Egyptian Journal of Community Medicine, 2024;42 (2):75 -83

Egyptian Journal of Community Medicine

Uptake and Safety of COVID 19 Vaccine Among Female Breast and Gynecological Cancer Patients - A Single Egyptian Center Experience

Rasha Mahmoud Allam[1], Omnia Mohamed [2], Youstina Elamir [3], Mohamed Rahouma [4], Hala Aziz Shokralla [2]

1 Cancer Epidemiology& Biostatistics-National Cancer Institute-Cairo University, Egypt
2 Medical Oncology-National Cancer Institute-Cairo University, Egypt.
3 Radiodiagnosis-National Cancer Institute-Cairo University, Egypt.
4 Surgical Oncology, National Cancer Institute-Cairo University, Egypt, Cardiothoracic Surgery Department, Weill Cornell Medicine, NY.

Submission Date:
2023-09-11

Revision Date:
2023-09-29

Acceptance Date:
2023-10-15

Key Words:
COVID-19 vaccine, uptake, safety, chemotherapy, female breast, gynecological cancer

A B S T R A C T

Background: Cancer patients, including those with gynaecological and breast malignancies, had a higher risk of COVID-19 infection and severe illness. However, there is limited research on COVID-19 vaccine acceptance and safety within this population. [7] **Objective:** to determine the COVID-19 vaccine uptake among female breast and gynaecological cancer patients and report vaccine-related side effects in this population. **Method:** This is a cross-sectional study among female breast and gynaecological cancers. We gathered information on patients' health conditions, cancer diagnosis with its stage, treatment, history of COVID-19 infection and its severity, the timing of infection in relation to chemotherapy, COVID-19 vaccination status, and any adverse effects. **Results**: Out of 370 patients, 40.3% have received the COVID-19 vaccine, 52.2% postponed it, and 7.6% refused vaccination. The Sinovac vaccine was the most received in the chemotherapy group (56%), followed by Pfizer (18.7%) AstraZeneca (18.7%), Johnson (5.3%), and Sputnik (1.3%). Patients with a higher education level were more likely to refuse vaccination. The refusal rate was associated with educational level, cancer type, cancer stage, and treatment type. In multivariable analysis, chemotherapy was associated with higher rate of vaccine refusal (OR = 2.588, 95% CI = 1.673, 4.002, p < 0.001). Vaccine side effects were highest in AstraZeneca and Pfizer having the highest rates (41.7% and 33.3%, respectively) but lowest in Sinovac (4.4% p<0.001). In multivariable analysis, gynaecological malignancies had an increased risk of developing side effects than breast cancer (OR = 3.54, 95% CI = 1.240-10.147, p = 0.018). **Conclusions**: Elderly patients with advanced-stage gynaecological cancers exhibited a higher vaccination refusal rate. No major safety concerns associated with COVID-19 vaccination were reported during chemotherapy.

INTRODUCTION

The COVID-19 pandemic has posed significant challenges to global health, with cancer patients being particularly vulnerable to extreme illness and mortality when infected.[1] In January 2022, COVID-19 vaccines had secured endorsement from the World Health Organization (WHO) and had been authorized for Emergency Use by the Food and Drug Administration (FDA). The EUA allows for the utilization of medical products that have not received official approval under specific conditions during a crisis. This authorization is granted when certain legal criteria are met, especially in situations where there are no acceptable, authorized, and

Corresponding Author: Rasha Mahmoud Allam, Department of Cancer Epidemiology & Biostatistics-National Cancer Institute-Cairo University, Egypt. Email: rasha.allam@nci.cu.edu.eg

readily available alternatives while waiting for the FDA's extensive and time-consuming approval process.[2]

