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ORIGINAL ARTICLE

Validation of the Italian version of Parkinson's Disease-Cognitive Rating Scale (PD-CRS)

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Abstract Cognitive impairment (CI) is a frequent feature associated with both early and advanced stages of Parkinson's disease (PD). An evaluation of cognitive functions is relevant to identify those parkinsonians at risk of developing dementia. In the present study, the Italian version of Parkinson's Disease-Cognitive Rating Scale (PD-CRS) assessing fronto-subcortical and cortical cognitive functions in PD was validated in 387 parkinsonians and was used to test the empirical validity of the item 1.1 (cognitive impairment) of the Italian version of MDS-UPDRS as screening tool for CI in PD. PD-CRS was free from floor and ceiling effect. The mean PD-CRS score was 76.1 (mean cortical score, 24.5 ± 4.6; mean subcortical score, 51.5 ± 17.5). The internal consistency was satisfactory ($\alpha = 0.89$); corrected item-total correlation was 0.570 (naming) to 0.696 (working memory). The correlation between PD-CRS and part I–IV of MDS-UPDRS was weak. The low agreement between classification of PD sample into patients with mild cognitive impairment (PD-MCI), dementia (PD-D) and normal cognition (PD-NC) according to scores of item 1.1 and classification according to cutoff scores of PD-CRS for PD-MCI, PD-D and PD-NC indicated a poor empirical validity of item 1.1 of MDS-UPDRS as cognitive screening tool for CI in PD ($K = 0.114$; weighted $K = 0.17$; SE of $K = 0.038$; 95 % confidence interval from 0.040 to 0.1895). The Italian version of PD-CRS is an easy, consistent and valid tool for assessment of the cognitive cortical and subcortical impairments in PD.

Keywords Parkinson's disease · Cognitive dysfunctions · Mild cognitive impairment · Dementia · Parkinson's Disease Cognitive Rating Scale (PD-CRS)

On behalf of the IRIS Study Group.

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Introduction

Cognitive impairment (CI) may frequently occur in PD patients without dementia, in both early and advanced stages of the disease [1]. Recently, it has been proposed that 25 % of newly diagnosed patients may present CI which fulfills criteria for mild cognitive impairment (MCI) [2]. The most frequent CI in PD are decreased attention and executive, visuospatial and memory dysfunctions [1]. Recent evidence suggests that impairment of the semantic memory and visuospatial functions, but not executive

functions, predicts progression to dementia in PD (PDD) [3]. It is relevant to identify those PD patients at risk of developing dementia by means of neuropsychological tools evaluating the whole spectrum of cognitive functions impaired over the course of the disease. To achieve it, Pagonabarraga et al. [4] developed a new PD-specific cognitive scale, named Parkinson's Disease-Cognitive Rating Scale (PD-CRS), which assesses both fronto-subcortical and cortical cognitive functions in PD patients. The authors demonstrated its validity and reliability as a tool for the diagnosis of PDD, and for detection of both mild fronto-subcortical deficits in nondemented PD patients and the transition from MCI to dementia [4]. The present prospective, multicenter study was designed both to validate the Italian version of PD-CRS in a large sample of PD patients, and to perform a deeper assessment and screening of cognitive aspects in PD patients. Moreover, the present study tested the empirical validity of item 1.1 (cognitive impairments) of the Italian version of MDS-UPDRS [5], a revised version of Unified Parkinson's Disease Rating Scale [6] as a screening tool for CI in PD against the Italian version of PD-CRS.

Materials and methods

This study was conducted in 17 Neurological centers, specialists in movement disorders in the context of the validation of the Italian version of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale [5]. According to previously published methods, PD patients were consecutively enrolled and included if: (1) they provided written and signed informed consent; (2) were native Italian-speaking subjects of either sex; (3) were patients suffering from Parkinson's disease ranging from mild to severe, based on clinical judgment; (4) were accompanied by a native Italian-speaking caregiver. Patients were excluded if they showed evidence of other central nervous system disorders or a degree of depression and/or dementia, which might prevent and/or affect ratings. Each center enrolled between 10 and 30 subjects for a total of 432 PD patients; 378 PD patients agreed to participate in the present study.

