




Quality of life in Parkinson's disease: Italian validation of the Parkinson's Disease Questionnaire (PDQ-39-IT)

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Abstract

Translation and cross-cultural adaptation of the 39-item Parkinson's Disease Questionnaire (PDQ-39) to the Italian culture was performed by Oxford University Innovation in 2008, but this version has never been validated. Therefore, we performed the process of validation of the Italian version of the PDQ-39 (PDQ-39-IT) following the "Consensus-Based Standards for the Selection of Health Status Measurement Instruments" checklist. The translated PDQ-39-IT was tested with 104 patients diagnosed with Parkinson's disease (PD) who were recruited between June and October 2017. The mean age of the participants was 65.7 ± 10.2 years, and the mean duration of symptoms was 7.4 ± 5.3 years. The internal consistency of the PDQ-39-IT was assessed by Cronbach's alpha and ranged from 0.69 to 0.92. In an assessment of test-retest reliability in 35 of the 104 patients, the intraclass correlation coefficient (ICC) ranged from 0.85 to 0.96 for the various subitems of the PDQ-39-IT (all $p < 0.01$). Spearman's rank correlation coefficient for the validity of the PDQ-39-IT and the Italian version of the 36-Item Short Form (SF-36) was -0.50 ($p < 0.01$). The results show that the PDQ-39-IT is a reliable and valid tool to assess the impact of PD on functioning and well-being. Thus, the PDQ-39-IT can be used in clinical and research practice to assess this construct and to evaluate the overall effect of different treatments in Italian PD patients.

Keywords Assessment tool · Health-related quality of life · HRQoL · Italy · Parkinson's Disease Questionnaire · Reliability · Validity

Introduction

Parkinson's disease (PD) is a common progressive, neurodegenerative disease, affecting 0.1% of the general

population and 1% of the population over 65 years [1]. In 2016, the estimated regional incidence rate of PD in Italy was 0.28 new cases/1000 person-years, with a prevalence of 3.89/1000 persons [2]. The disease incidence increases with older age and is more common among males than females [3, 4]. The clinical, social, and economic implications of PD are significant. Disability in PD is due to the presence of both motor and non-motor symptoms, which restrict both the self-sufficiency and social participation of patients, leading to a low quality of life (QoL) for both patients and their caregivers.

Several scales have been proposed to assess the QoL of PD patients [5]. Information on the QoL of PD patients and studies on the relationship between QoL and motor and cognitive functions are necessary both for research and clinical use to make informed decisions in healthcare and rehabilitation areas [6–8]. In a systematic review, Martinez-Martin et al. [9] concluded that four generic scales (EuroQoL [10], Nottingham Health Profile [11], 36-Item Short Form Health Survey (SF-36) [12], and Sickness Impact Profile [13]) and five specific

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scales (Parkinson's Disease Questionnaire Short Form [14], Parkinson's Disease Quality of Life Questionnaire [15], Parkinson's Impact Scale [16], Scales for Outcomes in Parkinson's Disease-Psychosocial [17], and the 39-Item Parkinson's Disease Questionnaire (PDQ-39) [18, 19]) could be recommended. The PDQ-39, developed in 1995 by Peto et al. [18, 19], is the most thoroughly tested and applied assessment tool to assess QoL in PD patients. The questionnaire consists of 39 items, divided into 8 subtests: mobility (10 items), activities of daily living (6 items), emotional well-being (6 items), stigma (4 items), social support (3 items), cognition (4 items), communication (3 items), and bodily discomfort (3 items). For each item, there are five possible answers: never, occasionally, sometimes, often, and always. The PDQ-39 is a patient-assessed instrument, which reflects the entire spectrum of health-related quality of life in PD patients, and research has shown that it is feasible, reliable, valid, comprehensive, and sensitive to change. The PDQ-39 is widely used worldwide, and it has been translated, culturally adapted, and validated into 13 different languages: English [18, 19], Spanish [20], American [21, 22], Greek [23], Chinese [24–26], Singaporean [27], Ecuadorian [28], French [29], Brazilian [30], Estonian [31], Iranian [32], Korean [33, 34], and Portuguese [35]. For the development of clinical practice and research in the field of PD, a practical and appropriate measurement scale is needed that is universally accepted. The goal shared by all health professions that deal with PD is improvement of QoL. To achieve this goal, instruments used in assessing the QoL in PD patients must be practical, appropriate, and validated for clinical use. The latter is also required to allow comparisons and meta-analyses of high-quality randomized controlled trials of individuals with PD.

