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Original Article

Factors Influencing Breast Cancer Survival Outcomes in the Central Region of Saudi Arabia

Amen Bawazir[1], Sadeem Alhalafi[2], Abdulrahman Jazieh[3,4,5], Wasif Ali Khan[1*], Rumaisa Ali Khan[6]

[1]Department of Basic Medical Sciences, College of Medicine, Almaarefa University, Riyadh, KSA.
[2]College of Public Health and Health Informatics, King Saud bin Abdul–Aziz University.
[3]Oncology department, King Abdullah Children hospital, KAMC, Riyadh, KSA.
[4]Cincinnati Cancer Advisors, Cincinnati, OH, USA.
[5]College of Medicine, Alfaisal University, Riyadh, KSA.
[6]Government Medical College, Chhatrapati Sambhajinagar (Aurangabad), Maharashtra, India.

Abstract

Background: Globally, breast cancer (BC) stands as the most common malignancy, predominantly affecting women, with observed trends of increasing incidence and mortality. Data concerning the survival of BC patients in Saudi Arabia (SA) is notably scarce. This study aims to pinpoint the specific factors that impact the survival rate (SR) among breast cancer patients in Saudi Arabia's central region.

Methods: This retrospective study analyzed data from 1405 breast cancer patients documented in the King Abdulaziz Medical City Cancer Registry from 2009 to 2018. The collected patient information included sociodemographic details and comprehensive tumor characteristics such as its location, histopathology, molecular subtypes, disease stage, and ultimate survival outcomes. To assess the relationship between these factors and patient survival, survival analyses were performed, incorporating Kaplan–Meier curves and Cox regression models, which were adjusted for potential confounding variables.

Results: Patients of older age (over 60 years) demonstrated a higher mortality risk from breast cancer. Invasive ductal carcinoma was the most frequently observed histopathologic subtype; however, invasive lobular carcinoma was linked to an elevated death risk. Adjusted Hazard Ratios from Cox regression indicated that BC patients with metastasis were six times (AHR=6.3; 95%CI=4.6–8.7, p<0.001) more likely to face a higher death risk compared to those with localized or regional tumors. Furthermore, patients diagnosed with triple–negative tumors were associated with twice the risk of death compared to other subtypes (AHR=2.1; 95%CI=1.4–2.9, p<0.001).

Conclusion: Both patient age and the presence of distant cancer spread are critical predictors of survival for breast cancer patients residing in central Saudi Arabia. Emphasizing early diagnosis, timely treatment, and consistent follow–up is essential for enhancing patient outcomes.

Keywords: Survival rate, Breast cancer, Histopathologic types, Molecular subtypes, Metastasis, Saudi Arabia.

Introduction

According to GLOBOCAN 2020, breast cancer (BC) accounts for 11.7% of all global cancer cases, making it the leading malignancy worldwide. The projected mortality rate for BC patients is expected to increase from 4.4 million in 2020 to 7.1 million by 2040.(1) Breast cancer survival rates vary globally, but generally, the 5–year survival rate has improved to approximately 91% when diagnosed at an early stage. Each year, about 2,261,419 women are diagnosed with BC, leading to nearly 684,996 deaths.(2) This outcome is largely preventable and disproportionately affects women, who are a vulnerable demographic globally.(3)

Most high–income countries systematically report annual cancer survivorship rates within their populations. Data from the National Cancer Institute (NCI) in the United States shows a consistent improvement in the 5–year survival rate for all cancers, rising from 50.3% in 1970–1979 to 67% in 2007–2013, with BC specifically reaching an 89.7% survival rate.(4–6) Enhanced cancer patient

Corresponding author: Dr. Wasif Ali Khan. MD, Department of Basic Medical Sciences, College of Medicine, Almaarefa University., Riyadh. Saudi Arabia. Tel: +966 11 4905555. Email: wkhan@um.edu.sa

survival is typically attributed to earlier diagnosis and improved treatment strategies.[7] Therefore, assessing malignancy survival rates in any population is crucial as a key healthcare system indicator. It is also vital to investigate factors contributing to lower survival rates among cancer patients, including demographic elements, histopathologic type, treatment modality, and comorbid conditions for each cancer type.