Neurological and neuropsychological assessment

All PD patients were evaluated with the Italian version of MDS-UPDRS including four parts [5]: Part I evaluates non-motor experiences of daily living (nM-EDL), Part II evaluates motor experiences of daily living (motor-EDL), Part III evaluates motor function, and Part IV evaluates motor fluctuations and dyskinesia. Moreover, demographic (age, gender, and education) and clinical aspects (age at onset, duration of disease, and drug treatment) were recorded. All PD patients were administered the Italian version of Parkinson's Disease-Cognitive Rating Scale (PD-CRS; [4]), a neuropsychological battery specific for assessing cognitive impairment in Parkinson's disease. It is composed of nine tests: (1) immediate free recall verbal memory (score 0–12); (2) confrontation naming (score 0–20); (3) sustained attention (score 0–10); (4) working memory (score 0–10); (5) clock drawing (score 0–10); (6) copy drawing of a clock (score 0–10); (7) delayed free recall verbal memory (score 0–12); (8) alternating verbal fluency (score 0–20); (9) action verbal fluency (score 0–30), with a total score of 134 (best score). Sum of scores of tests 1, 3, 4, 5, 7, 8, and 9 gives the subcortical score, and sum of scores of items 2 and 6 gives the cortical score.

Translation of the PD-CRS

The PD-CRS has been adapted to Italian language by a translation/re-translation method: the translation both of test and its accompanying instructions was examined in a consensus meeting, and then it was re-translated into English and finally approved in a second consensus meeting. To explore the appropriateness and the comprehensibility of the provisional Italian translation, an examiner administrated PD-CRS to a group of ten PD patients. Moreover, to assess patients' and examiners' understanding and ease of comprehension for instructions and response options, after each item some questions were made to the patients and examiner. A six-point Likert scale was used with 0 representing "very difficult" and 6 "very easy". The revised back-translation was revised by the Steering Committee, which gave a provisional approval of the translation to be used in the validation phase.

Validation phase

Before starting the validation phase, native Italian-speaking neurologists specialized in movement disorders or neuropsychologists participated in training sessions led by the Italian Coordination Team and aimed at standardizing the assessment methods. A specific manual with detailed guidelines for tests administration was provided to the investigators.

Trained neurologists or neuropsychologists approved the Italian version of the PD-CRS.

Statistical analysis

The following psychometric attributes were explored for the PD-CRS: acceptability, internal consistency, and construct validity. Acceptability was considered appropriate for each PD-CRS item if there were <5 % of missing values and <15 % of the respondents with the lowest and

highest possible scores (floor and ceiling effect; [7]). Moreover, skewness of total and two subscores (limits, −1 to +1) was determined [8].

Internal consistency was evaluated by means of Cronbach's alpha [9]. A value ≥0.70 was considered as acceptable [10]. Scaling assumptions referring to the correct grouping of items and the appropriateness of their summed score were checked using corrected item-total correlation (standard, ≥0.40; [11]).

Construct validity was explored by means of parametric Bravais–Pearson correlation among total score and two subscores of PD-CRS and part I–IV of MDS-UPDRS. Moreover, Spearman's rank correlation was performed between items assessing CI, hallucinations and psychosis, depressed mood, anxious mood, and apathy included in part I of MDS-UPDRS and total PD-CRS score. For the scale's internal validity, it was hypothesized that the correlation between the two subscales of PD-CRS would stand at 0.30–0.70. The influence of demographic and clinical aspects (age, sex, education, PD therapy, disease duration, symptoms at PD onset, disease severity, presence of depressed mood) on PD-CRS score was analyzed using the Mann–Whitney or Kruskal–Wallis tests.

As for empirical validity of the item 1.1 (cognitive impairments) of the Italian version of MDS-UPDRS as a screening tool for CI, Cohen's kappa coefficient was performed to assess the agreement between item 1.1 of MDS-UPDRS and PD-CRS in identifying PD patients with and without CI.

