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The CareGiver Oncology Quality of Life questionnaire (CarGOQoL): Development and validation of an instrument to measure the quality of life of the caregivers of patients with cancer

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ABSTRACT

Purpose: The study objective was to validate a specific quality of life (QoL) questionnaire for caregivers of cancer patients, the CareGiver Oncology Quality of Life questionnaire (CarGOQoL), based on the exclusive points of view of the caregivers.

Materials and methods: A 75-item questionnaire generated from content analysis of interviews with caregivers was self-completed by 837 caregivers of cancer patients. In addition to sociodemographic data and patient characteristics, self-reported questionnaires assessing QoL, burden, coping and social support were collected. Psychometric properties combined methods relying on both classical test theory and item response theory.

Results: The final 29 items selected assessed 10 dimensions: psychological well-being, burden, relationship with health care, administration and finances, coping, physical well-being, self-esteem, leisure time, social support and private life; they were isolated from principal component analysis explaining 73% of the total variance. The missing data and the floor effects were low. Some ceiling effects were found for B (34%). Cronbach's alpha coefficients ranged from 0.72 to 0.89, except private life (PL) (0.55). Unidimensionality of the scales was confirmed by Rasch analyses. Correlations with other instruments confirmed the isolated content and significant links were found with respect to patient's characteristics. Reproducibility and sensitivity to change were found satisfactory.

Conclusion: The CarGOQoL could provide a reliable and valid measure of caregivers of cancer patients' QoL which are key-actors in the provision of health care.

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1. Introduction

Cancer is a chronic disease that not only has an impact on patients but also considerably affects the quality of life (QoL) of these patients' caregivers.[1,2] Researchers have recognised that family caregiving, although having positive aspects for the caregiver, is often responsible of an emotional, physical, social and at time, financial burden.[3–8] Caregivers have been highlighted as key-actors in the provision of health care.[9] Caregivers contribute to the patients' adherence to and acceptance of treatments.[10]

Most previous studies focused on one or a few specific facets of the impact of cancer (social, psychological, etc.) and used instruments with weak psychometric properties.[11,12]

Mancini et al. reported primarily two QoL questionnaires developed for caregiver' populations.[13] The Caregiver Quality of Life Index (CQLI) is a straightforward questionnaire validated using a sample of five subjects.[14] The Caregiver Quality of Life Index-Cancer Scale (CQOLC)[15,16] which has been more thoroughly developed,[10] was based on a mixed approach combining interviews with cancer patient–caregiver dyads and experts' points of view,[11] validated using a homogeneous sample, with 20 spouses of 22 caregivers interviewed,[10] the items generated may not capture all of the domains of interest.[13]

We report the development and validation of a multidimensional QoL questionnaire for natural caregivers (NCG) of patients with cancer, assessing the impact on the caregivers' QoL, based on the exclusive caregivers' points of view, the CareGiver Oncology Quality of Life questionnaire (CarGOQoL).

2. Material and methods

2.1. *Population*

The sample was composed of caregivers of cancer patients from different oncology departments. Inclusion criteria for cancer patients were in- and out-patients; with a diagnosis of primary cancer; with a localised/regional or distant cancer. Inclusion criteria for caregivers were: 18 years of age or older; designated as the main NCG by the patient; able to speak/read French and free from cancer comorbidity.