According to World Health Organization (WHO) data for 2020, 3954 new BC cases were identified among Saudi women, with 1095 reported deaths.[8] Various studies in Saudi Arabia (SA) have documented a steady rise in the incidence and mortality of breast, colon, thyroid, bladder, and uterine cancers.[9–17] A 17–year retrospective analysis by Basudan et al. revealed a 55% increase in BC incidence over the study period, representing 30.9% of all cancer cases among Saudi females.[18] However, there is a scarcity of data regarding BC patient survival in SA. Consequently, this study aims to identify characteristics linked to the survival rate of breast malignancy in Saudi women treated at King Abdulaziz Medical City, Riyadh, SA, from 2009 to 2018. Furthermore, our findings will offer oncologists and policymakers valuable insights into BC patient outcomes, potentially serving as a guide to enhance prognosis and quality of care related to survival–attributable factors.

Methods

Study design and setting:

This retrospective cohort study included breast cancer patients who received treatment at King Abdulaziz Medical City, Riyadh, SA. Patient information was extracted from the Cancer Registry data collected over a decade, from 2009 to 2018, and subsequently analyzed.

Participants and sample size:

The study enrolled all patients, regardless of gender or age, documented in the hospital's records with a BC diagnosis between January 1, 2009, and December 31, 2018. Cases with incomplete data, such as missing age, gender, or any cancer–related specifics, were excluded.

2.3 Data Collection methods and measurement of outcome

An Excel spreadsheet was prepared to capture all necessary variables, including fundamental socio–demographic details (age group, sex, nationality, marital status) and significant clinicopathological parameters (tumor topography, histopathologic type, immunohistochemical status/molecular subtypes, disease stage, and patient survival status). Primary tumor locations were categorized as: nipple, central (subareolar), upper–outer quadrant (UOQ), upper–inner quadrant (UIQ), lower–outer quadrant (LOQ), lower–inner quadrant (LIQ), axillary tail of the breast, overlapping lesions (extending into multiple quadrants), and site not specified (NS).[19] The WHO classification of breast tumors was utilized for histopathologic typing,[20] classifying tumors as in–situ carcinoma, invasive ductal carcinoma (no special type – NST), invasive lobular carcinoma, and "others." Uncommon tumors like mucinous, metaplastic, and invasive papillary carcinomas were grouped under "others." Molecular subtypes, based on immunohistochemical status, were categorized into 'Luminal A' (estrogen receptor (ER) and/or progesterone receptor (PR) positive, human epidermal growth factor receptor (HER2) negative), 'Luminal B' (ER and/or PR positive, variable HER2/neu expression, higher proliferation index), 'HER2 positive', and 'Triple–negative' (ER, PR, and HER2 negative).[21 22] Stage IA tumors were termed 'localized,' stages IB–III were 'regional,' and stage IV tumors were classified as 'metastatic'.[23] Patient informed consent was not required as the study used only de–identified secondary data. Approval for the study was obtained from the Institutional Review Board (IRB) of the College of Public Health and Health Informatics (CPHHI), King Saud bin Abdulaziz University for Health Sciences (KSAU–HS), and King Abdullah International Medical Research Center (KAIMRC # SP 20/164/R).

Statistical Analysis

Descriptive statistics, including frequencies and percentages, were calculated for study items, participant demographic variables, and breast tumor histopathological characteristics. Bivariate analysis, using the chi–square test, was employed to identify associations between sociodemographic variables and survival outcomes (live status and deaths). All 1405 recorded cases were analyzed using Statistical Package for Social Sciences (SPSS) version 22 (IBM, New York, USA).

