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ORIGINAL ARTICLE

Validation of the Italian version of carers' quality-of-life questionnaire for parkinsonism (PQoL Carer) in progressive supranuclear palsy

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Abstract
Progressive supranuclear palsy (PSP) is a rare, rapidly progressive, neurodegenerative disease characterized by falls and ocular movement disturbances. Caring for a partner or relative who suffers from PSP entails a strenuous and demanding task, usually lasting for years that affects carers' everyday life routines and emotional and social well-being. The 26-item Parkinsonism Carers QoL (PQoL Carer) is a self-administered, concise instrument evaluating the quality of life of caregivers of patients with atypical parkinsonism (both PSP and multiple system atrophy). Here, the PQoL Carer was translated into Italian and validated in 162 carers of PSP patients (54.3% women; mean age (standard deviation), 62.4 (15.4)) diagnosed according to the Movement Disorder Society criteria and recruited in 16 third-level movement disorders centers participating in the Neurecanet project. The mean PQoL total score was 40.66 ± 19.46. The internal consistency was excellent (Cronbach's alpha = 0.941); corrected item-total correlation was > 0.40 for all the items. A correlation with other health-related quality of life measures as well as with behavioral assessments was shown suggesting adequate convergent validity of the scale. PQoL also correlated with patients' severity of disease. The discriminant validity of the scale was evidenced by its capacity to differentiate between carers with varying levels of self-reported health ($p < 0.001$). In conclusion, the Italian version of the PQoL Carer is an easy, consistent, and valid tool for the assessment of the quality of life in carers of PSP patients.

Keywords Progressive supranuclear palsy · Quality of life · Caregiver · Carer · Clinical trials

Abbreviations

EQ-5D	Euroqol 5D
EQ-VAS	Euroqol visual analogue scale
HADS	Hospital Anxiety Depression Scale
HADS-A	Hospital Anxiety Depression Scale – anxiety
HADS-D	Hospital Anxiety Depression scale – depression
HR-QoL	Health-related quality of life
MDS	Movement Disorders Society
PSP	Progressive supranuclear palsy
PSP-RS	Progressive Supranuclear Palsy rating scale
PQoL Carers	Carers' quality-of-life questionnaire for parkinsonism

Introduction

Progressive supranuclear palsy (PSP) is a rare, rapidly progressive, neurodegenerative disease characterized by falls and supranuclear vertical palsy with a prevalence of about 6 per 100,000 and associated with reduced life expectancy,

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increasing disability, and considerable impact on health-related quality of life (HR-QoL) [1]. Caregivers (usually relatives and partners) are profoundly involved in the care of those patients with a disruptive impact on different aspects of their quality of life [2]. Although carers play a pivotal role in PSP patients' natural history, there is a scant of studies assessing the distinct features of caregiving in this area [3].

The 26-item Parkinsonism Carers QoL (PQoL Carer) is a self-administered, concise instrument evaluating HR-QoL of caregivers of patients with atypical parkinsonism (both PSP and multiple system atrophy). Each item consists of 5 rating categories, ranging from 0 (no problem) to 4 (extreme problem) [4]. The original study validated such instrument in a large sample of native English speaker carers of PSP patients ($N = 187$) demonstrating high acceptability, construct validity, and potential usefulness as a carer-reported outcome measure in clinical trials [4]. A PQoL Carer cut off > 62 has been proposed for identifying carers with a greater burden as well as severe anxiety and/or depression [5].

The aim of the present study was to validate the Italian version of the PQoL Carer in a large sample of caregivers of PSP patients.

Methods

Questionnaire translation

The translation of the PQoL Carer in Italian was done according to a stepwise process as follows [6]: (a) the translation from the English original version into Italian was carried out by a movement disorders expert and Italian native speaker, fluent in English (M.P.); (b) the back translation of the Italian version into English was carried out by a native English-speaking translator, fluent in Italian, not involved in the original translation; (c) the English original version was compared with the back-translated one and the possible differences were debated, thus resulting in the revision and changing of the first Italian version; (d) a comprehension test for the new consensus version was carried out in order to assess if the questionnaire was easy to understand with an independent group of 10 carers of PSP patients from the Center for Neurodegenerative Diseases (CEMAND), University of Salerno, Italy. All the carers agreed to comment on the comprehensibility and relevance of the questionnaire items; and (e) the final Italian version of the PQoL Carer was produced (Table 1).

Validation phase

This study was conducted in 16 third-level movement disorders centers participating in the Neurecanet project coordinated by the CEMAND, University of Salerno. Carers of PSP patients were consecutively enrolled and included if (1) they provided written and signed informed consent; (2) were native Italian-speaking subjects of either sex; and (3) were caregivers of PSP patients diagnosed with either possible or probable PSP according to the Movement Disorder Society (MDS) criteria [7]. Each center enrolled between 1 and 25 subjects for a total of 162 carers of PSP patients.