In 2008, Oxford University Innovation, (<https://innovation.ox.ac.uk/>), a subsidiary of the University of Oxford in the UK (<https://innovation.ox.ac.uk/>), accepted a translated and adapted version of the PDQ-39 in Italian. However, the psychometric properties of the Italian translated version of the PDQ-39 (PDQ-29-IT) have not been evaluated. Therefore, the aim of this study was to review the PDQ-39-IT and to evaluate its psychometric properties.

Methods

This study was conducted by a research group composed by medical doctors and rehabilitation professionals from the “Sapienza” University of Rome and from “Rehabilitation & Outcome Measure Assessment” (R.O.M.A.) association. R.O.M.A. association in the last few years has dealt with the validation of many outcome measures in Italy [36–44]. We contacted the developers of the PDQ-39 to obtain permission to use the scale. We were informed that Oxford University Innovation, the

copyright holder, had already accepted a translated and adapted version of the PDQ-39 in Italian. After receiving the consent of Oxford University Innovation (<https://innovation.ox.ac.uk/>) in accordance with established guidelines [45], a focus group composed of one neurologist, one occupational therapist, and two physiotherapists assessed the level of comprehensibility and cognitive equivalence of the translated version (PDQ-39-IT) and verified the presence of possible confusing issues.

Sample According to previous validations of the tool [18–35], a minimum sample size of 86 participants with PD was required. The diagnosis of PD was based on the clinical diagnostic criteria of the Movement Disorder Society for PD [35]. We included patients older than 40 years, with a Mini-Mental State Examination score of ≥ 23 points [46, 47] and a minimum level of 5 years of education.

Consecutive individuals with PD were recruited from June to October 2017 from two University Hospitals in Rome, Italy (Sapienza University and Tor Vergata University). Eligible participants who met the inclusion criteria were informed about the study and invited to take part. All the participants included provided consent prior to the commencement of the study [48].

Measurements For each participant, the following demographic information was recorded: age, sex, years of education, employment status, disease duration (years), and disease severity according to the Hoehn and Yahr (H&Y) scale [49].

The PDQ-39 and SF-36 [12, 50] were used as outcome measures. SF-36 is a self-administered questionnaire designed to assess the health status of patients and has been validated for use in clinical practice and research [50].

Reliability and validity The reliability and validity of the culturally adapted scale (PDQ-39-IT) were assessed following the “Consensus-Based Standards for the Selection of Health Status Measurement Instruments” checklist [51]. For the assessment of test-retest reliability, a subgroup of patients was evaluated twice by the same examiner. The time interval between the test and retest was 3 days to ensure that the clinical condition of the patient remained stable. The retest was performed in person or by telephone interview. Test-retest reliability was measured by calculating the intraclass correlation coefficient (ICC). The scale was considered reliable at an ICC of > 0.70 .

The internal consistency of the PDQ-39-IT was evaluated by Cronbach's alpha, which was considered statistically significant at a cut-off of > 0.70 . Following the procedures of the original validation of the scale, we compared the scores of the PDQ-39-IT with those obtained with the Italian version of SF-36 using the Spearman's rank correlation coefficient.

Table 1 Demographic characteristics of patients enrolled

Variable	Mean \pm SD	Frequency (%)	Range
Gender			
Men		64 (62)	
Women		40 (38)	
Age	65.7 \pm 10.2		42–90
Symptoms duration (years)	7.4 \pm 5.3		0–26
MMSE	28.4 \pm 1.8		23–30
H&Y			
I		9 (8.6)	1–4
II		33 (31.7)	
III		45 (43.2)	
IV		17 (16.3)	
Education			
Primary school		8 (7.6)	
Middle school		33 (31.7)	
High school		45 (43.2)	
Graduated		18 (17.3)	
Employment status			
Employed		28 (27)	
Unemployed		6 (6)	
Retired		70 (67)	
Marital status			
Married		77 (74.0)	
Unmarried		27 (26.0)	

Data availability The PDQ-39-IT validated in this study is available in accordance with the copyright owner's royalties (process.innovation.ox.ac.uk/clinical/p/pdq-39/questionnaire/1).

