

Ten-year survival and prognostic factors for breast cancer in the southeast region of Brazil

Sobrevida de dez anos e fatores prognósticos para o câncer de mama na região Sudeste do Brasil

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ABSTRACT: Introduction: Breast cancer is an important public health issue in many parts of the world. Thus, it shows relevant incidence and is considered one of the main causes of death from cancer among women.

Objective: To analyze ten-year survival and prognostic factors in women with invasive breast cancer. **Methods:** The cohort was composed of 195 women assisted in an oncology referral center in the municipality of Juiz de Fora, state of Minas Gerais, Brazil, who were diagnosed with the disease in 2000 and 2001. Sociodemographic, tumoral, health service, and treatment-related characteristics were analyzed. The Kaplan–Meier method was used to estimate the survival functions and the Cox model of proportional hazards for the evaluation of prognostic factors. **Results:** The ten-year survival after diagnosis was of 56.3%. The major independent prognostic factors associated with increased risk of death were tumor size > 2.0 cm (hazard ratio – HR = 1.9; confidence interval – 95%CI 1.0 – 3.2) and presence of compromised lymph nodes (HR = 3.7; 95%CI 2.1 – 5.9). **Conclusion:** These findings reinforce the need of adopting actions that ensure access of the target population to the recommended diagnostic and therapeutic modalities, thus contributing to achieve earlier diagnosis and better survival rates.

Keywords: Breast neoplasms. Survival analysis. Prognosis. Indicators. Brazil. Epidemiology.

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Conflict of interests: nothing to declare – **Financial support:** none.

RESUMO: *Introdução:* O câncer de mama é um importante problema de saúde pública em diversas partes do mundo, apresentando relevante incidência e sendo considerado uma das principais causas de óbito por câncer no sexo feminino. *Objetivo:* Analisar a sobrevida de dez anos e os fatores prognósticos em mulheres com câncer de mama invasivo. *Métodos:* A coorte foi composta de 195 mulheres assistidas em centro de referência oncológica no município de Juiz de Fora, no estado de Minas Gerais, com diagnóstico da doença em 2000 e 2001. Foram analisadas características sociodemográficas, tumorais e relacionadas à utilização do serviço de saúde e do tratamento. O método Kaplan-Meier foi utilizado para estimar as funções de sobrevida e o modelo de riscos proporcionais de Cox para avaliação dos fatores prognósticos. *Resultados:* A sobrevida de dez anos após o diagnóstico foi de 56,3%. Os principais fatores prognósticos independentes associados ao aumento do risco de óbito foram tamanho de tumor > 2,0 cm (razão de risco – HR = 1,9; intervalo de confiança – IC95% 1,0–3,2) e presença de linfonodos comprometidos (HR = 3,7; IC95% 2,1–5,9). *Conclusão:* Os achados reforçam a necessidade da adoção de medidas que assegurem o acesso da população-alvo às modalidades diagnósticas e terapêuticas preconizadas, contribuindo para que sejam alcançados diagnósticos mais precoces e maior tempo de sobrevida.

Palavras-chave: Neoplasias da mama. Análise de sobrevida. Prognóstico. Indicador. Brasil. Epidemiologia.

INTRODUCTION

Breast cancer is a major public health problem in many parts of the world¹. It is considered the cancer with highest incidence and prevalence among women in both developed and developing countries².

Estimates suggest that half the number of new cases and 60% of deaths caused by the disease may occur in developing countries³. In countries such as USA, UK, France, and Australia, there was a decline in mortality over the last two decades⁴, whereas in Latin America, an increase in the mortality from the disease in the same period was observed⁵. In general, survival in Latin American countries is on average 20% below that of European countries and the USA⁵. In Brazil, following the global trend, an increase in incidence in general and a reduction in mortality from breast cancer in the south and southeast regions have been observed⁶.

