Morbidity and mortality among patients with breast cancer receiving anticancer treatment before and during the COVID-19 pandemic: A single tertiary center experience

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Abstract. Breast cancer is the most common cancer type in women in Saudi Arabia (SA). Globally, cancer treatment has been affected by the recent COVID-19 pandemic. The present retrospective study reviews the 30-day morbidity and mortality rates of patients with breast cancer receiving anticancer systemic treatment before (group1) and during the peak of the COVID-19 (group 2) pandemic at a tertiary center, King Abdulaziz University Hospital (Jeddah, SA). There were no differences between the two groups regarding sex, age, breast cancer stage distribution, intention to treat or class of anticancer treatment received. Patients treated during the peak pandemic period received delayed treatment. No statistically significant difference was observed in the 30-day morbidity or mortality rates, although there was a trend towards higher rates of morbidity among patients treated during the peak of the pandemic period. In group 2, only 2.3% of the patients tested positive for COVID-19, and there was no significant difference in the 30-day morbidity and mortality rates between COVID-positive and COVID-negative patients receiving anticancer treatment. Individuals with breast cancer are a vulnerable group of patients that should be treated with special care during pandemics or other crises that affect the health care system.

Introduction

Breast cancer (BC) is the most common malignancy in women in Saudi Arabia (SA) (1). According to the most recent statistics from the Ministry of Health (MOH), in 2018, 2814 Saudi women were diagnosed with BC, 43% are diagnosed with localized disease, 31% with regional disease and 13% with metastatic disease (2,3). In comparison, the SEER data base demonstrated more patients are presenting with localized disease, 64% and less patients with regional and metastatic disease, 29 and 6% (4). This leads to a poorer prognosis and lower potential for a cure. Moreover, given the advanced presentation, the treatment plan usually requires the introduction of chemotherapy either as a neoadjuvant or adjuvant modality.

In early 2020, the World Health Organization announced COVID-19 as a global pandemic, and numerous countries went through lockdown procedures; SA was no exception. This pandemic has affected patients on multiple levels (5). The economic and healthcare burden associated with the outbreak led to major disturbances in healthcare systems (5,6). The access of patients with cancer to healthcare and treatment was either delayed or interrupted. Patients living in rural areas experienced travel restrictions and delays in presentation due to access issues. Specifically, BC elective surgeries were delayed or canceled due to staff shortages, a reduction in operating room availability and limited available beds for elective admissions (7). Some patients with BC needed changes in their treatment plan, such as extended neoadjuvant treatment protocols while awaiting surgeries, while others who were supposed to have surgery first were started on neoadjuvant treatment as an alternative while awaiting resolution of the pandemic. Moreover, postoperative patients experienced a delay in adjuvant treatment (8).

Recent studies have demonstrated that patients with cancer are at a significantly increased risk of being infected with COVID-19 and have poorer outcomes, including hospitalization and death (9). This could be explained by several factors. Patients with cancer are immunocompromised, which makes them susceptible to infection and worse outcomes (10). Moreover, there is a high incidence of comorbidities in patients with cancer, which renders them more susceptible (11). In addition, introducing chemotherapy to their treatment protocols further suppresses their immunity, and decreases their physical activity and healthy oral nutrient intake (12). Finally, more frequent visits to the hospital to receive treatment could

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theoretically increase the risk of infection secondary to higher exposure to hospital personnel and other patients.

The present study aimed to compare the 30-day mortality and morbidity outcomes in patients with BC receiving systemic anticancer therapy at King Abdulaziz University Hospital (KAUH; Jeddah, SA) before and during the COVID-19 pandemic.

Patients and methods

Study design, population and setting. A retrospective chart review was performed using the electronic health records (EHR) of all adult patients diagnosed with BC who received anticancer treatment at KAUH. The study protocol was approved by the Research Committee of the Unit of Biomedical Ethics at KAUH (approval no. 333-20) and the requirement for informed consent was waived.

