

ORIGINAL

Validation, Reliability and Comprehension of the IBCSG Quality of Life Questionnaire Specific to Breast Cancer

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ABSTRACT

Objective: To evaluate overall survival in incident cases of oral cancer notified by the Goiânia population-based cancer registry between 1988 and 2002. **Patients and Methods:** A total of 313 incident cases of squamous cell carcinoma of the oral cavity were identified. The variables studied were: age, gender and clinical staging. Data regarding vital status were obtained from the medical charts of the hospital and clinics and from the Goiânia Mortality Data System. **Results:** Of the 313 incident cases of oral cancer notified between 1988 and 2002 that were identified in this study, 245 (72.7%) occurred in males and 92 (27.3%) in females. The five-year overall survival rate for oral cancer in Goiânia was 35.3% with a mean survival time of 30 months (95%CI, 27-32). There was no statistically significant difference in survival time between males and females (35.8% versus 33.9%; $p = 0.750$). In patients with tumors ≤ 4 cm, survival rate was 77%, whereas in patients with tumors > 4 cm, survival rate was 39% ($\mu = 35$ months, 95%CI, 31-38, $p < 0.001$). **Conclusion:** In patients with oral cancer, survival is associated with gender, age at diagnosis and treatment of these tumors. The low survival rates found indicate that the majority of tumors were at an advanced stage. Training healthcare professionals to clinically examine the oral cavity, to identify abnormalities in oral mucosa and to duly refer patients to a specialized service for early diagnosis would lead to an improvement in survival.

Keywords: breast cancer, quality of life, questionnaire, reliability, validation.

INTRODUCTION

Based on the data of the World Cancer Report¹, there are an estimated 1,050,000 new cases of breast cancer annually, 580,000 of which occur in developed countries. According to PERRY et al.², more than 1.1 million women around the world are diagnosed with breast cancer every year and 410,000 die from the disease.

Besides the impact of the diagnosis, MAMEDE et al.³ stress that breast cancer treatment, especially surgery, has a series of physical and emotional consequences, among which, those related to activities of daily living and social roles, figure prominently.

The increase in survival rates has been associated with a concern for the quality of life of cancer survivors. In 1993, the Quality of Life Group of the World Health Organization (WHO) defined quality of life as the perception individuals have regarding their position in life in the context of their culture and the system of values in which they are inserted, as well as in relation to their goals, expectations, standards and concerns. Quality of life is a broad-ranged concept affected in a complex manner by physical health, psychological state, degree of independence, social relationships and relations with the characteristics of the individual's environment⁴.

The International Breast Cancer Study Group (IBCSG) Quality of Life Questionnaire was drafted by BUTOW et al.⁵ in 1991 with the aim of assessing quality of life in patients with breast cancer (treated and in treatment). This questionnaire has not been validated in other countries, or at any rate, there is no publication of such validation. The questionnaire has been translated into Portuguese, but has not yet been validated in Brazil or any other country in Latin America. The IBCSG questionnaire has furnished the translated questionnaire and authorized carrying out its validation.

The aim of the present study was to validate, analyze the reliability and assess the comprehension of the IBCSG quality of life questionnaire specific to breast cancer.

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MATERIAL AND METHODS

The present study was carried out at Hospital A.C. Camargo, Antônio Prudente Foundation (São Paulo, Brazil). The sample was made up of 100 women undergoing routine exams at the Mastology Outpatient Clinic of the hospital. All women were between 27 and 90 years of age, with a diagnosis of breast cancer (either treated or in treatment) in any stage of the disease.

The calculation of the sample size was based on studies by SPRANGERS et al.⁶ and MOSCONI et al.⁷ In these studies, the lowest Cronbach's alpha coefficient was 0.40. Assuming a type I error = 5% and power = 90%, it was estimated that at least 62 patients were needed for the present study.

Following the routine outpatient check-up at the clinic, the patients were asked to participate in the study. Between August and September 2007, 111 women were asked to participate, among which 11 declined. Thus, the refusal rate was 9.9%. Patients who agreed to participate signed terms of informed consent. The project was submitted to the Ethics Committee of Hospital A.C. Camargo under process number 835/06 and was approved on September 26, 2006.