By means of survival, it is possible to evaluate the results of diagnostic and therapeutic advances in oncology, as well as to analyze the overall efficiency of cancer control by the health system^{7,8}. Over the past decade, the combination of population screening measures and advances in the treatment of the disease has contributed to the decrease in mortality and extension of survival in the developed countries⁵. Early diagnosis enables the detection of the disease at early stages and provides better therapeutic responses, which contribute to increased survival. However, this increase related to the screening should be interpreted with caution, as it may be partially explained by the early diagnosis, which enables the observation of the disease progression for a longer period of time (lead-time bias), and the identification of a greater number of cases

with prolonged detectable pre-clinical phase, which consequently show better prognosis (length-time bias)^{7,8}.

Several factors have been investigated to establish valid criteria for the objective evaluation of the prognosis of patients. Tumor characteristics, such as involvement of regional lymph nodes and tumor size, are seen as strong prognostic indicators in long-term follow-ups⁹. The literature indicates an inverse relationship between tumor size and survival, whereas the presence of lymph nodes is associated with the disease recurrence in the first decade after the treatment. High number of affected lymph nodes and involvement of the axillary apex and internal mammary lymph nodes indicate worse prognosis^{9,10}.

In addition to the characteristics of the tumor biology, sociodemographic aspects, and those related to health care also influence, directly or indirectly, the disease survival rate⁸⁻¹⁰.

This study aimed at evaluating the ten-year survival and the prognostic factors for breast cancer in women treated at a referral center for cancer care in southeastern Brazil.

METHODS

The population of the study consisted of a cohort of a hospital base, consisting of women with invasive breast cancer diagnosed between January 2000 and December 2001. The patients underwent surgical treatment and/or complementary therapy (chemotherapy, radiotherapy, or hormone therapy) in an oncology service in the municipality of Juiz de Fora, a medium-sized city in the southeast of Brazil.

The health institution in which the research was developed is one of three High Complexity Care Units in Oncology (UNACON) with radiotherapy and hematology services¹¹ of the municipality, which provide care on the Unified Health System (SUS) and on private health system for the city and surrounding areas. It is considered an important regional center of excellence in cancer care.

The recruitment of patients included in this study was carried out by searching the Hospital Cancer Registry (CHR) of the institution. Medical records of the participants enrolled in the service at the end of 1999 and early 2002 were also evaluated because the patient could have sought the service immediately before or after the establishment of the diagnosis.

By means of standardized form, data were collected by trained staff, which were supervised by physicians who were specialists in Pathology and Oncology. The data were reviewed by experts to improve the quality of data on pathological reports and tumor staging.

We tried to obtain the follow-up of ten years (120 months) for all patients included in the study. It was initially carried out checking the medical records, followed by the search in the database of the Mortality Information System (SIM) regional. The interrelationship of database records with the SIM was based on the probabilistic record linkage technique, considering three homologous fields inserted in both databases: name, name of mother, and date of birth. This analysis was carried out using the software ReLink 3 (version 3.1.6.3160)¹².

For patients who still remained with incomplete follow-up, telephone calls were made using the CHR of the institution, aiming at only acquiring information concerning the vital state. Subsequently, registration status in the Brazilian Social Security Database (CPF) of the Brazilian Internal Revenue Service (*Receita Federal*) was checked to obtain the vital status of the patient on the condition of being alive. The date of the last regular registration status identified (active CPF) was used as the date of last contact with the patient alive, for those who remained with incomplete follow-up.

For overall survival analysis, the release date of the histopathological report was considered the beginning of the count of survival period, and deaths identified by the end of follow-up were treated as failures. Women who remained alive until the end of follow-up and those with loss of follow-up were reproved.

Among women residents in the micro-region of the health system of Juiz de Fora, 201 cases of breast cancer were identified in the CHR of the institution. Among the cases, three were excluded owing to the lack of histopathological report and three because of carcinoma *in situ*. In conclusion, 195 women were investigated, and represented the study population.

At the end of data collection in the medical records and in the searches carried out, 51 cases remained with incomplete follow-up (26.1% of the study population). The median period of the follow-up was 84 months (25th percentile = 44 months, and 75th percentile = 120 months), which covered an average of 3,777 people/month.

