Advances in Pharmacology and Therapeutics Journal
Shahid Sadoughi University of Medical Sciences, Yazd, Iran

SHAHID SADOUGHI UNIVERSITY OF MEDICAL SCIENCES

Original Article

Investigation of COVID-19 Vaccine–Related Side Effects in Cancer Patients Referred to Shahid Sadoughi Hospital, Yazd, Iran

Running Title: COVID-19 Vaccine Side Effects in Cancer Patients

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ARTICLEINFO

Received: 02/18/2026
Accepted: 06/10/2026

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Abstract

Background: Patients with cancer are at heightened risk for severe COVID-19 outcomes due to immunosuppression caused by the disease and its treatments. While COVID-19 vaccines are recommended for this vulnerable group, limited data are available on their side effects in this population. This study aimed to investigate the adverse effects of COVID-19 vaccination among cancer patients referred to the oncology department and clinic of Shahid Sadoughi Hospital in Yazd, Iran.

Methods: A descriptive cross-sectional study was conducted among 300 patients with cancer aged 18 years or older who had received a COVID-19 vaccine. Participants were chosen through convenience sampling. Data were collected through interviews and medical records using a checklist covering demographic characteristics, cancer type, vaccine type, and vaccine-related side effects. Exclusion criteria included incomplete medical records and patients' unwillingness to be interviewed. Data were analyzed using SPSS version 22.

Results: The study showed that side effects in cancer patients was similar to those in the general population, with common local reactions such as injection-site pain and systemic symptoms such as fatigue and headache. No severe adverse effects were expected, except for mild to moderate symptoms.

Conclusion: COVID-19 vaccines appear to be safe for cancer patients, with tolerable side effects comparable to those reported in the general population. These findings provide reassurance about the timeliness of vaccination in this high-risk group, potentially reducing hesitancy.

Keywords: COVID-19 vaccine, Side effects, Cancer patients, Oncology, Vaccination safety

Citation: Astani A, Heidari F, Ali Farahat A, Zeinaddini M, Akhoundi Meybodi Z. Investigation of COVID-19 Vaccine–Related Side Effects in Cancer Patients Referred to Shahid Sadoughi Hospital, Yazd, Iran. Adv Pharmacol Ther J. 2025;5(4): 240-246.

Introduction

The novel respiratory illness caused by coronavirus disease 2019 (COVID-19) has posed significant challenges to global health since its emergence in late 2019(1-3). As of September 30, 2025, the pandemic had resulted in millions of deaths worldwide, with vulnerable populations such as older adults, individuals with comorbidities, and immunocompromised persons bearing the heaviest impact (4). Patients with cancer are a particularly high-risk group due to factors like advanced age, underlying health conditions such as hypertension and diabetes, and immunosuppression caused by cancer itself or by its treatment (5, 6).

Early studies showed that the mortality rate from COVID-19 was higher among patients with cancer, reaching 25.53% in some groups (7). This vulnerability was due to frequent hospital admissions and an increased risk of exposure to the diseases (8). As a result, cancer patients were prioritized for COVID-19 vaccination globally (9). Vaccines such as those from Pfizer-BioNTech, Moderna, AstraZeneca, and Sinopharm have shown high efficacy in preventing severe disease in the general population (10). However, cancer patients were excluded mainly from early clinical trials, leading to gaps in knowledge about vaccine efficacy, tolerability, and safety in this subgroup (11).

There have been limited studies investigating adverse events following COVID-19 vaccination in cancer patients. This study aimed to address this gap by evaluating adverse events following COVID-19 vaccination among cancer patients at Shahid Sadoughi Hospital in Yazd, Iran. By documenting adverse events, we aim to provide evidence-based reassurance, promote vaccine uptake, and reduce concern in this population. The research question focused on the nature, frequency, and severity of post-vaccination adverse events in comparison with those reported in the general population (12).