The primary outcome of the analysis was time–to–event, where the event was defined as death due to breast cancer. Patients who had not experienced this event by the study's conclusion on December 31, 2018, were categorized as 'alive.' Survival time was calculated in months, from the date of diagnosis until death or censoring. The 5–year survival rate represents the proportion of patients still alive five years post–diagnosis.

The study estimated median survival times and their 95% confidence intervals using the Kaplan–Meier method. The log–rank test was applied for statistical comparison of survival differences between groups. Cox proportional hazard modeling was used to identify predictors of survival among breast cancer patients, incorporating interaction

effects and adjusting for confounding factors. The risk associated with each predictor was reported as a hazard ratio (HR) with 95% confidence intervals (CI). A p–value of less than 0.05 was considered statistically significant.

Results

A total of 1405 documented BC cases were analyzed, comprising 1394 females (99.2%) and 11 males (0.8%).

Socio–demographic data and its association with patient survival:

The mean age at BC diagnosis was 51 years (interquartile range: 14–93). Patients aged 50–64 years accounted for 43.9% of diagnoses, while those under 50 years comprised 30.9% of all cases. Of the total, 1049 (74.7%) patients were married, and 1202 (85%) were Saudi citizens. Furthermore, 1072 (76.3%) patients were "alive," and 333 (23%) had died (Table 1). Findings from Table 2 demonstrated a strong correlation between older age and a higher mortality rate (P<0.001), while other variables did not show statistical significance (P value > 0.05).

Clinicopathologic parameters and its association with patient survival:

Most breast tumors involved multiple breast quadrants (overlapping lesions – 16.7%) or were in the upper–outer quadrant (16.4%). Tumors affecting the nipple and axillary tail were rare, observed in only 0.7% and 0.9% of cases, respectively. However, no statistically significant differences were noted between breast tumor site and survival rate. Invasive ductal carcinoma, no special type (NST), was the most frequent histopathologic type (83%), followed by in–situ carcinoma (7%) and invasive lobular carcinoma (6.8%). Molecular subtyping showed Luminal A (40.1%) as the most common subtype, followed by Luminal B (32.8%), HER2–positive (13.5%), and triple–negative (13.6%). Notably, histopathologic type exhibited a strong significant association with survival status (p=0.001).

The majority of cases presented with either regional (41.7%) or localized (38.8%) tumor stages. Patients with localized or regional tumors displayed significantly better survival rates compared to those with metastatic disease (p<0.001) [Table 2].

Table 3 illustrates the median survival analysis for sociodemographic variables, including gender, age, nationality, and marital status. Overall, a survival time of 60 months (equivalent to 5 years) showed a statistically significant association with age group (P–value < 0.001). Specifically, younger individuals (≤ 39 years) had a significantly longer median survival time compared to older age groups. Gender, nationality, and marital status were not found to be significantly associated with survival time.

For a general comparison of factors related to BC survivorship, the Kaplan–Meier test was conducted. Results indicated a strong statistical difference by age category, with younger patients exhibiting a superior survival rate compared to the age group ≥60 (p <0.001). No association was observed when assessing other variables such as gender (p <0.001), marital status (p=0.077), and nationality (Saudi or non–Saudi; p = 0.228).

The Kaplan–Meier test revealed significant associations between survival rates and both the stage at diagnosis and the site of breast cancer (p–value <0.001 for each) but not for histopathologic type and molecular subtypes.

Variables	Categories		**Alive** 1072(76.3)	**Dead** 333(23.7)
		No. (%)	**No. (%)**	**No. (%)**
Gender	Female	1394(99.2)	1063(76.3)	331(23.7)
	Male	11(0.8)	9(81.8)	2(18.2)
Age at diagnosis	<50 years	434(30.9)	328(75.6)	106(24.4)*
	50–64 years	617(43.9)	505(81.8)	112(18.2)
	≥65 years	354(25.2)	239(67.5)	115(32.5)
Marital status	Married	1049(74.7)	812(77.4)	237(22.6)
	Others	356(25.3)	260(73.0)	96(27.0)
Nationality	Saudi	1202(85.6)	912(75.9)	290(24.1)
	Non–Saudi	203(14.4)	160(78.8)	43(21.2)

Table 1. Association of BC patients with sociodemographic characteristics. (1405).

