Assessment of Efficacy and Safety of COVID-19 Vaccination in Cancer Patients of Pakistan

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- Sadaf Ishaq

Dedicated to my husband, ***Mr. Muhammad Athar Farooq****,*
whose tremendous support and cooperation lead me to this
wonderful accomplishment.


بسم الله الرحمن الرحيم

ABSTRACT

Protection through a thorough vaccination campaign has become crucial with the beginning of the second wave of COVID-19 infection globally, notably in Pakistan in March-April 2021. The effectiveness of vaccines in lowering the chance of contracting serious illnesses makes them essential weapons in the fight against COVID-19. According to the GLOBOCAN database, approximately, 19.3 million new cases in 2020 of cancer were recorded. which made it difficult for medical practitioners to safeguard so many "sensitive" people against COVID-19. The COVID-19 outbreak could only be stopped after it had begun through vaccination. Around the world, there is doubt regarding the effectiveness and safety of the current COVID-19 immunization. Investigating the adverse consequences of post-COVID-19 vaccination is the goal of this study, in cancer and non-cancer subjects who received a range of vaccinations, including inactivated viral vaccines (Sinopharm and Sinovac), RNA-based vaccines (Moderna and Pfizer), and non-replicating viral vaccines (AstraZeneca and Casino bio) based on Adenovirus (Sputnik-V). In this study, questionnaires and interviews were used to examine the concurrent side effects of various COVID-19 vaccines in populations with and without cancer. IBM-SPSS was used to analyze the data using a chi-square test and an independent sample T-test. The non-cancer category was where the majority of the negative effects were documented. Patients who received the vaccine safely under the care of the medical oncology clinic reported no significant toxicity. Concluded that these vaccines are safe for both cancer patients and people without cancer. Based on the information available, we advise cancer patients to get the inactivated viral-based COVID-19 vaccination.

Key words: COVID-19 Vaccination, Side effects of Vaccination , Cancer.

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ABBREVIATIONS

COVID-19	Coronavirus Disease of 2019
SARS –CoV- 2	Severe Acute Respiratory Syndrome Corona Virus 2
CCC	COVID-19 and Cancer Consortium
PHEIC	Public Health Emergency of International Concern
IARC	International Agency for Research on Cancer
WHO	World Health Organization
SPSS	Statistical Package for Social Sciences
ICIs	Immune Checkpoint Inhibitors

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CHAPTER # 1

Introduction

Cancer is one of the world's deadly diseases and the leading cause of death. Cancer claims the lives of almost a million Pakistanis each year. Cancer sufferers are amid the continuing worldwide pandemic COVID-19, which is comparable to the deep blue sea. Cancer patients undergoing active treatment are undoubtedly more vulnerable to infection or COVID-19 infection. The Covid-19 and Cancer Consortium (CCC-19 registry) inaugural report in 2020 states that they initially documented the data of 928 cancer patients who were infected with Covid-19 and reported a mortality rate of 13% [1-5].

The viral agent SARS-CoV-2, which can produce upper or lower respiratory tract infection, is what causes the coronavirus disease (COVID-19) (sinuses, nose, and throat). On January 30, 2020, the World Health Organization (WHO) designated the coronavirus disease 2019 (COVID-19) outbreak as a Public Health Emergency of International Concern (PHEIC), and on March 11 of the same year, COVID-19 was designated as a pandemic [6]. The COVID-19 coronavirus is more likely to infect cancer patients, suffering harmful consequences. A study found that 16,570 people with covid-19 positive findings were among the 273,000 people in the US who received a cancer diagnosis. This shows that cancer patients have a greater chance of contracting SARS-COV-2. Additionally, those who have been given a lung cancer, non-lymphoma, Hodgkin's, or leukemia diagnosis are more likely to get an infection. A higher death rate is shown in patients who have both cancer and COVID-19, than those who are only corona positive [7–9]