2.2. *Study design*

Research assistants invited the caregivers to participate, explaining the purpose of the study. Informed consent was obtained. Patients and their caregivers visited the cancer centre. During their visit, patient characteristics (gender, age, type of the cancer and date of diagnosis) were collected. At the same visit and after appointment the caregiver fulfilled socio-demographic information (gender, age, occupational status and duration of caregiving) and the specific CarGOQoL. The CarGOQoL consisted of an initial pool of 75 candidate items that were generated from content analysis of qualitative interviews with 77 informal adult caregivers of cancer patients (breast cancer, paediatric haematological malignancies or melanoma) with different relationships with the patients (parents, children, spouses, siblings, and friends). Caregivers were on average 48.1 years old, 64% being women. Interviews were performed to identify the items and the domains that impacted the caregivers' QoL. Several domains were identified as relevant: psychological well-being, leisure and everyday activities, occupation and finances, physical well-being, relationships with institutional caregivers, with family and friends and with the patient. These items were answered using a five-point Likert scale, defined as '1 – Never/Not at all', '2 – Rarely/A little', '3 – Sometimes/Somewhat', '4 – Often/A lot', '5 – Always/Very much'.[13] Caregivers also completed questionnaires assessing QoL, burden, coping and social support. We used the Short Form 36 (SF36) questionnaire consisting of 36 items describing eight dimensions: physical functioning, social functioning, role-physical problems, role-emotional problems, mental health, vitality, bodily pain and general health.[17] We also used the French Zarit caregiver burden inventory (ZCBI) assessing physical, psychological and economical factors,[18] the French ways of coping checklist (WCC) describing three dimensions: emotion-focused coping, problem-focused coping and social support seeking,[19] and the Oslo 3-item social support scale (OSSS), which assesses the levels of social support.

A random sample of the recruited population was retested 30 ± 5 and 90 ± 5 days later. At each retest, the caregiver informed us of changes in his/her life (positive or negative changes including health problems), and defined the patient's health status change (worsened, stable, improved) relative to day 0.

2.3. *Statistical analysis*

The analyses were carried out following three major steps: (i) item selection, (ii) the identification of a factorial structure and (iii) the study of the psychometric reliability and validity of the final version of the CarGOQoL.

2.4. *Item reduction*

To reduce the number of items, each of the 75 items was reviewed for adverse characteristics regarding item distribution,[20,21] missing data per item (MD) and inter-item correlations. Items considered for deletion were those with more than 15% MD, ceiling or floor effects over 70% or an absolute value of skewness exceeding 4.0, or with correlation coefficients with others items over 0.8. At the end of this step, 16 items were removed.

2.5. *Internal structure identification*

The database was split randomly into two random sub-samples of caregivers. To further reduce the number of items, the psychometric method was used in the first sub-sample using principal component analysis (PCA) with varimax rotation,[22] items were selected primarily according to their relationship with one another. During this factor analysis each dimension was examined in order to point out the items that would be candidate for deletion owing to low psychometric performance at a dimension level by studying the inter-item,

item-dimension and inter-dimension correlations (Pearson's *r*).[23] Other 30 items were removed at this step.

Confirmatory factor analysis (LISREL model) was used in the second sub-sample. Robust maximum likelihood Confirmatory Factor Analysis (CFA), was performed to test the fit to the model assessed by the computation of the root mean square error of approximation (RMSEA: <0.05, good fit; 0.05–0.08, fair or reasonable; >0.08 unsatisfactory fit), the non-normed fit index (NNFI), and the comparative fit index (CFI).[24] The NNFI and CFI are expected to be greater than 0.90 if the fit is adequate.[25]

2.6. *Psychometric validation*

The unidimensionality of each dimension was assessed using Rasch analyses, the Partial Credit Model (PCM). The scalability of each dimension's scale was assessed by the pattern of the item goodness-of-fit statistics (INFIT). Items with INFIT included in the]0.7;1.2[were kept ensuring that all the items of the scale tended to measure the same concept. The relevance of the grouping of items into the original structure isolated by PCA was examined using multitrait multi-item analyses, examining correlations between item scores and dimension scores. Each item should be highly correlated with its scale, thus supporting item-internal consistency (IIC); a correlation corrected for overlap of at least 0.4 is recommended.[23] In addition, items should be more highly correlated with their own scale than with the other dimension scales (item-discriminant validity, IDV). For each dimension scale and for the global index, internal consistency reliability was assessed using Cronbach's alpha coefficient. A Cronbach's alpha coefficient of at least 0.7 was expected for each scale.[26]

To explore the external validity, relationships between the CarGOQoL scores and other QoL scores were investigated by calculating Pearson's correlation coefficients. Dimensions measuring the same concept were expected to be highly correlated with each other. Discriminant validity was tested by examining hypotheses based on expected QoL differences relying on previous results.[5,15,16,27–29]