Cancer patients stand to gain significant advantages from receiving the COVID-19 vaccine. Present guidelines advocate vaccination for individuals with cancer, primarily because of their compromised immune systems. The timing of when to administer the vaccine can vary depending on the specific type of cancer and the treatment being pursued. As a general guideline, it is advisable to provide the vaccine before commencing chemotherapy, whenever feasible, or during the intervals between chemotherapy cycles, and avoid the initial phase of chemotherapy administration.[3]

Cancer patients exhibit low vaccination rates, indicating hesitancy.[4] Vaccine hesitancy, which is the reluctance to accept or refuse safe vaccines despite their accessibility, poses a significant worldwide health risk.[5] According to National Comprehensive Cancer Network (NCCN) recommendations, cancer patients receiving chemotherapy for solid tumors should receive the vaccine as soon as it becomes available. However, in certain circumstances, it may be appropriate to delay vaccination until an intensive chemotherapy regimen is completed, such as during induction therapy for acute leukemia protocols.[3]

Accessible data suggest that COVID-19 vaccination is safe in cancer patients, with minor vaccine-related side effects manifesting within 2-3 days after vaccination. In case of side effects, delaying the next chemotherapy cycle is advisable. On the other hand, studies suggest vaccine efficacy may be compromised in those with active cancer. The European Society of Medical Oncology (ESMO) issued statements endorsing COVID-19 vaccination for patients with cancer, with a particular emphasis on closely monitoring potential side effects and providing comprehensive patient education.[6]

Vaccine hesitancy can be attributed to various factors, including apprehensions regarding the safety and effectiveness of vaccines and the fear of experiencing adverse effects. The swift development of new SARS-CoV-2 vaccines employing innovative approaches has generated numerous inquiries and uncertainties among the public.[7] This study aims to assess the COVID-19 vaccine uptake among female breast and gynecological cancer patients and report vaccine-related side effects in this population.

METHODS

A cross-sectional study design was conducted. All patients were treated at the outpatient Medical Oncology Clinics, National Cancer Institute (NCI), Cairo University (CU), Egypt, from January 2022 to March 2022.

The study targeted female patients with breast cancer and gynecological malignancies (ovarian, cervical, and endometrial). All pathologies, such as invasive duct carcinoma (IDC), invasive lobular carcinoma (ILC) in female breast cancer, and all epithelial ovarian cancers, were included. Patients were at different stages (early, advanced, and metastatic) receiving chemotherapy, radiotherapy, or hormonal treatment.

All patients were recruited consecutively during the study time, and the sample size was estimated based on a previous study that reported an acceptance rate of 35% to get the COVID-19 vaccine. Using the Wan Nor Arifin calculator to attain a 95% confidence level ±5% precision level, 350 participants were needed, at least. [8, 9]

We collected data from patients while they were receiving chemotherapy in the clinic. The collected data included demographic data (age, educational level, and marital status), comorbidities (diabetes, hypertension, cardiac disease, chronic liver or kidney disease, and thyroid dysfunction), cancer diagnosis, stage (early, advanced, or metastatic), treatment modalities (chemotherapy, radiotherapy, or hormonal treatment), and treatment intent (curative or palliative). COVID-19 infection data included previous infections, diagnostic methods (PCR, radiological diagnosis, or clinical examination), infection frequency, hospitalization and oxygen support requirements, and the effectiveness of home treatment. Additionally, the study examined post-COVID complications or ICU admissions and the timing of infection in relation to chemotherapy and cancer diagnosis. The vaccine acceptance was assessed, and those who were already vaccinated were asked about the first vaccination date in relation to the timing of infection, the type of vaccine received, the number of booster doses, and vaccine-related side effects (fever, bone pains, flu-like symptoms, and injection site pain) and their severity. On the other hand, those who refused were asked about the cause.

The primary endpoint was the acceptance of patients to receive COVID vaccine. The secondary endpoint was reporting side effects of COVID-19 vaccination among female breast and gynecological cancer patients.