Results

The focus group session ensured that all the items in the PDQ-39-IT were similar or identical to the original English version of the tool [21]. In total, 112 individuals were considered

eligible for inclusion in the study. Of these, 104 individuals agreed to participate and were enrolled. All 104 participants completed the study. Demographic data of the patients studied are presented in Table 1.

Reliability The internal consistency of the PDQ-39-IT, as assessed by Cronbach's alpha, ranged from 0.69 to 0.92. The lower of these two values (i.e., 0.69) was obtained in the social support dimension, and the higher values (i.e., 0.92) were obtained in the mobility dimension. The dimensions of stigma and cognition were at the cut-off limit of 0.70. The other dimensions of activities of daily living, emotional well-being, communication, and bodily discomfort ranged from 0.76 and 0.87. Data on the internal consistency and reliability are summarized in Table 2.

In 35 of the 104 patients enrolled in the study, the PDQ-39-IT was administered twice, with an interval of 3 days between the tests. As shown by the ICCs, intrarater reliability ranged from 0.85 to 0.96, with a high level of agreement between the two ratings, (all $p < 0.001$). The test-retest reliability data are summarized in Table 3.

Due to the small number of patients in each of the H&Y stages, we could not perform a correlational analysis between disease severity as assessed by the H&Y stages and the scores of the various subitems of the PDQ-39-IT.

Validity Spearman's rank correlation coefficient for the validity of the PDQ-39-IT and the Italian version of the SF-36 was -0.50 ($p < 0.01$).

All dimensions of the PDQ-39-IT showed a positive and significant association with all the dimensions of the SF-36 questionnaire [12, 50]. The mean scores and correlation of both tools are reported in Tables 4 and 5.

Discussion

The quality of life in PD has been the focus of much interest [51–54]. To assess quality of life, a valid and

Table 2 Internal consistency reliability of Italian PDQ-39

Subtest	Number of items	Cronbach's alpha	Mean \pm SD	SD
Mobility	10	0.92	15.63	10.59
ADL	6	0.87	8.72	6.25
Emotional well-being	6	0.80	9.46	5.33
Stigma	4	0.70	4.45	3.70
Social support	3	0.69	1.65	2.29
Cognitions	4	0.70	4.88	3.47
Communication	3	0.76	3.08	2.85
Bodily discomfort	3	0.76	4.55	3.13

Table 3 Test-retest reliability of Italian PDQ-39

	Intraclass correlation	95% confidence interval		Value	Sig
		Lower bound	Upper bound		
Mobility	0.94	0.88	0.97	16.43	0.000
ADL	0.94	0.88	0.97	16.55	0.000
Emotional well-being	0.91	0.82	0.96	11.23	0.000
Stigma	0.91	0.82	0.96	11.18	0.000
Social support	0.85	0.71	0.93	6.80	0.000
Cognition	0.93	0.87	0.97	14.91	0.000
Communication	0.91	0.82	0.96	11.25	0.000
Bodily discomfort	0.96	0.93	0.98	28.07	0.000

reliable tool is needed that can be used worldwide. The present study assessed the psychometric properties of PDQ-39-IT.

In this study, we showed that the PDQ-39-IT displays satisfactory psychometric properties, namely good reliability and validity. The Cronbach's alpha coefficients in the present study (range of 0.69 to 0.92) were similar to those found by Peto et al. [18] in the original validation study and to those of the original British version [19]. They were also similar to those obtained in most translations [18–35] and validation studies [20, 26–28, 30, 31]. In this study, the Cronbach's alpha coefficient for the social support subtest was < 0.70, suggesting that this

dimension may not provide accurate data. However, the test-retest reliability of each subitem of the scale was reliable, as shown by the ICCs. In common with the original UK study [18], we used the Italian version of SF-36 [43] as a gold standard to assess construct validity. Among the eight dimensions of the PDQ-39, Spearman's rank correlation coefficients for the total score of the SF-36 were significant [50]. Most previous validation studies of the PDQ-39 in other cultural settings used a variety of rating scales and classifications to assess construct validity [18–35]. All these studies found statistically significant correlations between disease severity and some of the PDQ-39 domains.

