

Evaluation of Safety and Side Effects COVID-19 Vaccine in Cancer Patients Being Treated

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Abstract

According to the instructions of Iran's National Corona Response Committee in the Iranian Ministry of Health and Medical Education, patients undergoing treatments for their cancer are prioritized in Covid-19 vaccination. The present study was therefore conducted to investigate the toxicity and acute side-effects of a Covid-19 vaccine in cancer patients presenting to Medical Oncology Clinic of Kermanshah University of Medical Science. After excluding the patients with active infection and the recently-infected ones with Covid-19, they underwent the vaccination. The patients with cell counts exceeding 3,000 received two doses of the vaccine with a 21-day interval and treatment of their underlying disease was postponed for 7 days. The side-effects were mild and tolerable and included fever (case 10), pain at the injection site (7), dizziness (7), body pain (6), abdominal pain (6), myalgia (6), headache (6), chills (3), shortness of breath (3), diarrhea (1), runny nose (1) and dryness of the throat (1). No significant toxicity was reported in the patients who were safely vaccinated under the supervision of the medical oncology clinic.

Keywords: COVID-19 vaccines- cancer- side effect- Sinopharm

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Introduction

Covid-19 caused by an infectious agent belonging to the genus betacoronavirus was first identified in Wuhan, China and turned into a fatal pandemic that challenged health systems in all countries (Hu et al., 2021). Acute respiratory syndrome constitutes the worst clinical manifestation of this quickly and easily spreading disease (Wu et al., 2020). Wu and Mccolgan (2019) reported lack of pneumonia or a mild clinical picture in 81% of patients, severe involvement (hypoxemia, shortness of breath and over 50% lung involvement within 24-48 hours) in 14%, and critical conditions in 5% and mortality in 2.3%. Measures taken since the emergence of this pandemic such as social distancing, using gloves and face shields and screening for Covid-19 have decreased the spread of this disease (Aznab, 2019; WHO). In addition to causing global mortality, morbidity, anxiety and major psychological problems (Pera,2020; Pedrosa et al., 2020), Covid-19 exerted severe destructive effects on the world economy (James et al., 2021). The Covid-19 epidemic has unfortunately delayed and disrupted health care in cancer patients, and this may affect patient survival (Riera et al., 2021). The risks of mortality and infection with severe types of Covid-19 increase in individuals with underlying disease and older adults (CDC, 2020; Liu et al., 2021;

Shahidsales et al., 2021, Desai et al., 2021). The Centers for Disease Control and Prevention (CDC) reported high risks for developing severe Covid-19 and the associated mortality in cancer patients. The risk of the severe infection increases in patients with active cancer or metastasis and those in their first 5 years of treatment (Williamson et al., 2020; R  thrich et al.2020; Wang et al., 2021; Kuderer et al., 2020). Of course, in some studies, the role of the cancer stage in mortality has been more important (Aznab et al., 2022).Unfortunately, a low serological prevalence of SARS-CoV-2 antibodies has been observed among cancer patients after SARS-CoV-2 infection (Liu et al., 2020). Given the rapid spread of Covid-19 and increasing cases with its severe and potentially-fatal type, efforts were made from the very beginning to reduce the incidence and mortality of the disease by making vaccines, especially safe and healthy ones (Dong et al., 2020; Ariamanesh et al., 2022). Several professional organizations have provided primary guidelines on the role of the vaccine in patients with malignant diseases (Duly et al., 2022). Three COVID-19 vaccines receiving the US FDA emergency use authorization included the Pfizer-BioNTech recommended for ages of over 16 years and administered in two doses with an interval of 3 weeks (Pfizer–BioNTech, 2020, Coronavirus (COVID-19) Update 2021). The Moderna vaccine is recommended for ages of over 18 and

