, daytime hypersomnia, and sleep attacks [10-12].

Non-specific scales for assessment of nocturnal sleep, such as the Pittsburgh scale [13], or daytime sleepiness, such as the Epworth scale [14], have been used for evaluation of sleep disturbances in PD. In 2002, Chaudhuri et al [4] published the first ever specific scale for evaluation of nocturnal sleep quality in PD. Recently, this Parkinson's Disease Sleep Scale (PDSS) has undergone independent validation and cross-cultural adaptation to Spain [15]. In 2003, Marinus et al [5] published another spe-

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cific scale for PD (SCOPA-Sleep), designed to evaluate nocturnal sleep and daytime drowsiness.

The main aim of this study was to assess some basic metric attributes of the Spanish-version SCOPA-Sleep scale applied to a series of PD patients. As a secondary objective, it sought to analyze the association between sleep disorders and patients' and their caregivers' health-related quality of life (HRQL).

SUBJECTS AND METHODS

This was the first independent study on the metric properties of the SCOPA-Sleep and a pilot study for the Spanish version. A multicenter, open, cross-sectional, one point-in-time evaluation study.

Consecutive patients older than 40 years, both genders, with diagnosis of PD as per modified United Kingdom PD Society Brain Bank Criteria [16]. The modifications consisted of considering 'clear beneficial response to dopaminergic treatment' (not only to levodopa) and 'maintained response to dopaminergic treatment' (instead of response to levodopa treatment for more than 5 years) as support criteria (Section 3).

As an additional inclusion criterion, patients were required to have a stable caregiver, and both patients and carers were required to be 'able to read, to understand and to answer questionnaires' in the participant neurologist's opinion.

Exclusion criteria were defined as the absence of one or more inclusion criteria and the presence of any comorbidity that could interfere with or significantly modify evaluation of the effects caused by PD (e.g., blindness, serious systemic illness, residual hemiplegia, etc.).

Informed consent was obtained from all participant patients and caregivers. This study forms part of the Longitudinal PD Patient Study –Estudio Longitudinal de pacientes con Enfermedad de Parkinson (ELEP)–, approved by the Clinical Research Ethics Committees of the Princesa Hospital (Madrid) and the Carlos III Institute of Public Health [17].

Neurologist-based assessments

Hoehn and Yahr Staging (HY) [18]

In the present study, we applied the version included in the Unified Parkinson's Disease Rating Scale 3.0 [19].

Mini-Mental State Examination (MMSE) [20]

This test was applied to ascertain the cognitive state of patients included in the study.

SCOPA-Motor (SC-M) [21]. The SCOPA-Motor scale was designed within a program to develop specific PD measures –Scales for Outcomes in Parkinson's disease (SCOPA)–. It is made up of the following 3 sections: 1) Motor evaluation ('clinical examination' subscale, 8 items, and 'historical information' subscale, 2 items); 2) Activities of daily living (ADL) (7 items); and 3) Motor complications (4 items). Each item is scored from 0 (normal) to 3 (severe). The average time spent on administering this scale is 8.1 ± 1.9 minutes [21]. A cross-culturally validated Spanish version exists [22].

Clinical Impression of Severity Index (CISI-PD) [23]

This is a clinimetric index comprising four items (motor signs, disability, motor complications, and cognitive state) that are scored by the neurologist after the interview and examination. Each item is scored from 0 (normal) to 6 (severe). An index is obtained from the sum of these scores (range, 0 to 24), which reflects the neurologist's impression as regards the severity of the patient's state.

Patient-based assessments

Parkinson's Disease Sleep Scale (PDSS) [4]

This scale is composed of fifteen items, fourteen of which explore seven aspects relating to nocturnal sleep, such as global quality of nighttime sleep, difficulty falling sleep, presence of hallucinations, nocturia, etc. One item (item 15) evaluates the presence of unexpectedly falling asleep during the day. The time span explored is the preceding week. On a visual analogue scale that runs from 'always' (0) to 'never' (10), patients indicate their level of disability for each aspect assessed. The scale can be completed by patients themselves or by their caregivers [4].The maximum total PDSS score is 150: the lower the score, the worse the quality of sleep.