Methods

Study Design

This descriptive cross-sectional study was conducted in 2021 (Iranian calendar year 1400) at the Oncology Department of Shahid Sadoughi Hospital in Yazd, Iran.

Data Collection

Data were collected through researcher-led interviews and review of medical records using a pre-designed checklist. The checklist included demographic information, cancer type, and number of vaccine doses received, and other relevant variables. The cancer type variable was adjusted by limiting its categories and removing its confounding effects. The final study population included 300 patients diagnosed with breast cancer (120 patients) and gastrointestinal cancer (180 patients). All participants had received the Sinopharm vaccine.

Variables

Independent variables: age, sex, and cancer type.

Dependent variables: vaccine-related side effects (fever, muscle pain, joint pain, nausea/vomiting,

  DOI: https://doi.org/10.18502/aptj.v5i4.21764

headache, weakness, seizures, injection-site pain/swelling, thrombosis, hospitalization, generalized itching, skin rash, dizziness, and other reported symptoms).

Sampling

The sample size was calculated as 300 using PASS 15 software, assuming 95% confidence, 80% power, and a 5% margin of error, based on prior studies. Convenience sampling was used among patients with cancer aged 18 or older who had received a COVID-19 vaccine.

Inclusion and Exclusion Criteria

Inclusion: Patients with cancer over 18 years old, referred to the hospital, and vaccinated against COVID-19.

Exclusion: A history of anaphylaxis or severe allergy.

Statistical Analysis

Analytical tests were performed using SPSS software, version 26. Continuous variables were reported as mean ± standard deviation. For inferential analyses, Chi-square tests and independent t-tests were used where applicable. A p-value < 0.05 was considered statistically significant.

Results

The study included 300 patients registered in the COVID-19 registry at Shahid Sadoughi Hospital in Yazd. Only patients with breast cancer (n=120) or gastrointestinal cancer (n=180) who had received the Sinopharm vaccine were included, to reduce the potential influence of cancer type on post-vaccination adverse events. Data on adverse events not recorded in the registry were collected through telephone interviews. Patients who could not recall the relevant adverse events or vaccine doses were excluded.

The rates of vaccine-related side effects reported by patients in each cancer group are shown separately in **Table 1.** The occurrence of fever, nausea, vomiting, and diarrhea showed significant differences between the breast and gastrointestinal cancer groups.

Table 1 Frequency of COVID-19 Vaccine-Related Injection Side Effects by Cancer Type

Side Effect	Gastrointestinal Cancer	Breast Cancer	p-value
Injection-site pain/burning	121 (67.2%) absent, 59 (32.8%) present	78 (65%) absent, 42 (35%) present	0.69
Swelling	173 (96.1%) absent, 7 (3.9%) present	114 (95%) absent, 6 (5%) present	0.64
Fever	150 (83.3%) absent, 30 (16.7%) present	81 (67.5%) absent, 39 (32.5%) present	0.001
Fatigue	128 (71.1%) absent, 52 (28.9%) present	84 (70%) absent, 36 (30%) present	0.83
Nausea	136 (75.6%) absent, 44 (24.4%) present	105 (87.5%) absent, 15 (12.5%) present	0.01
Vomiting	156 (86.7%) absent, 24 (13.3%) present	115 (95.8%) absent, 5 (4.2%) present	0.008
Myalgia	138 (76.7%) absent, 42 (23.3%) present	91 (75.8%) absent, 29 (24.2%) present	0.86
Diarrhea	153 (85%) absent, 27 (15%) present	115 (95.8%) absent, 5 (4.2%) present	0.003

Note: "Absent" indicates patients who did not experience the side effect, and "present" indicates patients who did.

Baseline Age Characteristics of the Study Cohort

118 patients with breast cancer (93.8%) were female, while 95 patients with gastrointestinal cancer (52.8%) were male, and 85 patients (47.2%) were female.