Study periods. The data were collected over two periods. The first reflected the pre-COVID-19 pandemic period and included all patients who were treated in January 2020 (group 1). The second reflected the peak COVID-19 pandemic period and included all the patients who were treated between March 1, 2020, and June 30, 2020 (group 2). The follow-up was extended for 30 days after each specified period. Patients were followed-up until February 29, 2020, for the first period and until July 31, 2020, for the second period to determine treatment outcomes. Patients were contacted to confirm the outcomes in cases where they were not indicated in the EHR.

Inclusion and exclusion criteria. Adult patients (aged ≥16 years) diagnosed with breast cancer who received cytotoxic anticancer treatment, anti-human epidermal growth factor receptor 2 (HER-2) therapy and immunotherapy during the specified periods were included. Patients with breast cancer who were not receiving cytotoxic therapy, such as endocrine therapy alone or bone-modifying agents, were excluded. Patients undergoing treatment with other modalities such as surgery, radiotherapy, surveillance or supportive care were also excluded if they were not receiving cytotoxic therapy during the study period.

Data collection and outcomes of interest. The collected data included age, sex, body mass index (BMI), Eastern Cooperative Oncology Group performance status (ECOG-PS) (13), type of cancer, cancer stage as per the AJCC, 8th edition (14), treatment class (chemotherapy, immunotherapy or anti-HER2 therapy), route of administration [intravenous (IV), subcutaneous or oral], intent of treatment (curative or palliative), timing of curative treatment (neoadjuvant or adjuvant), line of anticancer treatment (first-, second-, third- or fourth-line and beyond), and the number of treatment cycles administered during the study period. Comorbidities were also collected and included diabetes mellitus, hypertension, stroke, chronic kidney disease, and chronic heart or lung disorders. COVID-19 nasopharyngeal swab test results were also collected. COVID-19 testing was performed only if clinically indicated. Outcomes of interest, namely 30-day morbidity and mortality rates, were calculated from the beginning of the last treatment cycle to 30 days afterwards. The last follow-up was defined as the date of the last recorded visit. Morbidity included any illness requiring hospitalization, including complications of therapy or cancer itself.

Statistical analysis. Qualitative data are expressed as numbers and percentages, and the χ^2 test was used to test the association between variables. Quantitative data are expressed as the mean ± standard deviation, and the Mann-Whitney test was applied for non-parametric variables. $P<0.05$ was used to indicate a statistically significant difference. Statistical analyses were conducted using STATA version 14.2 (StataCorp LP).

Results

Tables I and II summarizes the descriptive statistics of the overall cohort. In total, 222 patients were included in this study. The mean age was 50.97±11.23 years, 99.5% were female and 38.3% had stage IV disease. The mean BMI was 29.84±7.6 kg/m^2. The mean number of cycles per patient was 3.26±2.25. With regard to functional status, most patients had good baseline status, 92.3% had an ECOG category level of 0 or 1.

With regard to cytotoxic treatment, chemotherapy (60.8%) was the most commonly used anti-cancer treatment class, 75.7% had treatment through the IV route, 68.9% were treated with curative intent, 44.1% had adjuvant therapy and 89.2% were receiving 1st line therapy (Table II). The most frequently administered chemotherapeutic protocols over the study period (periods 1 and 2) were docetaxel, 61 patients (27.5%) and A.C (doxorubicin + cyclophosphamide), 15 patients (6.8%). Trastuzumab-based protocols were prescribed for a total of 86 patients (38.7%).

Regarding the main outcomes for the entire cohort, at the end of the 30-day follow-up period, 1.4% of patients succumbed due to disease progression, 11.7% had morbidities, 11.3% were hospitalized, 14% visited the Emergency Room (ER), 0.9% were admitted to the Intensive Care Unit (ICU), 3.2% had delay in chemotherapy and 0.5% had a dose reduction (Table II).