*P value <0.001

There was no association between histopathologic type and molecular subtypes with breast cancer survivorship, with p–values of 0.001 and 0.058, respectively. The 5–year survival rate was approximately 40% for metastatic tumors, significantly lower than the almost 90% for localized or regional tumors (p<0.001).

Table 2 demonstrates the association between various tumor–related factors and survival status in a cohort of 1405 breast cancer patients. In situ carcinoma showed significantly better survival compared to other histopathological types, especially invasive lobular carcinoma (ILC) (p–value <0.001). Conversely, BC stage significantly influenced survival (p–value <.001). Patients with localized disease had significantly better survival compared to those with regional or distant metastases. No statistically significant association was found between tumor location and survival, nor with molecular subtypes.

In a multivariate analysis, the Cox regression test was employed to assess the hazard ratio (HR) of survival in BC patients against variables including age, tumor site, histopathologic type, molecular subtypes, and tumor stage. An elevated risk of death [HR = 1.656, 95% CI = 1.218–2.252, p<0.001)] was observed in patients aged ≥ 60 years. However, no significant difference was noted when compared with those aged between 45–59 years (HR = 0.915, 95% CI = 0.677–1.237, p = 0.565). For topography, no correlation could be established between different tumor locations using HR.

Variables	Categories	Total	Alive	Deaths	
		No. (%)	No. (%)	No. (%)	P–value
Tumor location	Nipple	10 (0.7)	7 (70.0)	3 (30.0)	0.559
	Central portion	61 (4.3)	48 (78.7)	13 (21.3)	
	Upper–inner quadrant	81 (5.8)	53 (65.4)	28 (34.6)	
	Lower–inner quadrant	25 (1.8)	18 (72.0)	7 (28.0)	
	Upper–outer quadrant	230 (16.4)	177 (77.0)	53 (23.0)	
	Lower–outer quadrant	38 (2.7)	29 (76.3)	9 (23.7)	
	Axillary tail of breast	13 (0.9)	9 (69.2)	4 (30.8)	
	Overlapping lesion	234 (16.7)	181 (77.4)	53 (22.6)	
	Not specified	713 (50.7)	550 (77.1)	163 (22.9)	
Histopathologic type	In situ carcinoma	99 (7.0)	92 (92.9)	7 (7.1)	**0.001**
	Invasive ductal carcinoma (NST)	1168 (83.1)	886 (75.9)	282 (24.1)	
	Invasive lobular carcinoma	95 (6.8)	64 (67.4)	31 (32.6)	
	Others	43 (3.1)	30 (69.8)	13 (30.2)	
Molecular subtypes	Luminal A	433 (40.1)	334 (77.1)	99 (22.9)	0.071
	Luminal B	354 (32.8)	261 (73.7)	93 (26.3)	
	HER2 positive	146 (13.5)	115 (78.8)	31 (21.2)	
	Triple negative	147 (13.6)	99 (67.3)	48 (32.7)	
Stages	Localized	517 (38.8)	447(86.5)	70(13.5)	<0.001
	Regional	555 (41.7)	450(81.1)	105(18.9)	
	Distant Metastasis	260 (19.5)	121(46.5)	139(53.5)	

Table 2. Association between tumor characteristics and survival status. (1405)

Invasive carcinoma of no special type (NST)
*Molecular subtypes =1080

Variables	Categories	Median	95.0% CI	P–value
Gender	Male	110.53	84.06–137.01	0.824
	Female	107.51	104.51–110.51	
Age groups	≤44 years	105.59	100.61–110.58	**<0.001**
	45–59 years	114.82	110.63–119.00	
	> 60 years	93.30	86.76–99.83	
Nationality	Saudi	106.60	103.32–109.88	0.221
	Non–Saudi	112.02	104.86–119.17	
Marital status	Married	108.92	105.51–112.34	0.083
	Others	101.58	95.74–107.42	

Table 3. Median survival analysis for sociodemographic variables.

