Validation of the Holistic Comfort Questionnaire - caregiver in Portuguese-Brazil in a cohort of informal caregivers of palliative care cancer patients

Bianca Sakamoto Ribeiro Paiva[1,2,3*], André Lopes de Carvalho[1,2,4], Katharine Kolcaba[5], Carlos Eduardo Paiva[1,2,6*]

[1]Oncology Graduate Program, Cancer Hospital of Barretos, Barretos, São Paulo, Brazil

[2]Research Group for Palliative Care and Health-Related Quality of Life (GPQual) – National Council of Scientific and Technological Development (CNPq), Barretos Cancer Hospital, Barretos, São Paulo, Brazil

[3]Post-doctoral researcher, São Paulo Research Foundation (Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP) grant 2011/19312-7)

[4]Head and Neck Department, Barretos Cancer Hospital, Barretos, São Paulo, Brazil

[5] Ursuline College, Ohio, United States of America

[6]Department of Clinical Oncology – Breast and Gynecology Division, Barretos Cancer Hospital, Barretos, São Paulo

.

Short title: Validation of the Portuguese Version of the Caregiver Comfort Questionnaire ~~in Brazil~~

***Correspondence:**

Departamento de Oncologia Clínica- Rua Antenor Duarte Villela, 1331- Barretos – São Paulo, Brazil. Zip code: 14784-400. Emails: bsrpaiva@gmail.com and drcarlosnap@gmail.com. Tel.: +55 17-3321-6600 (extension 7075).

ABSTRACT (242 words)

Purpose: To perform a cross-cultural adaptation and assess the psychometric properties of the Brazilian version of the HCQ-caregiver in a sample of FCs of PC cancer patients. (spell out abbreviations first time used)

Methods: The HCQ-caregiver was applied by a trained interviewer to a sample of FCs of PC patients with advanced cancer. The mean score, *ceiling* and *floor* effects and skewness of each HCQ-caregiver item were measured. The instrument's internal consistency was assessed by means of Cronbach's alpha, and the test-retest reliability was assessed using the intraclass correlation coefficient (ICC). The convergent validity was assessed through the correlation between HCQ-caregiver and quality of life scores. Scores on the HCQ-caregiver were compared (discriminant validity) as a function of treatment setting and FC's self-perception of emotional health.

Results: The HCQ-caregiver was completed by 150 FCs of PC cancer patients; 50 participants were subjected to a retest two to seven days after the initial test. A ceiling effect was found in 19 items, four of which exhibited maximum response rates above 90% and inadequate results regarding skewness. Cronbach's alpha was 0.858, and the ICC was 0.961. The scores on the HCQ-caregiver exhibited moderate to strong correlations with the scores of quality of life. The FCs' perceptions of comfort did not differ as a function of the treatment setting but were greater when the FCs had a better self-perception of their emotional health.

Conclusions: The present study demonstrates the validity and reliability of the Brazilian version of the HCQ-caregiver.

Key Words

Comfort; validation; reliability; Portuguese version; palliative care; caregivers.

INTRODUCTION (2,961 words)

The personal experience of chronic disease cannot be isolated from family life history, is inserted into its particular cultural and spiritual/religious contexts and is impregnated with values related to the perception of the process of becoming sick [1]. The values expressed by individuals who assume responsibility for the care of their loved ones include hope, dignity, union, strengthening of family ties and strong interpersonal engagement [2]. The care of individuals with severe chronic diseases can impose a heavy physical and emotional load on family caregivers (FCs) because they must combine their own family duties with those of caregiving, quite often resulting in withdrawal from their professional, family and social lives [3,4].

Changes that occur in the course of treatment and the progression of disease itself often cause significant discomfort to the FC. Therefore, accurate identification of the degree to which caregiving interferes with the comfort of FCs is highly relevant. In fact, health-related comfort has been considered inherent to nursing practice since Florence Nightingale's time. The number of studies addressing the comfort construct began increasing in the 1990s, resulting in notions, dimensions and the elaboration of a theory to account for that phenomenon [5-8].