With regard to comparing the patients' disease and treatment characteristics between the two groups, patients in group 2 had a significantly higher mean number of cycles than those in group 1 (4.4±2.21 vs. 1.55±0.69) ($P<0.001$), which was due to the longer study period. No significant differences were found between the groups in terms of their age and sex distribution, BMI, ECOG performance classification, class of cytotoxic treatment administered, intention of treatment, type of curative treatment, line of treatment administered, comorbidities or disease stage at the time of treatment (Table III).

With regard to outcomes of interest, there was a trend towards increased morbidity, mortality, ICU admission, hospitalization, dose reduction and ER visits in group 2; however, none of these comparisons were statistically significant (Table IV). Group 2 had a significantly higher percentage of patients experiencing delays in treatment compared with group 1. Approximately two-thirds of the patients in group 2 had a delay in receiving treatment compared to none in group 1 ($P=0.028$; Table II).

As for COVID-19 cases among group 2, only 3 cases (2.3%) were found to be COVID-19 positive during the study period,

Table I. Distribution of studied patients according to their age, gender, Body mass index, number of cycles and ECOG.

Variable	All (n=222) No. (%)	Group 1 (n=89) No. (%)	Group 2 (n=133) No. (%)
Age (Mean ± SD)	50.97±11.23	50.59±10.92	51.21±11.47
Gender			
Female	221 (99.5)	88 (98.88)	133 (100)
Male	1 (0.5)	1 (1.12)	0 (0)
BMI	29.84±7.6	29.78±8.03	29.88±7.33
Number of cycles	3.26±2.25	1.88±0.69	4.39±2.21
ECOG	0.4±0.78	0.41±0.71	0.46±0.83

Table II. Distribution of studied patients according to treatment class, route, intention and line, comorbidity, stage, status of last follow up, 30-day morbidity and mortality, hospitalizations, ER visits, ICU admission, delay in chemotherapy and dose reduction.

Variable	n (%)
Class	
Chemotherapy	135 (60.8)
Immunotherapy	1 (0.5)
Targeted therapy	86 (38.7)
Route	
IV	168 (75.7)
SC	54 (24.3)
Intention	
Curative	153 (68.9)
Palliative	69 (31.1)
If curative	
Adjuvant	98 (44.1)
NA	69 (31.1)
Neo-adjuvant	55 (24.8)
Line	
1st	198 (89.2)
2nd	16 (7.2)
3rd	6 (2.7)
4th and beyond	2 (0.9)
Comorbidity	
No	172 (77.5)
Yes	50 (22.5)
Stage	
I	18 (8.1)
II	51 (23.0)
III	68 (30.6)
IV	85 (38.3)
Status at last follow-up	
Alive	219 (98.6)
Dead (disease progression)	3 (1.4)
30-day mortality	
No	219 (98.6)
Yes	3 (1.4)
30-day morbidity	
No	196 (88.3)
Yes	26 (11.7)
Hospitalizations	
No	197 (88.7)
Yes	25 (11.3)
ER visits	
No	191 (86.0)
Yes	31 (14.0)
ICU admission	
No	220 (99.1)
Yes	2 (0.9)
Delay in chemotherapy	
No	215 (96.8)
Yes	7 (3.2)
Dose reduction	
No	221 (99.5)
Yes	1 (0.5)

ER, Emergency Room; ICU, Intensive Care Unit; IV, intravenous; SC, subcutaneous.

with no significant difference between COVID and non-COVID cases according to 30-days mortality rate (P=0.829).

Discussion

The COVID-19 pandemic has affected patient care worldwide (15). In SA, patients with BC have suffered alterations in their care, especially during the peak of the pandemic in spring 2020 (16). Moreover, these patients are at a higher risk of suffering major consequences if infected with COVID-19 (17,18). In a retrospective study by Wang *et al* (9), the adjusted odds ratio for COVID-19 infection in patients with recently diagnosed BC was 6.74 (95% CI 6.06-6.91). The odds of COVID-19 infection were still consistently high in all

Table III. Differences between groups 1 and 2 according to age, sex, number of treatment cycles, ECOG-PS, class, treatment intention, line, comorbidity and stage.