Socio-demographic and clinical characteristics were obtained by means of a questionnaire and the IBCSG questionnaire was then introduced. Among the 100 patients, the questionnaire was self-administered by 92 and was administered in interview form to eight patients.

The questionnaire is made up of 10 items in the form of a linear analogue self-assessment scale (Figure 1). On each question, the patient places a vertical mark on a horizontal line (100 mm), the extremities of which indicate good and bad. The score is determined by the distance (mm) between the left end of the scale and the patient's mark.

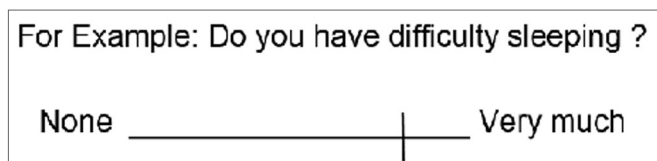


Figure 1. Calculation of the scale of the IBCSG questionnaire.

The score of each question ranges from 0 to 100 mm and the final score is the mean of the points. Higher scores denote a poorer quality of life.

$$IBCSG \text{ Score} = \frac{\sum_{i=1}^n Q_i}{n}$$

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) was used to analyze the convergent validity of the IBCSG questionnaire. Due to the lack of

a specific breast cancer questionnaire to be used as the "gold standard", the SF-36 was chosen for this purpose. The SF-36 questionnaire is a generic quality of life assessment tool that is easy to administer and understand. It is a multidimensional questionnaire made up of 36 items divided into eight subscales: functional capacity, physical aspects, bodily pain, general health state, vitality, social aspects, emotional aspects and mental health. The final score ranges from 0 to 100, with 0 corresponding to the worst general health status and 100 corresponding to the best (CICONELLI et al.,⁸ CASTRO et al.⁹). This questionnaire has been translated and validated for the Portuguese language (CICONELLI et al.⁸)

After finishing the SF-36, the patients were informed that an envelope containing the IBCSG questionnaire would arrive in the mail after two weeks, along with a pre-posted response envelope. Among the 100 patients initially interviewed, 95 sent in their responses (95%) for the reproducibility analysis.

The assessment of the comprehension of the questions and the questionnaire was carried out in two ways. For the individual assessment of the questions, a specific instrument was administered that assessed whether the question was difficult, confusing, had difficult and/or embarrassing words. To determine the degree of comprehension on the part of the patients regarding the questionnaire, a verbal-numeric scale was used (adapted from GRASSI-OLIVEIRA et al.¹⁰), which was placed at the end of each questionnaire (Figure 2). The patients were instructed to rate their comprehension of the questionnaire with a score of 1 to 5 upon answering all the questions.

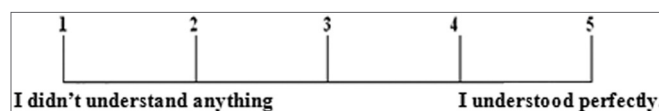


Figure 2. Verbal-numeric scale for the analysis of the degree of comprehension of the questionnaire.

Cronbach's alpha coefficient was used for the analysis of internal consistency in order to estimate the correlation between each item on the questionnaire and the other items or total score of the questionnaire. Moreover, validity was determined through construct validity and convergent validity. In order to determine whether the questionnaire is capable of discriminating different situations (SILPAKIT et al.¹¹), mean scores of women with and without lymphedema were compared using the Mann-Whitney test; women with lymphedema are expected to have a poorer quality of life when compared to those without lymphedema. To determine convergent validity, Spearman correlation coefficients were calculated between the scores of the IBCSG questionnaire and the scores of the SF-36 subscales in order to determine the ability of

the instrument in correlating (in magnitude and direction) with a predefined hypothesis (DE BOER et al.¹²). In the analysis of the reliability of the questionnaire, mean scores on the two interviews (test-retest) were compared using the Wilcoxon test. The intraclass correlation coefficient between two measurements was also calculated and agreement was determined between test-retest scores using the Bland-Altman method.