		AHR	95.0% CI	P–value
Age	≤ 44 years	R	–	–
	45–59 years	0.915	0.677 – 1.237	0.565
	≥ 60 years	1.656	1.218 – 2.252	<0.001
Histopathologic type	In situ carcinoma	R	–	–
	Invasive ductal carcinoma (NST)	1.825	.739–4.508	.192
	Invasive lobular carcinoma	2.963	1.117–7.864	.029
	Others	3.132	.979–10.023	.054
Molecular subtypes	Luminal A	R	–	–
	Luminal B	1.068	0.801 – 1.424	0.653
	HER2 positive	1.049	0.694 – 1.586	0.821
	Triple–negative	2.060	1.443 – 2.941	<0.000
Stages	Local	R	–	–
	Regional	1.546	1.118 – 2.137	.008
	Metastasis	6.361	4.622 – 8.753	.000

Table 4. AHR concerning different characteristics of the BC patients.

AHR=Adjusted Hazards ratio; R= Reference

Invasive lobular carcinoma carried a threefold higher risk of death compared to in–situ carcinoma (HR=2.96, 95% CI=1.11–7.86, p=0.029). Luminal type A tumors were the most prevalent. Triple–negative tumors showed twice the risk of death compared to other types (HR = 2.060, 95% CI =1.443 – 2.941, p=0.000). The Kaplan–Meier estimates and log–rank tests showed no overall significant association between histopathologic types (p=0.001 for association with survival status in bivariate analysis, but non–significant in survival time comparisons) or molecular subtypes (p=0.058) and survival. However, in multivariable Cox regression adjusted for age, tumor site, histopathologic types, molecular subtypes, and stage, significantly elevated risks were observed for invasive lobular carcinoma and triple–negative subtype (Table 4). This discrepancy likely reflects confounding by factors such as age and stage, as well as limited statistical power in subgroup comparisons. On the other hand, patients with metastatic tumors had a 6.3 times higher risk of death compared to localized or regional tumors (HR = 6.361, 95%CI = 4.622–8.753, p=0.000).

Discussion

Breast cancer is a major public health concern, contributing significantly to cancer–related fatalities among women in Saudi Arabia (SA). Its incidence and mortality rates in SA have seen an upward trend in recent years.[11] There is a clear need to assess BC survival rates within the Saudi population and to investigate factors that influence overall survival.

This study estimated the five–year survival rate for breast malignancy, considering variables such as age group, gender, nationality, marital status, tumor topography, histopathologic types, molecular subtypes, and disease stage. Our findings revealed a strong correlation between survival rate and age at BC diagnosis ($p < 0.001$), highlighting age as a critical predictor of mortality among BC patients. The calculated net survival rate was significantly better in females under 50 years of age ($p < 0.001$) compared to females aged 60 and above. Conversely, no statistically significant differences or associations were observed with other demographic variables such as marital status ($p = 0.077$) or nationality (Saudi versus non–Saudi; $p = 0.228$). Chen, Hai–Long, et al. similarly documented improved survival rates among BC cases in patients aged 40–49 compared to those aged 50 and above.[24] Other studies from Saudi Arabia, Jordan, and Sweden also reported comparable findings.[15 24–26]