Variable	Group 1 (n=89)	Group 2 (n=133)	P-value
Mean age ± SD[a]	50.6±10.92	51.22±11.47	0.857
Sex, n (%)[b]			0.401[c]
Female	88 (39.8)	133 (60.2)	
Male	1 (100.0)	0 (0.0)	
Mean BMI ± SD[a]	29.78±8.03	29.88±7.33	0.946
Mean umber of cycles ± SD[a]	1.55±0.69	4.4±2.21	<0.001[d]
Mean ECOG-PS ± SD[a]	0.42±0.72	0.47±0.83	0.616
Class, n (%)[b]			
Chemotherapy	51 (37.8)	84 (62.2)	0.551[c]
Immunotherapy	0 (0.0)	1 (100.0)	
Targeted therapy	38 (44.2)	48 (55.8)	
Treatment intention, n (%)[b]			
Curative	66 (43.1)	87 (57.9)	0.168
Palliative	23 (33.3)	46 (66.7)	
If curative, n (%)[b]			
Adjuvant	42 (42.9)	56 (57.1)	0.384
NA	23 (33.3)	46 (66.7)	
Neo-adjuvant	24 (43.6)	31 (56.4)	
Line, n (%)[b]			
1st	81 (40.9)	117 (59.1)	0.711[c]
2nd	6 (37.5)	10 (62.5)	
3rd	1 (16.7)	5 (83.3)	
4th and beyond	1 (50.0)	1 (50.0)	
Comorbidity, n (%)[b]			
No	67 (39.0)	105 (61.0)	0.522
Yes	22 (44.0)	28 (56.0)	
Stage, n (%)[b]			
I	7 (38.9)	11 (61.1)	0.998
II	21 (41.2)	30 (58.8)	
III	27 (39.7)	41 (60.3)	
IV	34 (40.0)	51 (60.0)	

[a]Mann-Whitney test used for statistical analysis; [b]χ^2 test used for statistical analysis; [c]Fisher's exact test used for statistical analysis; [d]P<0.05. SD, standard deviation; BMI, body mass index; ECOG-PS, Eastern Cooperative Oncology Group performance status.

patients with recently diagnosed cancer even after adjusting for other risk factors, including comorbidities, cancer treatment and nursing home stay, suggesting that the diagnosis of cancer itself is a risk factor for infection (8,9).

In the present study, no significant difference was found between patients receiving cytotoxic treatment for BC between the groups. Both groups were similar in terms of patient-, disease- and treatment-related characteristics. When comparing outcomes of interest during treatment, there was a general trend towards higher morbidity, hospitalization, ICU admission and ER visits in the group 2; however, this did not reach statistical significance. This could be explained by the fact that the sample size was small, with a low rate of morbidity and mortality. Nonetheless, despite having a longer period of treatment and more cycles, with longer follow-up for some patients in the early second period, there was still no significant increase in morbidity and mortality rate in the second group. In SA, a retrospective study was conducted to determine 30-day mortality and morbidity rates among patients with cancer receiving curative and palliative anticancer treatments during the COVID-19 pandemic at five large comprehensive cancer centers. The study found a 30-day morbidity rate of 28.2% for the total cases (17.9% for curative intent and 39.3% for palliative intent) and a rate of 75% for COVID-19 cases. The 30-day mortality rate significantly increased when considering the male sex, a BMI <25 kg/m^2, use of hormone therapy and greater number of cycles, but decreased with an ECOG-PS of 0-1, stage I-II cancer and treatment with curative intent (19).

Table IV. Difference between groups 1 and 2 according to status of last follow-up, 30-day morbidity and mortality, hospitalizations, ER visits, ICU admissions and dose reduction.