Table 1: Participants' characteristics (n=370)

Characteristics		Descriptive
Age (years)	Mean ± SD	52.11 ±10.9
	Range	(25-80)
Education level: N (%)	High (university degree and above)	42 (11.4)
	Middle (High school/Diploma)	268 (72.4)
	Illiterate	60 (16.2)
Comorbidity presence: N (%)	Yes	92 (24.9)
Cancer type: N (%)	Female Breast	296 (80.0)
	Gynecological	74 (20.0)
Stage: N (%)	Early	58 (15.7)
	Advanced	225 (60.8)
	Metastatic	87 (23.5)
Treatment modality: N (%)	Chemotherapy	235 (63.5)
	Hormonal	116 (31.4)
	Radiotherapy	2 (0.5)
	Follow up	17 (4.6)
Previous Covid infection: N (%) *	Yes	76 (20.5)
Timing of infection in relation to chemotherapy (n=76): N (%)	Pre-treatment	20 (26.3)
	During treatment	23 (30.3)
	Post-treatment	33 (43.4)
Treatment of Covid was done in (n=76): N (%)	Home management	65 (85.5)
	Need hospitalization	11 (14.5)
Covid vaccine uptake: N (%)	Yes	149 (40.3)
	Postponed	193 (52.2)
	Refused	28 (7.6)
Vaccination refusal or postponing causes (N=221): N (%)	They will take after chemotherapy cessions	48 (21.7)
	Cancer mortality exceeds Covid risk	10 (4.5)
	Had Covid already	17 (7.7)
	Safety precautions	128 (57.9)
	Waiting ministry call	18 (8.2)
Vaccine type (n=149): N (%)	AstraZeneca	24 (16.1)
	Johnson	4 (2.7)
	Pfizer	27 (18.1)
	Sinovac	91 (61.1)
	Sputnik	3 (2.0)
No. of doses received (n=149): N (%)	Single dose	11 (7.4)
	Two doses	129 (86.6)
	Three doses	9 (6.0)
Vaccine received in relation to Chemotherapy (n=139): N (%)	Pre	40 (28.8)
	During	39 (28.1)
	Post	60 (43.2)
Side effects occurrence (n=149): N (%)	Yes	24 (16.1)
Side effects type (n=24): N (%)	Fever	5 (20.8)
	Flu-like symptoms	3 (12.5)
	Injection site pain	16 (66.7)

*SD: Standard deviation, *: infection confirmed according to WHO criteria*

Table 2: Determinants of COVID-19 vaccination uptake in the studied group (n=370)

		N	COVID-19 vaccination uptake		COR (95%CI)	p-value
			Yes (n=149)	No (n=221)		
Age (years)	≤52	189	71 (37.57)	118 (62.43)	Reference	0.278
	> 52	181	78 (43.09)	103 (56.91)	1.26 (0.83-1.91)	
Educational level	Illiterate	60	26(43.33)	34 (56.67)	Reference	-
	Middle	268	114(42.54)	154 (57.46)	1.03 (0.59-1.82)	0.910
	High	42	9 (21.43)	33 (78.57)	2.80 (1.14-6.87)	0.024
Comorbidity presence	No	278	110 (39.57)	168 (60.43)	Reference	0.632
	Yes	92	39 (42.39)	53 (57.61)	1.12 (0.7, 1.81)	
Cancer type	Female breast cancer	296	129 (43.58)	167 (56.42)	2.09 (1.19, 3.66)	0.009
	Gynecological malignancies	74	20 (27.03)	54 (72.97)	Reference	
Stage	Early	58	32 (55.17)	26 (44.83)	Reference	-
	Advanced	225	91 (40.44)	134 (59.56)	1.81 (1.01, 3.24)	0.045
	Metastatic	87	26 (29.89)	61 (70.11)	2.89 (1.45, 5.77	0.003
Treatment type	Chemotherapy	235	75 (31.91)	160 (68.09)	Reference	<0.001
	Other treatment modalities	125	64 (54.81)	61 (45.19)	2.24 (1.43, 3.49)	
Covid infection	No	294	117 (39.80)	177 (60.20)	Reference	0.714
	Yes	76	32 (42.11)	44 (57.89)	1.10 (0.66, 1.84)	
Timing of infection in relation to Chemotherapy (n=76)	Post	33	17 (51.52)	16 (48.48)	Reference)	-
	During	23	6 (26.09)	17 (73.91)	1.29 (0.43, 3.95)	0.646
	Pre	20	9 (45.00)	11 (55.00)	3.01 (0.95, 9.54)	0.061
Covid management (n=76)	Home management	65	27 (41.54)	38 (58.46)	Reference	0.808
	Need hospitalization	11	5 (45.45)	6 (54.55)	1.17 (0.32, 4.24)	