Results

The Italian version of PD-CRS was administered to 378 PD patients (164 females and 214 males; mean age, 65.2 ± 10; mean levodopa equivalent daily dose, 666.59 ± 401.3). The mean PD-CRS score was 76.1 (mean cortical score, 24.5 ± 4.6; mean subcortical score, 51.5 ± 17.5), and the median was 78. Average time needed to complete the Italian version of PD-CRS was 26.51 ± 9.92 min.

Acceptability

95.8 % of data were totally computable and 4.2 % were missing value. The percentage of missing values was <5 % for all items. In the whole PD sample, neither ceiling nor floor effects were observed for the total PD-CRS. While no floor effect or outliers were observed for any cognitive item, a ceiling effect (>15 % of the respondents with the highest possible score) was observed in attention (25.2 %), clock drawing (26.7 %), and the copy of a clock (47.9 %). Skewness of total and two subscores of PD-CRS was within the standard limits (Table 1).

Reliability

Cronbach's alpha was 0.890 and so it was considered acceptable for internal consistency. No item improved Cronbach's alpha if removed. Corrected item-total correlation was 0.570 (naming) to 0.696 (working memory).

Convergent construct validity

The correlation between cortical and subcortical subscores of PD-CRS was 0.688. The parametric Bravais–Pearson correlation coefficient does not show noticeable association of PD-CRS (total score and two subscores) with all parts of MDS-UPDRS (Table 2). Spearman correlation coefficient revealed moderate association of PD-CRS with item 1.1 of MDS-UPDRS assessing cognitive impairments of ($r = -0.306$, $P < 0.001$) and low correlation with item 1.2 of MDS-UPDRS assessing hallucinations and psychosis ($r = -0.227$, $P < 0.001$), item 1.3 of MDS-UPDRS assessing depressed mood ($r = -0.188$, $P = 0.001$), item 1.4 of MDS-UPDRS assessing anxious mood ($r = -0.100$, $P = 0.066$), and item 1.5 of MDS-UPDRS assessing apathy ($r = -0.147$, $P = 0.005$) of MDS-UPDRS.

The Kruskal–Wallis showed no significant influence of gender on total score, and subcortical and cortical scores (Table 3). Moreover, patients with elementary education and with an age above 65 years showed lower total, cortical and subcortical scores than patients with middle school, upper school, and university education and patients with an age below 65 years (Table 3). As for clinical aspects, PD sample was divided into three groups according to PD therapies: (i) group treated with DA agonists (including DA agonists alone and DA agonists and MAO-B/COMT inhibitors); (ii) group treated with L-DOPA, encompassing LDOPA/carbidopa alone and L-DOPA plus MAO-B/COMT inhibitors; (iii) group treated with L-DOPA + DA agonists with or without MAO/COMT inhibitors or anticholinergics. The ANOVA showed that patients treated with DA agonists performed better than the other two groups both on total score and two subscores of PD-CRS (Table 3). The Kruskal–Wallis test showed that patients with PD duration ≤6 years and with age at PD onset <60 years had higher total, cortical, and subcortical scores on PD-CRS. As for disease severity assessed by the investigators as mild, mild to moderate, moderate, and severe, patients with severe disease reported significantly lower cortical and subcortical scores than patients with moderate disease, whereas no significant difference was found among other groups (mild vs mild to moderate and mild to moderate vs moderate). No significant influence of motor phenotype of PD (tremor-dominant type vs akinetic-rigid type) on patients' performance on PD-CRS was found (Table 3). Finally, PD patients with depressed mood

Table 1 Italian version of Parkinson's Disease-Cognitive Rating Scale acceptability