Enrolled subjects completed the PQoL Carer together with a few questions including age, gender, their relationship with the patient, hours spent daily with the patient, and whether they were living in the same premises with the patient. Carers were also asked to compare their current state of health to that 12 months ago, by indicating whether it was (1) better, (2) much the same, or (3) worse. They also completed the EQ-5D (three-level version) [8], a 5-item standardized self-report health status instrument assessing the individual's level of health status on five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression); the EQ-VAS (visual analogue scale), a self-rating of overall health ranging from 0 (worst imaginable health state) to 100 (best imaginable health state); and the Hospital Anxiety and Depression Scale (HADS) [9], an instrument comprising 14 items, seven of which measure anxiety (HADS-A) and the remaining seven depression (HADS-D). The scores on each scale range from 0 to 21, with higher scores on each scale indicating more anxiety or depression, respectively. Corresponding PSP patients were evaluated with the PSP rating scale (PSP-RS) by a movement disorders specialist [10].

Before starting the validation phase, involved centers participated in a training session led by the Coordination Center (University of Salerno) and aimed at standardizing the assessment methods.

The project was approved by the local Ethics committee.

Statistical analysis

The following psychometric properties were explored for the PQoL Carer: acceptability, internal consistency, and construct validity. Acceptability was considered appropriate for each PQoL Carer item if there were ≤ 5% of missing values and ≤ 15% of the respondents with the lowest and highest possible scores (floor and ceiling effect). Moreover, skewness of total score (limits, − 1 to + 1) was determined [6].

Internal consistency was evaluated by means of Cronbach's alpha [11]. A value ≥ 0.70 was considered acceptable [12]. 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; [13]).

Table 1 Item-total correlation of the PQoL Carer

Item	Item-total correlation
1. Per prendersi cura del Suo parente/partner necessita di uno sforzo fisico?	0.538*
2. E' difficile prendersi cura dei Suoi problemi di salute?	0.714*
3. Ha avuto problemi di salute (es. ha sofferto di mal di schiena o dolori articolari)?	0.468*
4. Pensa che prendersi cura di una persona malata sia stressante?	0.714*
5. Si sente affaticato o stanco?	0.710*
6. Si sente frustrato o annoiato?	0.716*
7. Si sente triste?	0.663*
8. Si sente solo o abbandonato?	0.629*
9. Si sente arrabbiato o tradito?	0.651*
10. Sente che il Suo sonno è disturbato?	0.621*
11. Si preoccupa del Suo parente/partner?	0.618*
12. Pensa che sia emotivamente difficile avere a che fare con i problemi fisici del suo parente/partner?	0.521*
13. La comunicazione con il Suo parente/partner è peggiorata?	0.586*
14. Il suo rapporto con il suo parente/partner è cambiato?	0.563*
15. Pensa sia difficile avere a che fare con il cambio di personalità del suo parente/partner?	0.479*
16. Pensa sia difficile tollerare il cambio di ruoli tra Lei e il Suo parente/partner?	0.684*
17. Pensa che la Sua intimità sia stata compromessa?	0.518*
18. Si sente in trappola?	0.762*
19. Sente di non fare molte cose per se stesso/a ultimamente?	0.757*
20. E' diventato difficile fare le cose spontaneamente?	0.638*
21. Esce di meno?	0.705*
22. Trova che la vita sia noiosa?	0.567*
23. Vede meno amici e familiari?	0.661*
24. La Sua vita familiare ha risentito della situazione?	0.687*
25. Sente di prendersi più responsabilità di quelle che dovrebbe?	0.566*
26. Pensa di non avere abbastanza supporto?	0.639*

*Correlation is significant at level 0.01 (two-tailed)

The convergent validity of the scale was evaluated by correlation (Spearman's correlation test) of PQoL Carer with (a) patients' PSP-RS, based on the assumption that the degree of severity of the patient's motor condition impacts on the carer's HR-QoL [4] and (b) EQ-5D and the EQ-VAS, as well as the HADS.

The discriminant validity of the scale was evaluated with the ANOVA test: we evaluated whether PQoL Carer significantly differentiated between (a) carers with varying levels of current health problems compared with that of 12 months ago (better, much the same, worse) and (b) carers with varying health levels based on their scores on the EQ-VAS (EQ-VAS score less than 35, less than 50, less than 70, 70 or greater).

The *T* test or ANOVA test with post hoc, as appropriate, was used to verify the impact of gender and geographical location in Italy (North, Center, South) on PQoL Carer.