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administered in two doses with an interval of 4 weeks (Moderna, 2020). The J&J/Janssen vaccine is approved for ages of over 18 and administered in a single dose (Johnson & Johnson, 2020). The WHO also approved the Sinopharm vaccine in emergency cases (Taylor, 2021). The Ministry of Health and the Covid-19 Committee at the ministry faced a lack of accurate information about the effectiveness and safety of the vaccine in cancer patients. The Ministry recommended vaccination for all cancer patients based on the recommendations of the CDC and Shanghai Cooperation Organization and existing knowledge about other commonly-used vaccines such as influenza vaccine. On April 21, 2020, the Iranian Ministry of Health and Medical Education initiated a national campaign of vaccination against Covid-19 for cancer patients undergoing treatment in an attempt to rapidly vaccinate all individuals at risk by the end of April 2021 using the Sinopharm vaccine. The vaccine was made readily available to the patients despite its commonly-observed side-effects such as fever, fatigue and muscle pain, its uncommon side-effects such as dizziness and anorexia and its rare side-effects such as acute allergic reaction, lethargy and drowsiness (Beatty et al., 2021, Shimabukuro, 2021). The WHO also identified acute disseminated encephalomyelitis as a rarely-observed neurological disorder in patients receiving the vaccine (Kania et al., 2021). The institutional policy in the Department of Medical Oncology at the University of Medical Sciences was to encourage the vaccination in cancer patients irrespective of their disease stage, type of treatment and life expectancy.

Materials and Methods

Given the notification issued by the Ministry of Health through the media regarding the vaccination, all cancer patients undergoing treatment in the Medical Oncology Clinic were contacted and invited for the vaccination. Vaccine side effects are explained to patients and consent is obtained. Recently-infected patients with Covid-19 were supposed to be vaccinated later at an appropriate time. Patients with conditions such as active acute infection undergoing treatment were advised to postpone their vaccination until their recovery. The exclusion criteria comprised an age of below 18 years, side-effects associated with uncontrolled and impaired immune system, WBC counts of below 3,000 per μ l both before and after G-CSF administration and lack of a proper performance status. The standard recommended dose of the vaccine was administered on days 1 and 21, and the second dose was not administered if the patient developed Covid-19 after receiving the first dose. The second dose was, however, administered in the present study 5 weeks after the first. The patients began to undergo routine treatments seven days after their vaccination. They were provided with a checklist to record the side-effects of the vaccine and present in severe cases. The patients who had recently developed cancer were advised to be vaccinated before undergoing cancer therapy, and those with delayed cancer treatment were urged to give priority to their treatment over vaccination.

Results

Approximately 487 cancer patients, including 313 men and 174 females were vaccinated. Demographic information of cancer patients vaccinated is shown in Tables 1 to 4. These patients had been receiving different treatments for different cancers and they had no history of allergy that hinder their vaccination. Out of the 7 patients, belonging to the families of war veterans had received AstraZeneca (n=4) and Sputnik (n=3) vaccines in affiliated centers. Owing to their old age, one patient had received AstraZeneca and three Sputnik in their nearby centers. These 11 cases had neither made arrangements with the Medical Oncology Clinic and nor presented to the university-designated centers. A total of 476 patients ultimately received the Sinopharm vaccine according to the Ministry of health instructions. No significant vaccination side-effects were reported in patients with comorbidities such as heart disease, rheumatic diseases, diabetes and hepatitis. Multiple primary malignancies observed in two patients who received the Sinopharm vaccine included myeloma/colon cancer in one and breast cancer/dysgerminoma in the other. No vaccination side-effects were also observed in two patients receiving pembrolizumab for their Hodgekin's disease and metastatic colon cancer. The PCR test was found positive for Covid-19 in two patients ten to twelve days after their vaccination; pulmonary infection was the clinical picture of Covid-19 in one with breast cancer and lung and brain metastases. Diarrhea was observed in the other case with glioblastoma multiforme. The side-effects were mild and tolerable and mostly included fever (n=10), pain at the injection site (n=7), dizziness (n=7), body pain (n=6), abdominal pain (n=6), myalgia (n=6), headache (n=6), chills (n=3), shortness of breath (n=3), diarrhea (n=1),

Table 1. Frequency, Percentage Eligible Cancer Patients for Getting COVID19 Vaccine (Vaccination from April 21, 2020)

Type	Frequency	Percent
Breast	174	34.8
Gastric & Colon	107	21.4
HL&NHL&CLL&CML&MM&AML&HCL	96	19.2
Ovarian	9	1.8
Lung	18	3.6
Pancreatic biliary Tract	16	3.2
Glioblastoma Multiform	4	0.8
Bladder & Kidney	9	1.8
Melanoma	3	0.6
Metastasis of unknown origin	2	0.4
Head and Neck Cancer	7	1.4
Osteosarcoma	2	0.4
cervix/Uterine	10	2
Esophageal & GEJ	4	0.8
GIST	5	1
Sarcoma	5	1
Other*	16	3.2
Total	487	100

Table 2. Demographic Characteristics of Patients in Different Types of Solid Tumor