Reproducibility was assessed using ICC between the first assessment at the time of enrollment and the second assessment, 30 days after, in a sub-sample of stable caregivers defined as: no positive or negative changes in their lives and patient's health status reported by the caregiver as stable and no changes in patient care. Sensitivity to change was assessed between the first assessment (at enrollment) and 90 days after in two sub-samples: (i) improved: caregivers reporting positive changes (without negative changes) and the improvement of the patient's health status between the two assessments, (ii) worsened: caregivers reporting negative changes (without positive changes) and patient's health status declined. Effect sizes (ES) and Delta changes (δ) were computed. An ES of at least 0.2 is recommended for supporting a minimal sensitivity to change.[30]

Acceptability was assessed by computing the time required to complete the questionnaire and the percentage of MD.

Data analyses were performed using PASW 17.0.2 computer software, MAP–R, Winstep and LISREL software.

3. Results

3.1. *Sample characteristics*

The study sample included 837 caregivers, aged 18–85 years, 34.6% of whom were men. Caregivers' and patients' characteristics are summarised in Table 1.

3.2. *Scoring*

The negatively worded item scores were reversed so that higher scores indicated a higher QoL. For each individual, scores of the dimensions were computed if at least half of its contributive items were answered. The score of each dimension was obtained by computing the mean of the items scores for that dimension. An index was computed as the mean of the dimension scores. All dimension scores and the index were linearly transformed and standardised on a 0–100 scale (the higher the score, the better the QoL).

3.3. *Validity*

3.3.1. *Internal structural validity*

The iterative process of item selection resulted in a final version comprised of 29 items describing 10 domains (Supplementary appendix). Each dimension was named according to its constitutive items: psychological well-being (PsWB); burden (B); relationship with health care (RHC); administration and finances (AF); coping (COP); physical well-being (PhWB); self-esteem (SE); leisure time (LEI); social support (SS) and private life (PL). The 10-factor structure was supported by PCA with varimax rotation and accounted for 73% of the total variance.

The structure was confirmed with CFA (RMSEA = 0.04, NNFI = 0.90 and CFI = 0.92). The overall scalability of the CarGOQoL was satisfactory; most items showed a good fit to the Rasch model within each dimension, and only one item ('Have you been under the impression that your health is weak?') showed an INFIT statistic outside the acceptable range.

The correlation between each item and its contributive dimension was higher than the correlation with the other dimensions. Internal consistency was satisfactory for all dimensions, except PL. The floor effect ranged from 0.4% to 6.4%, and the ceiling effect ranged from 3.2% to 34.1% (B). Internal consistency was high for the global index (0.90) and for dimensions except for PL (0.55). The inter-dimension correlations were all significant except those for PhWB and SE; these correlations varied from 0.06 to 0.39, except for PsWB and COP and PsWB and PhWB. The item and dimension scales characteristics are summarised in Table 2.

3.3.2. *Reproducibility and sensitivity to change*

Test–retest reliability explored using a sub-sample of 30 caregivers was satisfactory with a high ICC ranging from 0.52 to 0.80 except for LEI (Table 2). Among the 49 caregivers defined as improved at day 90, significant ES and δ were found for the PsWB, COP and SS dimensions and for the global index of CarGOQoL. The analyses performed on the 29 worsened caregivers assessed by ES confirmed the sensitivity to change of the

Table 1 – Subjects' characteristics.

Caregivers (N = 837)	n (%) or Mean ± SD
Gender[a]	
Women	545 (65.4)
Men	288 (34.6)
Age (years)	51.6 ± 13.8
Living with a partner	607 (72.5)
Alone	230 (27.5)
Relationship with the patient	
Partner	425 (51.3)
Parent	197 (23.7)
Child	125 (15.1)
Others[b]	82 (9.9)
Time of caregiving, months: median [25–75th perc]	13 [4–57]
Patients (N = 837)	n (%)
Gender	
Women	452 (54.0)
Men	385 (46.0)
Type of cancer	
Breast	222 (26.8)
Lung	139 (16.8)
Haematological	156 (18.8)
Head and neck	82 (9.9)
Cerebral	50 (6.0)
Others[c]	188 (22.7)

[a] Number of missing values = 4.

