Assessing Quality-of-Life of Cancer Caregivers in Spain: Validation of CQOLC-Spain Scale and Elements of a Cross-Cultural Analysis

Abstract

Objective: To validate a Spanish version of the "Caregivers Quality-of-Life-Index-Cancer" (CQOLC) in Spain (named CQOLC-S).

Design: The American original CQOLC was translated, then retro-translated following international standard steps, under supervision of a steering committee. Pilot interviews permitted adaptation of items. Questionnaires in Spanish hospitals (ambulatory and hospitalization). The validation process employed exploratory and confirmatory analysis, and reliability assessment. Other useful demographics were collected for future subgroups studies.

Setting: Oncology department of 2 Spanish Public Hospitals (pilot n=35; valid questionnaires n=200).

Participants: Adult primary caregivers of patients with all types of solid cancer, in all phases of the disease-no restriction on cancer type or family-relationship, in contrast to most previous CQOLC studies.

Intervention: None.

Main outcomes measures: Sociodemographic data; CQOLC-Spain psychometric properties.

Results: Six factor analyses reveal a 5-factors structure, very close to but distinct from the US original scale, distinct from the Asian and other European scales (which displayed from 1 to 9 factors). Three factors were already present in the original US scale (F1-BURDEN, F2-DISRUPTIVENESS, F3-POSITIVE ADAPTATION), while 2 new factors appeared: F4-RELATIONSHIP and F5-CONCERN FOR PATIENT. Reliability index are good (alpha=0.81, good alphas for each factor), higher extracted variance ratio (59.4%) than all previous CQOLC studies.

Conclusion: The CQOLC-Spain questionnaire addressing cancer-patients primary caregivers, translated from the original CQOLC, is validated and reliable. It can be incorporated in a permanent quality-of-care improvement strategy for both caregivers and patients. Methodological improvements for sampling and for CQOLC scales validations across countries are suggested, while cross-cultural comparison demonstrates the need for ongoing research: the CQOLC-S should now be tested in Latin/North-American Spanish-speaking populations.

Keywords: Quality indicators; Surveys; Statistical methods; Human factors; Cross-cultural issues; Caregivers cancer; Quality of life; CQOLC; Validation; Psychometrics; Spain

Introduction

Cancer is a leading cause of death, ranked first or second in most developed countries such as Singapore, the USA, France, Turkey, Spain, just right after cardiovascular diseases [1-5]. Moreover, cancer diagnosis impact Quality-of-Life (QOL) for patients, and family-caregivers. Assessing cross-cultural validation is key in medicine and social sciences as, beyond language translation issues, the way people experience emotions and needs may vary. Cultural attributes impact patient-caregiver satisfaction with care, health and quality-of-life [6-7], necessitating cross-cultural scale, and psychometric validation studies. Cancer-caregivers quality-of-life (CQOLC) is studied in such perspective here.

We actually propose to validate the most widely caregiver-QOL scale, named CQOLC [2], for the first time in Spain, and to present its more common and most divergent, characteristics against already validated CQOLC scales abroad, particularly the original American scale constructed and validated in the USA by Weitzner et al. [2].

Research framework

To provide optimal health care, it is important to understand the nature and effect of caregivers' social/emotional reactions [8,9]. Lack of information, or communication [10,11], insufficient preparation [12], the demands of daily tasks, impact caregiver QOL in a manner equal to, or greater than, the impact on patients' QOL [13,14], justifying a caregiver-centered approach [15,16].

The most widely used scale used for studying oncology primary caregivers QOL is the 35-items Caregivers Quality-of-Life-Index-
Cancer (CQOLC) [2]. In the original United-States English version of CQOLC, 27 items are conserved after the scale purification, and load on 4 factors: F1-BURDEN, F2-DISRUTIVENESS, F3-POSITIVE ADAPTION and F4-FINANCIAL CONCERN (leaving 8 single items, conserved in the scale but not loading on a specific factor). Subsequently, the CQOLC has been validated in 8 countries: Singapore [1], France [3], Turkey [4], Iran [17], China [18], Korea [19], Portugal [20] and Taiwan [21], showing varying psychometric properties across countries. We propose to validate CQOLC in Spain, naming it CQOLC-S.

The final questionnaire and research project were supervised and approved by the Scientific-Ethical Committee of the Segovia Public General-Hospital.