Type	Stage I	Stage II	Stage III	Stage IV	Relapsed	Total
Breast Cancer	15	69	59	24	7	174
Colon Cancer	4	30	23	18	4	79
Gastric Cancer	1	2	10	9	6	28
Pancreatic biliary Cancer		2	6	8		16
Ovarian Cancer			4	4	1	9
NSLC&SCC			12	6		18
Bladder & Kidney Cancer		5	3	1		9
Head and Neck Cancer		1	6			7
Uterine& Cervix Cancer		2	2	4	2	10
Sarcoma		3		2		5
Melanoma			1	2		3
GIST						5
Esophageal& GEJ			4			4
Brain tumor						4
Osteosarcoma						2
MUO				2		2
Other						16
Total						391

Other cancers include: Hepatocellular Carcinoma (1 case: Advanced); Pelvic Kidney (1 Case), Skin Squamous Cell Carcinoma (2 case: Advanced); GTN (3 Case: Advanced) ; Malignant Mesothelioma (2 Cases: Advanced);Mucinous Carcinoma Appendix (1 case: Advanced); Desmoids tumor (1case); Intestine Neuroendocrine(case :2 Case) ;Intestine Adenocarcinoma(3 case: Stage II)

runny nose (n=1) and dryness of the throat (n=1) by frequency(Table 5,6). A single case with severe lower extremity motor dysfunction and impaired balance relatively recovered. None of the reported side-effects required hospitalization or special interventions.

Discussion

According to the US CDC, vulnerability to Covid-19, severity of this disease and its mortality can be high in cancer patients. Covid-19 vaccines can help decrease problems in these patients, and this group are therefore prioritized in vaccination (Hwang et al., 2021); nevertheless, the issues requiring clarification in cancer patients receiving Covid-19 vaccines include the effects and potentially-significant side-effects of the vaccine in patients with immunodeficiency (Waleed et al., 2020), the risk of allergy to adjuvant substances in certain vaccines, the potential of these vaccines for protecting against severe Covid-19, and the prognosis and response to treatment considering interactions of the vaccine with the cancer and medications used. Treatments such as chemotherapy, immunotherapy and radiotherapy can counteract the effect of the vaccine (Noguchi et al., 2014; Body et al., 2022,). Although cytotoxic chemotherapeutics affect and suppress the proliferation and synthesis of (DNA) and the cell cycle, this suppression is incomplete and leads to the immune response to vaccination (Monin et al., 2021). The immune system can also respond to the vaccine in cancer patients undergoing targeted therapies with receptor tyrosine kinase inhibitors such as erlotinib, sunitinib and imatinib or monoclonal antibodies such as trastuzumab given that these medications do not directly suppress the

immune system (Kersh et al., 2017; de Lavallade et al., 2013). Immunity is estimated to be achieved about two weeks after receiving the first dose of the vaccine and increase afterwards. The reinforcing second dose helps prolong immunity and boost the immune system. The present study administered the Sinopharm vaccine in 476 of the patients. This inactivated vaccine promotes hormonal responses and its effects have been demonstrated in phase I and I clinical trials. The present findings showed no significant side-effects requiring interventions except for immobility and imbalance in one case with metastatic gastric cancer who relatively recovered after a week. The vaccine was therefore approved in terms of acute toxicity. Except for a mild fever, no significant side-effects were observed in the 11 patients who received Astrazeneca and Sputnik vaccines. The patients did not afford to have their immunity level investigated after their vaccination. Following up the patients to determine the incidence of Covid-19 and its severe type can help clarify the effect of this vaccine. Only two patients developed Covid-19 ten to twelve days after their vaccination. In line with most treatment groups, the present study recommends the vaccine for cancer patients undergoing treatment as soon as it is made available. The CDC, American Cancer Society and American (Oncology ASCO,2020), National Comprehensive Cancer Network (DiGiulio,2021) also recommend that cancer patients should be vaccinated when vaccines are available. More comprehensive studies over longer follow-ups are required for completely evaluating the advantages and disadvantages of Covid-19 vaccines. Immunity is achieved at least 2-3 weeks after receiving the first dose of the vaccine. Given the risk of infection with Covid-19 even in vaccinated individuals

Table 4. Demographic Characteristics of Patients in Different Types of the most Common Solid Tumor