COR: crude odds ratio, P<0.05 is statistically significant

Statistical methods: Data were analyzed using SPSS statistical package version 28. Age was described using means, standard deviations (SD), and range. Categorical variables were described as frequencies and percentages and compared using the Chi-square test. Crude odds ratios (95% confidence intervals) were estimated. Logistic regression was applied to get adjusted odds ratios and measure factors affecting the magnitude of vaccine acceptance and side effects occurrence. The regression model included all significant factors (at a p-value of 0.1) on the univariate level using the stepwise method. A probability (p-value) less than 0.05 was considered significant. All tests were two-tailed.

RESULTS

Participants' characteristics

Three hundred seventy female patients (74 with gynecological malignancies and 296 with female breast cancers) were involved in that study. Table 1 shows the characteristics of the studied patients. The median age was 52.5 years for breast cancer patients and 51 years for gynecological cancer patients. Two hundred thirty-five patients (63.5%) were on chemotherapy.

Approximately two-thirds (59.7%) of the patients preferred to postpone or refuse the COVID-19 vaccine. The most frequent reasons for refusal or postponing were concerns regarding safety (57.9%) and a desire to postpone vaccination until after chemotherapy sessions (21.7%). Other factors included waiting for ministry

Table 3: COVID-19 vaccination side effects in relation to the Subjects' Characteristics (n=149)

		N	COVID-19 vaccination side effects		COR (95%CI)	p-value
			Yes (N=24)	No (N=125)		
Age (years)	≤52	71	16 (22.5)	55 (77.5)	2.55 (1.02, 6.38)	0.042
	> 52	78	8 (10.3)	70 (84.2)	Reference	
Educational level	High	9	2 (15.8)	7 (77.8)	Reference	-
	Middle	114	18 (75.0)	96 (76.8)	1.52 (0.29-7.93)	0.617
	Illiterate	26	4 (15.4)	22 (84.2)	1.57 (0.23-10.49)	0.641
Comorbidity presence	No	110	20 (18.2)	90 (81.8)	1.94 (0.62, 6.09)	0.247
	Yes	39	4 (10.3)	35 (89.7)	Reference	
Cancer type	Female breast cancer	129	17 (13.2)	112 (86.8)	Reference	0.014
	Gynecological malignancies	20	7 (35.0)	13 (65.0)	3.55 (1.24, 10.15)	
Stage	Advanced	117	20 (17.1)	97 (82.9)	1.44 (0.46, 4.57)	0.320
	Early	32	4 (12.5)	28 (87.5)	Reference	
Treatment type	Chemotherapy	75	9 (12.0)	66 (88.0)	Reference	0.170
	Other treatment modalities	74	15 (20.3)	59 (79.7)	1.86 (0.76, 4.58)	
Covid infection	No	117	18 (15.4)	99 (84.6)	Reference	0.646
	Yes	32	6 (18.8)	26 (81.2)	1.27 (0.46, 3.52)	
Covid management (n=32)	Home management	27	6 (22.2)	21 (77.8)	Reference	0.436*
	Need hospitalization	5	0(0)	5(100.0)	3.33 (0.16, 68.49)	
Timing of infection in relation to Chemotherapy (n=32)	Pre	9	2 (22.2)	7 (77.8)	Reference	0.951
	During	6	1 (16.7)	5 (83.3)	1.43 (0.10-20.44)	0.793
	Post	17	3 (17.6)	14 (82.4)	1.33 (0.18-9.91)	0.779
Vaccination type	AstraZeneca	24	10 (41.7)	14 (58.3)	Reference	-
	Pfizer	27	9 (33.3)	18 (66.7)	1.43 (0.46-4.47)	0.540
	Sinovac	91	4 (4.4)	87 (95.6)	15.54 (4.28-56.41)	<0.001
	Others	7	1 (14.3)	6 (85.7)	4.29 (0.44-41.37)	0.208
Number of doses received	One dose	11	2 (18.2)	9 (81.8)	3.60 (0.48-27.11)	0.214
	Two doses	129	18 (14.0)	111 (86.0)	4.93 (4.93-1.21)	0.026
	Three doses	9	4 (44.4)	5 (55.6)	Reference	
Vaccine received in relation to Chemotherapy (n=139)	Pre	40	7 (17.2)	33 (82.5)	Reference	-
	During	39	3 (7.7)	36 (92.3)	2.55 (0.61-10.67)	0.201
	Post	60	14 (23.3)	46 (76.7)	0.69 (0.25-1.92)	0.484