The most commonly reported side effect was injection-site pain and burning, affecting 101 patients (33.7%). Fatigue was the second most common, experienced by 88 patients (29.3%), followed by myalgia in 71 patients (23.7%). Other side effects and their frequencies are listed in **Table 2.**

Table 2. Frequency of COVID-19 Vaccine Injection Side Effects in Cancer Patients

Side Effect	Number of Patients	Percentage
Pain and burning	101	33.7%
Swelling	13	4.3%
Fever	69	23%
Fatigue	88	29.3%
Nausea	59	19.7%
Vomiting	29	9.7%
Myalgia	71	23.7%
Diarrhea	32	10.7%

In both breast cancer and gastrointestinal cancer patients, no significant differences in average age were observed according to the presence of most COVID-19 vaccine side effects. Among patients with breast cancer, those who experienced nausea, vomiting, or myalgia had lower mean ages, whereas the opposite pattern was observed for several other side effects. Similarly, in gastrointestinal cancer patients, myalgia and vomiting were associated with slightly lower mean ages. Detailed information for both cancer types is presented in **Table 3.**

Table 3. Mean Age of Cancer Patients by COVID-19 Vaccine Side Effect

Side Effect	Breast Cancer Mean Age (SD) Absent	Breast Cancer Mean Age (SD) Present	Gastrointestinal Cancer Mean Age (SD) Absent	Gastrointestinal Cancer Mean Age (SD) Present	p-value (Breast)	p-value (GI)
Fatigue	49.8 (11.8)	53.4 (10.8)	53.9 (14.6)	54.1 (15.1)	0.12	0.92
Nausea	51.4 (11.8)	47.5 (9.4)	53.9 (14)	54.2 (16.9)	0.23	0.89
Vomiting	51.1 (11.7)	46.1 (7.7)	54 (14.7)	53.3 (14.9)	0.39	0.80
Myalgia	51.1 (11.5)	50.3 (11.9)	54.2 (14.2)	53.2 (16.3)	0.77	0.71
Diarrhea	50.6 (11.6)	56.8 (8.5)	54.3(15.1)	52.2(12.4)	0.24	0.49
Pain and burning	50.4(12)	51.7(10.8)	54.3 (14.3)	53.3 (15.6)	0.56	0.69
Swelling	50.7(11.5)	53.5(13.8)	53.7 (14.7)	59.8 (15.3)	0.57	0.28
Fever	50.7(12)	51.1(10.7)	53.5 (14.8)	56.2 (14.3)	0.86	0.36

Table 3 aligns the two cancer types side by side, showing the mean age ± SD for patients with and without each side effect, along with their p-values.

Vaccine Side Effects by Sex in Gastrointestinal Cancer Patients

The distribution of COVID-19 vaccine-related side effects among patients with gastrointestinal cancer was generally similar between females and males, with no significant differences observed for most side effects ($p > 0.05$). The exception was myalgia, which occurred more frequently in females than in males ($p < 0.05$). Overall, sex did not appear to influence the occurrence of vaccine-related side effects, aside from myalgia (**Table 4**).

  DOI: https://doi.org/10.18502/aptj.v5i4.21764

Table 4. Distribution of COVID-19 Vaccine Side Effects by Sex in Gastrointestinal Cancer Patients

Side Effect	Female Absent	Male Absent	Female Present	Male Present	p-value
Pain and burning	56 (46.3%)	65 (53.7%)	29 (49.2%)	30 (50.8%)	0.71
Swelling	82 (47.4%)	91 (52.6%)	3 (42.9%)	4 (57.1%)	0.81
Fever	69 (46%)	81 (54%)	16 (53.3%)	14 (46.7%)	0.46
Fatigue	62 (48.4%)	66 (51.6%)	23 (44.2%)	29 (55.8%)	0.60
Nausea	63 (46.3%)	73 (53.7%)	22 (50%)	22 (50%)	0.67
Vomiting	77 (49.4%)	79 (50.6%)	8 (33.3%)	16 (66.7%)	0.14
Myalgia	59 (69.5%)	77 (91.1%)	26 (30.5%)	18 (18.9%)	0.03
Diarrhea	72 (47.1%)	81 (52.9%)	13 (48.1%)	14 (51.9%)	0.97

Note: No statistically significant differences were observed for most side effects according to sex ($p > 0.05$), except for myalgia ($p < 0.05$).