Type Cancer	Means Age(y)	Stage I	Stage II	Stage III	Stage IV	Relapsed	F/M (n%)	Type T.A.C	Type Gem/NAV	Type Trastuzumab	RT	Oral Drug
Breast Cancer	49.76	15(8.6%)	69(39.6%)	59(33.9%)	24(13.7%)	7(4%)	97.6/2.31	65(37.3%)	25(14.3%)	34(19.5%)	20(11.4%)	30(17.2%)
	Means Age(y)	F/M (n%)	Stage I	Stage II	Stage III	Stage IV	Relapsed	Type T. T.C.F	Type T. Foltri/ Carboplatin	Type T. RT	Type T.	Type T.
Gastric Cancer	51.63	19/9 67/8/32.3	4(14.2%)	11(39.2%)	8(28.4%)	5(17.8%)	12(42.8%)	13(46.4%)	4(14.2%)			
	Means Age(y)	F/M (n%)	Stage I	Stage II	Stage III	Stage IV	Relapsed	Type T. Folfox4	Type T. Foltri/ avesin	Type T. Foltri. Ebitux	Type Capacitabin/Oxaliplatin	Type T.
Colon Cancer	51.52/55.46	55/34 (69.6%/30.4%)	44.3(39.7%)	35.4(30.6%)	21(26.5%)	5(6.3%)	45(56.9%)	12(15.1%)	9(11.3%)	22(27.8%)		

Table 3. Demographic Characteristics of Patients in Different Types of Hematologic Malignancy

Type Cancer	Stage I	Stage II	Stage III	Stage IV	Relapsed	Refractory	Mean Ag(yr)	Treatment ABVD ^a	Treatment Bendat/Gem/Oxa ^b	Treatment RT ^c	M/F
HodgkinB Lymphoma	4(18.8%)	6(28.2%)	3(14.1%)	-	5(23.5%)	2(10%)	36.7	12(56.4%)	6(28.2%)	2(9.4%)	11/8
					Low Grade(n)	Flu/Cyc/Ritu- mab ^d	Bendam/Rituxi- mab ^e	Treatment RT	Refractory		
Non Hodgkin Lymphoma	Stage I	Stage II	Stage III	Mean Ag (yr)	7(31.5%)	3	4	Hyper CVADg	Maintenance		8/4
	2(9%)	7(31.5%)	13(58.5%)	52.7yr	High Grade	CHOP-Rf	ESHAP/MINE ^e				
Chronic Blymphoid Leukemia	Mean Ag(yr)	F/M	Flu/Cyc/R	Bend/Rituxi- mab	Chlorambucil	8	1	1	5		
	59.88	8/9	5(35.2%)	3(17.6%)	15(68.5%)						
Chronic BMyleoid Leukemia	Mean Age(yr)	Male(n)	Female(n)	Imatinib	Nilotinib	15	1				
	45.68	8	8								
Acute BPrmyelocitic Leukemia	Arseenic : 3 Patients at Induction	ATRA:1 patient at Consolidation	Arseenic : 4 patients in Maintenance Therapy	Multiple My- eloma	Thalidomide : 2	Velcade:4 patients	C-VADj: 3patients	Linatidomide/ Melphalan:1			

ABVD^a, ABVD adriamycin (doxorubicin)-bleomycin-vinblastine-dacarbazine; C-VAD^b, CVAD-Th cyclophosphamide, vincristine, doxorubicin, dexamethasone-thalidomide; RT^c Radiotherapy; Bendam/Rituximab^d, Flu/Cyc/Ritumabd, mFludarabim /cyclophosphamide/Rituximab; CHOP-R^e, cyclophosphamide, vincristine, doxorubicin, Prednisoln-Rituximab; ESHAP/MINE^e, Etoposide, Ifosfamide, Mitoxantron/ Etoposide, Cisplatin, MethylPrednisol on, Cyctarabin; Hyper CVAD^g, cyclophosphamide, vincristine, doxorubicin

Table 5. Adverse Effect of Vaccination Based on Disease Stage in Different Types of Cancer