Based on the PQoL Carer cut-off value of 62 [5], caregivers were divided into two groups: subjects with reduced QoL and subjects with preserved QoL. The two groups were compared on demographic and behavioral variables.

Correlations were considered strong with coefficient > 0.70, moderate with coefficient between 0.30 and 0.70, and negligible with coefficient < 0.30. Significance level was set at $p \leq 0.05$.

Statistical analysis was performed with SPSS (Version 23).

Results

One hundred sixty-two carers of PSP patients (54.3% women) were included in the present study. Mean (standard deviation) age was 62.4 (15.4) years old, 92% were patients' relatives spending together with the patient a mean of 16.5 (9.1) h. Seventy-two percent declared to live on the same premises as the patients. The mean ± standard deviation PQoL Carer was 40.66 ± 19.46 and the median ± interquartile range (IQR) was 39.50 ± 28.

Table 2 Convergent validity of the PQoL Carer

	Spearman's correlation	p
Age	0.052	0.526
Patients' PSP-RS	0.308	< 0.001
EQ-5D mobility	0.312	< 0.001
EQ-5D self-care	0.191	0.026
EQ-5D usual activities	0.352	< 0.001
EQ-5D pain/discomfort	0.292	< 0.001
EQ-5D anxiety/depression	0.410	< 0.001
EQ-VAS	− 0.503	< 0.001
HADS-A	0.401	< 0.001
HADS-D	0.414	< 0.001

Acceptability

A total of 99.86% of data were totally computable and 0.14% were missing values. The percentage of missing values was ≤ 5% for all items. Neither ceiling nor floor effects were observed for the PQoL Carer (lowest possible score = 1, 0.6%; highest possible score = 97, 0.6%). The skewness of PQoL Carer was within the standard limits (score = 0.271).

Reliability

Cronbach's alpha was 0.941 indicating a high level of internal consistency. No item improved the value of Cronbach's alpha if removed. Item-PQoL Carer correlation was ≥ 0.40 for all items; items 18 ($r = 0.762$) and 19 ($r = 0.757$) had the highest correlation coefficient (Table 1).

Convergent construct validity

A moderate correlation of the PQoL Carer score was pointed out with patients' severity of disease (PSP-RS), with other HR-QoL measures such as EQ-VAS and three dimensions of the EQ-5D (mobility, usual activities, and anxiety/depression), whereas a significant but poor correlation was found with self-care and pain/discomfort dimensions of the EQ-5D. Moreover, PQoL Carer score moderately correlated with the score on HADS-A and HADS-D. No significant correlation was found between PQoL Carer score and carer's age (Table 2).

The analysis showed no significant impact of either gender or geographic location on PQoL Carer (Table 3). The ANOVA test showed a significant impact on the variable "Carers' health today compared with health 12 months ago" on PQoL Carer; in particular, carers reporting worse condition showed higher values than those reporting much the same condition

Table 3 Impact of gender and geographic location on PSPQoL Carer and the distribution of scores of the PQoL Carer across levels of carers' current health compared with health 12 months ago and self-ratings of overall health

Variable	Type	PQoL Carer
Gender	Men ($N = 74$)	39 (16.4)
	Women ($N = 88$)	42 (21.6)
	p	0.333
Geographic location	North ($N = 57$)	43.1 (17.4)
	Center ($N = 52$)	39.4 (20.4)
	South ($N = 53$)	39.2 (20.5)
	p	0.487
Carers' health today compared with health 12 months ago	Better ($N = 6$)	40.6 (13.5)
	Much the same ($N = 71$)	30.4 (17.4)
	Worse ($N = 82$)	49.7 (17.2)
	p	< 0.001*
Carers' rating of overall health: EQ-VAS score	Less than 35 ($N = 8$)	62.2 (10.9)
	Less than 50 ($N = 28$)	51.6 (20.5)
	Less than 70 ($N = 13$)	49.1 (15.5)
	70 or greater ($N = 95$)	33.4 (15.6)
	p	< 0.001°

Values are shown in mean (standard deviation), unless otherwise specified

*Much the same versus worse, $p < 0.001$; better versus much the same, $p = 0.117$; better versus worse, $p = 0.253$

°Less than 35 versus less than 50, $p = 0.118$; less than 35 versus less than 70, $p = 0.110$; less than 35 versus 70 or greater, $p < 0.001$; less than 50 versus less than 70, $p = 0.801$; less than 50 versus 70 or greater, $p < 0.001$; less than 70 versus 70 or greater, $p = 0.002$

Table 4 Comparison between the two groups of carers based on the PQoL cut-off of 62