Kolcaba (1994) defined comfort as the satisfaction of basic human needs, and existing in three forms, relief, ease and transcendence. She defined two dimensions of comfort. One concerns its forms, i.e., *relief* – when the specific needs of comfort of a patient are met; *ease* – when the patient is in a state of calm or contentment (no prior need required); and *transcendence* – the state of comfort in which patients are able to overcome their problems or pain. The other dimension concerns the contexts in which patient comfort can occur: *physical* – pertaining to bodily sensations; *psychospiritual* – pertaining to the internal awareness of self, including esteem, identity, sexuality and meaning in one's life; *sociocultural* – pertaining to interpersonal, family and societal relationships, as well as family traditions, rituals and religious practices; and *environmental* – pertaining to the external background of human experience (temperature, light, sound, odor, color, furniture, etc.).

In the search for a valid standardized instrument ~~fit~~ for application to informal caregivers of individuals with breast or genital cancer in the terminal stage of disease, in Brazil, Rezende et al. [9,10] performed a translation of the Holistic Comfort Questionnaire to Portuguese, which they called the General Comfort Questionnaire – caregiver.

Given the limited number of instruments validated for use in Brazil available to assess informal caregivers, the aims of the present study were to perform a cross-cultural adaptation and assess the psychometric properties of the Brazilian Portuguese version of the Holistic Comfort Questionnaire-caregiver (HCQ-caregiver).

METHODS

Study design and selection of participants

The present cross-sectional study employed methods for adaptation and validation of an assessment instrument; the corresponding data were collected from August to November 2013. The study used a convenience sample recruited at the palliative care (PC) outpatient clinic and inpatient PC ward of the Cancer Hospital of Barretos (Barretos, São Paulo, Brazil). The sample comprised FCs of patients with advanced breast or genital cancer, from both genders, able to communicate in the Brazilian Portuguese language and older than 18 years old. Individuals with a personal history of cancer in the past 10 years and those with neuropsychiatric

disorders that were liable to interfere with their ability to understand and respond to questionnaires according to the researcher's judgment were excluded. FCs were defined as individuals with significant participation in the patients' treatment and care (most days of the week), with the following degrees of kinship: child, spouse, mother, father, sibling, boy/girlfriend, grandparent, uncle/aunt or first cousin.

Ethical issues

The study complied with the ethical standards of the Declaration of Helsinki and Brazilian National Health Council (Conselho Nacional de Saúde – CNS) Resolution no. 196/1996 and was approved by the ethics committee of the Cancer Hospital of Barretos (Hospital de Câncer de Barretos – HCB/544/2011). All of the participants signed an informed consent form.

Data collection

All of the participants were interviewed by the same interviewer (BSRP) in a private room away from their ill relative. The participants were given the option to self-respond to the questionnaires or have them given by the interviewer.

To assess the test-retest reliability, 50 participants were subjected to a second interview two to seven days later.

Assessment instruments

Holistic Comfort Questionnaire-caregiver (HCQ-caregiver)

The HCQ-caregiver was formulated by Novak et al. [11] in 2001 and based on Kolcaba's holistic comfort theory [5,6]. This questionnaire comprises 49 items that assess holistic comfort in a unidimensional manner. The answer options vary from 1 (strongly disagree) to 6 (strongly agree), and the final score is calculated by adding the scores for each item; thus, the range can vary from 49 to 294. From the 49 items, 26 of them must be reversed for calculation of the HCQ-caregiver score, because they are not instances of comfort. Inclusion of negative items is done to reduce response bias.

World Health Organization – Quality of Life (WHOQOL-bref)

The WHOQOL-bref is a short version of the original WHOQOL-100. It is valid and reliable in Brazil [12,13]. The WHOQOL-bref comprises 26 items covering physical, psychological, social-relationship and environmental domains and two other items that measure overall Health-Related Quality of Life (HRQOL) and health. Each item is answered from 1 to 5, and the score in each of the four subscales can range from 4 to 20. A higher score indicates a higher HRQOL. The internal consistency of this instrument in our study was $\alpha = 0.801$.