[b] Brother/sister (38), friend (34), uncle/aunt/nephew/niece/cousin (10).

[c] Prostate/urologic (65), digestive (30), genital (22), sarcoma (14), rare cancer (48), other (9).

SE, PL dimension and for the global index of CarGOQoL (Table 3).

3.3.3. *Convergent and discriminant validity*

The index was significantly correlated with all of the SF36 dimensions, Pearson's coefficients ranged from 0.24 to 0.67 (Table 4). The PhWB dimension showed high correlations with the SF36 dimensions describing the physical domain: role limitations due to physical health, vitality, bodily pain, general health and the physical composite score. PsWB was highly correlated with the dimensions related to the psychological domains: mental health and the mental composite score. High correlations were also found between social functioning and both PsWB and PhWB. Two dimensions that were not assessed by SF36 (RHC and SE) were globally uncorrelated or were more weakly correlated with the SF36 dimensions (–0.02 to 0.19).

As expected, SS was the dimension that most correlated with the OSSS score, and the B dimension was most correlated with the ZCBI score. High correlations were found between the WCC's emotion-focused coping dimension and the 'psychological-like' dimensions (COP and PsWB).

Women reported statistically significant lower scores for emotional dimensions, such as PsWB, B and COP and for the PhWB dimension, than male caregivers (Table 5). Globally, no differences were found with regard to caregivers' age, except for the RHC and AF dimensions for which older caregivers had better scores, and for the PL dimension. Caregivers living with a partner reported no differences, except for AF and SS, for which better scores were found. Caregivers reported worse QoL when the patient was a man and when the patient was older for PsWB, B, RHC, PhWB and SE dimensions. Caregivers who were children of the patients often reported significantly lower QoL scores in most dimensions. No or weak correlations were found concerning the patient's disease or the caregiving duration.

3.3.4. *Acceptability*

The average time required for completion of the questionnaire was 5.79 ± 4.03 min. The proportion of missing values per dimension never exceeded 10%.

Table 2 – Dimension characteristics of the 29-item final version of the CarGOQoL.

Dimension (items)	MD (%)	Mean ± SD	IIC minimum –maximum	IDV minimum –maximum	Floor effect (%)	Ceiling effect (%)	ALPHA	INFIT minimum –maximum	Test-retest ICC[a]
Psychological well being (4)	1.1	53.8 ± 25.3	0.64–0.74	0.74–0.79	2.5	4.8	0.89	0.86–1.11	0.63
Burden (4)	4.5	81.3 ± 20.9	0.44–0.64	0.60–0.69	0.4	34.1	0.82	0.84–1.12	0.69
Relationship with healthcare (3)	7.2	64.2 ± 23.9	0.58–0.65	0.65–0.71	2.3	9.8	0.83	0.72–1.05	0.69
Administration and finances (3)	6.3	77.8 ± 23.1	0.38–0.58	0.50–0.62	1.0	28.8	0.74	0.85–1.10	0.80
Coping (3)	3.0	57.7 ± 26.9	0.38–0.57	0.46–0.58	3.2	10.4	0.72	0.89–1.00	0.52
Physical well being (4)	3.1	64.2 ± 23.8	0.39–0.63	0.56–0.74	1.3	9.1	0.83	0.85–1.30	0.72
Self-esteem (2)	4.9	73.3 ± 21.2	0.60	0.63	1.2	21.8	0.77	0.96–1.00	0.74
Leisure time (2)	4.3	47.0 ± 23.1	0.63	0.63	6.4	3.2	0.78	0.79–0.85	0.40
Social support (2)	3.1	64.5 ± 27.7	0.53	0.56	4.5	17.5	0.72	0.98- 1.00	0.69
Private life (2)	8.1	59.3 ± 24.8	0.33	0.38	3.0	11.1	0.55	0.97–1.03	0.59
Index	17.3	65.0 ± 14.0	–	–	0.0	0.1	0.90	–	0.76

CarGOQoL scores ranging from 0 to 100, the higher the score the better the quality of life (QoL).