Methods

The original questionnaire was translated into Spanish then retro-translated following international standards [22]. Pilot testing (n=35) of the Spanish version, the CQOLC-S, led to the removal of 2 items (Q7, Q16) unadapted to the Spanish context, due to healthcare-system or to sociological reasons - this process is similar to most other CQOLC cultural psychometric studies, which removed between 2 (France) and 8 items (Portugal).

Participants and procedure

Caregivers and patients were approached in ambulatory and hospitalization sections of Oncology units of two Spanish hospitals. Both patient and caregiver had to confirm that the caregiver was the primary person caring for the patient, adult, and had no mental disorders. Questionnaires were distributed and collected (n=212, N=200 after removing monotonous responses and incomplete questionnaires) in two hospitals in Segovia and Madrid area in 2015-2016.

To enhance generalizability of the findings, we accepted all caregiver-patient family-relationship types, in contrast to previous studies: for example the US one excluded parents of an ill-child, the France one excluded non-spousal caregivers, and many other studies excluded non/low-educated caregivers as well as those who had a personal cancer diagnosis. We felt that they should not be excluded because all types of caregivers (e.g. parents, non-spouses) also experience the stress of caregiving and are part of the caregivers-population.

We also accepted all types of solid tumor cancer diagnoses and this is a major improvement in the literature on the question as for example, the original US study only considered 3 types, the Iranian 1 type, the Portugal 3 types only [2,17,20]. Moreover, other studies do not specify the types of cancer diagnoses [1,3,4,18,19]. In sum mary, this study not only addresses the use of a Spanish CQOLC, but is also the first CQOLC psychometric study with such high generalizability to all types of cancer patients, and of cancer-caregivers.

Results

Table 1 presents population frequencies, highlighting the majority of female (63.3%) and senior caregivers (mean-age=53.6 years, SD=15), those results being in line with the other published studies on CQOLC scales, worldwide. What is new is that we collected and go collecting much more data which seem relevant to us for future comparative analysis across subgroups, collecting variables such as Religion, or for instance How old is the patient-caregiver relationship, the Nature of the Relationship (spouse, son/daughter, father/mother, companion, husband/wife, etc.), the Level of education of the caregiver, and so on.

Table 1: Population frequencies and socio-demographic information

| Gender       | %  |
|--------------|----|
| Male         | 36.7|
| Female       | 63.3|

| Relationship to patient | %  |
|-------------------------|----|
| Married couple (Wife/Husband) | 46.7|
| Son or Daughter          | 31.1|
| Sibling                  | 10  |
| Others (cousins, uncles/aunts, parents) | 9.3 |
| Missing                  | 2.7 |

| Cancer Diagnosis of Patient | %  |
|-----------------------------|----|
| Colo-Rectum                 | 27 |
| Breast                      | 21.8|
| Lung                        | 8.6 |
| Head & Neck                 | 4.2 |
| Gastric/Eosophagus          | 7.3 |
| Pancreas                    | 6.2 |
| Prostate                    | 5.2 |
| Gynecologic (ovarian, uterine, cervix) | 7.9|
| Renal/urothelial            | 2.1 |
| Miscellaneous*              | 9  |
| Missing                     | 0.7 |

| Caregiver Age (Years) | %  |
|-----------------------|----|
| 18 to 29              | 5.6 |
| 30 to 39              | 11.4|
| 40 to 49              | 21.4|
| 50 to 59              | 25.3|
| 60 to 69              | 19  |
| 70 to 79              | 14.5|
| 80+                   | 2.8 |

| Caregivers Living with the Patient | %  |
|-----------------------------------|----|
| Yes                               | 63.3|
| No                                | 36.7|

| Education          | %  |
|--------------------|----|
| No elementary education | 5.9|
| Elementary education | 29.4|

| High School       | %  |
|-------------------|----|
| Professional training | 21.1|
| University education | 26.3|
| Missing            | 3.1 |
| Religion           | 100 |
| Catholic           | 80.6|
| Agnostic/Atheist   | 12.5|
| Other              | 4.2 |
| Missing            | 2.7 |

*Miscellaneous: Melanoma, neuroendocrinal, thyroids, testicular, sarcoma, brain, hematologic

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Main outcome measures

Exploratory Factor-analysis (EFA) was conducted using SPSS.23 with oblique-PROMAX rotation (because previous research has reported that factors are correlated, precluding orthogonal rotation [23]). Scale purification was conducted (purification-criteria = factor loading>0.40, loading-differences between two factors>0.35). Other publications take sharp items purification decisions without justifying or detailing them, in our opinion: we therefore tried to detail each steps of our analysis, to make sure we removed the minimum of items, hence conserving as much “information” as possible as recommended in the literature [23]. The results are detailed hereafter.