RESULTS

The age of the women ranged from 27 to 90 years (mean = 56.5 years, standard deviation = 12.4 years, median = 54.4 years) and the most frequent age range was between 50 and 59 years (33%), followed by 40 to 49 years (24%). Approximately 76% of the patients covered the costs of their check-ups either through a health insurance plan or paid privately. Other demographic aspects were: 64% of the patients were married, 51% had a complete university education, 53% were working at the time of the study and 69% were Catholic.

Age at the time of diagnosis ranged from 26 to 89 years (mean = 51.6 years, standard deviation = 11.8 year, median = 50.1 years). Only 12% received the diagnosis when under 40 years of age. At the time of the interview, 48% of the patients had received the diagnosis less than two years earlier. Mean time elapsed since the diagnosis was 4.8 years (standard deviation = 6.4 years, median = 2.3 years), ranging from 0 to 34 years. Regarding the clinical status of the patients, 38% were in clinical stage I, followed by 37% in clinical stage II. Only one patient was not undergoing treatment for cancer and 17% had homolateral lymphedema of the upper limb.

The IBCSG questionnaire score ranged from 0 to 59.48 mm (mean = 20.32 mm, standard deviation = 13.65 mm, median = 17.23 mm). Cronbach's α was 0.72. The highest mean scores were achieved on the questions regarding weariness (33.37 mm) and hot flashes (33.19 mm). The lowest scores were for support from people that surround patient (4.82 mm), sensation of nausea (10.48 mm) and appetite (12.11 mm). It should be kept in mind that higher scores denote poorer quality of life.

In the analysis of construct validity, there were statistically significant differences in the mean scores. Comparing the groups with and without lymphedema, the former group had a higher mean score on the IBCSG questionnaire (27.56 x 18.85; $p = 0.019$). In the analysis of convergent validity, the questionnaire was correlated with nearly all the SF-36 subscales, with the exception of vitality and social aspects (Table 1).

Only six patients considered all the items on the IBCSG confusing and only one patient considered the

Table 1. Spearman's correlation coefficient (r) between the IBCSG and SF-36 (Hospital A.C. Camargo, August to October 2007).

SF-36 Scales	IBCSG r (p)
Physical Functioning	-0.38 (< 0.001)
Role-Physical	-0.45 (< 0.001)
Bodily Pain	0.55 (< 0.001)
General Health	0.32 (0.001)
Vitality	0.05 (0.650)
Social Functioning	0.07 (0.522)
Role-Emotional	-0.50 (< 0.001)
Mental Health	-0.29 (0.004)

questionnaire difficult. No item was considered to have difficult and/or embarrassing words. The mean score given to the comprehension of the questionnaire as a whole was 4.89 (SD = 0.373, median = 5.00).

Table 2 displays the comparison of the IBCSG questionnaire scores on the test and retest. There were no statistically significant differences in mean scores between the test and retest. Figure 3 displays the dispersion plot between the test and retest, revealing that the IBCSG questionnaire exhibited a strong linear correlation.

Table 2. Comparison of means between the test and retest of the IBCSG and intraclass correlation coefficient (R_{icc}), (Hospital A.C. Camargo, August to October 2007).

Test mean (SD)	Retest mean (SD)	p^*	R_{icc} (p)
20.59 (13.91)	22.99 (17.38)	0.16 8	0.73 (<0.001)

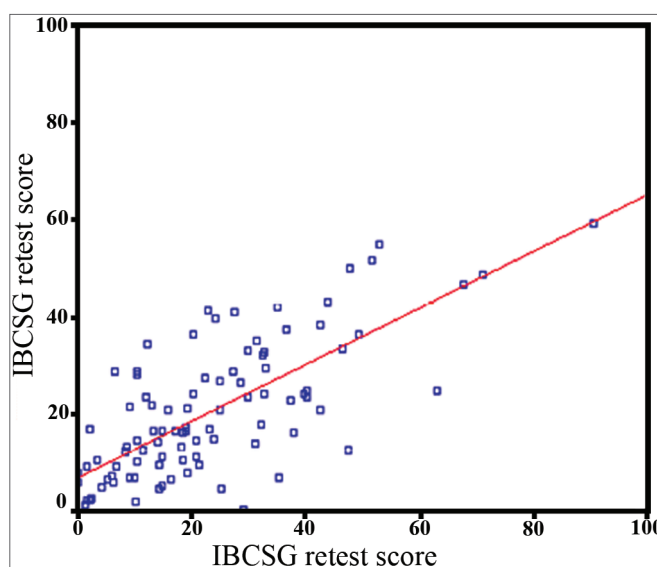


Figure 3. Dispersion diagram of the IBCSG scores on the test and retest. (Hospital A.C. Camargo, August to October, 2007).