Variable	Group 1 (n=89)	Group 2 (n=133)	P-value
Status of last follow-up			0.276[a]
Alive	89 (40.6)	130 (59.4)	
Dead (disease progression)	0 (0.0)	3 (100.0)	
30-day mortality			0.276[a]
No	89 (40.6)	130 (59.4)	
Yes	0 (0.0)	3 (100.0)	
30-day morbidity			0.522
No	80 (40.8)	116 (59.2)	
Yes	9 (34.6)	17 (65.4)	
Hospitalizations			0.658
No	80 (40.6)	117 (59.4)	
Yes	9 (36.0)	16 (64.0)	
ER visits			0.573
No	78 (40.8)	113 (59.2)	
Yes	11 (35.5)	20 (64.5)	
ICU admission			0.517[a]
No	89 (40.5)	131 (59.5)	
Yes	0 (0.0)	2 (100.0)	
Dose reduction			>0.999[a]
No	89 (40.3)	132 (59.7)	
Yes	0 (0.0)	1 (100.0)	

[a]Fisher's exact test was used for statistical analysis. ER, Emergency Room; ICU, Intensive Care Unit.

In the present study, no significant change was observed in the care of patients with BC receiving cytotoxic treatments despite the effect of the pandemic on a number of aspects of BC treatment pathways at KAUH. In a large multicenter cohort study from the UK, where treatment pathways were examined in 3,776 patients, most treatment pathways did not undergo significant changes from the pre-COVID crisis era (20). With regard to adjuvant chemotherapy, even when omitted in 81 patients that would have received the therapy in the pre-COVID crisis era, the median benefit was only 3% using 'NHS Predict', a predicative tool developed in the UK to assess survival in patients with BC after surgery. These patients were at low risk, as they were postmenopausal, had no or low nodal burden disease, and most had estrogen receptor-positive disease. This study reflected on the use of a holistic approach in managing patients with BC during the COVID crisis period (20).

In the present study cohort, the incidence of patients with BC testing positive for COVID-19 was low (2.3%), which is similar to another report from a larger cohort series (21). In this large multicenter retrospective analysis by Vuagnat *et al* (21), it was also found that baseline comorbidities other than BC should be the focus during COVID-related morbidity and mortality assessments. The mortality rate was recorded as higher by 6.7%, compared with the general population at the time of the study, whereas it ranged from 3.7 to 18.2% across multiple large countries in the world. In the present cohort, there was no significantly increased risk of morbidity or mortality in patients with BC on active treatment in the second group that tested positive for COVID-19 infection.

The present study retains the inherent limitations of retrospective reviews. Moreover, it reports the experience of a single tertiary institution in the country, which may not be reflective of the nation-wide experience. Future collaborative assessment of the morbidity and mortality outcomes of patients with BC and other cancer types, in the setting of COVID-19 and other pandemics or crises, in other national institutes, is warranted to drive the allocation of human and financial resources if necessary. Additionally, it is essential to review the institutional and national preparedness measures that were taken, and to implement policies and procedures to ensure system readiness in future times of pandemic. Finally, it is imperative for extra measures to be taken, to ensure that patient outcomes remain unaffected by this or any future pandemics.

Based on the present results, the outcomes of patients with BC at KAUH did not seem to be affected by COVID infection. However, taking extra measures to improve outcomes and avoid morbidities and mortalities in vulnerable groups of patients is highly warranted.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

MA, RU, OI and NT all contributed significantly to the study design, data collection and analysis, and writing and/or editing of the manuscript. SB contributed significantly to the statistical analysis and the writing and editing of the manuscript. MA and NT confirm the authenticity of all the raw data. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the Research Committee of the Unit of Biomedical Ethics at King Abdulaziz University Hospital (Jeddah, Saudi Arabia; approval no. 333-20) and the requirement for informed consent was waived.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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