Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Outcome Analysis of Breast Cancer Patients - A Retrospective Study

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Abstract

Introduction: Breast cancer is one of the most common cancers in women and is the second leading cause of cancer-related death in women. Survival rate can be used as a yardstick for assessing the standard of any cancer therapy and this helps in developing cancer-related policies and programs.

Purpose: To find out 5-year survival of breast cancer patients treated in the year 2014 at Government Medical College, Kozhikode, and to evaluate the prognostic factors and the difference in survival based on the stage of presentation.

Methods: A retrospective audit of breast cancer managed in the year 2014 was carried out and now reporting 5-year disease-free survival (DFS), overall survival, and prognostic factors of patients treated at Government Medical College, Kozhikode.

Results: This study included 369 breast cancer patients with ages ranging from 20 to 90 years with a median age of 50 years. Two hundred and twenty patients had early breast cancer and 149 had locally advanced breast cancer (LABC). A 5-year DFS in exhaled breath condensate (EBC) was 91.5% and in LABC was 62.2%. The 5-year overall survival in the EBC group was 92.3% and in the LABC group was 65.7%. The factors adversely affecting survival were found to be tumor size, number of positive nodes, hormone receptor negativity, and lymphovascular space invasion.

Conclusion: The survival rates in the study were comparable with documented Indian studies. Tumor size, node positivity, lymphovascular space invasion, and hormone receptor negativity are important negative prognostic factors for breast cancer.

Key words: Breast cancer, Disease-free survival, Overall survival, Prognostic factors

INTRODUCTION

Breast cancer is a leading cancer and second-leading cause of cancer-related death in women. In India, the crude rate and age-adjusted risk vary from 12.7–34.8 to 13.9–41/100,000 population across several states, according to the Indian Council of Medical Research sponsored population-based cancer registry program. A report stated that cancer caused 5% of disability-adjusted life years in the Indian population in 2016. During the last decade, breast cancer has been rising steadily in India, and in 2012, it was the most common cancer among women in India, a way ahead of cervical cancer.

Access this article online

www.ijss-sn.com

Month of Submission : 06-2023
Month of Peer Review : 06-2023
Month of Acceptance : 07-2023
Month of Publishing : 08-2023

Data on the clinical profile of early breast cancer in India are scant. Due to differences in genetics, environment, lifestyle, socio-demographic structure, and ethnicity, the presentation and behavior of breast cancer in India may be diverse. Early breast cancer patients usually with a painless breast mass or an abnormal screening mammogram. Advanced tumors may have skin changes, bloody nipple discharge or occasionally changing size and shape of the breast.

Several features help predict the probability of successful outcome after treatment of breast cancer. The established prognostic factors for this condition include histological subtype, tumor grade, estrogen receptor status, HER2/neu amplification, lymphovascular invasion, genetic profile, age, race obesity, and body mass index of which the most important being the size of the primary tumor and status of the regional lymph node. Survival rates can be used as a yardstick for assessing the standards of any cancer therapy. This help in developing cancer-related

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policies and estimating baseline survival rates in each patient population.

This retrospective analysis is intended to evaluate the 5-year survival rate and prognostic factors of carcinoma breast in patients who were initiated on treatment in 2014 at the Government Medical College, Kozhikode. The 2014 data give us a snapshot of trends over the last 7 years and outcomes of patients managed as per the guidance and evidence-based medicine