WHOQOL-SRPB (Spirituality, Religiousness and Personal Beliefs)

This instrument consists of eight domains and 32 items assessing spirituality and personal beliefs. Individual items are rated on a Likert scale of five points, where one indicates negative perceptions and five indicates positive perceptions; thus, higher scores represent better spiritual QOL [14]. The WHOQOL-SRPB has been previously validated in Brazil [15]. The internal consistency of this instrument in our study was $\alpha = 0.969$.

Validation Procedures

Two phases were included in the validation procedure:

Phase I – Cultural adaptation

The HCQ-caregiver version translated to the Brazilian Portuguese language by Rezende et al. [9,10] was not subjected to cross-cultural adaptation. As we identified some cultural inconsistencies in that version, we decided to perform a formal cross-cultural adaptation of the instrument in collaboration with the author of the original version. For that purpose, the translated version was assessed by an expert panel that included a nurse, a dentist and a clinical oncologist, all of whom are widely experienced in the adaptation and validation of health-related assessment instruments. A standard form was used for assessment of semantic/idiomatic, cultural and conceptual equivalence. The experts assessed each item in the instrument independently and were requested to rate them as (-1) non-equivalent, (0) could not be assessed/I do not know or (+1) equivalent and to suggest changes for items rated (0) or (-1). Finally, the expert panel met to discuss the results and reach a consensus. The final adapted version was discussed with and approved by the author of the original questionnaire.

Phase II - Psychometric properties

Missing responses were calculated as the percentage of missing responses per questionnaire. An item non-response rate of up to 4% was considered acceptable [16]. In the calculation of the HCQ-caregiver score, the missing items were replaced with the mean value of the items that were answered. Floor and ceiling effects were calculated as the percentage of participants who achieved the minimum and maximum possible scores for each item, respectively. Skewness was to the extent to which the values of the distribution were clustered towards one or the other end of the distribution. Ceiling or floor effects over 70% or an absolute value of skewness exceeding 4.0 were considered inadequate [17].

Internal consistency

Internal consistency was assessed using Cronbach's alpha coefficient, which should be ≥0.70 to be considered adequate [18].

Test-retest reliability

The test-retest reliability was assessed by means of the intraclass correlation coefficient (ICC). Values over 0.70 were considered adequate [18]. Considering holistic comfort as a dynamic construct, and also taking into consideration ~~the fact~~ that a significant fraction of the patients had reached the terminal stage of disease and exhibited fast worsening of symptoms and loss of functionality, we decided to perform the retests two to seven days after the initial tests.

Hypothesis testing

Some hypotheses were formulated a priori:

(1) Convergent validity – As there was no instrument validated for the Brazilian Portuguese language to assess comfort, we decided to compare HCQ-caregiver scores with scores from the WHOQOL-bref and WHOQOL-SRPB. We expected that the HCQ-caregiver global score would exhibit positive correlation (r > 0.4) with the total WHOQOL-bref score, as well as with its physical, psychological, environmental and social domains and also with the WHOQOL-SRPB global score [16].

(2) Known-group validity – This analysis was performed to establish whether the instrument was able to discriminate among clinically different subgroups of FCs. Our initial hypothesis was that FCs of outpatients would exhibit higher levels of holistic comfort compared to FCs of inpatients, whom one would expect to exhibit poorer clinical conditions. In addition, we believed that the FCs' self-perceptions of emotional health may have correlated with their perception of comfort. For that reason, the following question was posed to FCs: "How do you assess your emotional health?" The FCs were divided into three groups based on their self-perception of emotional health: (1) very bad or bad, (2) fair and (3) good or excellent. The results were compared using the non-parametric Mann-Whitney and Kruskal-Wallis tests.

The statistical analysis was performed using SPSS software (version 20.0). P-values lower than 0.05 were considered statistically significant.

RESULTS

Phase I – Cultural adaptation

A total of 22 of the 49 items in the initial Brazilian Portuguese version of the HCQ-caregiver exhibited problems of adaptation and required changes (**Table 1**).