Cancer patients were disadvantaged by this pandemic in several ways, including delayed diagnosis, restricted access to necessary medical treatment, and poor management. Additionally, cancer patients were regarded as a high-risk group because they had a 3.5-fold greater likelihood of needing mechanical breathing or dying after being admitted to

an intensive care unit [10]. With the beginning of a second wave of COVID-19 infection over the world in March-April 2021, vaccination of cancer patients becomes essential. Patients and oncologists had to decide which vaccinations including the COVID-19 shot to prioritize when vaccine supplies were low. Clinical studies for COVID-19 vaccination only include a small number of cancer patients. It is unclear how much this vaccination benefits cancer patients [11]

1.1 Statistics of Cancer

According to the GLOBOCAN database 2020, there were 178388 new diagnoses of cancer recorded, it is estimated that 117149 people died from cancer, and the prevalence over the preceding five years was 329547. The revised Globocan 2020, which was issued by the IARC on December 14th, contains fresh estimates of the global cancer burden, showing that 10.3 million people will die from cancer and 19.3 million people would be diagnosed in 2020. The International Agency for Research on Cancer (IARC) has estimated that 1 in 5 people will develop cancer at some time in their life, and that 1 in 8 men and 1 in 11 women will die from it. More than 50 million people, according to these latest figures, are still alive five years after receiving a cancer diagnosis [2].

1.2 Statistics of COVID-19 In Pakistan

There were two verified cases on February 26, 2020, but by the end of August 2022, there were over 603 million cases nationwide. 6.47 million people will have passed away globally by August 31st, 2022. 131 M (59.5%) persons in Pakistan have received every recommended vaccination [3]. (WHO)

1.3 COVID-19 Vaccination

There are three primary approaches to vaccine development. They vary depending on whether a full virus or bacterium is used, only the immune system-stimulating elements

of the germ, or just the genetic material that carries the instructions for generating certain proteins in place of the whole virus.

Chemicals, heat, or radiation are used in inactivated viral vector vaccines to destroy or inactivate the disease-causing virus, bacterium, or a very near related. The vaccines Sinopharm and Sinovac are included. In a live-attenuated vaccination, a virus that has been weakened or one that is strikingly identical to it is included. This approach employs technology similar to that of the inactivated vaccine and is scaleable. However, those with compromised immune systems might not be good candidates for these vaccinations. CanSino Bio and AstraZeneca fall within this category. In order to stimulate an immune response without actually spreading disease, a viral vector vaccine employs a safe virus to transfer specific parts, or proteins, of the target germ. To do this, a safe virus is altered to include the instructions for synthesizing specific pathogen-related components. In contrast to previous vaccination approaches, a nucleic acid vaccine only makes use of the region of the microbe's genetic code that includes the instructions for specific proteins, not the entire organism. For the creation of proteins like Pfizer and Moderna, our cells adhere to the instructions found in DNA and RNA [12].

1.4 Side Effects of Vaccination:

A list of possible side effects is provided by vaccine manufacturers with their products. Adverse vaccination reactions show the vaccine's efficacy and the building of immunity to the illness. Among the side effects include pain and swelling at injection site, redness or a rash at the injection site, enlarged lymph nodes, fatigue, headache, cold, fever, muscle and joint discomfort, and nausea. [13]. According to the Centers for Disease Control and Prevention (CDC), the majority of these symptoms should disappear within a few days [14]. Vaccination frequently has some benefits in lowering the risk of developing severe SARS-CoV-2 illness and mortality, according to published evidence. One of the key

factors influencing whether or not someone is ready to receive the COVID-19 vaccine is fear of its unfavorable side effects [15].

1.5 Aims and Objectives

Objectives of this research are:

1. To assess the impact of the COVID-19 vaccination's side effects on the Case group (cancer patients) as well as the control group (Non-cancer individuals)
2. To compare which vaccine has more severe side effects on the Case group as well as the control group.
3. To identify which vaccine is best suitable for the Case group as well as the control group.