METHODS

Newly diagnosed breast cancer patients from stage I to IIIC are included in the study. A retrospective audit of carcinoma breast cases registered in the year 2014, using the details in the master file of the patients kept in the department was carried out. Detailed data collection including patient age, presenting symptom, menstrual status, parity, family history, the initial stage of presentation, pathological stage, hormone and Her2 status of the patient, grade, lymph-vascular space invasion (LVSI) status, treatment details and type of surgery were obtained from master file kept in the department. Patients' follow-up details for 5 years of diagnosis were collected. The details of recurrence, if any, were collected from the clinical examination details of the patient, radiological investigations, and histopathology report from the master file. Three hundred and sixty-nine patients' details were used for the final analysis. Usual workup for newly diagnosed breast cancer patients includes complete blood count, biochemistry with mammogram, and pathology confirmation. In locally advanced breast cancer (LABC), a metastatic workup including chest X-ray, ultrasonography abdomen/computed tomography thorax and abdomen are done. Early breast cancer patients are offered breast conservation if there are no known contraindications. Those who were not eligible for conservation or did not choose it proceeded with modified radical mastectomy (MRM). If the patient presents with LABC or a tumor breast ratio inadequate for conservation, then neoadjuvant chemotherapy followed by surgery is done. All patients who were operated for breast cancer underwent axillary clearance. Patients with Her2/Neu-positive breast cancer were offered neoadjuvant and adjuvant trastuzumab. Pre-menopausal women with hormone receptor-positive disease received 5 years of adjuvant tamoxifen, while post-menopausal women were given 5 years of aromatase inhibitor, letrozole. All women who underwent breast conservation surgery were given adjuvant radiation to the involved breast. In case of high-risk, patients this is followed by a boost to the tumor bed. Post-mastectomy women with T1T2N0 Stage were not offered adjuvant radiation unless they got neoadjuvant chemotherapy. All women with lymph node positivity and those who received neoadjuvant chemotherapy received adjuvant radiation to the chest wall and supraclavicular fossa. Follow-up after treatment done by careful history and physical examination done every 3 months for 3 years, followed by 6 months for 2 years and annually thereafter. The diagnostic mammogram was done every 6 months for the first 2 years, followed by yearly thereafter. Statistical analysis was done using IBM SPSS statistics software. Descriptive and inferential statistical analysis have been carried out in the present study. Frequencies and percentages have been used for variables. The Kaplan–Meier estimator was used to estimate the survival function. Log-rank test was used to assess the statistical significance of univariate analysis. The Cox hazard regression model was used for multivariate analysis to assess the impact of individual prognostic factors on survival.

RESULTS

The complete data set consists $n = 369$ observations who were diagnosed with carcinoma breast in the year 2014 and treated with a radical indent (stage I, II, and III). The time scale used in the study is "month since diagnosis to 60 months."

Descriptive Data

A total of 369 patients were studied, of which 59.6% (220) had early breast cancer and 40.4% (149) had LABC.

Patients above the age of 20 years were included in the study. The median age of the study population was 50. In exhaled breath condensate (EBC) group 164 (75.56%) out of 220 patients presented within 3 months of onset symptoms, 28 (12.21%) patients between 3 and 6 months, and 28 (12.21%) after 6 months of onset of symptoms. Among LABC patients 79 (52.02%) out of 145 presented within 3 months of the onset of symptoms, 36 (25%) patients between 3 and 6 months, and 34 (22.9%) after 6 months of the onset of symptoms. Of 369 patients studied, 164 (44.2%) were in the reproductive age group and 205 (55.8%) were post-menopausal. In both groups, most of the patients were post-menopausal females and 11% (41) were nulliparous. A positive family history of breast-ovarian malignancies was found in 7.9% of studied patients. The commonest histological type of breast cancer was infiltrating ductal carcinoma in the population studied. Most of the patients in EBC were Grade 2. In LABC Grade 1 tumor. About 48.5% of patients were node negative on pathological examination. This include patients who received neoadjuvant chemotherapy and

patients who were taken up for upfront surgery. About 23.6% of patients had lymph vascular space emboli. Among EBC patients 17.72% had LVSI and among LABC patients 32.21% had LVSI. About 59.1% of the patients were ER-positive this include 141 patients in the EBC group and 77 patients in the LABC group. The majority of ER-positive tumors were in the EBC group. Her2/Neu amplification was seen in 95 (25.7%) patients. About 45% of Her2/Neu-positive patients were in the EBC group and 54.7% in the LABC group. Among early breast cancer patients, 91.4% (202) underwent MRM surgery and 8.5% (19) underwent breast conservation surgery. In the LABC group, 96.62% of patients (144) underwent MRM and 3.4% (5) had BCS. Post-surgery margin positivity was seen in 6 (2.7%) of early breast cancer patients and 3 (6%) of LABC patients. About 23.3% of patients received electron beam RT and 47.2% received photon beam RT. Of the total 95 Her2/Neu-positive patients, 79 completed anti-Her2/Neu targeted therapy. About 29.5% of patients took endocrine therapy with tamoxifen and 30.1% of patients took letrozole therapy. Recurrence in the form of local recurrence or distant failure was studied in both groups separately. Among the early breast cancer group, 18 patients out of 220 had disease recurrence within 5 years of follow-up (8.1%). In LABC group, 54 patients had disease recurrence (36.24%). Two patients in the EBC group developed locoregional recurrence. In the LABC group, 9 patients out of 149 had a locoregional recurrence in the form of chest wall, axillary, or supraclavicular lymph node recurrence. The most frequent sites of metastasis in EBC patients were bone and lung. About 5 patients had bone and lung secondaries in 5 years. In LABC patients bone secondaries were the most common form of metastasis followed by brain metastasis.

