# Original Article

# Assessing the Quality of Life in Women with Breast Cancer Through the Questionnaire SF-36

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### **Abstract**

**Objective:** Assess the repercussion of breast cancer in the quality of life of women who had already submitted themselves to some type of treatment, through the application of Questionnaire SF-36. **Methods:** A case control study of an exploratory and descriptive nature with 75 women carriers of breast cancer and 75 controls during the period of April to June, 2006. Statistical analysis was done through the program Epi.Info 6.0, using Fisher or  $\chi^2$  test; considered significant p <0.05. **Results:** The study showed that all patients with breast cancer consider, in relation to one year prior, their state of health equal or better, with statistically significant difference in relation to the controls (p = 0.0007). The average of the assessment of the functional capacity in patients with breast cancer, when compared with the controls, evidenced a lower functional capacity in the patients with breast cancer, but without statistical difference. The comparison between the patients with breast cancer and the controls in relation to the alterations of their physical health in the last four weeks evidenced a significant worsening in the patients with breast cancer. (p=0.0004, R0=4.00, 95% CI 1.40-10.9). In relation to painful symptoms and emotional, family and social aspects, no statistical differences between the cases and controls were observed. **Conclusion:** There is affirmation to no observed differences in the quality of life when comparing women with breast cancer to the controls, when utilizing Questionnaire SF-36.

Keywords: Breast Neoplasms; Questionnaires; Quality of Life

### Introduction

According to data of the Instituto Nacional do Câncer - INCA, breast cancer is the leading cause of death in women in Brazil.<sup>1</sup> Most of the time, the diagnosis is established in a late phase of the disease, due to an ineffective policy of control and screening of the disease, which has mammography, allied to the clinical exam of the breast and the self-exam, as fundamental instruments. <sup>2-3</sup> In spite of the diagnosis, many times done in more advanced stages of the disease, new early detection methods and new treatment possibilities are appearing, resulting in a survival increase in these

women.

This improvement of life expectancy opposes an alteration in the state of overall health, since breast cancer and the proposed treatments cause a great impact in the lives of these women. Bergamasco and Ângelo<sup>4</sup> consider that breast cancer has a profound psychosocial impact in the patients and their relatives. They experience prejudice, fear of death, suffering from mutilation, fear of the appearance of the lymphedema and even feelings

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of social depreciation.<sup>4-5</sup>

Breast cancer and its treatment, many times mutilating, can lead a woman to alterations in her self-image, functional loss and psychic, emotional and social alterations. Those alterations, present in those that undergo the treatment for mammary carcinoma, can be quantified through a quality of life scale.<sup>6</sup>

Quality of life (QL), related to health, is a complex assessment based on subjective perceptions, experiences and expectations that people express.

It is recognized that, in clinical oncologic practice maybe more than in other areas, the patient experiences extreme variations of the symptomatology from beginning to end of treatment. One of the factors that soon interfere in the understanding of what constitutes QL for a person is the inexistence of a thoroughly accepted definition. In general, its construction is a multidimensional concept, measuring different aspects or domains of life that include physical, psychic, social and functional well-being.<sup>7</sup>

The use of questionnaires for the assessment of the quality of life has been recognized as an important area of scientific knowledge in the health field. In controlled clinical experiments, they serve as instruments of measure of the results and as an important component of cost-utility analysis of treatment.<sup>8</sup>

The questionnaires of QL assessment can be specific or generic. The specific ones are capable of specifically evaluating certain self-aspects of a population with a particular disease. The generic ones were built to assess the QL of people with more than one condition or reflecting on the impact of a disease on the lives of patients in several populations; exemplified, utilized in our research, Medical Outcomes Study 36-item Short Form Health Survey (SF-36), developed by Ware and Sherbone<sup>9</sup> and validated for the Portuguese language by Ciconelli.<sup>10</sup>

The aim of this is study is to compare the quality of life of women with breast cancer with healthy women.

# Methodology

# Type of study/perspective

A case control study of an exploratory and descriptive nature.

# Period/subject of the study

The work was carried out during the period of April to June, 2006. The population was composed exclusively by 75 women with breast cancer that were submitted to modified radical mastectomy (Madden), chemotherapy and adjuvant radiotherapy with clinical stage IIa or IIb (patient) and by 75 healthy women (controls). The collection was made by convenience with the patients that were receiving treatment on the day that the questionnaire was applied.