*COR: crude odds ratio; P<0.05 is statistically significant; *Haldane-Anscombe correction was used to estimate OR & its 95%CI*

guidance (8.2%), a previous COVID-19 infection (7.7%), and the belief that the risk of cancer mortality outweighed the risk of COVID-19 (4.5%) as illustrated in Table (1).

A total of 149 patients received the vaccine. The distribution of the timing of COVID-19 vaccination in relation to chemotherapy was as follows: 43.2% received the vaccine after any form of chemotherapy, 28.8% received it before chemotherapy, and 28.1% received it while actively undergoing chemotherapy treatment. The most common side effect of the COVID vaccines was pain

Table 4: Multivariable analysis for COVID-19 vaccination uptake and its side effects

Independent factors	p-value	AOR	95% CI for AOR
Vaccination refusal			
Treatment modality (chemotherapy intake versus other types of treatment)	<0.001	2.588	(1.673-4.002)
Vaccination side effects			
Cancer type (gynecological malignancies versus Female breast cancer)	0.018	3.548	(1.240-10.147)

AOR: Adjusted odds ratio, CI: confidence interval

at the injection site (66.7%), while fever and flu-like symptoms, such as headache, fatigue, or bone pains, were reported in 20.8% and 12.5 % of the cases, respectively (Table 1).

Factors associated with COVID-19 vaccination:

The analysis revealed interesting patterns regarding COVID-19 vaccine uptake among different groups. Illiterate individuals and those with middle-level education were more inclined to receive the vaccine than those with university degrees (OR= 1.03 and 2.80, respectively). Furthermore, in contrast to individuals diagnosed with other gynecological malignancies, those with female breast cancer were found to have a higher likelihood of receiving the COVID-19 vaccine. (OR = 2.09). Higher percentage of vaccine delay and refusal was observed among individuals with advanced or metastatic cancer (OR = 1.81 and 2.89, respectively) and those undergoing chemotherapy compared to individuals receiving other lines of treatment (OR = 2.24), as indicated in Table 2. After multivariate analysis as shown in table 4, treatment type emerged as the sole statistically significant predictor for vaccine hesitancy. Specifically, chemotherapy was strongly associated with higher odds of vaccine refusal compared to other lines of treatment (OR = 2.588, 95% CI = 1.673, 4.002, p < 0.001).