Survival Analysis

Kaplan–Meier is used for estimating the overall survival and the Cox regression model to analyze how covariates affect survival disease-free survival (DFS) was assessed separately in EBC and LABC. Patients in EBC had significantly better disease-free survival than LABC, as expected. From the Kaplan–Meier estimator, 5-year DFS for EBC was 91.5 (95% CI 87.776–95.224), and 5-year DFS for LABC was 62.2 (95% CI 53.968–70.432) [Figure 1]. A total of 70 deaths occurred during the study period –18 deaths in the EBC group and 52 deaths in the LABC group. Twelve deaths were due to breast cancer-unrelated causes. The 5-year overall survival in the EBC group was 92.3% (95% CI 88.77–95.828) [Figure 2]. The 5-year overall survival in the LABC group was 65.7% (95% CI 60.35–74.746). Cerebrovascular and cardiovascular were the leading causes of cancer-unrelated deaths.

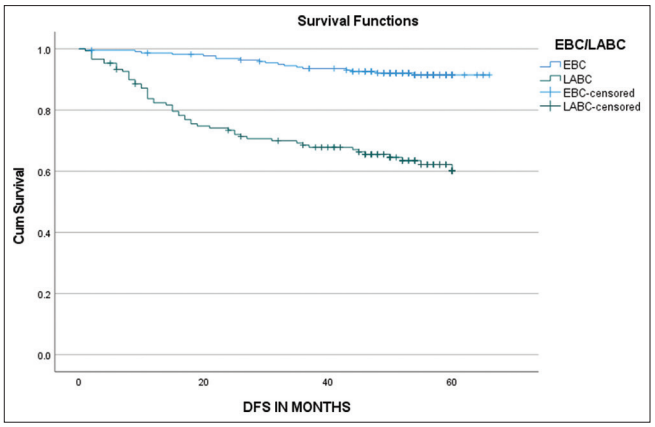

Figure 1: Disease-free survival of the study population

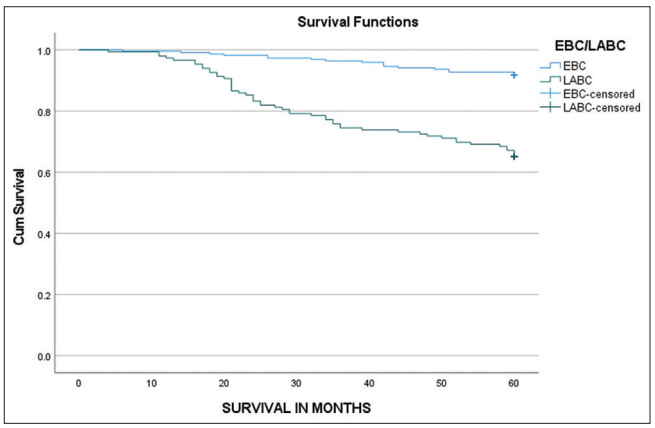

Figure 2: Overall survival of the study population

Univariate analysis of the whole study population showed that the association of tumor size, number of nodes, grade, ER status, and LVI with survival was statistically significant. Menstrual status, HER 2-amplification status, and adjuvant radiation did not show a statistically significant association with survival [Table 1]. Univariate analysis in EBC patients showed that LVSI and ER status were significantly associated with survival. However, menstrual status, HER 2-amplification status, and grade of tumor were not significantly associated with survival [Table 2]. Univariate analysis in LABC patients showed that LVSI and ER status were significantly associated with survival. However, menstrual status, HER 2-amplification status, and grade of tumor were not significantly associated with survival [Table 3].

In multivariate Cox regression analysis, tumor size (heart rate [HR] 2.714, 95% CI 1.947–7.776, $P < 0.001$), nodal status (HR 2.668, 95% CI 1.288–5.530, $P = 0.008$), and LVSI (HR 3.306.95% CI 1.757–5.247, $P < 0.001$) emerged as factors associated with poor prognosis independent of others. ER-positive status (HR 0.591, 95% CI 0.359–0.973, $P = 0.039$) was found to be protective [Table 4].