The following variables were verified: age at diagnosis (< 40, 40–49, 50–59, 60–69 and ≥ 70 years); skin color (white, not white); tumor size (up to 2.0 cm and > 2.0 cm); lymph node involvement; stage (I, II, III, and IV); estrogen receptor (ER), progesterone receptor (PR), and HER2; type of the health service (public or private); private health insurance coverage; time elapse between diagnosis and surgery (≤ 4 weeks, > 4 weeks); type of surgery (conservative, radical); existence of tumor marker tests, and use of radiotherapy, chemotherapy, or hormone therapy.

The χ^2 test and, when necessary, Fisher's exact test were used to evaluate the differences in the distribution of the variables analyzed, and those with $p \leq 0.05$ were considered as statistically significant.

The method proposed by Kaplan–Meier was applied to evaluate the survival probability, and the comparison of survival functions in relation to the variables was performed using the log-rank test.

Cox proportional hazards model was applied to evaluate the prognostic factors, computing the hazard ratio (HR) and corresponding 95% confidence intervals (95%CI). Variables were selected by means of the significance obtained in the Cox univariate model, considering the value of $p \leq 0.2$. The variables included in the multivariate analysis were removed by the process of backward elimination. Only those variables that maintained $p \leq 0.05$ remained in the final multiple model.

The likelihood ratio test was used to verify the significance of the parameters of the reduced models, and Schoenfeld residuals test was used to assess proportionality of Cox models.

Input and descriptive analyses of data were performed using the software Epi Info 2012 (Centers for Disease Control, Atlanta, USA), and the software Stata (StataCorp, Texas, USA, version 10.0) was used for the analysis of survival and prognostic factors. The study was approved by the Ethics Committee of the *Universidade Federal de Juiz de Fora*, under the opinion 151,219.

RESULTS

In the study cohort, the mean age at diagnosis was 57.8 years and the median age was 57 years (percentiles: 25 = 47 years, and 75 = 69 years). White women (79.7%) were predominant. With regard to the distribution of tumor characteristics in the study population, a higher percentage of tumors larger than 2 cm (65.1%); absence of lymph node involvement (55.4%); stage II (52.6%); positive ER (74.7%) and PR (69.7%); and negative HER2 (57.5%) were observed.

Among the characteristics associated with the use of health services, 110 (56.4%) patients sought the public health service, and half of the population had health insurance. For 166 (86.0%) patients, the elapsed time between diagnosis and surgery was ≤ 4 weeks and for 98 (53.6%) patients, the type of surgery has been conservative. As complementary treatment, 61.5% underwent chemotherapy, 59.5% underwent hormone therapy, and 40.5% underwent radiotherapy. The percentage of execution of tumor marker tests was 76.0.

At the end of the study, 76 deaths were registered. With regard to the total population, patients who progressed to death exhibited significantly higher percentage of tumor size > 2 cm (75.7%); lymph nodes involvement (67.6%); advanced stage (III and IV = 44.0%); assistance in public service (69.7%), and absence of health insurance (60.0%). Table 1 shows the distribution of the characteristics of patients and unadjusted ten-year survival functions, according to the study variables.

The ten-year survival observed in the study population was 56.3% (95%CI 48.3 – 63.5), with the highest observed among the patients who had better prognosis characteristics, such as tumor size ≤ 2 cm (68.2%; 95%CI 54.7 – 79.2); absence of lymph node involvement (74.1%; 95%CI 63.1 – 82.3), and staging I (75.1%; 95%CI 57.1 – 86.3) and II (63.0%; 95%CI 51.7 – 72.4).

Use of the private health service ($p = 0.01$), having health insurance ($p = 0.02$), and conservative surgery ($p < 0.001$) led to highest survival rates. The patients who underwent tumor marker tests showed longer survival ($p = 0.08$). There was no statistically significant difference in survival according to the sociodemographic characteristics, the results of tumor markers (ER, PR, and HER2), the complementary treatment modalities, and the time elapse between diagnosis and surgery.