Item/subscale PD-CRS	Mean	Median	SD	Min–max	Skewness	Floor effect (%)	Ceiling effect (%)
Immediate verbal memory	7.6	8	2.2	2–12	−0.1	0.5	3.7
Confrontation naming	15.9	16	3.3	4–20	−0.8	0.3	12.2
Sustained attention	6.9	8	3.2	0–10	−1	9	25.7
Working memory	5.1	5	2.7	0–10	−0.1	6.6	4
Clock drawing	7.5	8	2.6	0–10	−0.9	0.8	27.5
Copy drawing of a clock	8.6	9	2.1	0–10	−1.9	0.5	47.9
Delayed recall memory	5.2	5	2.8	0–12	0.1	4.8	1.3
Alternating verbal fluency	8.3	8	4.7	0–20	0.4	2.4	2.4
Action verbal fluency	10.7	10	5.1	0–30	0.5	0.5	0.3
Subcortical score	51.5	52	17.5	11–91	−0.1	0.3	0.5
Cortical score	24.5	26	4.6	8–30	−1	0.3	9.5
Total score	76.1	78	20.9	21–120	−0.3	0.3	0.5

PD-CRS Parkinson's Disease-Cognitive Rating Scale

Table 2 Convergent validity of the Italian version of Parkinson's Disease-Cognitive Rating Scale

	Total PD-CRS score (*r*)	Subcortical PD-CRS score (*r*)	Cortical PD-CRS score (*r*)
Age	−0.527	−0.521	0.750
Age at diagnosis of PD	−0.387	0.388	−0.254
LEDD	−0.228	0.22	−0.22
Hoehn and Yahr scale	−0.415	−0.413	−0.315
MDS-UPDRS: nM-EDL (part I)	−0.347	−0.339	−0.292
MDS-UPDRS: Motor-EDL (part II)	−0.446	−0.436	−9.37
MDS-UPDRS: part III	−0.413	−0.411	−0.315
MDS-UPDRS: part IV	−0.195	−0.195	−0.146
Total PD-CRS score	1	0.987	0.793
Subcortical PD-CRS score	0.987	1	0.688
Cortical PD-CRS score	0.793	0.688	1

PD-CRS Parkinson's Disease-Cognitive Rating Scale, *LEDD* levodopa equivalent daily dose, *MDS-UPDRS*: *nM-EDL* (Part I) Movement Disorders Society-Unified Parkinson's Disease Rating Scale: non-motor experiences of daily living (Part I), *MDS-UPDRS*: Motor-*EDL* (Part II) Movement Disorders Society-Unified Parkinson's Disease Rating Scale: motor experiences of daily living (Part II), *MDS-UPDRS* Movement Disorders Society-Unified Parkinson's Disease Rating Scale

performed worse than non-depressed PD patients on total score and on subcortical score, whereas they showed similar cortical score (Table 3).

To evaluate empirical validity of the item 1.1 (cognitive impairment) of the Italian version of MDS-UPDRS as screening tool for CI, the whole PD sample was divided into patients with and without dementia according to both established cutoff scores (PD-dementia, PDD: score $\leq$64; Mild Cognitive Impairment, PD-MCI: score 65–81; normal cognition, PD-NC: score $\geq$82 [4, 12]) and different scores of item 1.1. of MDS-UPDRS. For this item, a score = 0 indicates normal cognition, score = 1 indicates slight CI (Impairment complained by patient or caregiver with no concrete interference with the patient's ability to carry out normal activities and social interactions), and score = 2, 3 or 4 indicates mild, moderate, or severe CI which reduces their functional autonomy, respectively (Table 4). The strength of agreement between the classification of whole sample in patients with PD-MCI, with PD-D and without CI according to cutoff of PD-CRS and the classification according to scores on item 1.1. of MDS-UPDRS is considered to be poor ($K = 0.114$; weighted $K = 0.17$; SE of $K = 0.038$; 95 % confidence interval from 0.040 to 0.1895).