Reported side effects following COVID-19 vaccination:

Young age was associated with a higher likelihood of experiencing COVID-19 vaccination adverse effects than older age groups (OR = 2.55, p = 0.042). Additionally, cases with gynecological malignancies were more likely to experience side effects than female breast cancer cases (OR = 3.55, p = 0.014). AstraZeneca and Pfizer vaccines were associated with a higher presence of side effects than any other types (p value<0.001). According to multivariate analysis shown in table 4, cancer type was the only statistically significant predictor for experiencing vaccine side effects. Additionally, gynecological malignancies were strongly associated with higher odds of experiencing vaccine side effects than female breast cancer (OR = 3.548, 95% CI = 1.240 - 10.147, p = 0.018).

DISCUSSION

The COVID-19 pandemic has posed significant challenges to healthcare systems worldwide, with vaccination campaigns being crucial in controlling the spread of the virus. This study investigated the COVID-19 vaccine uptake and associated factors among female breast or gynecological cancer patients, shedding light on vaccination dynamics in this vulnerable group. Moreover, the study explored the incidence of vaccine side effects and their relationship with the type of vaccine received and underlying malignancies.

The results revealed that among the oncology patients, 40.3% received the COVID-19 vaccine, 52.2% postponed it, and 7.6% refused vaccination. These statistics highlight the complex decision-making process that oncology patients face regarding vaccination. Understanding the reasons behind these choices is vital for tailoring interventions to increase vaccine acceptance. Furthermore, the safety and adverse events of COVID-19 vaccines were assessed. The current study estimate aligns with a similar study by Forster et al., where 5.2% of patients declined the vaccine.[10, 11] The acceptance and awareness of COVID-19 vaccines among cancer individuals can vary based on many factors, including access to information, geographical location, individual or cultural beliefs, and trust in the healthcare systems.[10-13]

Notably, the Sinovac vaccine had the highest utilization rate at 56%, followed closely by Pfizer and AstraZeneca, each accounting for 18.7%. Sputnik and Johnson vaccines were less commonly chosen at 1.3% and 5.3%, respectively. These preferences may reflect regional availability and healthcare provider recommendations, warranting further investigation.[14]

Our study also found that patients with a higher level of education were more likely to refuse vaccination. This finding raises important questions about the role of health literacy, access to information, and trust in healthcare systems in shaping vaccination decisions. Addressing the concerns of this group may require targeted educational initiatives.[15, 16]

Interestingly, the refusal rate for COVID-19 vaccination was significantly higher among gynecological malignancy cases than among female breast cancer cases (72.97% vs. 56.42%, p = 0.009). This divergence may be attributed to various factors, including differences in treatment regimens, perceived risks, and patient demographics. Further research is warranted to explore these nuances and develop tailored strategies to improve vaccine acceptance among gynecological malignancy patients.[17- 19]

Our study revealed varying percentages of reported vaccine side effects, with AstraZeneca and Pfizer having the highest rates at 41.7% and 33.3%, respectively. In contrast, 95.6% of Sinovac recipients reported no side effects (p < 0.001). These findings emphasize the importance of monitoring and managing side effects, which may impact vaccine hesitancy. Additionally, cases with gynecological malignancies had an increased risk of developing side effects (29.2%, p = 0.018, OR = 3.54, 95% CI = 1.240-10.147), highlighting the need for enhanced support and surveillance for this patient group.[20]

Individuals with cancer need to consider the benefits and potential risks associated with COVID-19 vaccination. Healthcare providers and organizations play a vital role in educating these patients, particularly those at a higher risk of severe illness from the virus and addressing any concerns or misconceptions. The safety and effectiveness should be extensively tested for vaccines authorized for emergency use in the general population. However, specific studies examining the safety and efficacy of COVID-19 vaccines in individuals with cancer are scarce. Hence, it is imperative to consider COVID-19 vaccine safety in females diagnosed with breast and gynecological malignancies. Injection site pain was reported at 66.7%, aligning with prior studies that reported injection site reaction or pain exceeding 65%.[21]