Table 2 shows the final multiple model with correspondents HR (unadjusted and adjusted). The survival curves of the variables are presented in Figure 1. The lymph nodes involvement and the size of the tumor were identified as the main independent

Table 1. Distribution of the characteristics of patients and unadjusted ten-year survival function, according to the variables of the study.

Characteristics	Cases (n) [#]	%	Under-10 years (%)	95%CI	p-value*
Total of cases	195	100.0	56.3	48.3 – 63.5	
Color of skin					
White	145	79.7	57.7	48.5 – 65.7	0.37
Not white	37	20.3	44.9	27.1 – 61.3	
Age at diagnosis (years)					
< 40	17	8.7	57.0	26.5 – 78.8	0.16
40 – 49	43	22.1	66.1	49.4 – 79.5	
50 – 59	44	22.6	51.1	33.9 – 65.8	
60 – 69	46	23.6	65.6	47.1 – 79.0	
≥ 70	45	23.1	42.9	27.9 – 57.0	
Size of the tumor (cm)					
≤ 2.0	66	34.9	68.6	54.5 – 79.2	0.01
> 2.0	123	65.1	49.0	38.9 – 58.3	
Lymph nodes involvement					
Negative	102	55.4	74.1	63.1 – 82.3	< 0.001
Positive	82	44.6	36.6	27.2 – 49.9	
Staging					
I	45	23.4	75.1	57.1 – 86.3	< 0.001
II	101	52.6	63.0	51.7 – 72.4	
III	39	20.3	26.3	12.9 – 41.8	
IV	7	3.6	14.3	0.71 – 46.5	
Estrogen receptor					
Negative	37	25.3	53.0	34.9 – 68.2	0.24
Positive	109	74.7	61.0	50.3 – 70.4	
Progesterone receptor					
Negative	44	30.3	57.7	40.7 – 71.4	0.50
Positive	101	69.7	59.7	48.4 – 69.3	

Continue...

Table 1. Continuation.

Characteristics	Cases (n)*	%	Under-10 years (%)	95%CI	p-value*
Total of cases	195	100.0	56.3	48.3 – 63.5	
HER2					
Negative	73	57.5	64.2	50.8 – 74.8	0.27
Positive	54	42.5	55.1	39.8 – 68.1	
Service type					
Public	110	56.4	46.9	36.5 – 56.6	0.01
Private	85	43.6	68.9	56.6 – 78.4	
Health insurance					
No	97	50	47.9	36.5 – 58.3	0.02
Yes	97	50	65.0	53.6 – 74.3	
Time elapse between diagnosis and surgery (weeks)					
≤ 4	166	86	55.8	47.2 – 63.6	0.80
> 4	27	14	61.3	36.8 – 78.7	
Type of surgery					
Conservative	98	53.6	71.1	59.2 – 80.1	< 0.001
Radical	85	46.4	45.1	33.8 – 55.7	
Tumor markers					
Absent	46	24	44.0	27.8 – 59.1	0.08
Present	146	76	59.3	50.0 – 67.4	
Chemotherapy					
Did not use	120	61.5	54.3	44.0 – 63.4	0.36
Used	75	38.5	59.7	46.5 – 70.6	
Hormone therapy					
Did not use	116	59.5	57.1	46.7 – 66.3	0.70
Used	79	40.5	54.9	42.2 – 66.0	
Radiotherapy					
Did not use	79	40.5	56.9	44.5 – 67.6	0.54
Used	116	59.5	56.4	45.8 – 65.6	

*Total (n) of variables may differ depending on missing data; Under-10 years (%): ten-year survival; 95%CI: 95% confidence interval; *log-rank test for each variable.

prognostic factors. The risk of death from breast cancer was approximately three times higher for the presence of axillary lymph node involvement (HR = 3.5, 95%CI 2.1 – 5.9) and approximately twice as high for tumors larger than 2.0 cm (HR = 1.8, 95%CI 1.0 – 3.2). It was also showed a reduced death risk for patients who had health insurance (HR = 0.6, 95%CI 0.4 – 0.9).