MD, missing data; IIC, item-internal consistency; IDV, item-discriminant validity; ALPHA, Cronbach's alpha.INFIT, item goodness of fit statistic.

[a] ICC: intraclass correlation coefficients. Thirty stable patients at 30 days defined as: no positive or negative changes in caregivers' lives and patients' health status reported by caregivers as stable and no changes in patient care.

Table 3 – Sensitivity to change: delta and effect size of QoL changes.

	Improved caregivers [a] N = 49		Worsened caregivers[b] N = 29	
CarGOQoL dimensions	Delta	ES	Delta	ES
Psychological well being (4)	14.67***	0.56	–1.94	–0.07
Burden (4)	0.18	0.01	0.07	0.00
Relationship with healthcare (3)	0.54	0.02	–4.02	–0.14
Administration and finances (3)	2.65	0.14	–2.98	–0.10
Coping (3)	9.84**	0.34	–4.17***	–0.19
Physical well being (4)	1.87	0.08	0.00	0.00
Self-esteem (2)	0.27	0.01	–4.91	–0.27
Leisure time(2)	1.86	0.08	–4.02	–0.19
Social support (2)	5.43**	0.20	–3.02	–0.12
Private life (2)	–2.87	–0.13	–7.87	–0.34
Index	3.65*	0.31	–4.13	–0.33

Delta change between day 0 and day 90 (final score – initial score).

ES, effect size ((final score – initial score)/initial score's standard deviation).

[a] Positive or no changes in caregivers' lives, patients' health status reported by caregivers as stable or improved and positive or no changes in patients' care.

[b] Negative or no changes in caregivers' lives, patients' health status reported by caregivers as stable or worsened and negative or no changes in patient's care.

* *p* value <0.05.

** *p* value <0.01.

*** *p* value <0.001.

Table 4 – Correlations between CarGOQoL and other self-reported measures.

		PsWB	B	RHC	AF	COP	PhWB	SE	LEI	SS	PL	Index
SF36	Physical functioning	0.18***	0.19***	0.12**	0.22***	0.08*	0.33***	0.05	0.06	0.20***	0.17***	0.27***
	Social functioning	0.56***	0.43***	0.11**	0.31***	0.41***	0.60***	0.09*	0.23***	0.18***	0.33***	0.57***
	Role limitations due to physical health	0.35***	0.36***	0.10*	0.30***	0.25***	0.48***	0.01	0.18***	0.11**	0.23***	0.41***
	Role limitations due to emotional problems	0.41***	0.32***	0.15***	0.25***	0.34***	0.47***	0.12**	0.17***	0.10**	0.27***	0.47***
	Mental health	0.69***	0.41***	0.19***	0.29***	0.51***	0.65***	0.14**	0.34***	0.18***	0.35***	0.67***
	Vitality	0.60***	0.36***	0.18***	0.32***	0.38***	0.64***	0.16***	0.29***	0.17***	0.33***	0.62***
	Bodily pain	0.33***	0.29***	0.02	0.31***	0.20***	0.52***	–0.02	0.22***	0.16***	0.23***	0.38***
	General health	0.37***	0.29***	0.12**	0.28***	0.23***	0.49***	0.12**	0.19***	0.23***	0.26***	0.45***
	PCS SF36	0.15***	0.21***	0.03	0.25***	0.05	0.36***	–0.02	0.11**	0.17***	0.15***	0.24***
	MCS SF36	0.66***	0.39***	0.18***	0.28***	0.51***	0.62***	0.15***	0.30***	0.14**	0.36***	0.65***
OSSS		0.13**	0.22***	0.18***	0.16***	0.09*	0.12**	0.15***	0.13**	0.47***	0.24***	0.37***
ZCBI		–0.48**	–0.69**	–0.20**	–0.39**	–0.36**	–0.51**	–0.13**	–0.26**	–0.21**	–0.40**	–0.64**
WCC	PFC	–0.07	–0.09*	0.15**	–0.11**	–0.04	–0.11**	0.18**	0.01	0.07	–0.03	0.05
	EFC	–0.43**	–0.26**	–0.12**	–0.24**	–0.51**	–0.39**	–0.08*	–0.14**	–0.08*	–0.24**	–0.46**
	SSS	–0.19**	–0.13**	0.16**	–0.10**	–0.10**	–0.16**	0.13**	–0.03	0.17**	–0.08*	–0.03

CarGOQoL dimension scores: PsWB, psychological well being; B, burden; RHC, relationship with healthcare; AF, administration and finances; COP, coping; PhWB, physical well being; SE, self-esteem; LEI, leisure time; SS, social support; PL, private life; scores ranging from 0 to 100, the higher the score the better the QoL.