In a recent study, researchers compared the side effects of COVID-19 vaccines in a cohort of 170 patients who had received immune checkpoint inhibitors. The most frequently reported side effects included localized pain at the injection site (63%), fatigue (34%), and muscle pain (34%). Importantly, no adverse events necessitating hospitalization or medical intervention were reported in this group.[11, 21, 22]

Our results suggest that females with gynecological malignancies may experience more side effects than those with breast cancer. Vaccine side effects are typically mild and transient, including fatigue, pain at the injection site, muscle pain, headache, fever, and chills. These side effects are normal and indicate that the immune system responds to the vaccine and usually resolves within a few days.[23] However, the occurrence and severity of side effects can differ among individuals regardless of their cancer type.[10] Individuals with gynecological malignancies may experience a higher frequency or intensity of side effects due to various factors, such as their specific cancer treatments and potential interactions between the vaccine and their medications.

***Limitations*:** The study's sample was recruited from a single cancer center, which may introduce selection bias, as it could include patients more inclined to accept COVID-19 vaccines. Additionally, the study's cross-sectional nature can determine associations but does not allow for establishing causation over time. Furthermore, immunogenicity assays were not conducted as part of the standard clinical routine to accurately assess the effectiveness of the administered vaccine.

***Recommendation*:** Several key strategies should be considered to enhance COVID-19 vaccination efforts among female breast and gynecological malignancy patients. First, there is a critical need to prioritize vaccination for these patients to effectively reduce COVID-19-related hospitalizations, morbidity, and mortality. Accompanying this prioritization, it is essential to increase awareness, education, and support from healthcare professionals to address vaccine safety concerns among cancer patients. Furthermore, strengthening collaboration among healthcare providers, cancer care organizations, and policymakers is vital to enhance vaccine acceptability, raise awareness, and ensure safety. Future research endeavors should encompass multi-center studies with diverse patient demographics and cancer types. These studies can provide valuable insights into evolving vaccine acceptance trends over time and the influence of various factors on decision-making. Lastly, comprehensive vaccination campaigns and educational initiatives should be

implemented to address the psychological factors contributing to vaccine hesitancy.

CONCLUSIONS

Our study provides valuable insights into the COVID-19 vaccine landscape among oncology patients. It highlights the need for tailored interventions to address vaccine hesitancy, especially among gynecological malignancy cases. Higher vaccination refusal rates were observed among elderly patients with advanced-stage gynecological cancers. No major safety concerns were reported for COVID-19 vaccination during chemotherapy treatment. However, close monitoring remains necessary to assess adverse events, clinical outcomes, and vaccine effectiveness in cancer patients. Receiving the vaccine while on active treatment is safe, and most side effects are tolerable and short-lived.

Ethical Consideration

The study was conducted according to the declaration of Helsinki and local ethical guidelines for research on humans. Patients signed an informed consent after fully explaining the study's aim and assuring them that data were dealt anonymously. The study obtained an IRB approval from the National Cancer Institute, Cairo University (approval number: EB2110-504-075)

***Funding source*:** The authors received no financial support related to this research."

***Conflict of interest*:** All authors have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

***Acknowledgment*:** We would like to thank all the participants who participated in this study and the staff at the National Cancer Institute for their support.

***Data availability*:** The corresponding author will provide the datasets used in this study upon receiving a reasonable request.

***Author contributions*:** Rasha Mahmoud Allam: Idea, literature search, data analysis and writing; Omnia Mohamed: Idea, literature search, and writing; Youstina Elamir: reversion of the images and confirm diagnosis of covid cases; Mohamed Rahouma: literature search and writing; Hala Aziz Shokralla: Critical review, reversion of the data and literature search.

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Cite this article as: Allam, R. et al. Uptake and Safety of COVID 19 Vaccine Among Female Breast and Gynaecological Cancer Patients - A Single Egyptian Center Experience. *Egyptian Journal of Community Medicine*, 2024; 42 (2):75-83.
DOI: 10.21608/ejcm.2023.235782.1271