Phase II – Psychometric properties I think this whole paragraph could be incorporated into Table 2, "Caregiver Characteristics"

A total of 156 FCs were invited to participate in the study; three refused, and another three were excluded (personal history of cancer = 2, ongoing treatment for lung cancer = 1). The final sample comprised 150 FCs, out of whom 117 (78%) were female, 125 (83.3%) had children, 113 (75.3%) were married, 114 (76%) were the patient's spouse or child and 141 (94%) had some formal religious affiliation. The mean (standard deviation [SD]) age of the sample was 60 (13.3) years old. Fifty-one (34%) participants cared for outpatients and 99 (66%) for inpatients. The distribution of the patients' Eastern Cooperative Oncology Group – Performance Status (ECOG-PS) was as follows: grade 0 (n = 1, 0.7%), 1 (n = 20, 13.3%), 2 (n = 31, 20.7%), 3 (n = 58, 38.7%) and 4 (40, 26.7%). **Table 2** describes the characteristics of the FCs included in the study.

HCQ-caregiver scores

The participants took an average (SD) of 7.33 (1.64) minutes to complete the 49 items of the HCQ-caregiver. A total of 116 (77%) questionnaires were given by the interviewer, and 34 (23%) were self-applied. The mean (SD) score on the HCQ-caregiver was 214.7 (25.6) and varied from 130 to 261. Following reversion (greater values indicate greater holistic comfort), the mean score in some items was very high (item 4, mean = 5.88; item 7, mean = 5.75; item 23, mean = 5.88; item 47, mean = 5.93; item 49, mean = 5.8), while in others, it was very low (item 34, mean = 1.42; item 45, mean = 1.55; item 48, mean = 1.93) (**Table 3**). The values of the correlation coefficient corresponding to items 4, 6, 8, 23, 24, 31, 34, 36, 46 and 47 relative to the total HCQ-caregiver score were low (< 0.2). Nineteen items (19 out of 49, 38.7%) exhibited floor or ceiling effects, of which items 7, 23, 47 and 49 exhibited very high values (more than 90%) of maximum responses. Four items (7, 23, 47 and 49) exhibited inadequate results based on skewness (**Table 3**).

Only 12 items had missing responses ~~occurred~~ in the full sample of 150 questionnaires (7,350 items), thus representing a mean of 0.08% missing responses per questionnaire. All missing responses were due to difficulty in understanding the question.

Reliability (internal consistency)

Cronbach's alpha was 0.858 (95% confidence interval – CI: 0.824-0.889).

Test-retest reliability

The retest was performed 4.62 (2.3) days after the initial test on average (SD). The ICC was 0.961 (95%CI: 0.932-0.978).

Hypothesis testing

Convergent validity This information might be easier to comprehend in a table

The correlation of the total HCQ-caregiver score with the WHOQOL-bref domain and the WHOQOL-SRPB global spirituality domain was assessed, and values for the correlation coefficient were as follows: overall quality of life ($r = 0.688$, $p < 0.01$), physical domain ($r = 0.415$, $p < 0.01$), psychological domain ($r = 0.570$, $p < 0.01$), social domain ($r = 0.561$, $p < 0.01$), environmental domain ($r = 0.619$, $p < 0.01$) and global spirituality ($r = 0.639$, $p < 0.01$).

Known-group validity

The median value (25th-75th percentiles) of the HCQ-caregiver scores corresponding to the FCs of outpatients (median = 222; $p25^{th}$-$p75^{th}$ = 201-233) did not exhibit significant differences compared to the FCs of inpatients (median = 217; $p25^{th}$-$p75^{th}$ = 194-234; $p = 0.596$). There was a significant difference ($p < 0.001$) in the median ($p25^{th}$–$p75^{th}$) HCQ-caregiver score among the groups of FCs established based on their self-perception of emotional health: very bad or bad (median = 202.5; $p25^{th}$-$p75^{th}$ = 181.1-225.5); fair (median = 222; $p25^{th}$-$p75^{th}$ = 206-235); and good or excellent (median = 231; $p25^{th}$-$p75^{th}$ = 214-244.5).

DISCUSSION

In the present study, after having performed the cross-cultural adaptation of the HCQ-caregiver to the Brazilian Portuguese language, we investigated its psychometric properties in a sample of FCs of palliative care cancer patients. As a whole, the instrument can be considered valid and reliable; nonetheless, some adjustments are needed to reduce the ceiling effect.