The women seen with breast cancer were in the age group from 40 to 65 years, with treatment end at the maximum one year and without active signs of the disease at the time of questionnaire application.

Inclusion criteria of the controls: healthy women; without comorbidities; with clinical breast exam, mammography and normal mammary ultrasound.

# Sample size

The data of Conde et al.<sup>11</sup> was used as reference for the calculation of the sample size regarding the 75 women with breast cancer randomly chosen for the quality of life assessment. Using the data of these authors and admitting a minimum difference between the groups of 15%, alpha error of 5% and a power (1-b) of 80%, the total number of calculated subjects was 150 (75 cases and 75 controls).

# Place of study/context

The study was developed with a group of women that frequent the mastology clinic of Santa Casa de Misericórdia de Sobral in Ceara (cases) and in the gynecological cancer prevention clinic with women without complaints, who accomplished periodic collection of cervical oncotic cytology (controls).

# **Data collection instrument**

Used as a data collection instrument in the study was Questionnaire SF-36, translated and evaluated for Portuguese by Ciconelli. The raw data obtained in the responses are converted into considered data, which are transformed in values from 0 to 100 (0=worse; 100=better) for the calculation formula: Considered value – inferior limit x 100 / Variation (score range).

# Statistical analysis

The comparison with other variable categories was done through contingency tables.

The chi-square test was used with Yates' correction for continuity for comparison of proportions. When one of the expected frequencies was inferior to five, Fisher's exact test was used. The level of established statistical significance was p <0.05, with important tendency of statistical significance for values between 0.10 and 0.05. The point scores of the domains of SF-36 were compared with variable categories through Kruskal-Wallis test. Multivariate analysis was made through lineal regression by the program MINITAB, version 11.2. Initially, variables with value of p < 0.25 in the univariate analysis were included in the model. Soon afterwards, the variables with a smaller significance level were removed from the model, until the remaining variables had statistical significance with value of p <0.05. Eight models of multiple lineal regression were developed; one for each domain of SF-36.

# Ethical and legal aspects of the research

The research obeyed Resolution 196/96 on research involving human beings. This resolution incorporates under the ethics of the individual and the collectivities the four basic references of bioethics: autonomy; non-maleficence; beneficence and justice. It sees to ensure the rights and duties that respect the scientific community, the research subject and the state. The research was developed after consent of the Ethics and Research Committee of UVA.

#### Results

The sample was characterized by 75 patients with breast cancer and 75 healthy women as controls in the age group from 40 to 65 years. Seeking the appropriate understanding of the results, data is presented in tables, exhibiting epidemiologic data and analyzing the functional, emotional and social aspects involved with the quality of life of those women assessed through Questionnaire SF-36. In Table 1 differences between cases and the controls were not noticed in relation to socioepidemiologic factors, evidencing homogeneity between the groups.

Questionnaire SF-36 interrogates the interviewees about their health, staying informed as

how the individual feels and how well they are capable of exercising their daily activities.

The first assessed item is how the individual considers their general state of health. The study showed a superior number of patients with breast cancer in relation to the controls that consider their general state of health good or excellent with statistical difference (p=0.01, OR=2.84, 95% CI 1.10-3.24), Table 2.

The women of the study were interrogated about the comparison of their current health condition in relation to one year prior. It was observed that all the patients with breast cancer considered, in relation to one year prior, the condition of their health equal or better, with significant statistical difference in relation to the controls (p=0.0007, OR = 4.60, 95% CI 1.64-8.62).

Questionnaire SF-36 evaluated in the two groups the average of the assessment of the functional capacity in patients with breast cancer, when compared to the controls, evidencing a smaller functional capacity in the patients with breast cancer; however, without statistical

**Table 1 -** Comparison of cases (n=75) and controls (n=75) in agreement with sociodemographic factors

	Cases (n=75)	Controls (n=75)	р
Age	57.7	55.5	0.453
(average + SD)	<u>+</u> 13.5	<u>+</u> 10.3	
Race			
White	47	40	0.856
Non-white	28	35	
Marital status			
Married	43	51	0.804
Divorced	32	24	
Family Income			
1-10 min. salaries	66	64	0.954
>10 min. salaries	08	11	
Hypertension or Diabetes			
Yes	27	25	0.965
No	08	10	
Smoking			
Yes	42	41	1.000
No	33	34	