Table 1: Summary of univariate analysis of all the patients

Variable	Subgroup	Number	Overall survival %	*P*-value
Tumor size	≤2 cm	48	89.6	<0.001
	2–5 cm	189	86.2	
	>5 cm	73	83.6	
	Local infiltration	59	54.2	
Number of positive nodes	0	179	91.6	<0.001
	1–3	107	80.4	
	3–9	57	64.9	
	>9	26	46.2	
ER	Positive	218	87.2	<0.001
	Negative	151	72.2	
HER2	Positive	95	76.8	0.233
	Negative	274	82.5	
Grade	G1	90	90.0	0.047
	G2	191	77.5	
	G3	88	79.5	
LVSI	Present	87	62.1	<0.001
	Absent	282	86.9	
Menstrual status	Menstruating	164	82.3	0.604
	Post-menopausal	205	80.0	
Adjuvant radiation	None	109	88.1	0.079
	Electron	86	79.1	
	Photon	174	77.6	

LVSI: Lymph-vascular space invasion

Table 2: Summary of univariate analysis in EBC

Variable	Subgroup	Number	Overall survival %	*P*-value
ER	Positive	141	95.0	0.017
	Negative	79	86.1	
HER2	Positive	43	91.5	0.756
	Negative	177	93.0	
Grade	G1	79	91.1	0.398
	G2	103	90.3	
	G3	38	97.4	
LVSI	Present	39	76.9	<0.001
	Absent	181	95.0	
Menstrual status	Menstruating	101	94.1	0.275
	Post-menopausal	119	89.9	

EBC: Exhaled breath condensate, LVSI: Lymph-vascular space invasion

Table 3: Summary of univariate analysis in LABC

Variable	Subgroup	Number	Overall survival %	*P*-value
ER	Positive	77	72.7	0.023
	Negative	72	56.9	
HER2	Positive	52	63.5	0.842
	Negative	97	66.0	
Grade	G1	11	81.8	0.469
	G2	88	62.5	
	G3	50	66.0	
LVSI	Present	48	50.0	0.007
	Absent	101	72.3	
Menstrual status	Menstruating	63	63.5	0.698
	Post-menopausal	86	66.3	

LABC: Locally advanced breast cancer, LVSI: Lymph-vascular space invasion

DISCUSSION

Survival analysis is a branch of statistics for analyzing the expected duration of the time for one event to occur. In this study, the following methods are used for calculating the probability of survival of breast cancer patients after 5 years of diagnosis.

1. Kaplan–Meier curve - plot to visualize the survival curve
2. Log-rank test to compare survival curves between two groups
3. Cox proportional hazard regression to describe the effect of variables on survival.

The statistical significance level is taken as $P < 0.05$. The results are described by hazard ratio, confidence interval from the summary of the Cox model, and *P*-value.

Table 4: Multivariate analysis using Cox proportional-hazards model

Variable	Hazard ratio	95% confidence interval	*P*-value
Tumor size (T1, T3)	2.714	1.947–7.776	<0.001
Nodal status (N0, N3)	2.668	1.288–5.530	0.008
Grade (G1, G3)	1.286	0.880–1.878	0.193
LVSI (Present, Absent)	3.306	1.757–5.247	<0.001
ER Status (Positive, Negative)	0.591	0.359–0.973	0.039
HER2 NEU (Positive, Negative)	0.659	0.372–1.141	0.134
Margin Status (Positive, Negative)	1.666	0.789–3.514	0.180
Post-op RT (None, Photon)	0.440	0.174–1.114	0.083

The table model was significant at a *P*<0.001

A hazard ratio >1 indicates that there is an incremental change in hazard in that category in relation to the reference category. In our study, 59.6% of the total study population

were early breast cancer and 40.4% were LABC. Most patients in India are diagnosed at an advanced stage as per the cancer statistics 2020 report on national cancer registry programs.[1] Our data show slight EBC predominance because we excluded all metastatic cases at presentation and patients who are unfit for treatment with a radical indent from the study. Cancer awareness programs and health education measures also have led to increased awareness among women in Kerala and the stage at which they present to health-care facilities improved compared to the past.

The maximum number of patients were in the 40–50 years age group in our study. Epidemiological studies at global and regional levels suggest breast cancer occurs at younger premenopausal ages in Indian and Asian women. Indian women having breast cancer are found to be a decade younger than Western women.[1] Cancers in young tend to be more aggressive. India may face a potential breast cancer epidemic over the next decade as our population adopts major lifestyle changes in diet, exercise, late marriage, bearing children at a later age, and decreasing parity and breastfeeding. This warrants a screening program for Indian women which should be started earlier than the Western population standard considering this age shift.