The HCQ-caregiver proved to be easy to understand, which was confirmed by the low item non-response rate found. In addition, although this instrument is long (49 items), it only took an average of seven minutes to complete. This fact is even more significant when we take the educational level of the sample into consideration because 56% of respondents had attended up to the last grade of elementary school, and 39% had only four years of formal schooling.

The mean HCQ-caregiver score was 87% of the maximum possible (294 points). Although the results were slightly lower than those originally reported by Novak et al. [11], they indicate high levels of holistic comfort in the investigated population. The rate of ceiling or floor effects was 38%. In four items, the rate of maximum responses was 90% and the skewness value was inadequate. When an assessment instrument is used to detect clinical changes over time, high scores at *baseline* and the presence of a significant ceiling effect interferes with its sensitivity to detect targeted changes, which may result in an increase in type II errors in clinical trials [19].

The instrument's internal consistency proved to be adequate, as Cronbach's alpha was 0.858. In the study where the HCQ-caregiver was first developed[11], Cronbach's alpha varied from 0.89 to 0.97.

Unidimensional instruments that comprise a large number of items tend to exhibit higher levels of internal consistency compared to those with smaller numbers [20]. As the number of HCQ-caregiver items is large, removal of some of them causes very little change in the overall Cronbach's alpha value. That fact notwithstanding, some items patently exhibited poor correlation with the HCQ-caregiver total score, which suggests that they could be excluded with a consequent increase in the instrument's internal consistency. Further studies conducted with Brazilian populations may give support to the use of a simplified version of the HCQ-caregiver that includes only the items with best mutual correlation.

The retest was performed with 50 FC, and the results were considered adequate. In the palliative care setting, the clinical conditions of patients change quite quickly, and thus, retests pose a challenge. In the present study, retests were performed two to seven days after the initial tests, which may be considered adequate based on the abovementioned circumstances [21].

Given the lack of other valid instruments to measure FC discomfort, we chose to compare the HCQ-caregiver scores with scores from a HRQOL generic questionnaire, the WHOQOL-bref, together with a module specific for spirituality (WHOQOL-SRPB). Although these instruments measure different constructs, the relationship between the perception of holistic comfort and HRQOL is demonstrated by the moderate-to-strong levels of correlation found, as anticipated.

Our initial hypothesis was that the HCQ-caregiver scores of FCs of inpatients (assumed to exhibit poorer clinical conditions) would be lower compared to scores of FCs of outpatients. However, in spite of the different physical environments and clinical conditions, we did not find significant differences in the scores exhibited by those two groups of FCs. The high rate of ceiling effects found could account for the instrument's low sensitivity to detect clinical differences (known-group validity) [18]. These facts notwithstanding, we were able to confirm that the FCs' self-perception of emotional health directly correlated to their perception of holistic comfort, as was anticipated.

The present study exhibits some limitations. One derives from the lack of any instrument serving as a gold standard for the assessment of comfort in our sample, which would have allowed comparison of the HCQ-caregiver scores. For that purpose, we chose HRQOL instead because of its relationship with the perception of holistic comfort. More particularly, WHOQOL-bref and WHOQOL-SRPB were selected because they were already validated for the Brazilian population, and their psychometric properties are adequate [12,13,15]. A second limitation is the lack of data on the instrument's responsiveness. As the instrument's sensitivity to detect different groups was dubious, and instruments with high ceiling effects can exhibit poorer responsiveness, further studies are needed to determine the responsiveness of the HCQ-caregiver.

To conclude, the HCQ-caregiver was easy to understand and was completed quite quickly. It exhibited adequate internal consistency and test-retest reliability. Nevertheless, the high rate of ceiling effects found and the instrument's doubtful ability to detect different groups suggest that adjustments are needed, e.g., increasing the response scale from six to 10 points. Further studies are needed to determine the instrument's responsiveness and the known-group validity.

ACKNOWLEDGEMENTS

CONFLICT OF INTEREST

The authors have full control over the primary data and agree to allow the journal to review the data if requested. In addition, they declare no conflict of interest.