First analysis. We conducted a first Exploratory factorial analysis (EFA), using an orthogonal Varimax forcing it to retain 4 factors, to see how it behaves (replicating the original US structure). The resulting structure is not adequate: the Component matrix shows that several items load very high on several factors, with two or three loadings superior to 0.40 (they are QOL3-Impact on daily shedule, QOL15-Mental strain, loading both on F1 and F2). Furthermore, several items do not load at all on any factor (at the minimum threshold of 0.40) and should be removed: QOL35-Family interest, QOL25-Adverse effects of treatment, QOL23-Informed about illness. This shows forcing a 4-factor solution as in the original US scale is not adequate here ; we then proceeded to Oblique rotations recommended in the literature [23]. The results are detailed hereafter.

Second analysis. We launched a Promax oblique rotation leaving the structure free to rotate as. All the terms of the Anti-image matrix are superior to 0.59, and the KMO is equal to 0.829, the Bartlett test is significant at 0.000 level, so factor analysis is allowed. All communalities are superior to 0.48 so no items need to be removed. The Kaiser test (eigen-value<1) points to 9 factors with 61.7% of the extracted variance, as well as the Elbow test and the Scree test. The Pattern matrix leads us to remove 4 items (Q9-Fear death of patient, Q5-Maintenance of outside activities, Q21-Patient’s eating habits, Q17-Guilty). Item Q12-Spirituality loads on 2 factors for the moment, but we do not remove it yet, as removing other items may improve its behavior inside the rotated scale. Promax rotation is again launched after items removal.

Third analysis. The new structure points to 6 factors (Elbow and Scee test) or to 8 factors (Kaiser test) extracting 62.6% of the variance. All items load on one factor or more, now. We can remove items loading on 2 factors (Q3-Impact on daily shedule, Q35-Family interest) and launch a new rotation.

Fourth analysis. The Elbow test point to 5 factors, the Scree and the Kaiser test point to 7 factors, extracting 60.4% of the variance. Only Q12-Spirituality load on 2 factors, though its low loading (0.408) is very close to the threshold of 0.40 (therefore, this loading on a 2d factor could almost « disappear » and we could almost conserve item Q12). Still, it was also removed from almost all other studies on CQOLC. We removed it, though there is a doubt about whether we should stop the factorial analysis here.

Fifth factorial analysis, removing Q12. The Elbow test point to 5 factors, the Scree and the Kaiser test to 6 factors with 57.7% of extracted variance. Item Q23-Informed about illness load on no factor at all, and is removed.

Sixth factorial analysis, removing Q23. The final scale conserves 6 factors as shown by the three converging Elbow, Scree and Kaiser tests, conserving 59.4% of the extracted variance. The details of the scale structure can be seen in Table 2.

Table 2: Final factor structure, pattern matrix and loadings.

| Pattern Matrix after the 6th rotation (Promax) | Co-Opponent |
|---------------------------------------------|-------------|
|                                             | 1 | 2 | 3 | 4 | 5 | 6 |
| QOL29.Change in priorities/Me molesta que mis prioridades hayan cambiado | .837 |
| QOL26.Responsibility for patient’s care/La responsabilidad que tengo sobre el cuidado en casa de mi ser querido me sobrepasa | .765 |
| QOL30 Protection of patient/La necesidad de proteger a mi ser querido me molesta | .741 |
| QOL24.Transportation/Me molesta tener que estar disponible para hacer de chófer y/o acompañar a mi familiar a las consultas y los tratamientos | .726 |
| QOL13.Day-to-day focus/Me molesta que mi atención esté limitada al día a día | .601 |
| QOL1 Alteration in daily routine/Me molesta que mi rutina diaria esté alterada | .537 |
| QOL14.Sadness/Me siento triste | .863 |
| QOL1 Modif. Level of stress/Me siento estresado/a | .765 |
| QOL15.Mental strain/Me siento bajo una creciente tensión mental | .722 |
| QOL19.Nervousness/Mi nivel de preocupaciones se ha incrementado | .715 |
| QOL18.Frustration/Me siento frustrado/a | .590 |

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The final factor analysis on the final CQOLC-S scale demonstrated good internal consistency [23] with a high global Cronbach-alpha (0.814) on the final conserved scale (24 items), and good or acceptable consistency levels on each factor (all > 0.60; varying from 0.61-0.83) (Table 2).