Discussion

Several studies have shown that patients with cancer are at increased risk of COVID-19 infection and its adverse outcomes (13, 14), and vaccination has therefore been considered as a preventive measure for this population. It is essential to identify vaccine-related adverse events in different groups, especially in people with cancer. Prior studies have reported common side effects such as injection-site pain, fatigue, fever, and myalgia (14, 15).

In this study, pain and burning, weakness and fatigue, fever, and myalgia were reported by 34%, 30%, 23%, and 24%, respectively. Similar to our findings, Adzhab et al. also reported pain and burning, weakness and fatigue, fever, and myalgia as the most frequent side effects among patients with breast and colorectal cancer. It should be noted that, as in our study, more than 90% of patients had received the Sinopharm vaccine (16).

Studies by Tran et al. in 2021 and Waissengrin et al. also reported injection site pain as the most common complication of vaccine injection, with weakness and fatigue in second place (2, 14, 17).

Male patients reported slightly higher rates of side effects, though these differences were not statistically significant. This observation is consistent with So et al. and Safarnezhad et al., who found that male sex may predict higher vaccine-related adverse effects and stronger serologic responses (2, 16). Age was not significantly associated with side effects, although patients reporting side effects had slightly higher mean ages. This pattern agrees with earlier findings that cancer patients over 50 years tend to have weaker antibody responses to vaccination, which may explain the lack of age-related differences in side-effect profiles (16).

Among gastrointestinal cancer patients, pain and burning (32.8%), fatigue (28.9%), nausea (24.4%), and myalgia (23.3%) were the most common side effects. Compared to breast cancer patients, those with gastrointestinal malignancies experienced higher rates of nausea, vomiting, and diarrhea but lower rates of fever. These results are consistent with Li et al., who observed injection-

site pain (20%), fatigue (11%), and myalgia (6%) as the most frequent adverse effects among 157 gastrointestinal cancer patients (17). Although other studies have reported rare adverse effects such as thromboembolic events, myocardial infarction, erythema multiforme, and Stevens-Johnson syndrome, none were observed in the present study (18-20).

Notably, studies comparing Sinopharm with mRNA-based vaccines such as Pfizer-BioNTech and Moderna suggest that inactivated vaccines tend to produce fewer systemic side effects, though sometimes with lower immunogenicity (2, 14). The mild side-effect profile observed here supports the safety and tolerability of Sinopharm in cancer patients. However, the retrospective design of this study introduces recall bias and lacks precise data on concurrent treatment regimens, which could influence reported outcomes. Despite these limitations, the findings reinforce that COVID-19 vaccination is safe for patients with breast and gastrointestinal cancers and should be strongly encouraged in this vulnerable population.

Conclusion

In conclusion, the most common side effects of the COVID-19 vaccination among patients with breast and gastrointestinal cancers were injection-site pain and burning (34%), fatigue (30%), fever (23%), and muscle aches (24%). While fever occurred more often in breast cancer patients, those with gastrointestinal cancers were more likely to experience nausea, vomiting, and diarrhea.

Acknowledgment: None

Conflict of interest: The authors declared no conflict of interest

Funding: None

Authors' contributions: Z.A.M. and F.H. were responsible for the design of the study. A.F performed experiments. A. A and MZ analyzed and interpreted the results and A. A wrote the manuscript. All authors also contributed to the critical revision of the manuscript for important intellectual content, approved the final version, and are accountable for the integrity of its content.

Ethical Considerations: This study was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, with the IR.SSU.MEDICINE.REC.1400.415 code. Informed consent was obtained, and the confidentiality of information was maintained.

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