Discussion

The present study is the first to validate the Italian version of PD-CRS in PD patients, and appears to be suitable, reliable, and easily applicable in Italian PD population. The scale as a whole showed high acceptability since data were computable for 97.1 % and the percentage of missing

Table 3 Cortical, subcortical, and total Parkinson's Disease-Cognitive Rating Scale scores according to demographic and clinical aspects of PD sample

Variables	Type	Total PD-CRS	Cortical score	Subcortical score
Gender	Females ($n = 164$)	76.3 ± 21.8	24.4 ± 4.4	51.9 ± 18.6
	Males ($n = 214$)	75.4 ± 19.8	24.5 ± 4.6	50.9 ± 16.4
	P	0.7142	0.5960	0.5782
Age	≤65 years ($n = 173$)	86.5 ± 17.79	26.2 ± 3.4	60.3 ± 15.7
	>65 years ($n = 205$)	66.8 ± 18.7	23 ± 4.8	43.8 ± 15.1
	P	<0.0001	<0.0001	<0.0001
Treatment	DA agonist ($n = 56$)	90.1 ± 14.8	26.6 ± 3	63.6 ± 13.2
	L-Dopa ($n = 120$)	68.1 ± 20.8	23.3 ± 4.8	44.8 ± 17.2
	L-Dopa + DA agonist ($n = 191$)	76 ± 20.1	24.4 ± 4.5	51.6 ± 16.8
	P	<0.0001	<0.0001	<0.0001
Age of PD onset	<60 years ($n = 186$)	82.5 ± 19.6	25.5 ± 3.8	56.9 ± 16.9
	≥60 years ($n = 192$)	69.4 ± 19.9	23.5 ± 4.9	45.9 ± 16.1
	P	<0.0001	<0.0001	<0.0001
Disease duration	≤6 years ($n = 186$)	80.2 ± 18.5	25.4 ± 4	54.8 ± 15.8
	>6 years ($n = 192$)	71.6 ± 22	23.6 ± 4.8	48.1 ± 18.3
	P	0.0003	0.0002	0.0009
Motor phenotype	Akinetic-rigid type ($n = 238$)	75.8 ± 20.9	24.4 ± 4.6	51.3 ± 17.5
	Tremor-dominant type ($n = 140$)	75.8 ± 20.6	24.4 ± 4.3	51.4 ± 17.3
	P	0.9289	0.5712	0.9421
Current disease severity	Mild ($n = 103$)	84.7 ± 18.3	25.9 ± 3.5	58.7 ± 16.4
	Mild to moderate ($n = 129$)	77.8 ± 17.7	24.7 ± 4.3	53.1 ± 14.6
	Moderate ($n = 115$)	70.7 ± 22.4	23.5 ± 5.1	47.2 ± 18.3
	Severe ($n = 31$)	56.8 ± 16.6	21.7 ± 4.2	35.2 ± 13.4
	P	<0.0001	<0.0001	<0.0001
Education	Elementary school ($n = 122$)	61.9 ± 17.8	21.8 ± 4.9	40.1 ± 13.9
	Middle school ($n = 111$)	78.8 ± 17.2	25.4 ± 3.7	53.3 ± 14.8
	Upper school ($n = 97$)	84.9 ± 18.4	26 ± 3.6	58.9 ± 16.1
	University ($n = 48$)	86.2 ± 21.4	25.9 ± 3.7	60.3 ± 18.8
	P	<0.0001	<0.0001	<0.0001
Depressed mood	Depressed patients ($n = 228$)	73.3 ± 21.5	24.1 ± 4.7	49.2 ± 18
	Nondepressed patients ($n = 150$)	79.7 ± 19	24.9 ± 4.1	54.8 ± 15.9
	P	0.0026	0.0925	0.0010

Table 4 Distribution of PD-CRS classes of cognitive impairment (normal cognition, PD-NC; mild cognitive impairment, PD-MCI; dementia, PDD) by scores of MDS-UPDRS item 1.1 (cognitive impairment)

	Item 1.1 of MDS-UPDRS		
	0	1	2, 3, 4
PD-CRS (categories)	(%)	(%)	(%)
PD-NC (≥82)	101 (47.4)	43 (36.1)	8 (17.4)
PD-MCI (65–81)	74 (34.7)	39 (32.8)	13 (28.3)
PD-D (≤64)	38 (17.8)	37 (31.1)	25 (54.3)

PD Parkinson's disease, *NC* normal cognition, *MCI* mild cognitive impairment, *PD-D* Parkinson's disease dementia

values was <5 % for all items. The acceptability of the Italian version is also supported by the absence of both ceiling and floor effects for the cortical, subcortical, and total PD-CRS scores, as reported in the original study [4] and in the Spanish validation study [13]. A ceiling effect in attention, clock drawing and copy of a clock (25.2, 26.7 and 47.9 %, respectively), exploring attention/executive functions, and visuoconstructional abilities was observed; the result might indicate either that cognitive domains were less impaired than others in our large PD sample or that the above-mentioned items did not capture cognitive dysfunctions in a high proportion of PD patients, as previously suggested [13].