1.6 Literature Review

Cancer is a broad category of disorders that can spread to other tissues and organs when aberrant cells divide fast. Cancer is one of the leading causes of death around the globe. According to the World Health Organization (WHO), cancer will account for around 1 in 6 fatalities in 2020 [16]. Antitumor immunotherapy led to a significant increase in the number of cancer patients who underwent physical changes to become immuno-compromised individuals (e.g., immune checkpoint inhibitors [ICIs]). Instead, individuals get tumor treatment that somehow alters their immune system. This may indicate that these individuals are more vulnerable to disease and infections [17]. With the covid-19 pandemic outbreaks globally cancer patients were more prone to it, due to their compromised immunity. There is a knowledge gap as well, particularly for COVID-19, a new Covid-19 breathing condition that affects cancer patients. Contrary to certain viruses, Covid-19 has not been shown to result in more serious, life-threatening infections in immunocompromised people.

A COVID-19 infection in certain people causes an uncontrolled aberrant

inflammatory response that damages lung tissue in addition to the specific viral pathogenicity. COVID-19 may therefore provide a concern to cancer patients receiving immunotherapy (e.g., ICIs). Patients, especially those receiving aggressive oncologic therapy, may be among the infectious population's most vulnerable individuals. Specific data on tumor history, anti-tumor therapy, respiratory course, laboratory tests, and mortality rates are scarce [18]. Oncology departments in the affected countries had to change swiftly and create new groups with clear objectives.

The inactivated SARSCoV-2 virus is used to create SinoVac in order to elicit an immunological response. The SinoPharm-produced SARS-CoV-2 Vaccine (Vero Cell) is an inactivated variation of the Covid-19 vaccine. Inactivated vaccinations expose the immune system to the virus using inactivated viral particles without running the danger of a severe illness reaction. The immunization can prevent the majority of people from acquiring COVID-19, even if it is not 100% effective, according to the World Health Organization [21], and there may be a very small percentage of people who do not obtain protection even after receiving the vaccine. There is currently a lot of study being done on the post-vaccination adverse effects, including cancer patients reported after vaccination, and there have been multiple studies done over the last 3 years as COVID-19 immunization is a recent phenomenon after COVID-19 pandemic. However, there are many features of the COVID-19 vaccine that remain unknown.

CHAPTER # 2

Materials & Methods

Since the purpose of the study was to assess the efficacy and safety of COVID-19 vaccination against cancer patients in Pakistan, the following are the hypotheses of the study.

2.1 Hypotheses

H1: Case group has a higher acceptance of COVID– 19 vaccines by representing fewer side effects than the control group.

2.2 Sub- Hypotheses

H1.1: COVID – 19 Vaccine is well tolerated in different types of cancer.

Instruments: Following instruments were used in this study.