	PQoL ≤ 62	PQoL > 62	*p*
Age	62.5 (15.1)	62 (17.2)	0.891
Women/men, *n* (%)	69/67 (50.7/49.3)	19/7 (73.1/26.9)	0.052
Living in the same premises as the patients, yes/no, *n* (%)	96/38 (71.6/28.4)	22/4 (84.6/15.4)	0.225
Hours spent daily with the patient	16.1 (9.2)	18.8 (8.2)	0.160
Patients' PSP-RS	39.9 (15)	49 (20.9)	0.028
HADS-A	6 (4)	9.3 (4.6)	< 0.001
HADS-D	6.1 (3.5)	9.4 (4.6)	< 0.001
EQ-VAS	72.2 (16.5)	48.9 (21.4)	< 0.001
Carers' health today compared with health 12 months ago (better/much the same/worse)	6/67/60 (4.5/50.4/45.1)	0/4/22 (0/15.4/84.6)	< 0.001

Values are shown in mean (standard deviation), unless otherwise specified

EQ-VAS, Euroqol visual analogue scale; *HADS-A*, Hospital Anxiety Depression Scale – anxiety; *HADS-D*, Hospital Anxiety Depression scale – depression; *PQoL*, quality-of-life questionnaire for parkinsonism; *PSP-RS*, progressive supranuclear palsy rating scale

(Table 3). The Kruskal-Wallis test showed a significant impact on the variable "Carers' rating of overall health: EQ-VAS score" on PQoL Carer; in particular, carers having an EQ-VAS score of 70 or greater showed lower values than those having an EQ-VAS score less than 35, less than 50, and less than 70 (Table 3).

Twenty-six (16%) of carers scored > 62 on the PQoL Carer. Those carers presented worse condition compared with that 12 months before, higher HADS-A and HADS-D as well as lower EQ-VAS compared with carers scoring ≤ 62 on the PQoL Carer (Table 4). Furthermore, corresponding patients presented higher PSP-RS (Table 4).

Discussion

Here, we showed that the Italian version of the PQoL Carer is acceptable and easily applicable in the Italian carers of PSP patients. This is also the first application of the PQoL Carers in an independent sample after the original study supporting high levels of reliability of the scale [4].

The scale as a whole showed high acceptability since data were computable for 99.86% and the percentage of missing 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 PQoL Carer total score, as reported in the original study [4].

The internal consistency of the Italian version of the PQoL Carer is high and acceptable (alpha = 0.941) with an item-total score correlation of ≥ 0.40 for all items with values close to those obtained in the original study [4].

As for convergent and divergent construct validity, the PQoL Carer showed unnoticeable association with demographics. Such low correlation may be indicative of a satisfactory divergent validity and suggests the scale is suitable for carers of PSP patients of any age.

Evidence of adequate construct validity has been shown for the Italian version of the PQoL Carer. The construct validity was supported by a moderate correlation between PQoL Carer total score and other HR-QoL measures such as the EQ-5D and EQ-VAS.

Similar to the original study [4], the PQoL Carer also presented a moderate association with severity of the disease of PSP patients, as assessed with the PSP-RS. Indeed, these data support the hypothesis that HR-QoL of carers is related to patients' severity of disease.

Furthermore, we showed a moderate association between PQoL Carer and HADS both anxiety and depression scores, confirming a relationship between carers' HR-QoL and such behavioral symptoms [4, 5].

Neither gender nor geographic location in Italy had a significant impact on PQoL Carer in our sample, further supporting the reliability of the questionnaire for both sexes and all over the country.

The ANOVA test provided supportive evidence of the discriminant validity of the PQoL Carer. Scores on the scale significantly differentiate between carers with varying levels of the variable "current state of health compared with health 12 months ago" ($p < 0.001$) and carers with varying levels of self-reported health based on their scores on the EQ-VAS ($p < 0.001$) (Table 3).

Our study has several strengths. First, this is the largest sample of Italian carers of PSP patients collected to date, as large as in the original study [4]. Second, several centers across Italy joined the study; thus, the results are representative of all the country. Furthermore, all included carers had the corresponding patients evaluated in a third-level movement disorders center according to the MDS criteria as well as

PSP-RS [7, 14]. Finally, the low proportion of missing data increases the validity of our findings.

Our study has limitations. Although we sought to include caregivers of patients at all stages of PSP, it is likely that carers of patients in more advanced stages who cannot attend outpatient clinics were underrepresented in our sample.

In conclusion, the PQoL Carer Italian version showed high acceptability and good validity and reliability in assessing HR-QoL in carers of PSP patients. Further use of such assessment both in clinical and in research context is supported by its ease of application as well as its adequate psychometric properties.

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Compliance with ethical standards

The project was approved by the local Ethics committee.

Conflict of interest The authors declare that they have no conflict of interest.

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