However, these results contrast with a study conducted in the United States (US), which indicated that most women presented with BC after age 50, with an average diagnosis age of 60 years.[27] Furthermore, the United Kingdom's (UK) five–year survival rate (2009–2013) showed a gradual increase in survivorship from 85% for women aged 15–39, peaking at 92% for those aged 60–69, before declining to a low of 70% in patients aged 80–99. These inconsistencies with our findings may be attributable to differences in life expectancy between women in KSA and the UK.[28]

In a study by Wu et al., the frequency of breast malignancy locations was reported as 50.2% in UOQ, 11.9% in LOQ, 21.9% in UIQ, 5.7% in LIQ, and 10.3% in central locations. In our study, these figures were 16.4% in UOQ, 2.7% in LOQ, 5.8% in UIQ, 1.8% in LIQ, and 4.3% in central locations. Additionally, most BCs involved multiple quadrants (overlapping lesions – 16.7%) or were diagnosed in the UOQ (16.4%). The 5–year survival rate assessed by Wu et al. for tumors in the LIQ group was significantly lower than for cases with tumors in other breast locations, a finding consistent with our study.[29]

Tumors originating in the axillary tail of the breast exhibited the lowest survival rate, although their prevalence was considerably low. In the current study, the multivariate Cox regression model for adjusted hazard risk indicated that the primary tumor site had no significant effect on patient prognosis regarding the 5–year survival rate. This aligns with the study by Jayasinghe et al. (2009),[30] but contradicts the conclusions of Wu et al., who found malignancy in the LIQ to be associated with a poorer prognosis and an independent prognostic factor for Chinese women.[29] Sohn et al,[31] reported that patients with malignancy in the UOQ had a better prognosis than those with tumors in other quadrants. However, the prognostic value of the primary tumor location remains debated [32]. Furthermore, in 50.7% of cases in our study, the tumor's location was unspecified, or data was unavailable, which might contribute to the observed discrepancies between studies. Moreover, because of the substantial missing data on primary tumor location, our findings related to tumor topography should be interpreted with caution, as they may not fully capture potential associations and may contribute to discrepancies with prior studies.

Invasive ductal carcinoma, NST, was the most prevalent histopathologic type, accounting for 83.1% of cases, followed by in–situ carcinoma (7%). This aligns with studies conducted by Albasri et al. in the Madinah region of KSA, who reported invasive ductal carcinoma, NST, and in–situ carcinoma at 85.2% and 8%, respectively [33]. Another study from Hofuf, Al Hassa region by Amin et al. concluded that infiltrating ductal carcinoma was the most common histopathologic type, comprising 78.7% of BC cases [34].

For BC patients, ER, PR, and HER2 are crucial prognostic factors for both clinicians and patients [35]. Globally, HER2 is found in approximately 30% of breast malignancies, leading to aggressive disease, poor prognosis, and decreased survival rates.[36] In our study, the apparent discrepancy between unadjusted Kaplan–Meier analyses (which showed no significant associations of histopathologic type or molecular subtype with survival curves) and adjusted Cox regression findings (which showed significant risks for invasive lobular carcinoma and triple–negative tumors) is largely attributable to differences between unadjusted and adjusted models. Confounding variables (e.g., older age and metastatic stage being more prevalent in certain subtypes) and smaller subgroup sizes may obscure associations in unadjusted tests, whereas multivariable adjustment helps to isolate independent effects. For example, triple–negative breast cancers demonstrated approximately twice the risk of death compared with Luminal A, Luminal B, and HER2 positive subtypes; however, this finding should be interpreted with caution because treatment data were unavailable, and treatment is known to differentially affect outcomes across subtypes. Triple–

negative BCs are typically more aggressive, challenging to treat, and have a higher recurrence chance than other subtypes. The 5–year survival rate for Luminal A, Luminal B, and HER2 was around 80%, whereas for triple–negative, it was 70%. However, SEER statistics reported significantly higher rates for Luminal A (94.42%), Luminal B (90.66%), HER2–neu positive (84.81%), and triple–negative (77.13%).[37]