Type	S ^a	H ^β (n=6)	M ^λ (n=6)	F ^δ (n=10)	R ^E (n=1)	D ^φ (n=1)	A ^Γ (n=6)	B ^H (n=6)	C ^l (n=3)	P ³ (n=7)	D _i ^K (n=1)	Dy ^Λ (n=3)	Diz ^M (n=7)	D ^N (n=1)
Gastric	IV			*AZ										
Breast	II	*			*		*							
PBC	III													
Gastric	III		*			*								
Small Lc	III											*		
Ovarian	III						*							
Ovarian	Ren							*						
HL	II								*					
Breast	II		**	**			**							
Colon	II							*						
Esophge	IV	*												
Breast	IV	*												
MM			STg	*										
Breast	III			*										
colon	III			*AZ				*						
Ovarian	Refm		*	*										
Breast	II													*
CLL												*		
breast	III						*							
NSLC	IV													*
Uterine	III													*
Breast	III											*		
HL	Ren							*						
breast	III													*
breast	II													*
HL														*
breast	IV													*
Breast	IV													*
Ovarian	III		*	*										
breast	III								*					
breast	III							*						
colon	IV									*				
Colon	II										*			
Colon	IV								*					
Colon	III							*						
NSLCl	III									*				
Colon	II									*				
Cervix	II									*				
CML										*				
Breast	II									*				
Gastric	III									*				
Breast	IV				*ST									
APL				*ST										

S^a, Stage ; H^β, Headache ; M^λ, Myalgia ; F^δ, Fever ; R^E, Runny nose ; D^φ, DMS ; A^Γ, Abdominal pain ; B^H, Bodyache ; C^l, Chill ; P³, Pain at the injection site ; D_i^K, Diarrhea ; Dy^Λ, Dyspnea ; Diz^M, Dizziness Dr^N, Dryness of the throat, Re^v, Relapsed; Ref^h, Refractory; *AZ, Astrazenca; ST^v, SputniK

Table 6. Frequency and Percentage of Eligible Cancer Patients in Terms Comorbidity, and the Adverse Effect of Vaccination Based on Cancer Types (Vaccination from April 21, 2021)

Type	Comorbidity		The adverse effect of vaccination		Total
	Yes	No	Yes	No	
Pancreatic biliary Tract	0 0.00%	7 100.00%	0 0.00%	16 100.00%	16
Bladder & Kidney	0 0.00%	9 100.00%	0 0.00%	9 100.00%	9
Breast	1 0.90%	106 99.10%	17 0.9.7%	157 90.30%	174
Cervix	0 0.00%	0 100.00%	1 16.70%	5 83.30%	6
Colon	1 1.20%	78 98.80%	7 8.90%	72 91.10%	79
Glioblastoma Multiform	0 0.00%	4 100.00%	1 25.00%	3 75.00%	4
Hematological	2 0.00%	94 100.00%	7 9.40%	87 90.60%	96
Lung	0 0.00%	14 100.00%	1 5.60%	17 94.40%	18
Melanoma/MUO	0 0.00%	0 100.00%	0 0.00%	4 100.00%	4
Gastric Cancer/Esophageal	0 0.00%	2 100.00%	3 10%	27 90%	30
Head and Neck Cancer	0 0.00%	0 100.00%	0 0.00%	7 100.00%	7
Osteosarcoma	0 0.00%	0 100.00%	0 0.00%	2 100.00%	2
Ovarian	0 0.00%	6 100.00%	1 12.20%	8 88.80%	9
Germ Cell Tumor	0 0.00%	2 100.00%	0 0.00%	2 100.00%	2
GIST	0 0.00%	4 100.00%	0 0.00%	4 100.00%	4
Sarcoma	0 0.00%	5 100.00%	0 0.00%	5 100.00%	5
Uterine	0 0.00%	3 100.00%	1 25%	3 75.00%	4
Other	0 16.70%	18 83.30%	0 0.00%	18 100.00%	18
Total	5	482	39	448	487

and with a lower severity, these patients are advised to observe health protocols.

In conclusion, the side effects of vaccination have been acceptable. Due to the impossibility of performing serological tests for Covid-19 after vaccination, to prove the effectiveness of vaccination in patients in this study, it is not possible to comment on the effectiveness of the vaccine in the prevention of symptomatic Covid-19. But in the long-term follow-up of these patients, only two patients developed symptomatic Covid-19 and no vaccinated person with cancer has died from Covid-19.

Therefore, vaccination is recommended as the most important factor in preventing symptomatic and lethal Covid-19

Author Contribution Statement

MA contributed to concepts, design, the definition of intellectual content, clinical studies, manuscript preparation, manuscript editing, manuscript review, and data acquisition and is the guarantor; MC; SD; MR contributed to concepts, design, literature search,

data acquisition, data analysis, manuscript preparation, manuscript editing, and manuscript review

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Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Availability of data and material

No additional data are available.

Ethics approval

Approval was obtained from the ethics committee of Kermanshah University of Medical Sciences.

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