SCOPA-Sleep (SC-Sleep) [5]

This scale has two sections, Nocturnal Sleep (SC-NS) and Daytime Sleepiness (SC-DS), which evaluate problems in these respective domains during the 'last month'. The SC-NS consists of five items addressing trouble falling asleep, fragmentation and duration of sleep, early waking, and feeling of having had too little sleep. Score options for items range from 0 (no problem) to 3 (a lot of problems), with the limits of the total score being 0 and 15. Following this section is a global evaluation of nighttime sleep with seven response options (1, 'very well' to 7, 'very bad'). The SC-DS scale evaluates daytime hypersomnia in the preceding month. It includes 6 items dealing with the frequency of falling asleep in certain situations (e.g., unexpectedly, sitting down peacefully, watching television or reading, or speaking to somebody). Each item can score from 0 (never) to 3 (frequently), thus making the maximum possible score, 18.

Hospital Anxiety and Depression Scale (HADS) [24]

This is composed of 14 items, seven identifying anxiety and seven for depression. Each item scores from 0 (no problem) to 3 (extreme problem). Scores higher than 10 on each subscale are indicative of anxiety or depression, respectively. Marinus et al. [25] report that the HADS' metric properties mean that it can be applied to PD patients.

SCOPA-Psychosocial (SC-PS) [26]

This scale was designed to evaluate the psychosocial impact of PD. It consists of 11 items, each of which assesses the severity of a particular problem during the preceding month, using a score ranging from 0 (not at all) to 3 (very much). It includes information on psychosocial functioning and difficulties vis-à-vis daily living and recreational activities, relationships with family and friends, dependence, isolation and concern about the future.

EuroQoL [27,28]

Intended for use in econometrics, this is an instrument designed to measure HRQL on the basis of preferences. It contains a descriptive part, comprising five items with three answer levels (1 = there are no problems or symptoms, to 3 = problems or severe symptoms). The descriptive system can thus generate 243 different health profiles. To each of these profiles, a preference index or social tariff can be assigned, ranging from 1.0 (perfect health state) to 0.0 (death). Such an index is obtained by means of techniques such as time trade-off (the indices used in the present study) or the analogue visual scale.

The EuroQoL also includes a question on the course of respondents' general state of health in the previous 12 months and a visual analogue scale for evaluation of their current ('today') health state (from 0 = worst imaginable health state, to 100 = best imaginable health state).

Caregiver-based assessments

PDSS-based questionnaire

A questionnaire containing the same items as the PDSS was purpose-designed to obtain an evaluation by caregivers (evaluation by proxy) of sleep disturbances that might go unnoticed by patients.

Hospital Anxiety & Depression Scale (HADS)

Administered to assess caregivers' mood.

EuroQoL

Administered to assess caregivers' own perceived health state.

SF-36 [29,30]

This is a generic measure of health-related quality of life, which includes eight dimensions of health state focusing on:

- Functional aspects, such as physical functioning (10 items), social functioning (2 items), and role limitations due to physical (4 items) and emotional (3 items) problems.
- Well-being, which integrates the domains of mental health (5 items), vitality (4 items) and bodily pain (2 items).
- General health (5 items).
- Change in health status over time (1 item).

Table I. Store distribution of the applied measures.