The variables analyzed did not violate the principle of proportionality of risks, and the results achieved in Schoenfeld residuals test was $p = 0.48$. Therefore, these values are not statistically significant for any of the variables inserted in the final multiple model.

DISCUSSION

By means of this study, the main characteristics of women with breast cancer, who were treated at a medium-sized cancer referral center in a city of southeastern Brazil, could be clarified. An overall ten-year survival was observed in 56.3% of the cases. In addition, the main associated predictors were observed: lymph node involvement, tumor size, and having private health insurance.

In Brazil, there are few studies evaluating the survivability of breast cancer in periods longer than five years after diagnosis. However, the estimate obtained in this study is lower than that found in a hospital-based cohort of the municipality of Santa Maria, in the state of Rio Grande do Sul, which achieved overall survival of 78.7%¹³. Total survival found was also lower than that achieved in a hospital-based cohort of the *Instituto Nacional do Cancer José Alencar Gomes da Silva*, which evaluated the overall survival of women according to the triple negative immunohistochemical profile without lymph node involvement, and obtained a value of 61.6%; the other women in the same study showed a 70.1% survival at the end

Table 2. Crude and adjusted hazard ratios of the variables of the final multivariate model.

Characteristics	Unadjusted HR	95%CI	Adjusted HR*	95%CI	p-value
Lymph nodes involvement					
Negative	1	2.2 – 6.2	1	2.1 – 5.9	< 0.001
Positive	3.7		3.5		
Size of the tumor (cm)					
≤ 2.0	1	1.1 – 3.3	1	1.0 – 3.2	0.04
> 2.0	1.9		1.8		
Health plan					
No	1	0.4 – 0.9	1	0.4 – 0.9	0.04
Yes	0.6		0.6		

HR: hazard ratio; CI: confidence interval; *adjusted by age in the continuous format, in addition to the other variables described in the table.