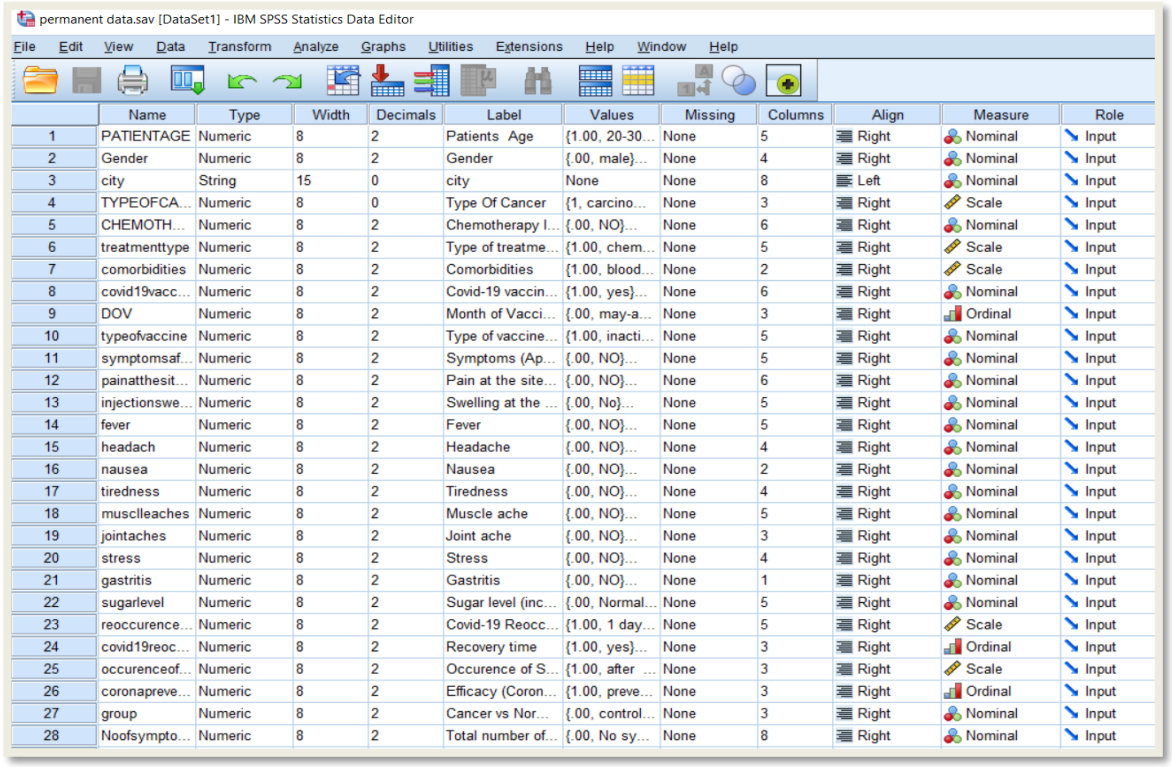
2.3 Demographics Questionnaire

This includes questions about the participant's socio-demographic factors (age, gender, and locality), Previous COVID-19 infection, kind of vaccine received, and side effects of COVID-19 vaccination (injection site pain, swelling at the injection site, muscle pain, joint pain, headache, fever, fatigue, nausea, stress due to fear of vaccination, Gastritis and increase in sugar level) and clinical factors about the diagnosis, presence of metastatic disease, and modality of the therapy was completed. (type of cancer, duration post-diagnosis, stage of cancer, and current treatment method) related to their illness.

2.4 Research Design

It was a cross-sectional, observational study with a self-administered questionnaire delivered to every patient, conducted between May 2022 to June 2022 at the Oncology Department of Combined Military Hospital Rawalpindi. The study involved two different groups of people: 100 healthy persons (non-cancer) who make up the control group and

100 cancer patients who make up the case group.