		Mean	SD	Range
Age		69.63	9.25	48-85
Duration of disease		7.72	5.01	0-20
MMSE		2.25	3.16	14-30
SCOPA-Motor				
Examinatión		8.54	4.45	1-22
ADL		7.70	4.38	1-22
Complications		2.82	2.98	0-11
CISI-PD		8.90	4.62	2-22
HADS-Ansiety		7.24	4.30	0-18
HADS-Depression		7.14	3.60	1-17
EuroQoL-Tariff		0.59	0.26	0.02-1
EuroQoL-AS		60.00	16.87	10-99
SCOPA-Psychosocial		24.37	17.61	0-72.7
PDSS		98.10	25.01	37.9-140.0
SCOPA-Sleep				
SC-NS	Item 1	0.41	0.71	0-3
	Item 2	0.92	0.91	0-3
	Item 3	0.91	0.91	0-3
	Item 4	1.07	1.11	0-3
	Item 5	0.83	1.01	0-3
Total SC-NS		4.13	3.64	0-11
Nocturnal sleep previous month		2.95	1.57	1-7
SC-DS	Item 1	0.85	0.98	0-3
	Item 2	1.22	1.02	0-3
	Item 3	1.48	1.04	0-3
	Item 4	1.19	0.55	0-3
	Item 5	0.47	0.72	0-3
	Item 6	0.39	0.87	0-3
Total SC-DS		4.55	3.52	0-16

MMSE: Mini-Mental State Examination; CISI-PD: Clinical Impression of Severity; Index for Parkinson's disease; HADS: Hospital Anxiety and Depression Scale; PDSS: Parkinson's Disease Sleep Scale; SC-NS: SCOPA-Nocturnal sleep; SC-DS: SCOPA-Daytime sleepiness; SD: standard deviation

For each dimension, scores are standardized, ranging from 0 (worst health state) to 100 (best health state). Finally, the individual dimension scores are combined to provide a physical and mental component index [31].

Data analysis

The following metric attributes of the SC-Sleep were analyzed: acceptability; scaling assumptions; internal consistency; construct validity; and precision.

Data quality refers to the instrument's fitness for use in a clinical context and is determined by the proportion of fully computable data, after missing data and their location have been considered. The maximum acceptable limit for missing and non-analyzable data is 5% [32].

The acceptability of the measure indicates to what extent the distribution of the scores represents the true distribution of health state in the assessed sample. To determine this property, parameters such as the distance between the mean and the median, floor and ceiling effects (ideally less than 15%) [33] and skewness (acceptable limits: –1 to +1) [34] are taken into account.

Scaling assumptions refer to the correct grouping of items in the corresponding scales or dimensions, and to what extent it is appropriate for the respective scores to be directly added to produce a total score representative of the construct to be measured. To this end, item-total correlation, duly corrected for overlap, was analyzed. A value of 0.40 [35] was taken as the minimum standard limit. Items should demonstrate higher correlations (+ 2 × standard error of the correlation coefficient) with their own scale than with the other in the multitrait analysis [32].

Internal consistency is one of the attributes of a measure's reliability. This property is based on the homogeneity (intercorrelation) of the items that comprise the scale. The most appropriate statistic for exploring this property is Cronbach's α coefficient. A value of 0.70 was taken as the lower limit for α [35]. Other techniques for ascertaining this attribute are item homogeneity coefficient (the mean of the inter-item correlation coefficients; acceptable lower limit = 0.30) [36] and factor analysis.

Validity assessment tests whether an instrument really measures what it purports to measure. Construct validity refers to the evidence that enables scores to be interpreted according to the theoretical implications associated with the construct that is being measured; convergent validity refers to the correlation with other accepted measures for the same or related constructs (in which case the coefficients should be high); and divergent or discriminant validity refers to the relationships with variables that measure other unrelated constructs (in this case correlation coefficients should be low). We hypothesized that there would be: a high correlation between the SC-NS and PDSS ($r \geq 0.60$) and a moderate correlation between the SC-DS and PDSS (r = 0.30-0.59); a weak association between SC-Sleep subscales and patients' age, duration of PD, HY, and MMSE (r = 0.10-0.29); a moderate relationship between SC-Sleep and SC-M, CISI-PD, HADS, SC-PS and EuroQoL (r = 0.30-0.59) [15, 37]; and a high correlation between the SC-NS and the PDSS-based questionnaire completed by caregivers. Since the data did not fit a normal distribution, the Spearman rank correlation coefficient was used.