REFERENCES

1. Surbone A, Baider L, Weitzman TS, Brames MJ, Rittenberg CN, et al. (2010) Psychosocial care for patients and their families is integral to supportive care in cancer: MASCC position statement. Support Care Cancer 18: 255-263.
2. Sand L, Olsson M, Strang P (2009) Coping strategies in the presence of one's own impending death from cancer. J Pain Symptom Manage 37: 13-22.
3. Hebert RS, Schulz R, Copeland VC, Arnold RM (2009) Preparing family caregivers for death and bereavement. Insights from caregivers of terminally ill patients. J Pain Symptom Manage 37: 3-12.
4. Leow MQ, Chan MF, Chan SW (2013) Predictors of Change in Quality of Life of Family Caregivers of Patients Near the End of Life With Advanced Cancer. Cancer Nurs.
5. Kolcaba K (1991) A taxonomic structure for the concept comfort. Image J Nurs Sch 25: 4.
6. Kolcaba K (1994) A theory of holistic concept comfort for nursing. J Adv Nurs 19: 6.
7. Santin S (1998) Cuidado e/ou conforto: um paradigma para a enfermagem desenvolvido segundo o costume dos filósofos Care and/or comfort: a paradigm for nursing based on the philosophers' ethos]. Texto e contexto 7: 21.
8. Morse JM (2000) On comfort and comforting. Am J Nurs 100: 34-37; quiz 38.
9. Rezende VL, Derchain SM, Botega NJ, Vial DL (2005) Revisão crítica dos instrumentos utilizados para avaliar aspectos emocionais, físicos e sociais do cuidador de pacientes com câncer na fase terminal da doença [A critical review of instruments used to assess emotional, physical and social aspects in caregivers of terminal cancer patients]. Rev Bras Cancerol 51: 9.
10. Rezende VL, Derchain S, Botega NJ, Sarian LO, Vial DL, et al. (2010) Avaliação psicológica dos cuidadores de mulheres com câncer pelo General Comfort Questionnaire [Psychological assessment of caregivers of women with cancer with the General Comfort Questionnaire]. Paidéia 20: 9.
11. Novak B, Kolcaba K, Steiner R, Dowd T (2001) Measuring comfort in caregivers and patients during late end-of-life care. Am J Hosp Palliat Care 18: 170-180.
12. Berlim MT, Pavanello DP, Caldieraro MA, Fleck MP (2005) Reliability and validity of the WHOQOL BREF in a sample of Brazilian outpatients with major depression. Qual Life Res 14: 561-564.
13. Chachamovich E, Trentini C, Fleck MP (2007) Assessment of the psychometric performance of the WHOQOL-BREF instrument in a sample of Brazilian older adults. Int Psychogeriatr 19: 635-646.
14. Group WS (2006) A cross-cultural study of spirituality, religion, and personal beliefs as components of quality of life. Soc Sci Med 62: 1486-1497.
15. Panzini RG, Maganha C, Rocha NS, Bandeira DR, Fleck MP (2011) Brazilian validation of the Quality of Life Instrument/spirituality, religion and personal beliefs. Rev Saude Publica 45: 153-165.
16. Fayers P, Machin D (2007) Quality of life: the assessment, analysis and interpretation of patient-reported outcomes. UK: Wiley.
17. Minaya P, Baumstarck K, Berbis J, Goncalves A, Barlesi F, et al. (2012) 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. Eur J Cancer 48: 904-911.
18. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, et al. (2007) Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 60: 34-42.
19. Pardasaney PK, Latham NK, Jette AM, Wagenaar RC, Ni P, et al. (2012) Sensitivity to change and responsiveness of four balance measures for community-dwelling older adults. Phys Ther 92: 388-397.
20. Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, et al. (2002) Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res 11: 193-205.
21. Paiva CE, Barroso EM, Carneseca EC, de Padua Souza C, Dos Santos FT, et al. (2014) A critical analysis of test-retest reliability in instrument validation studies of cancer patients under palliative care: a systematic review. BMC Med Res Methodol 14: 8.