Short Form 36 (SF36) dimensions, PCS SF36, physical composite score, MCS SF36, mental composite score, scores ranging from 0 to 100, the higher the score the better QoL.

OSSS, Oslo social support scale, one total score (three items), scores ranging from 3 to 14, the higher the score the stronger support.

ZCBI, Zarit caregiver burden inventory, one total score (22 items), scores ranging from 0 to 88; the higher the score increased burden.

WCC, ways of coping checklist, three dimensions; PFC, problem-focused coping, EMC, emotion-focused coping, SSS, social support seeking; the lower the score the better coping.

* *p* value <0.05 (Pearson's correlation).

** *p* value <0.01 (Pearson's correlation).

*** *p* value <0.001 (Pearson's correlation).

Table 5 – Comparisons (mean ± standard deviation) and correlations (*r*) of CarGOQoL scores with respect to caregivers' and patients' characteristics.

		PsWB	B	RHC	AF	COP	PhWB	SE	LEI	SS	PL	Index
Caregiver's gender	Women	48.8 ± 25.0	79.9 ± 22.5	61.8 ± 24.2	76.7 ± 24.3	56.2 ± 26.6	60.5 ± 23.9	73.3 ± 20.9	47.0 ± 23.6	64.9 ± 27.0	60.2 ± 26.3	62.0 ± 12.4
	Men	60.2 ± 24.1	83.5 ± 19.0	63.8 ± 22.9	80.2 ± 21.7	62.5 ± 25.9	71.0 ± 21.3	71.3 ± 21.7	48.5 ± 23.8	64.9 ± 28.9	58.4 ± 22.1	66.2 ± 12.9
	p value	0.000	0.024	0.284	0.051	0.003	0.000	0.228	0.402	0.996	0.351	0.000
Caregiver living with a partner	No	54.7 ± 27.0	83.2 ± 21.6	63.0 ± 24.1	75.2 ± 23.9	58.4 ± 26.8	66.4 ± 24.0	72.7 ± 20.3	49.0 ± 24.9	61.3 ± 27.9	58.3 ± 26.2	63.2 ± 13.2
	Yes	55.7 ± 25.6	82.1 ± 20.2	65.1 ± 23.4	79.5 ± 22.5	59.2 ± 27.4	65.4 ± 23.7	73.4 ± 21.2	47.8 ± 23.2	66.5 ± 27.5	60.9 ± 24.6	64.7 ± 13.5
	p value	0.608	0.492	0.269	0.018	0.706	0.606	0.643	0.513	0.016	0.197	0.195
Relationship status	Spouse	54.2 ± 24.1	80.8 ± 20.7	63.5 ± 23.5	79.2 ± 22.4	61.2 ± 25.7	65.1 ± 22.8	72.5 ± 21.7	46.6 ± 23.1	67.3 ± 28.1	57.7 ± 24.4	64.4 ± 13.0
	Parent	61.2 ± 28.1	86.9 ± 18.0	73.8 ± 19.7	78.8 ± 22.2	57.2 ± 31.2	67.6 ± 25.0	76.5 ± 19.3	49.4 ± 24.0	65.8 ± 24.1	62.8 ± 26.5	65.9 ± 13.7
	Child	44.5 ± 24.7	78.1 ± 22.8	56.1 ± 25.3	75.0 ± 23.8	53.6 ± 25.9	61.6 ± 23.5	68.6 ± 21.2	48.9 ± 21.9	64.0 ± 29.1	60.6 ± 24.2	60.7 ± 13.4