The ability of a measure to detect differences at a point in time among patients who are ranked according to different levels of severity, is known as discriminative validity. This was assessed using the Mann-Whitney and Kruskal-Wallis tests, with differences being deemed statistically significant at p values lower than 0.05.

The precision (sensitivity) of a measure is its ability to detect small differences. The statistic recommended for this purpose is standard error of measurement ($SEM = SD \times \sqrt{1 - r_{xx}}$, where SD is the standard deviation and r_{xx} the coefficient of reliability) [38,39].

The association between sleep dysfunction and deterioration in patients' HRQL was determined by the correlation between PDSS and SC-Sleep scores and EuroQoL and SC-PS parameters. To analyze the impact of patients' sleep dysfunction on caregiver's HRQL, sleep scales scores were correlated with caregivers' EuroQoL and SF-36 indices.

RESULTS

A total of sixty-eight PD patients, 61.8% males, were included (Table I). According to HY, the patients distribution was as follows: stage 1, 10.6%; stage 1.5, 6.1%; stage 2, 59.1%; stage 2.5, 9.1%; stage 3, 7.6%; stage 4, 4.5%; and stage 5, 3.0%. Patients were receiving treatment with: levodopa, 82.35%; dopamine agonists, 63.24%; selegiline, 13.24%; amantadine, 2.94%; and apomorphine, 1.47%. Their level of education was: university or equivalent, 13.4%; high school, 20.9%; primary, 53.7%; and no formal education, 11.9%.

The mean age of caregivers, 77.3%, women, was 62.9 ± 12.3 years. Their level of education was: university, 21.5%; high school, 21.5%; primary, 40.0%; and no formal education, 16.9%.

The descriptive statistics of the scales applied to or used by the patients are shown in table I. A total of 39 caregivers were requested to complete the PDSS-based questionnaire on patients' sleep (mean score: 96.1 ± 31.5; range: 20-150).

One patient failed to answer SC-DS items 5 and 6 (missing data, 1.5%; computable, 98.5%). All SC-NS data were available (100%). Accordingly, data quality was satisfactory.

The scores registered for all SC-Sleep items covered the complete theoretical range. In contrast, the total score of both subscales failed to reach the higher theoretical score limit (Table I). The distance of the mean to the median was 0.63/15 (4.2%) for the SC-NS and 0.55/18 (3.05%) for the SC-DS. Although the SC-NS displayed no floor effect (5.90%), it nevertheless showed a mild ceiling effect (22.1%), with the corresponding values for the SC-DS being 3.0% and 10.45%, respectively. Skewness proved to be 0.47 for the SC-NS and 1.20 for the SC-DS. To sum up, a slight ceiling effect for the SC-NS and skewness for the SC-DS were observed.

Item-total correlations were higher than the standard, 0.40 [35], except for item 6 of the SC-DS (r = 0.21), which registered substandard convergent validity (Table II). Hence, with single exception of SC-DS item 6, all items on both subscales were deemed to fit the scaling assumptions (Table II).

Cronbach α coefficient values were 0.84 for the SC-NS and 0.75 for the SC-DS, with item homogeneity coefficient values of 0.52 and 0.36, respectively. All these coefficients proved higher than the established minimum limit. The exploratory factor analysis (principal components, orthogonal rotation) showed one factor explaining 62% of the variance in the SC-NS, and two factors explaining 68% of the variance in the SC-DS. The first of these latter two factors comprised the first three items of the SC-DS (falling asleep unexpectedly, falling asleep while sitting peacefully, falling asleep while watching television or reading), and the second comprised the last three items (falling asleep while talking to someone, problems staying awake during day, and experiencing falling asleep during the day as a problem).