<sup>\*</sup> p <0.05 is considered significant

**Table 2 -** Comparison between cases and controls in relation to quality of life questions through Questionnaire SF-36

-	Cases	Controls	р
	(n=75)	(n=75)	
Women that considered their general state of health excellent or good	66	54	0.01
Women that considered their health better than one year prior	74	54	0.0007
Women with physical health limitations in the last four weeks	51	26	0.0004

(n) number of individuals \* p < 0.05 is considered significant

CI: Confidence Interval

difference (values of functional capacity: minimum=00 and maximum=100 points), with p=0.76, OR=0.63, 95% CI 0.54-6.75; Table 2.

The study shows the comparison between the patients with breast cancer and the controls in relation to the limitations for physical aspects in the last four weeks, evidencing a significant worsening in the patients with breast cancer. (p=0.0004, OR=4.0, 95% CI 2.90-19.0), Table 2.

In relation to the criteria related to pain, significant difference was not observed between the cases and controls. Only four patients and three controls presented pain of important intensity (p=1.00), with similar measures between the cases and controls; Table 3. There was not a significant difference between the two groups in relation to the limitations of social aspects. Seventy-four patients with breast cancer and 73 controls stated that their health condition didn't interfere in their social relationships with relatives and friends (p=1.00), with similar measures between the groups (Table 3).

Vitality was evaluated in the two groups; however, significant difference was not evidenced in the average of the scoring of the two groups; group with breast cancer (average=61.0) and group controls (average=62.5); Table 3.

As for the limitations for emotional aspects, it was asked if during the last four weeks emotional problems interfered with their social activities (visiting friends, relatives, etc.). In both groups, 16 patients fulfilled the requirements that a small part of the time or at no time presented emotional limitations in the last four weeks (p=1.00).

**Table 3 -** Values of the assessed domains for Questionnaire SF-36 in a population of women with breast cancer (cases) and without the disease (controls)

Variable	Cases*	Controls*
Functional Capacity	61.1	62.4
Physical Aspects	42.3	88.2
Pain	54.8	56.2
General State of Health	72.3	45.4
Vitality	61.0	62.5
Social Aspects	70.8	71.2
Emotional Aspects	53.4	55.7
Mental Health	68.4	70.0

\* The individual scale for each one of the items varies from 0 to 100 points.

### **Discussion**

In the health area, the interest in the quality of life concept is relatively recent and has been more evident in the last decades. This quality of life expression is used in two lines: in the day-to-day language of common citizens, politicians and professionals of several areas and in the context of scientific research in the area of economy, sociology and several specialties in the areas of health. There is a growing interest in quality of life as an indicator in clinical judgments of specific diseases, as much to evaluate the physical and psychosocial impacts and dysfunctions as to evaluate incapacities. 12

There exists a great difficulty for the authors in defining QL because that definition reflects subjectivity, in other words, it can only be assessed by the same individual, but skips the multidimensionality of the construction, because QL is composed of different dimensions: physical; psychological; functional and social. This conceptual difficulty, in part, explains why in practice it is not usual to infer about it.

Short Form-36 (SF-36) is a quality of life measuring instrument developed in the late eighties in the USA. It was applied in several situations with good sensibility, eliminating the problem of excessive distribution at the top of the scale as in the responses "excellent "and "very bad". <sup>13</sup> The questionnaire used in the research, SF-36, is a generic instrument; however, it was chosen by the authors due to the fact that it was used in other domestic studies <sup>13-14</sup> and validated for Portuguese by Ciconelli. <sup>10</sup> It has subjectivity as a characteristic, in other words, part of the presupposition that only the person involved can judge their QL and as

such, their assessment depends on the individual report. <sup>14</sup> An approach different in the assessment of QL was opted for; through case-control study. Conde et al. <sup>11</sup> and evaluated specific factors of QL with emphasis for the climacteric symptoms and sexuality inside of a group just of women with breast cancer, observing that most of the participants of the study considered their quality of life good, results similar to what was found in our group of women with breast cancer. It is believed that that good evaluation is due to the multiprofissional support offered by our institution, through psychological support and self-help groups, in addition to the attention given by relatives, which would also explain the fact that patients consider their current quality of life better than one year prior.