	Other	63.0 ± 26.0	86.3 ± 20.1	62.6 ± 23.5	77.8 ± 26.4	59.3 ± 26.2	69.5 ± 25.4	76.4 ± 18.8	51.5 ± 27.5	65.3 ± 27.6	67.6 ± 25.3	66.5 ± 14.2
	p value	0.000	0.000	0.000	0.360	0.036	0.069	0.006	0.282	0.692	0.007	0.008
Caregiver's age class	<40	54.5 ± 26.7	82.3 ± 20.5	60.1 ± 22.8	74.5 ± 22.3	56.9 ± 26.6	67.7 ± 23.9	72.1 ± 18.9	49.8 ± 23.8	67.9 ± 24.4	64.3 ± 24.9	63.4 ± 12.4
	40–59	55.1 ± 26.3	82.7 ± 19.6	65.3 ± 24.0	78.0 ± 23.1	58.8 ± 27.7	64.5 ± 24.7	73.2 ± 22.0	48.3 ± 24.5	64.6 ± 28.0	57.9 ± 25.4	64.0 ± 14.5
	>59	56.4 ± 24.9	81.7 ± 22.3	66.1 ± 23.5	81.8 ± 22.7	61.0 ± 27.00	66.0 ± 22.5	73.5 ± 20.9	46.6 ± 22.6	63.4 ± 29.3	60.6 ± 24.1	65.1 ± 12.7
	p value	0.735	0.846	0.031	0.006	0.314	0.337	0.794	0.395	0.254	0.024	0.467
Patient's gender	Women	57.5 ± 26.1	82.5 ± 20.5	63.4 ± 23.7	78.8 ± 23.2	59.8 ± 22.9	68.9 ± 22.6	72.9 ± 20.6	49.1 ± 24.7	65.1 ± 28.4	60.4 ± 23.8	65.2 ± 13.6
	Men	47.9 ± 23.0	79.6 ± 22.1	61.7 ± 23.7	77.1 ± 23.5	57.1 ± 25.9	59.2 ± 23.5	71.9 ± 22.0	45.7 ± 22.0	64.7 ± 26.9	58.2 ± 25.7	61.8 ± 12.8
	p value	0.000	0.077	0.317	0.357	0.190	0.000	0.520	0.062	0.862	0.264	0.002
Patient's age class	<18	65.0 ± 27.0	87.8 ± 15.9	74.8 ± 20.3	79.3 ± 21.1	60.9 ± 30.9	70.6 ± 24.7	77.5 ± 19.0	51.0 ± 23.6	65.8 ± 27.4	64.2 ± 27.0	67.6 ± 13.5
	18–70	54.0 ± 25.3	82.6 ± 20.0	61.8 ± 23.7	78.1 ± 23.1	57.9 ± 26.8	65.5 ± 23.2	71.8 ± 21.4	47.8 ± 23.8	65.9 ± 27.3	60.0 ± 24.4	64.0 ± 13.3
	>70	50.6 ± 25.1	76.0 ± 25.3	66.5 ± 23.3	78.5 ± 24.0	61.6 ± 25.2	61.3 ± 24.5	75.1 ± 20.2	46.5 ± 23.2	60.8 ± 29.2	57.0 ± 25.7	62.3 ± 13.4
	p value	0.000	0.000	0.000	0.862	0.273	0.006	0.012	0.272	0.156	0.075	0.011
Patient's disease duration	*r*	0.011	-0.043	-0.045	-0.028	-0.076	0.022	-0.045	0.017	-0.114	-0.005	-0.030
	p value	0.780	0.289	0.267	0.496	0.060	0.584	0.261	0.683	0.005	0.901	0.479
Caregiving duration	*r*	0.129	0.042	0.063	-0.009	-0.019	0.075	0.002	0.059	-0.088	0.037	0.026
	p value	0.000	0.252	0.092	0.818	0.598	0.041	0.963	0.111	0.017	0.324	0.505

CarGOQoL dimension scores: PsWB, psychological well being; B, burden; RHC, relationship with healthcare; AF, administration and finances; COP, coping; PhWB, physical well being; SE, self-esteem; LEI, leisure time; SS, social support; PL, private life; scores ranging from 0 to 100, the higher the score the better the QoL.