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	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure	Role
1	PATIENTAGE	Numeric	8	2	Patients Age	{1.00, 20-30...	None	5	Right	Nominal	Input
2	Gender	Numeric	8	2	Gender	{.00, male}...	None	4	Right	Nominal	Input
3	city	String	15	0	city	None	None	8	Left	Nominal	Input
4	TYPEOFCA...	Numeric	8	0	Type Of Cancer	{1, carcino...	None	3	Right	Scale	Input
5	CHEMOTH...	Numeric	8	2	Chemotherapy I...	{.00, NO}...	None	6	Right	Nominal	Input
6	treatmenttype	Numeric	8	2	Type of treatme...	{1.00, chem...	None	5	Right	Scale	Input
7	comorbidities	Numeric	8	2	Comorbidities	{1.00, blood...	None	2	Right	Scale	Input
8	covid19vacc...	Numeric	8	2	Covid-19 vaccin...	{1.00, yes}...	None	6	Right	Nominal	Input
9	DOV	Numeric	8	2	Month of Vacci...	{.00, may-a...	None	3	Right	Ordinal	Input
10	typeofvaccine	Numeric	8	2	Type of vaccine...	{1.00, inacti...	None	5	Right	Nominal	Input
11	symptomsaf...	Numeric	8	2	Symptoms (Ap...	{.00, NO}...	None	5	Right	Nominal	Input
12	painatthesit...	Numeric	8	2	Pain at the site...	{.00, NO}...	None	6	Right	Nominal	Input
13	injectionswe...	Numeric	8	2	Swelling at the ...	{.00, No}...	None	5	Right	Nominal	Input
14	fever	Numeric	8	2	Fever	{.00, NO}...	None	5	Right	Nominal	Input
15	headach	Numeric	8	2	Headache	{.00, NO}...	None	4	Right	Nominal	Input
16	nausea	Numeric	8	2	Nausea	{.00, NO}...	None	2	Right	Nominal	Input
17	tiredness	Numeric	8	2	Tiredness	{.00, NO}...	None	4	Right	Nominal	Input
18	musclleaches	Numeric	8	2	Muscle ache	{.00, NO}...	None	5	Right	Nominal	Input
19	jointaches	Numeric	8	2	Joint ache	{.00, NO}...	None	3	Right	Nominal	Input
20	stress	Numeric	8	2	Stress	{.00, NO}...	None	4	Right	Nominal	Input
21	gastritis	Numeric	8	2	Gastritis	{.00, NO}...	None	1	Right	Nominal	Input
22	sugarlevel	Numeric	8	2	Sugar level (inc...	{.00, Normal...	None	5	Right	Nominal	Input
23	reoccurence...	Numeric	8	2	Covid-19 Reocc...	{1.00, 1 day...	None	5	Right	Scale	Input
24	covid19reoc...	Numeric	8	2	Recovery time	{1.00, yes}...	None	3	Right	Ordinal	Input
25	occurenceof...	Numeric	8	2	Occurence of S...	{1.00, after ...	None	3	Right	Scale	Input
26	coronapreve...	Numeric	8	2	Efficacy (Coron...	{1.00, preve...	None	3	Right	Ordinal	Input
27	group	Numeric	8	2	Cancer vs Nor...	{.00, control...	None	3	Right	Nominal	Input
28	Noofsympto...	Numeric	8	2	Total number of...	{.00, No sy...	None	8	Right	Nominal	Input

Figure 1: Data Collection Form

2.5 Data Collection

A total of 245 eligible individuals participated in this study; however, 20 people left the survey incomplete, and 25 refused to participate. So, 45 individuals were excluded from the study. Thus, 200 participants submitted their written consent: 100 with cancer (Case group) and 100 without cancer (Control group). All fully vaccinated individuals who agreed to complete an individual paper questionnaire were included and excluded from those patients who were not vaccinated. Those who were chosen received no compensation.

The current study used a cross-sectional research approach. First, the approval letter for data gathering was signed by the head of the biological sciences. An approval letter, together with study procedures, was delivered to the hospital research departments for data collection. The researcher's interview was done after obtaining permission from the

hospitals. The motivation for the study, as well as full details of the data gathering procedure, were covered in the interview. A few days later, the ethical review board and ethics committee of the individual hospitals obtained ethical permission. The data gathering procedure began by submitting research approval letters to the medical and radiation oncology departments. Later, cancer patients were solicited for participation in the study, and questionnaires were provided individually by the researcher to obtain the necessary data for the study.

From May 2022 to June 2022, data was collected consistently from cancer patients. Before assessing patients, formal introductions were given, and the goal of the research was explained in simple terms to the patients. They were both verbally explained and given an informed consent form that mentioned avoiding injury, safeguarding anonymity and confidentiality, and having the ability to withdraw from the study. Their desire to participate was expressed by a signed written informed permission. The investigator explained any questions about questionnaires throughout the survey administration procedure.