Correlation coefficients between the SCOPA-Sleep subscales and the other measures applied in the study are shown in the table III. In line with our working hypothesis, the correlation between the SC-NS and PDSS (which also measures quality of the nocturnal sleep) was high (r_S = –0.70), and the relationship between the SC-DS and PDSS was moderate (r_S = –0.41). The SC-NS registered moderate associations (r_S = 0.30-0.59) with the HADS (anxiety and depression sections) and Motor complications of the SC-M. The SC-DS displayed moderate coefficient values with HY and the CISI-PD (Table III). The remaining correlations were weak. No significant association was observed between sleep scales scores (including the PDSS) and patients' age or disease duration.

The SC-NS showed a significant correlation with the question on global evaluation of nocturnal sleep (r_S = 0.81) and with item 1 (global quality of night sleep) of the PDSS (r_S = –0.65, p <0.0001). The correlation between SC-DS and PDSS item 15 (unexpectedly falling asleep during the day) was moderate (r_S = –0.52, p <0.0001), as was the correlation between SCOPA-Sleep and the PDSS-based questionnaire completed by caregivers (r_S = –0.50 with the SC-NS; r_S = –0.53 with the SC-DS) (Table III).

There were no significant gender-related differences in the SCOPA-Sleep scores. The SC-NS score displayed a non-statistically significant rising trend as HY stage increased. The SC-DS registered a non-linear trend, with highest values in stage 3 (7.75 points) and inferior values in the lower and higher stages (e.g., 2.4 in stage 1 and 5.5 in stage 5) (Kruskal-Wallis, p = 0.03).

Mean SC-NS scores increased significantly with global evaluation of night sleep (Table IV) (Kruskal-Wallis, p <0.0001). The SEM was 1.45 for the SC-NS and 1.76 for the SC-DS.

The correlation coefficients between patients' HRQL measures and sleep rating scales (both SC-Sleep and PDSS) were weak overall (r_S = –0.06 at –0.27). The SC-NS and PDSS showed a moderate association with the SCPS (r_S = 0.37 and –0.36; p = 0.002 and 0.004, respectively).

With respect to the impact of patients' sleep dysfunction on caregivers' HRQL, the correlation between patients' sleep rating scales and caregivers' HRQL measures ranged from –0.01 (SC-DS and the physical component of the SF-36) to –0.23 (SC-DS and the EuroQoL tariff). The PDSS-based questionnaire completed by caregivers correlated moderately with the EuroQoL tariff (r_S = 0.34, p <0.05) and weakly with the other caregiver HRQL parameters (r_S = 0.03-0.29; p = n.s.).

Table II. SCOPA-Sleep scaling assumptions (n = 67).

	Correlations [a]		
	Ítem-total (corrected)	Total SC-NS	Total SC-SD
SC-NS			
Item 1	0.53	–	0.12
Item 2	0.75	–	0.30
Item 3	0.71	–	0.16
Item 4	0.62	–	0.26
Item 5	0.75	–	0.29
SC-DS			
Item 1	0.43	0.10	–
Item 2	0.61	0.10	–
Item 3	0.56	0.10	–
Item 4	0.43	0.10	–
Item 5	0.45	0.15	–
Item 6	0.21	0.35	–

[a] Spearman rank correlation coefficients (r_S standard error = 0.12). SC-NS: SCOPA-Nocturnal sleep; SC-DS: SCOPA-Daytime sleepiness.

Table III. Correlation [a] between SCOPA-Sleep and the other measures applied in the study.