The internal consistency of the Italian version of PD-CRS is high, acceptable ($\alpha = 0.89$; corrected item-total correlation = 0.570–0.696), and close to values obtained in the original study ($\alpha = 0.85$; corrected item-total correlation = 0.73–0.87, [4]) and in validation study of Spanish version of PD-CRS ($\alpha = 0.85$; corrected item-total correlation = 0.57–0.73, [13]). The finding indicated a significant interrelation among all cognitive items of PD-CRS and supported that this scale was characterized by high reliability [4].

As for convergent and divergent validity, PD-CRS showed unnoticeable and weak association with measures for severity of motor and psychological symptoms of PD assessed by Part I–IV of MDS-UPDRS. The low correlation may be indicative of a satisfactory divergent validity and may be explained by the fact that the scales evaluate different constructs: the PD-CRS is a battery tailoring exclusively cognitive functions, whereas part I of MDS-UPDRS evaluates the severity of both cognitive as well as behavioral disturbances (i.e., apathy, anxiety, hallucinations). Evidence of adequate construct validity has been shown for Italian version of PD-CRS. The construct validity was supported by moderate correlation between PD-CRS and item 1.1 of MDS-UPDRS assessing specifically severity of CI and by cognitive differences observed among categories of patients grouped by age, education, PD therapy, disease severity, and duration. The findings have revealed that the severity of cortical and subcortical cognitive alterations assessed by the Italian version of PD-CRS increase significantly with advanced age at evaluation and age at diagnosis of PD, Levodopa treatment, more severe motor symptoms, longer PD duration, and depressed mood, as previously reported [14–16]. The apparently moderate convergent validity of the PD-CRS should be further explored using other measures of cognitive abilities.

In the present study, empirical validity of item 1.1 of MDS-UPDRS as screening tool for CI was evaluated. The finding about poor agreement between classification of PD sample in patients with normal cognition, MCI or PD-D according to scores of item 1.1 and the same classification according to established cutoff scores of PD-CRS [4] suggested low empirical validity. However, the poor agreement between the two tools may depend on the fact that they are different; PD-CRS is a cognitive battery including several specific tests, whereas item 1.1 of MDS-UPDRS is a part of a face-to-face interview with patient and/or caregiver.

The poor agreement between two cognitive instruments may suggest that whenever possible, it is advisable to gather information about cognitive functioning using self- and informant-report tools and cognitive screening instruments validated in PD. Moreover, taking into account that diagnosis of MCI is based on test scores only while diagnosis of dementia is a functional diagnosis based on clinical judgment, it seems relevant to clarify that item 1.1 MDS-UPDRS can be used only as a cognitive screening tool to detect CI in PD patients, but not to make a diagnosis of MCI or dementia.

The finding of significant different performances regarding patients with normal cognition, with MCI and with PDD on all items of PD-CRS, indicates that the severity of cognitive impairment increases in the following order: patients with normal cognition < patients with MCI < patients with PDD, as stated in a previous report [4].

In conclusion, the Italian version of PD-CRS is an applicable and valid tool for assessing cognition in PD patients. Moreover, the poor agreement between PD-CRS and the item 1.1 (cognitive impairments) of MDS-UPDRS confirms the need to apply an objective neurocognitive test in evaluating cognitive functioning. Since MCI is associated with reduced metabolism in posterior cortical areas in both early and advanced stages of disease as well as cortical structural changes [17–19], and it is a risk factor for the development of dementia [3], the application of appropriate cognitive screening tools may reveal subtle CI and identify PD patients at high risk of dementia.

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