About 44% of patients in our study population were premenopausal. In EBC and LABC groups, most patients were post-menopausal. Recent studies show a significant increase in breast cancer rates among premenopausal subjects. In a study, the risk of developing breast cancer increased in both pre- and post-menopausal patients who had early onset of menarche and late menopause possibly due to the increase in the duration of hormonal exposure.[2]

In the general population, about 5–10% of breast cancer cases are due to inheritance of highly penetrant cancer susceptibility genes BRCA1 and BRCA2.[3] Our study also shows that positive family history of breast-ovarian malignancy was present in 7.9% of the study population. Inherited breast and ovarian cancer tend to occur at younger ages.

Special types of invasive carcinomas were rare in our study population. About 96% of all patients had infiltrative ductal carcinoma. Asian and Indian women had more invasive ductal carcinoma and less invasive lobular carcinoma than the Caucasian population, according to SEER data 2010. This may be due to a lower use of post-menopausal hormone treatment in these patients. A study from India done by Goel *et al.* also shows infiltrating ductal carcinoma in >90% of patients.[4]

On analyzing tumor size in our study population, a maximum number of patients had tumor sizes 2–5 cm. Studies show a combination of clinical examination with mammography and breast ultrasound for better estimation of tumor size for staging purpose.[5] In a study reported from India by Nair *et al.* maximum patients had tumors of size between 2 and 5 cm.[6]

Most of the patients in the study population had grade II tumors. 46.8% of patients with EBC and 59.06% of patients with LABC had grade II tumors.

Most of our patients (48.5%) had pathological negative axillary lymph node status as neoadjuvant chemotherapy might have down-staged axilla before surgery. Studies show an approximately 23% chance of lymph node metastasis even in T1 patients. Multivariate analysis in a study done by Andreas Barth *et al.* showed LVSI nuclear grade and tumor size are independent predictors of axillary lymph node metastasis.[7]

In our study population, 23.6% of patients had LVSI. A study done by Ryu *et al.* showed that LVI was present in 34.8% of breast cancer patients.[8] Zhao *et al.* conducted a study on the prognostic role of LVSI and found LVSI in 40% of the study population.[9]

In our study population, 64% of patients in EBC and 51% in LABC were ER-positive. A study done by Nair *et al.* showed similar results-hormone receptor positivity was seen in 64% of EBC and 51% of LABC.[6] A multi-institutional study from India in 2020 showed that ER-positive tumors constitute 64.1% in the Indian population.[10]

HER2/NEU amplification was seen in 19% of EBC and 34% of LABC patients. It was 17% of EBC and 36% of LABC in the study conducted by Nair *et al.*[6] There is lot of heterogeneity in HER2 receptor positivity among Indian population which ranges from 16% to 36%.[11]

In our study, 8.5% of EBC patients and 3.4% of LABC patients underwent breast conservation therapy. Very low rates of BCS have been reported in India from most centers mainly because of the unacceptability of the safety of conservative surgery by patients and reluctance to undergo post-operative RT. However, Nair *et al.* had shown a BCS rate of 63% among EBC patients.[6]

Post-operative margin positivity was seen in 2.7% of patients in EBC and 6% of patients in LABC. Microscopic involvement of resected margin was associated with an increased risk of local recurrence following breast conservation surgery and hence every effort should be made to achieve negative margins intraoperatively.[12]

In our study, 29.5% of patients did not have indications for adjuvant RT. About 23.3% and 47.2% received electron beam RT and photon beam RT, respectively. Allocation to these various groups was based on department protocol.

Of the 95 HER2/NEU-positive patients, 79 completed HER2/NEU-targeted therapy with Trastuzumab. Cardiac comorbidity and financial constraints were the reasons for incomplete therapy.

About 29% of the patients took endocrine therapy with Tamoxifen and 30% received Letrozole based on menstrual status. Major switching trials showed greater recurrence reduction in patients taking an AI during any point in the trial, even with varied treatment regimens. Overall, AI's reduced recurrence rates by nearly 30% compared to tamoxifen in all studies.[13]

In a study done by Bartelink *et al.*, the recurrence rate in EBC was 7.3%.[14] Klein *et al.* showed a recurrence rate of 31% in LABC.[15] Our study showed a recurrence rate of 8.1% and 36.24% in EBC and LABC, respectively.