	SC-NS	*p*	SC-DS	*p*
Hoehn and Yahr	0.18	NS	0.38	0.002
Mini-Mental State Examination	–0.06	NS	–0.25	0.05
HADS-Anxiety	0.53	0.0000	0.08	NS
HADS-Depression	0.35	0.003	0.10	NS
SCOPA-Motor				
Examination	–0.03	NS	0.24	NS
ADL	0.13	NS	0.25	0.05
Complications	0.32	0.007	0.16	NS
CISI-PD	0.21	NS	0.31	0.01
EuroQoL-Tariff	–0.27	0.05	–0.22	NS
EuroQoL-VAS	–0.10	NS	–0.26	0.05
PDSS	–0.70	0.0000	–0.41	0.001
PDSS by proxy (carer)	–0.53	0.0005	–0.50	0.002

[a] Spearman rank correlation coefficient. CISI-PD: Clinical Impression of Severity Index for Parkinson's Disease; HADS: Hospital Anxiety and Depression Scale; PDSS: Parkinson's Disease Sleep Scale; SC-NS: SCOPA-Nocturnal sleep; SC-DS: SCOPA-Daytime sleepiness.

DISCUSSION

Valid, specific measures are required to assess the diversity of manifestations that may be present in PD patients. This need has led to the design of numerous evaluation methods over the last five decades [40]. Recent years have witnessed increasing recognition of the importance of a complete evaluation that

Table IV. SCOPA-Nocturnal sleep score distribution by the anchor question.

Overall, how well have you slept at night during the past month?	*n*	Score
Very well	13	0.70 ± 1.2
Well	20	2.1 ± 1.7
Rather well	10	3.1 ± 2.2
Not well but not badly	13	7.4 ± 2.8
Rather badly	7	7.9 ± 1.9
Badly	4	9.5 ± 1.7
Very badly	1	11.0 ± 0

Test de Kruskal-Wallis, $p < 0.0001$.

encompasses the great variety of non-motor manifestations that can affect patients' quality of life [1-3,41].

Practically all PD patients suffer night sleep disturbances and/or day hypersomnia [4,41]. Useful instruments, capable of reflecting the type and severity of these dysfunctions and their response to therapeutic strategies, are therefore regarded as essential.

The first specific scale for assessing sleep disorders in PD (PDSS) was published by Chaudhuri et al in 2002 [4]. Subsequently, the validation of the PDSS was completed in an independent study conducted in Spain, after the necessary cross-cultural adaptation [15]. Marinus et al published another specific scale for evaluation of sleep disturbances in PD, known as the SC-Sleep [5]. To our knowledge, this scale has, as yet, neither been subjected to independent validation nor been adapted for use in a Spanish setting. The main objective of this study, albeit preliminary, was to assess some basic metric attributes of this scale.

Analysis of data quality and acceptability shows that the SC-Sleep is a viable scale, with a mild ceiling effect in the SC-NS domain (22.1%), in line with the data reported in the original study (17.7%) [5].

In our study, item 6 of the SC-DS was shown by the scaling assumptions analysis to be substandard. In contrast, the study by Marinus et al [5] showed that all the item-total correlation coefficients exceeded the standard criterion of 0.40. Nevertheless, in view of the differences in size and characteristic of the two samples, no conclusion can be drawn on this point.

Both the SC-NS and SC-DS obtained α and item-homogeneity coefficients higher than the established limit, demonstrating that their internal consistency is satisfactory. However, there was a qualitative difference with respect to the findings by Marinus et al [5], according to which α was almost equivalent for the two subscales (difference = 0.03), with it being slightly higher for the SC-DS. Yet, in our study, not only was the difference between the subscales greater (0.09), but it was also in favour of the SC-NS. At all events, both studies coincide in substantiating the reliability of the two subscales. While the exploratory factor analysis confirmed the unidimensionality of the SC-NS, the following two factors were identified in the SC-DS: the first included items 1 to 3 and could be defined as 'drowsiness in inactivity'; and the second contained items 4 to 6 and was related to 'inappropriate daytime sleepiness'.