Table 4 PDQ-39-IT and SF-36 mean scores

	Min	Max	Mean	SD
Total	8	128	52.38	28.66
Tot. mobility (1–10)	0	39	15.63	10.59
Tot. ADL (11–16)	0	24	8.80	6.27
Tot. emotional well-being (17–22)	0	22	9.37	5.36
Tot. stigma (23–26)	0	14	4.43	3.68
Tot. social support (27–29)	0	9	1.65	2.29
Tot. cognitions (30–33)	0	15	4.88	3.47
Tot. communication (34–36)	0	11	3.08	2.85
Tot. bodily discomfort (37–39)	0	8	3.57	2.23
Total	62	118	96.93	10.19
Tot. physical functions (3–12)	10	30	21.19	5.96
Tot. role physical limitations for discomfort	3	8	5.31	1.54
Limit. ruolo disagi fisici (13–16)				
Tot. pain dolore (21–22)	2	11	5.83	2.49
Tot. general health (1. 33–36)	4	24	16.97	2.92
Tot. vitality (23.27.29.31)	4	22	15.17	3.28
Tot. social function (20.32)	1	8	5.63	1.06
Tot. role limitations emotional for distress (17–19)	0	6	4.18	1.37
Tot. mental health (2.24.25.26.28.30)	8	29	22.64	3.59

Table 5 Spearman's rank correlation coefficient for PDQ-39-IT and SF-36

	TOTAL	Tot. physical functions (3–12)	Tot. physical functions (3–12)	Tot. physical functions (3–12)	Tot. physical functions (3–12)	Tot. physical functions (3–12)	Tot. physical functions (3–12)	Tot. physical functions (3–12)	Tot. physical functions (3–12)
Total	-0.51**	-0.71**	-0.56**	0.48**	0.20*	-0.08	0.14	-0.58**	-0.20*
Tot. mobility (1–10)	-0.53**	-0.79**	-0.59**	0.47**	0.15	0.01	0.17	-0.51**	-0.19
Tot. ADL (11–16)	-0.47**	-0.67**	-0.52**	0.43**	0.20*	-0.07	0.15	-0.48**	-0.18
Tot. emotional well-being (17–22)	-0.28**	-0.34**	-0.33**	0.30**	0.15	-0.06	0.09	-0.41**	-0.20*
Tot. stigma (23–26)	-0.26**	-0.31**	-0.27**	0.17	0.11	-0.07	0.02	-0.32**	-0.14
Tot. social support (27–29)	-0.26**	-0.27**	-0.33**	0.26**	-0.01	-0.25**	0.10	-0.31**	-0.03
Tot. cognitions (30–33)	-0.29**	-0.39**	-0.32**	0.40**	0.06	-0.10	0.002	-0.48**	-0.11
Tot. communication (34–36)	-0.32**	-0.36**	-0.32**	0.20*	0.10	-0.15	-0.002	-0.36**	-0.14
Tot. bodily discomfort (37–39)	-0.22*	-0.37**	-0.23*	0.48**	0.16	-0.17	0.15	-0.34**	-0.08

**Correlation is significant at the 0.01 level (2-tailed)

*Correlation is significant at the 0.05 level (2-tailed)

Limitations of the study

A limitation of our study is that we were unable to correlate PDQ domains and disease severity due to the small number of subjects in each H&Y stage. The distribution of patients by severity was unbalanced (fewer patients with stages I and IV). In addition, patients were recruited from two university hospitals in Rome, and therefore we cannot exclude that the results we obtained in these settings could be different from those obtained in other geographical areas. To overcome this limitation, future studies should include larger samples of PD patients from different areas throughout Italy with better balanced distribution of severity.

Conclusions

In conclusion, the PDQ-39-IT is an acceptable, valid, and reliable tool to measure the quality of life of Italian PD patients. It provides Italian clinicians with a valid, reliable, rapidly administrable, and standardized scale to measure quality of life in PD, thereby enabling clinicians in all healthcare and rehabilitation professions to make informed decisions. It also provides Italian researchers with a PD assessment tool that is used worldwide and that can be employed in high-quality and comparable randomized controlled trials.

Compliance with ethical standards

All the participants included provided consent prior to the commencement of the study [48].

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