Casso et al. <sup>15</sup> Fukui et al. <sup>16</sup> and Bardwell et al. <sup>17</sup> showed the importance of the psychological support for the patients with breast cancer, considerably improving their quality of life and their reintegration into society.

The most negative aspects found in women with breast cancer, when compared to the control group, were in relation to the requirements of functional capacity and physical health. Those findings can be related with the small number of patients of the study and also due to the patients having been submitted to mastectomy exclusively, not allowing a comparative evaluation between the groups that underwent radical or conservative surgery. Questionnaire SF-36 is used as an overall indicator of QL, more frequently identifying alterations of the physical component than of the mental component.<sup>18</sup> In spite of authors relating negative psychological repercussions in women submitted to mastectomy, it is worth emphasizing that the questions used are not validated, hindering the reproducibility of their results. 19 That fact doesn't invalidate the obtained results; however, that consideration is necessary so that the interpretation of the same ones is made with caution. The use of different questionaires, validated or not, hinders the comparison of the studies. Another aspect to be remembered is that even the use of specific and validated questionnaires cannot identify differences in the QL of women submitted to quadrantectomy or mastectomia.18

In a transversal cut study done in Germany, in addition to the European Organization for Research and Treatment of Cancer Quality of Life Core (EORTC QLQ-30) questionnaire, aspects related to the surgical treatment were assessed through specific questions. <sup>20</sup> The quality of life comparison didn't show significant differences between women submitted to mastectomy or conservative surgery, after a median of 3.8 years from

the surgery,<sup>20</sup> which was compatible with what was found in our research.

There are countless complications of physical order, deriving from the complexity of the muscles and of the extirpation of the ganglial chains that occur in a mastectomy, the patient that suffers surgery of the breast can experience possible complications that include the accumulation of blood (hematoma) in the local incision, infection and late accumulation of serosanguineous liquid (seroma) after drain removal.

Regarding the raised complaints, difference was not observed between the study group and the controls. That can be attributed to rehabilitative support through the participation of physiotherapists and psychologists developed in our institution. Casso et al. 15 found that one-third of the women who undergo surgical treatment for breast cancer presented painful symptoms, which runs into what we found, thus showing the importance of early rehabilitation measures for quality of life improvement of these women.

The relationship with friends and relatives (social and emotional aspects) was not altered with the diagnosis and treatment of breast cancer in most of the patients of the study. Breast cancer determines mobilization in the family context, aiming to provide adequate emotional support to the woman. Thus, it is possible that it is under the spouse's responsibility to provide most of the emotional support that the woman needs for a positive attitude in face of antineoplastic diagnosis and treatment. However, breast cancer is associated to psychological stress not just in the woman, but also in her partner.<sup>21</sup> The spouses of women with breast cancer can report depression, sleep alterations, sexual dysfunctions and difficulties in the workplace. <sup>21</sup> The partner can be a source of support or stress, depending on the quality of the couple's relationship. The emotional stress associated to the marital relationship can compromise QL. <sup>22</sup> Women satisfied with their partners tend to be well psychologically. <sup>23</sup> In spite of the possible negative repercussions of breast cancer, women with that neoplasia don't seem to experience more separations or marital crises than those that don't confront the disease. Difficulties in the marital relationship occur mainly with women that probably already presented those difficulties when diagnosed.<sup>24</sup>

The analysis of the several factors that contribute to QL suggests that its influence is more intense in the first years that follow diagnosis and the antineoplastic treatment. It is not uncommon for QL

to be referred to as "good" or "excellent" after breast cancer diagnosis. An important observation in that sense is the need of greater emotional support during and after diagnosis. This support cannot be limited by period nor by treatment type. In that way, we will be closer to the concept of integral attendance to woman's health and contributing to the improvement in the quality of life of these women.

Case-control studies, as done, preclude causal association because they only suggest the interrelation between self-referred health conditions, quality of life and data as treatment type instituted in women with breast cancer, which could be useful in the search of this causality and to be evaluated in other types of studies with larger casuistry.

## Conclusion

We can affirm that differences were not observed in the quality of life when comparing women with breast cancer to the controls, when utilizing Questionnaire SF-36. Longitudinal studies should be done with the objective of obtaining greater explanations on the causality of the relationships between breast cancer and quality of life.

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