About 18 patients out of 220 EBC patients and 54 out of 149 LABC patients developed recurrence within 5 years of diagnosis. Bone metastasis was the most frequent site of metastasis in the both EBC and LABC. Metastasis of breast cancer cells to bone consists multiple sequential steps. Once breast cancer cells arrest in bone, bone is a storehouse of a variety of cytokines and growth factors, and thus provides an extremely fertile environment for the cells to grow.[16]

Survival analysis included 369 patients, of which 220 had EBC and 149 had LABC. DFS of the study population was assessed separately in EBC and LABC. DFS of patients with EBC was significantly better than LABC patients as expected. About 5-year DFS in EBC was 91.5% and in LABC was 62.2%. In a study done by Nair *et al.*, 5-year DFS in EBC was 85.5% and in LABC was 67.7%.[6]

During the study period, 70 patients died in the study population. Eighteen deaths were in the EBC group and 52 in the LABC group. Tweleve deaths were due to breast cancer-unrelated causes. Cerebrovascular accidents and cardiovascular diseases were the leading causes of cancer-unrelated deaths.

In univariate analysis of our study, factors adversely affecting overall survival were found to be tumor size, number of positive nodes, ER-negative status, high grade of tumor, and LVSI. On sub-group analysis, it was found that tumor grade did not affect survival in both EBC and LABC groups. Other than tumor grade, all the above-mentioned factors were significantly associated with survival in both groups.

The multivariate analysis using Cox proportional hazards model was done to assess the impact of individual factors on survival in the study population. The analysis showed that tumor size, node status, ER status, and LVSI had a significant impact on survival independent of other factors tested. The study showed patients who had T3 tumors at presentation is having a 2.7 times probability of death compared to patients with T1 tumors. Similarly, the N3 node at presentation is having 2.6 times the probability of death compared to node-negative patients. The hazard ratio for LVSI was 3.3 in the study population.

Nodal status was found to be the primary prognostic discriminant of breast cancer survival by Fisher *et al.*, in 1983.[17] Carter *et al.* reported two of the most important prognostic indicators for breast cancer to be tumor size and extent of axillary lymph node involvement.[18] Elston and Ellis showed from their study that histological grade forms part of the Nottingham prognostic index, together with tumor size and lymph node stage can be used to stratify individual patients for appropriate therapy.[19] Elston *et al.* studied the effect of vascular invasion on recurrence and survival and concluded that histological assessment of vascular invasion provides independent prognostic information.[20]

ER positivity was found to be protective with a hazard ratio of 0.59 among the patients studied. In a study from Kerala done by Vettuparambil *et al.*, hormone-receptor status showed a statistically significant association with overall survival and the highest mortality was found among ER/PR-negative patients.[21]

Margin positivity, HER2/NEU status, and post-operative RT failed to show any effect on survival in the Cox regression model. EBCTCG metanalysis 2011 showed an absolute reduction in breast cancer mortality by 3.8% with adjuvant RT at 15 years.[22] Hence, a long-term follow-up of these patients may be needed to confirm the survival benefit of adjuvant RT.

CONCLUSION

The 5-year overall survival of breast cancer patients treated with a radical indent at Tertiary cancer care center Kozhikode in the year 2014 was 92.3% in the early breast cancer group and 65.7% in the LABC group. The DFS in early breast cancer patients was 91.5%, while LABC patients were 62.2%.

In this study, the tumor size, node status, ER status, and LVSI showed a significant impact on survival. These results were comparable with documented Indian studies.

ACKNOWLEDGMENT

Dr. Ajayakumar T Professor and Head, Department of Radiotherapy, Government Medical College, Kozhikode, Dr. Dinesan M, Assistant Professor, Department of Radiotherapy, Government Medical College, Kozhikode for Dr BIJU GEORGE, Associate Professor, Department of Community Medicine, Government Medical College Kozhikode. Dr Nidhin PD for all the help rendered to me in various aspects of this study and for being with me always. Dr. Amrutha Mohan.

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How to cite this article: Mohan A, Dinesan M, Ajayakumar T. Outcome Analysis of Breast Cancer Patients - A Retrospective Study. Int J Sci Stud 2023;11(5):18-24.

Source of Support: Nil, **Conflicts of Interest:** None declared.