As hypothesized, a close association was found between each SC-Sleep subscale and the respective PDSS parameters for nocturnal sleep and daytime hypersomnia. The correlation between SC-NS and the question on global evaluation of night sleep proved similar to that of the original study (0.81 vs. 0.85) [5]. The convergent validity of the SC-Sleep scale is therefore viewed as satisfactory. As for the other measures, the SC-NS showed moderate correlations with mood disturbances and motor complications. In addition, a moderate association was found between the SC-DS and PD severity measures, suggesting that nocturnal and daytime sleep dysfunctions have different relationships with the range of aspects evaluated by us.

As in the original study [5], the SC-Sleep failed to identify significant differences among patients with different levels of severity or disease duration. Similarly, these differences were not observed when the PDSS was used, either in this or in other previous studies [15]. This suggests that: 1) relationships between sleep dysfunction and disease severity, motor or cognitive status tend to be loose; 2) the type of sleep disturbance could change over time without significantly modifying total scale scores; or 3) sleep disturbances are present from the beginning of the disease and do not increase despite the progression of the disease [15,42].

The SC-NS displayed excellent discriminative validity vis-à-vis global evaluation of night sleep. The lack of a similar anchor question in the SC-DS means that this particular attribute cannot be explored in the same way for this subscale.

The influence of sleep disturbances on PD patients' HRQL has been highlighted [43-45], but this relationship has yielded low-to-moderate correlation coefficients between specific measures that evaluated both aspects (PDQ-39 and PDSS) in previous studies ($|r_S| = 0.26$-0.39) [15,46]. In the present study, while a moderate correlation was observed between the sleep scales (SC-NS and PDSS) and the SC-PS, the correlation between both scales and the EuroQoL was low or nonexistent. Further studies are called for, in order to apply the data furnished by the new specific measures and thereby enhance our knowledge of these aspects.

Although patients' sleep disorders influence caregivers' sleep and quality of life [47], the present study failed to find a significant association between patients' sleep disorders and caregivers' HRQL. However, a PDSS questionnaire adapted for proxy assessment showed that there was a moderate relationship between the EuroQoL index and caregiver evaluation of patients' sleep disorders.

The limitations of this study are linked to the characteristics of the sample, with scant representation of patients in the most advanced stages of the disease and those with the most severe sleep disturbances. These facts limit the generalizability of the results. Yet the quality of the relevant SC-Sleep metric attributes, assessment of which constituted the main objective of this pilot study, was nevertheless confirmed. Stability of the measure (test-retest) was not checked.

The SC-Sleep is a viable scale, with appropriate scaling assumptions, internal consistency, and construct validity. On the whole, the impact of sleep dysfunctions on patients' and caregivers' HRQL proved to be low, yet these relationships should be explored by means of specific studies, which have a design different to ours and implement newly-developed specific measures [17].

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ESTUDIO PILOTO SOBRE UNA MEDIDA ESPECÍFICA PARA LOS TRASTORNOS DEL SUEÑO DE LA ENFERMEDAD DE PARKINSON: SCOPA-SUEÑO