Our findings also indicated a high mortality rate among patients presenting with distant metastasis compared to those with localized or regional tumor extension ($p < 0.001$). For BC patients diagnosed in the US between 2012 and 2018, the 5year relative survival rate for localized BC (SEER stage) is about 99%, which is considerably higher than the 86.5% reported in our study.[38] In addition, the difference is even more pronounced for metastatic cases, with survival around 40% in our cohort. Several factors may contribute to these lower survival rates in central Saudi Arabia despite its developed healthcare infrastructure, including latestage diagnosis driven by screening delays or limited awareness. Additionally, referral bias at our tertiary center (King Abdulaziz Medical City) may have skewed the sample toward more advanced cases. Disparities in access to specialized multidisciplinary care and poor followup adherence, particularly among rural patients, may further contribute to these variations. Breast cancer is considered a primary public health issue, and various factors influencing BC survival rates require comprehensive review and assessment by policymakers in every country, including KSA. Further multi–center research is needed to identify the multifactorial roles of socio–demographic factors and clinicopathologic parameters affecting BC patient survival rates and to pinpoint any specific prognostic factors related to a particular population.

Limitations

Our study has several limitations. As a retrospective cohort analysis relying on secondary data, there was a risk of excluding numerous data points or encountering poor quality or incomplete information. For instance, data related to the primary tumor site showed extreme skewness, with more than half of patients having unspecified or missing tumor locations. This limitation reduces the interpretability of findings related to tumor topography and may lead to underpowered or biased estimates in survival analyses. Furthermore, cases from rural and remote areas faced challenges with regular follow–up, leading to a significant portion of cases being missed and thus not included in the survival analysis. Additionally, this study was conducted at a single institution, meaning the reported findings may not be generalizable to the entire country. The absence of detailed treatment data is a significant limitation that may confound observed survival differences across molecular subtypes. While registries in the USA and UK provide sufficiently comprehensive data to support robust treatment–survival analyses, local registries currently lack this depth. Consequently, the Saudi Ministry of Health should prioritize upgrading national cancer databases to align with Western standards.[35,39] Consequently, conclusions regarding subtype–related survival differences should be interpreted with caution, as they do not account for potential treatment effects.

Conclusions

We conclude that the critical prognostic factors influencing the survival rate of breast cancer patients in the central region of Saudi Arabia are patient age and the presence of distant metastasis at diagnosis. Our results underscore the importance of early diagnosis, prompt management, and consistent follow–up for BC patients. The comparatively lower survival rates observed in our cohort, relative to those reported in highincome countries, may reflect later stages at presentation, referral patterns to tertiary centers, and potential disparities in access to specialized care, thereby underscoring the need for enhanced early detection strategies. Policymakers, physicians, pathologists, and oncologists must collaborate to devise strategies to enhance diagnosis and treatment protocol implementation, investigate the reasons behind this discrepancy, and adopt effective measures to improve BC patient prognosis. We believe it is essential to raise awareness among women and family medicine physicians to integrate BC screening plans, including clinical examination and mammography, into their standard office examinations for the earliest possible diagnosis. Future nationwide research should be conducted to document BC patient survival rate trends and include additional factors such as treatment type, co–morbid conditions, and genetic differences between BC patients in SA and elsewhere, which could offer more in–depth insights into BC survivorship in SA.

Availability of data and materials: The data set used for this analysis was provided by the Cancer Registry Department in King Abdulaziz Medical City (KAMC), Ministry of National Guard for Health Affairs (MNGHA) upon request. Data can be obtained from the cancer registry via a formal application from an intended user.

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University, Riyadh, Saudi Arabia.

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Contact :
The Gulf Federation for Cancer Control
P. O. Box 26733 Safat 13128 Kuwait
Tel. (00965) 22530186 / 22530184 Fax: (00965) 22510137
website : http://www.gffcc.org
email : gffccku@yahoo.com

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