The Bland-Altman plot of the IBCSG demonstrated that the questionnaire had good random distribution around the zero bias line, with few points outside the limit (Figure 4).

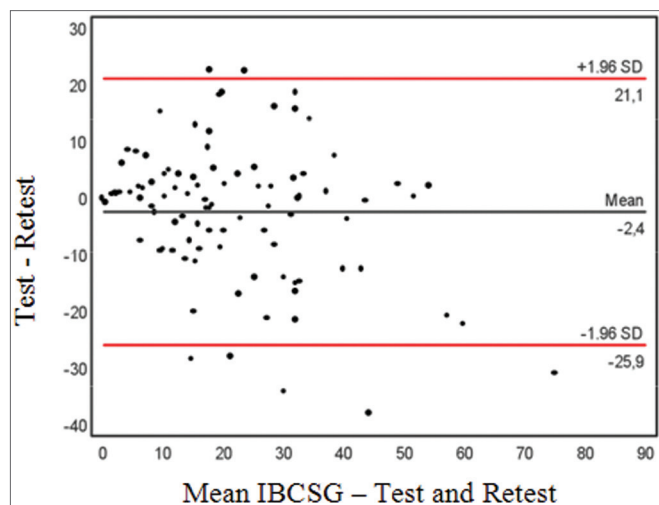


Figure 4. Bland-Altman plot of IBCSG questionnaire on test and retest. (Hospital A.C. Camargo, August to October 2007).

DISCUSSION

In 1991, BUTOW et al.⁵ drafted a questionnaire with the aim of assessing quality of life in women treated or in treatment for breast cancer. For this, two aspects were taken into consideration. First, it needed to be applicable in a clinical routine, which means it had to be simple and well focused. For this, a LASA scale was used, in which the patient makes a vertical mark on a horizontal line (100 mm) that indicates two extremes (good and bad). Secondly, the instrument needed to have standard criteria of reliability and validity, as well as discriminate changes that women go through during the course of the disease.

In the present study, some patients considered the scale confusing and thought it would be important for the researcher to be present due to the distinctive way the questionnaire is filled out. According to McCORMACK et al.¹³, a LASA scale is actually a simple method, but its low sensitivity is a significant limitation. Another issue raised by the patients was the difficulty they had in quantifying their answers – exactly what meant “more or less”, “nearly always”, etc.

The internal consistency of the IBCSG questionnaire was 0.72. According to STREINER and NORMAN¹⁴, a questionnaire may be considered as having good consistency when achieving a Cronbach’s α above 0.70. In a study by COATES et al.¹⁵ involving 166 patients in Australia, this scale achieved a coefficient of 0.80. In a study carried out in Switzerland by SARENMALM et al.¹⁶, this parameter was not presented.

In the construct validity, the IBCSG was capable of discriminating between the groups with and without lymphedema. This result was expected, as patients with lymphedema presumably achieve poorer results in the assessment of quality of life. The study carried out by BERNHARD et al.¹⁷ demonstrated that the questionnaire was capable of perceiving an improvement in arm movement between the first and third month of treatment.

Among the eight subscales of the SF-36 questionnaire, only two, vitality and social aspects, had no significant association with the IBCSG. This analysis was not performed in the studies carried out by HURNY et al.¹⁸, BERNHARD et al.¹⁷ and SARENMALM et al.¹⁶.

The results of the present study were generally similar to those described in previous studies, thereby demonstrating that the IBCSG can be used to assess the quality of life of patients with breast cancer in Brazil.

CONCLUSION

The IBCSG quality of life questionnaire demonstrated good internal consistency, discriminate capacity, convergent validity and reliability. The questionnaire also received some complaints, mainly due to the LASA scale, but the score regarding its comprehension was high. These results allow the questionnaire to be used in the assessment of quality of life in Brazilian women with breast cancer.

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