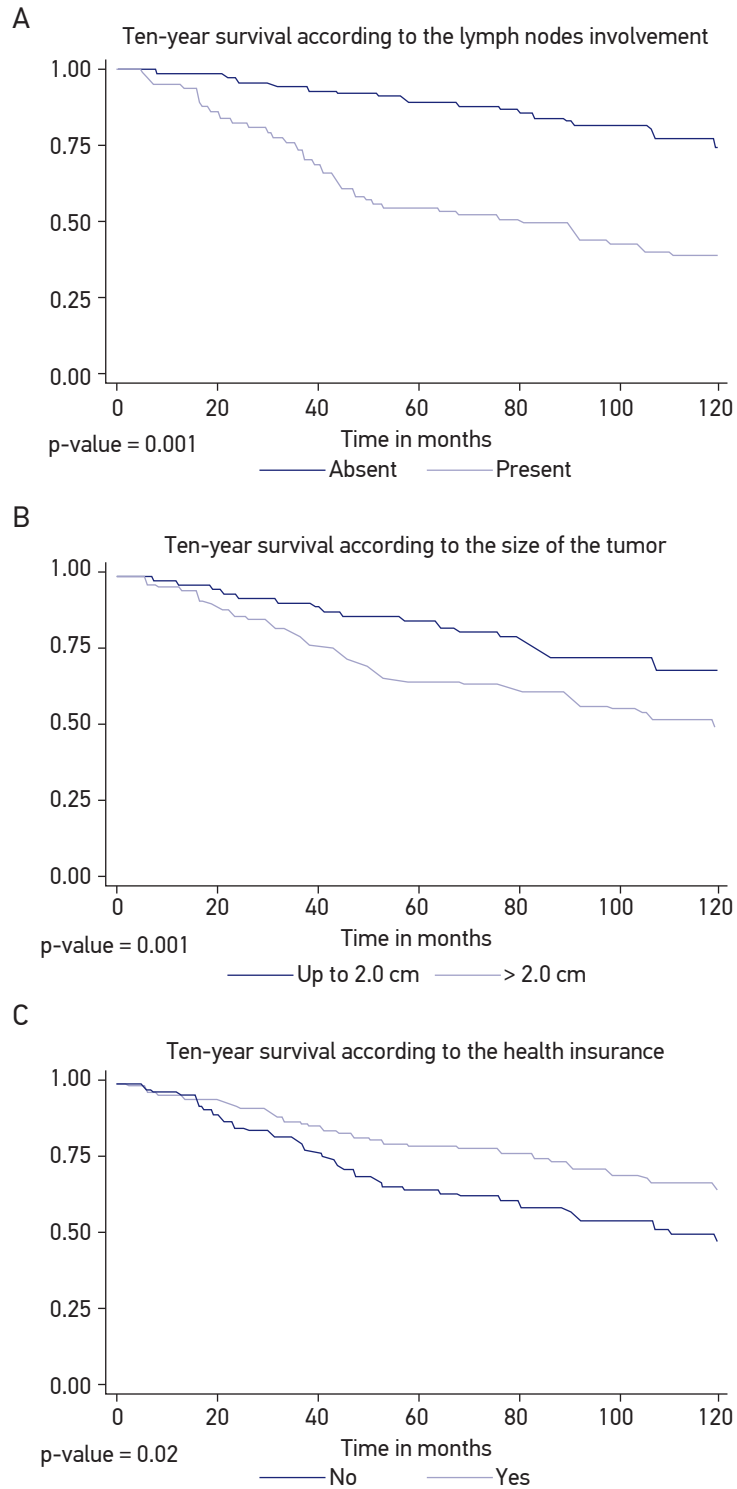


Figure 1. Survival curves according to the variables maintained in the final model.

of ten years of follow-up¹⁴. However, in a specific ten-year survival analysis carried out in a hospital cohort of the city of Joinville, Santa Catarina, an estimate of 57.8% was found, which is very close to that of this study¹⁵.

Similar behavior was observed in the relative ten-year survival analysis (50.0%) by Abreu et al.¹⁶, in a population-based cohort investigated between 1988 and 1990 in the city of Goiânia, Goiás.

In the study carried out by Allemani et al.¹⁷, which was based on data records of the population, the relative ten-year survival among European women with breast cancer diagnosed between 2000 and 2002 showed values above 70% in most regions of the European continent. This percentage corroborates the results obtained by Soerjomataram et al.⁹ in a systematic review, in which they concluded that most Western developed countries had ten-year survival rates of around 70.0%. However, it is worth noting that the Eastern European countries (54.2%), Slovakia (46.3%), Czech Republic (58.0%), and Slovenia (59.3%) had survival rates that were closer to those found in this study.

It is worth noting that the differences found between the results obtained in this study and those of the studies mentioned earlier should always consider the population investigated, the evaluation period, the different methods applied, especially the criteria for inclusion and exclusion of the population, and the types of analysis applied to the calculation of survival, which may explain some of the observed differences, particularly with regard to international studies, which used data from population-based cancer registries and estimated relative survival⁷.

Lymph node involvement and the size of the tumor were the main prognostic factors which remained strongly associated with increased risk of death in the research population. These findings are in agreement with the literature^{18,19}, which suggests, as proposed by Rakha and Ellis¹⁰, that even over long periods of follow-up, such as ten years, the effects of these prognostic factors remain unchanged.

The reduced mortality risk in patients who had private health insurance can be explained by the high percentage of women who had earlier diagnosis of the disease in this group, with characteristics such as stage I (34.0%), absence of lymph node metastasis (65.6%), and size of the tumors ≤ 2 cm (45.3%). Therefore, it should be considered that the variable “owns health plan” may represent a *proxy* for socioeconomic status, which may indicate more carefulness about health, owing to better income and education conditions. These are characteristics that together may contribute to greater access to early diagnosis. The result is consistent with what was observed during the study conducted by Brito²⁰, who showed increased risk of death from breast cancer among women without health insurance. This finding also reinforces the importance of early diagnosis and corroborates the literature findings, which indicate that it is possible to decrease mortality from breast cancer in 21.0–29.0% among women who participate in screening processes during 14–16 years of follow-up^{21,22}.