We see that the 3 first factors adequately mirror the original American factors of the seminal research by Weitzner et al. [2]: F1=Burden, F2=Disruptiveness, F3=Positive adaptation. Weitzner et al. [2] had then conserved 8 items called « single items », not included in one specific factor, as did the Duan et al. [18] and the Chinese team. We find a similar situation in a pseudo « factor F6 » which displays a low internal consistency and cannot be considered as a real factor (Alpha = 0.463< 0.6): it includes an item of the US scale factor F4 (Q8-Financial concern) and 2 other items expressing concern for the future (Q20-Impact on family members, Q25-Adverse effects of treatment).

We also find out a very interesting result: two new factors appear: F4 Relationship and F5 Concern for patient’s health, which were not present as a factor in the US study - as those items were mostly scattered among the 8 « single items ». Conversely, in the case of the Spanish study, they form a consistent factor, not with a very high level of consistency, but still acceptable (Alpha>0.6) (Table 3).

The Factor F4 “Financial concern” presents in the US study [2] was not supported in our analyses, most likely due to the European healthcare-systems which largely eliminates financial preoccupation.

Table 3: Final factors with their names and reliability index.

| Factors in Spanish Scale | Items | Proposed Factor Name | Reliability, Cronbach Alpha |
|--------------------------|-------|----------------------|----------------------------|
| Factor F1                | Q29, Q26, Q30, Q24, Q13, Q1 | Burden | Similar to US scale | 0.829 |
| Factor F2                | Q14, Q11, Q15, Q19, Q18, Q2 | Disruptiveness | Similar to US scale | 0.832 |
| Factor F3                | Q10, Q27, Q33 | Positive adaptation | Similar to US scale | 0.735 |

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| Factor F4 | Q22, Q28, Q34, Q4 | Relationship | new factor (mainly coming from the 8 single items in the US scale, not loading on the 4 US factors) | 0.606 |
| Factor F5 | Q32, Q31 | Concern for patient | new factor (mainly coming from the 8 single items in the US scale, not loading on the 4 US factors) | 0.672 |
| Single items which do not achieve forming a sixth factor | Q8, Q25, Q20 | Concern for future | Financial strain + preoccupation for future (coming from the single 8 items in the US scale not loading on the 4 US factors) | 0.463 |

Global Cronbach’s alpha for the whole scale | 0.814 |

Appendix: CQOLC, Spanish vs original American version.

| N | CQOLC-S Spain (Current study) | CQOLC Original, Weitzner et al. [2] |
|---|-------------------------------|----------------------------------|
| 1 | Me molesta que mi rutina diaria esté alterada | It bothers me that my daily routine is altered |
| 2 | Mi sueño es menos reparador | My sleep is less restful |
| 3 | Me molesta el haber perdido el control de mi vida cotidiana | My daily life is imposed upon |
| 4 | Estoy satisfecho/a con mi vida afectiva y/o sexual | I am satisfied with my sex life |
| 5 | Es un desafío mantener mis intereses externos a la familia | It is a challenge to maintain my outside interests |
| 6 | Estoy bajo presión financiera | I am under a financial strain |
| 7 | Estoy preocupado por mi cobertura de seguro | I am concerned about our insurance coverage |
| 8 | Mi futuro económico es incierto | My economic future is uncertain |
| 9 | Tengo miedo del hecho de que mi ser querido pueda morir | I fear my loved one will die |
| 10 | Tengo una visión más positiva desde que mi ser querido está enfermo | I have more of a positive outlook on life since my loved one’s illness |
| 11 | Mi nivel de estrés y preocupaciones se ha incrementado | My level of stress and worries has increased |
| 12 | Mi sentido de la espiritualidad se ha incrementado | My sense of spirituality has increased |
| 13 | Me molesta que mi atención esté limitada al día a día | It bothers me, limiting my focus to day-to-day |
| 14 | Me siento triste | I feel sad |
| 15 | Me siento bajo una creciente tensión mental | I feel under increased mental strain |
| 16 | Me siento apoyado por mis amigos y vecinos | I get support from my friends and neighbors |
| 17 | Me siento culpable | I feel guilty |
| 18 | Me siento frustrado/a | I feel frustrated |
| 19 | Me siento nervioso/a | I feel nervous |
| 20 | Me preocupa el impacto de la enfermedad de mi familiar sobre los hijos u otros miembros de la familia | I worry about the impact my loved one’s illness has had on my children or other family members |
| 21 | Tengo dificultades para lidiar con los cambios en los hábitos alimenticios de mi familiar | I have difficulty dealing with my loved one’s changing eating habits |
| 22 | He desarrollado una relación más cercana con mi ser querido | I have developed a closer relationship with my loved one |
| 23 | Usted u otros cuidadores familiares siempre recibieron información del médico sobre lo que podrían esperar durante el proceso de cuidado | I feel adequately informed about my loved one’s illness |