Resumen. Introducción. *En la enfermedad de Parkinson (EP) existe una alta prevalencia de trastornos del sueño.* Objetivos. *Comprobar los atributos métricos básicos de la escala SCOPA-sueño para pacientes con EP; objetivo secundario: analizar el impacto del trastorno del sueño en la calidad de vida relacionada con la salud (CVRS) del paciente y de su cuidador principal.* Sujetos y métodos. *68 pacientes con EP y sus cuidadores principales. Se aplicaron: Hoehn y Yahr, SCOPA-motor, impresión clínica de gravedad (CISI-PD), escala PDSS,* Hospital Anxiety and Depression Scale, *SCOPA-psicosocial y EuroQoL. El cuidador cumplimentó un cuestionario PDSS sobre el sueño del paciente y las medidas de la CVRS (SF-36, EuroQoL). Se analizaron la aceptabilidad, las asunciones escalares, la consistencia interna, la validez de constructo y la precisión de la SCOPA-sueño.* Resultados. *La SCOPA-sueño mostró aceptabilidad satisfactoria y asunciones escalares. La subescala sueño nocturno (SC-Sn) presentó leve efecto techo (22,1%), y la subescala somnolencia diurna (SC-Sd), defectuosa validez convergente del ítem 6; la consistencia interna de ambas resultó satisfactoria (alfa = 0,84 y 0,75, respectivamente). SC-Sn correlacionó significativamente con la PDSS (*r_S *= –0,70) y con el cuestionario PDSS cumplimentado por el cuidador (*r_S *= –0,53), y fueron menores los valores respectivos para la SC-Sd (*r_S *= –0,41 y –0,50). Error estándar de la medida: SC-Sn, 1,45; SC-Sd, 1,76. La CVRS del paciente y la del cuidador mostraron una escasa correlación con las medidas de sueño.* Conclusiones. *La escala SCOPA-sueño es viable, consistente y útil para evaluar el trastorno del sueño en pacientes con EP. La relación entre la CVRS y la alteración del sueño fue débil. [REV NEUROL 2006; 43: 577-83]*

Palabras clave. *Calidad de vida relacionada con la salud. CISI-PD. Enfermedad de Parkinson. Evaluación.* Parkinson's Disease Rating Scale. *SCOPA-sueño. Trastorno del sueño.*

ESTUDO PILOTO SOBRE UMA MEDIDA ESPECÍFICA PARA AS PERTURBAÇÕES DO SONO ASSOCIADAS À DOENÇA DE PARKINSON: SCOPA-SONO

Resumo. Introdução. *A doença de Parkinson (DP) associa-se a uma elevada prevalência de perturbações do sono.* Objectivos. *Comprovar os atributos métricos básicos da escala SCOPA-sono para doentes com DP; objectivo secundário: analisar o impacto das perturbações do sono na qualidade de vida relacionada com a saúde (QVRS) do doente e do seu principal cuidador.* Sujeitos e métodos. *Foram estudados 68 doentes com DP e respectivos cuidadores. Aplicaram-se as escalas: Hoehn e Yahr, SCOPA-motor,* Clinical Impression of Severity Index for Parkinson's Disease *(CISI-PD), escala PDSS,* Hospital Anxiety and Depression Scale, *SCOPA-psicosocial e EuroQoL. O cuidador preencheu um questionário PDSS sobre o sono do doente e as medidas da QVRS (SF-36, EuroQoL). Foram analisadas a aceitabilidade, as assunções escalares a consistência interna, a validade de construção e a precisão da SCOPA-sono.* Resultados. *A SCOPA-sono revelou aceitabilidade satisfatória e assunções das escalas. A subescala sono nocturno (SC-Sn) apresentou um discreto efeito tecto (22,1%) e a subescala sonolência diurna (SC-Sd) uma validade convergente imperfeita do item 6; a consistência interna de ambas resultou satisfatória (alfa = 0,84 e 0,75, respectivamente). SC-Sn correlacionou-se significativamente com a PDSS (*r_S *= –0,70) e com o questionário PDSS preenchido pelo cuidador (*r_S *= –0,53), e foram menores os valores respectivos para a SC-Sd (*r_S *= –0,41 e –0,50). O erro standard das medidas foi: SC-Sn, 1,45; SC-Sd, 1,76. A QVRS do doente e do cuidador revelou uma ténue correlação com as medidas do sono.* Conclusões. *A escala SCOPA-sono é viável, consistente e útil para avaliar a perturbação do sono em doentes com DP. Detectou-se uma ténue relação entre a QVRS e a alteração do sono. [REV NEUROL 2006; 43: 577-83]*

Palavras chave. *Avaliação. CISI-PD. Doença de Parkinson. Escala para avaliação da doença de Parkinson. Perturbação do sono. Qualidade de vida relacionada com a saúde. SCOPA-sono.*