The age range did not associate with survival time in unadjusted analysis. Although the prognostic effect in the literature is still controversial^{15,18}, this variable was selected and

maintained in a continuous format in the final model, owing to its importance and because it provides better fit to the model, with risk of death of only 4% with aging.

The ten-year survival in nonwhite women (44.9%) was lower than that found in white women (57.7%), although the skin color variable was not maintained in the final model. Among nonwhite women, 32.4% had advanced staging of disease (III and IV), 83.7% were treated only in the public health service, and 75.6% of them had no private health insurance coverage. The variable “skin color” has been used as a method to indicate the socioeconomic level of the women affected by the disease and the inequalities in the access to treatment^{1,23}, which reinforce the need for its evaluation. A fact that may have contributed to justify the loss of significance of this variable after adjustment is the intense ethnic miscegenation in Brazil, which undermines the standardization of skin color classification, as well as the effect of individual perception variations of health services professionals^{16,18}.

Although staging has lost significance during the multivariate analysis, this variable showed a behavior that was inversely proportional to survival. This finding is in agreement with the literature, suggesting that more advanced staging has worse prognoses for breast cancer^{10,13}.

Studies show that the use of complementary treatments in the treatment of breast cancer promotes the increased survival and may reduce up to 57.0% the long-term mortality²⁴⁻²⁶. In this study, the complementary treatment modalities evaluated (chemotherapy, hormone therapy, and radiotherapy) were not associated with disease-specific survival, which may be related, at least in part, to the difficulty of more detailed evaluation of the therapeutic approach, which is influenced by type and dosage applied, usage period, and concomitant treatments.

The tests which enable the evaluation of tumor biology have been widely used in cancer care, both for estimating the tumor behavior and for guiding the systemic therapy to be used^{10,27}. In this population, the lack of tumor marker tests was observed in only 8.2% of the private service users, whereas in the public service the percentage was 36.4%. It is also worth noting that the presence of the markers was associated with better survival (59.3%; 95%CI 50.0 – 67.4) compared to its absence. This finding suggests that not performing such tests may be linked to the difficulty of access to the methods of diagnosis and treatment, which indicates differences in the socioeconomic status of the women affected by the disease.

This study highlights the relevance of the information available in the health services that provide assistance to cancer patients in the country, which enables to characterize the profile of its users and to estimate the survival. Even considering the limitations of using retrospective secondary data, this information is extremely useful for the adoption of measures aimed at preventing and controlling the disease by health managers, for the evaluation of the quality of the care provided and for the accessibility to the health system, as well as for the evaluation of diagnostic and therapeutic advances.

CONCLUSION

The findings of this research enable the estimate of the long-term breast cancer survival, which is still poorly explored in Brazil, as well as reinforce the importance of early diagnosis by the screening performed by mammography, which can contribute to prevent the occurrence of nodal metastases and diagnoses at more advanced stages. Another essential fact is the guarantee of access to immunohistochemistry, which are highly relevant in contemporary clinical decisions, leading to the adoption of more accurate and effective therapeutic indications.

The combination of early detection actions and the improvement of therapeutic measures has been identified as primarily responsible for the improved survival and consequently for the reduction in mortality from breast cancer in developed countries^{4,9}. In Brazil, the adoption of measures to ensure all women have access to the best available diagnostic and therapeutic modalities is essential.

ACKNOWLEDGMENTS

The authors would like to thank Professor Dr. Rosalina Jorge Koifman for the valuable suggestions. In addition, Maria Teresa Bustamante-Teixeira would like to thank the *Conselho Nacional de Desenvolvimento Científico e Tecnológico* for the researcher scholarship (PQ 307087/2015-8) and the *Fundação de Amparo à Pesquisa do Estado de Minas Gerais* (PPM-00204-13; APQ 03630-12).

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Received on: 09/28/2015

Final version presented on: 05/17/2016

Approved on: 05/31/2016