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### Discussion

Our research confirms that the CQOLC scale is an important tool for oncologists, and that country-of-origin impacts its psychometric properties: some research reports 4-factors solutions, the USA [2], Iran [17], Korea [19], Portugal [20] and Turkey [4]]. Others studies differ: Singapore [1] concludes to 5 factors, France [3] mentions “1 or 9 Factors” without a clear conclusion, China [18] finds “4 Factors+free items” (they do not conclude more clearly). Moreover, common language and/or geographical area are not the only influential consideration: for instance, in a largely “Chinese cultural area”, we still see that the Singaporean, Chinese and Taiwanese scale structures do differ from each other. Last, our Spanish CQOLC-S structure (6 factors) differs significantly from its two nearby-countries, France (3 or 9 factors) and Portugal (4 factors).

### Contributions

We provide a CQOLC-S scale validated in Spain for the first time. Moreover, we have suggested the limits of previous studies, addressing them by recruiting all types of caregivers and all solid tumor cancer types. Our approach reflects a more realistic approach to caregiving, improving generalizability.

The three first of the original US-scale 4 factors [2], namely BURDEN-DISRUPTIVENESS-POSITIVE ADAPTATION, are confirmed. Two new emotional factors appear: F4 Relationship and F5 Concern for patient's health. These new F4 and F5 factors unknown in the US scale gather most of the 8 single items which were left on no factor in the original scale [2].

An important finding is that all the final factors are significantly correlated, with correlations varying from 0.086 (F2 with F4) to 0.43 (F2 with F5). Such finding fully justifies the choice of oblique (and not orthogonal) rotations in factorial analysis, increasing our analysis robustness again. Such finding suggests that maybe, items purifications due to might have been were too strict in the previous cross-cultural CQOLC validations.

### Limitations and Research Avenues

Collected sociodemographic information provides original data for future scale structure comparisons, based on (e.g.) family relationship, relationship duration, previous caregiving experience, religious intensity, etc. Scale structures may also vary according to age, gender, and relationship duration, suggesting a need for future subgroup, CQOLC scales structure and psychometric properties, in Spain and in all other countries.

We report a CQOLC-S scale validated among Spanish participants. Researchers now need to compare how the CQOLC-S structure differs among Spanish-speaking populations in Latin-America, North-America, Africa, Asia (500 million people worldwide).

Our sample, though superior in size to several other samples used, could be enlarged; we will also try in the future to include more provincial cities hospitals. Last, we have not dedicated a specific survey to palliative care with cancer caregivers at home, which is nevertheless an important and increasing issue in cancer care.

Several methodological discrepancies existing across previous CQOLC studies deserve deeper critical analysis. For instance, caregivers’ samples might include (as we did here) all types of caregiver-patient relationship; they might also include all solid cancer diseases, instead of only 1, 3 or 4 types as do most of the published CQOLC scale validations. Such practice is to be continued.
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Following EFAs, a confirmatory factorial analysis should also be conducted in the scale validation process and we will do so in a future project.

Research addressing the content of the CQOLC, particularly spirituality and social connectedness, deserves more attention.

Overall, multicultural studies are key in instrument translation-validation, but we believe there is a need to continue to Meta-analyze previous CQOLC validation methodologies and harmonize methodology across countries, a work still to be done, as we noticed many methodological discrepancies across the studies published on CAOLC validations.

In summary, we have presented a validated instrument, the CQOLC-S, to assess quality-of-life among Spanish-speaking caregivers of Spanish cancer patients. Our next step concerning cancer-caregivers QOL will consist of assessing how CQOLC-S varies across caregiver subgroups according to Age, Gender, Type of Patient relationship, Years of relationship with patient, Type of tumor, Duration as a caregiver, Religion and Religious practice intensity, providing the M.D. with a better understanding of how sociodemographics may impact CQOLC.

Compliance with Ethical Standards

This research has been conducted under the ethical and scientific supervision of the Research Unit of the General Hospital of Segovia (Spain).

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Conflict of Interest

Authors declare that they have no conflict of interest in publishing their article.

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