4. Discussion

We have designed, developed and validated a self-administered instrument comprising 29 items to assess the impact of cancer and its treatment on caregivers' QoL.

Our sample size was much larger than that used in other studies that have developed and validated caregivers' QoL instruments.[11] While in other studies, it was difficult to obtain a diverse group of male and female caregivers and caregivers who were partners, parents and children,[11] a diverse group of caregivers participated in our study.

The construct validity of CarGOQoL was supported by PCA and was confirmed by CFA. The high psychometric properties could be related to the development of the CarGOQoL based on qualitative interviews of caregivers,[13] while the CQOLC[15,16] was developed by combining the points of view of caregivers, patients and experts. It is generally agreed that the content of QoL measures should be derived from relevant persons because of discrepancies between these persons' and experts' points of view.[31] This approach allows the identification of specific dimensions. "Self-esteem" focuses on a valorisation of positive aspects of caregiving.[2]

The results for sensitivity to change are encouraging showing the index as satisfactory. The involvement of caregivers is essential for optimising treatment compliance, continuity of care, and social support,[33,34] providing a measure of responsiveness is of major interest in allowing the use of the CarGOQoL.

Testing of the convergent validity of the CarGOQoL scores showed that they were consistent with those of the generic SF36 questionnaire and the tools assessing social support or burden levels. Dimensions relative to physical aspects taken from the SF36 were highly correlated with our PhWB dimension and high correlations were also found between both the social functioning dimension and the mental composite score and our PsWB dimension. The dimensions that were not correlated with the SF36 dimensions highlighted the need of specific QoL questionnaires. In addition, strong correlations were found among the psycho-behavioural questionnaires, there were correlation between the OSS and SS dimensions, between the ZCBI and B dimensions and between the dimension of emotion-focused coping described by WCC and the COP dimension of the CarGOQoL.

Links with socio-demographic and clinical characteristics, supported some of our assumptions. This support allowed us to obtain evidence that there are significant differences between men and women with respect to their caregivers' QoL scores and with respect to the following domains: PsWB, B, COP and PhWB. We found that women experience a more negative impact on their QoL than men, in accordance with the existing literature in general[35,36] and in the context of the cancer caregiving in particular[15,16,27,38]. Women are often expected to be the caregivers and more often reported burden and worse QoL. Consistent with our findings, previous studies have suggested that adult child caregivers reported higher levels of stress, and consecutively lower levels of QoL.[8] These findings indicate that the relationship to the patient impacted the caregiver's perception of caregiving as burdensome and/or beneficial and was closely associated with the caregiver's QoL.[37,38] Correlations between caregiver' age and QoL were not found, in contrast to previous reports.[5,29] Additionally, longer reported cancer or caregiving durations were not found to be related to worse QoL of the caregivers in this study, in contrast to the "wear-and-tear" conceptual model.[39] These results seems to be more in line with the adaptational model suggesting that caregivers learn to adapt and accommodate to the role and do not experience increased negative effects on their QoL over time.[38,40]

The low rate of missing data and the short time of completion assure future use of this measure.

4.1. *Limitations*

One of the limitations of the study was the lack of information on clinical severity and level of disability. This information would have been helpful in the analysis of construct validity and sensitivity to change. Some others limits must be highlighted, one item did not show a good fit to the Rasch model; the internal consistency of PL dimension reached only 0.55 and the ceiling effects observed in B and AF may have limited the ability to detect QoL improvement. Besides, only half of the dimensions showed ICC <0.70 and sensitivity to change showed change only in three dimensions and in the index, but these results could be explained by the smallness of the size of the subsamples and the shortness of the recall period.

Although further studies may be needed to test the questionnaire in various cultural contexts, the CarGOQoL could provide a valid measure of caregivers' QoL related to cancer patients.

Conflict of interest statement

There are no financial disclosures from any authors, neither personal nor other relationships with other people or organisations within that could inappropriately influence this work.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ejca.2011.09.010.

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