It was chosen to use Urdu scales for data collecting to account for the language barrier. A pilot study was carried out before data collection to see whether the instruments were culturally suitable for the demographic being studied. Thirty cancer patients who agreed to participate in this study were contacted for it. The study questionnaires were distributed, and the participants were asked for input on how well they could understand and comprehend the instruments that had been chosen. Their suggestions were taken into account, and adjustments were made as a result. The researcher then delivered the questionnaires to each person to gather the necessary information for the study.

2.6 Ethical Considerations:

The head of the hospital's oncology department received the permission letter from the

director of the ethical review board. The cancer patients who were approached for the research provided written, informed consent and signed it. Formal introductions were made by the researcher before the administration of the instruments chosen for the investigation. The participants were orally informed of the study's goals and the purpose of the scales. The study procedure was advanced by obtaining the participants' written informed permission to avoid any damage and fraud. They had been offered the option to withdraw from the research and had their privacy and confidentiality guaranteed. The participants in the research were asked to complete all of the items without skipping a beat and to provide truthful responses to all of the questions.

2.7 Data Analysis:

For the statistical analysis, IBM SPSS Statistics v. 26.0 was employed. Descriptive statistics (frequency, percentage) were computed, and the chi-square test of independence was used to assess the association between categorical factors, the presence of side effects, and the kind of vaccination delivered. The odds ratio was calculated using binomial logistic regression analysis. It was used to investigate the predictors of vaccination side effects. A statistically significant p-value of < 0.05 was used.

CHAPTER # 3

Results

The purpose of the current study was to evaluate COVID-19 vaccination safety and effectiveness for cancer patients in Pakistan. Cancer patients receiving treatment and visiting the hospital were chosen for these exploratory aims. For the present study, the data were collected from cancer patients and entered into SPSS. Before conducting any statistical analysis; the data were screened out for data entry errors. Since the data was collected through one-to-one interaction, it did not display any missing value. To analyze data, several statistical procedures were done. These procedures include a t-test used to get the average mean value, Chi-square method was used to assess the relationship between side effects and vaccination. In addition, the percentages of cases and non-cases were assessed in the given sample. In the end, binary logistic regression was computed to investigate the predictors of vaccination side effects in study variables, while keeping the other variables (Covariates) constant.

3.1 Descriptive Statistics

To examine the sample characteristics, frequencies and percentages of demographic and clinical variables were computed.

Table 1: Frequencies (f) and Percentages (%) of demographics and clinical Variables(N=200).

Variables	Categories	F	%
Patient Age	20-30	24	12.0
	31-40	52	26.0
	41-50	59	29.5
	51-60	43	21.5
	above 60	22	11.0
Gender	Male	102	51.0
	Female	98	49.0
Type of cancer	Carcinoma	66	33.0
	Sarcoma	14	7.0
	Blood cancer	20	10.0
Type of treatment	Chemotherapy	50	25.0
	Radiotherapy	9	4.5
	Hormonal therapy	6	3.0
	Current chemo and radio therapy	26	13.0
	Surgery and chemo	9	4.5
Comorbidities	Blood Pressure	30	15.0
	Diabetes	19	9.5
	None	151	75.5
Type of Vaccine	Inactivated virus based vaccine	158	79.0
	RNA based vaccine	26	13.0
	Non Replicating viral vaccine	10	5.0
	Adeno virus based vaccine	6	3.0

Table 1 indicates frequencies and percentages of study participants comprised of an almost equal number of males and females with an age range from twenty to above sixty years. All individuals were vaccinated with a different type of vaccine. Cancer patients receive different types of treatment according to their respective diseases. In addition,

the frequency was high for participants with carcinoma. Chemotherapy was a more frequent treatment method followed by medications and radiotherapy.

3.1.1 Distribution of Age Group for COVID-19 Vaccination:

Out of the 200 participants who responded to the questionnaire, 102 (51%) were women and 98 (49%) were males. Among them 158 candidates had received the SinoVac and SinoPharm vaccine (or 79%), 26 candidates (or 13%) had received Pfizer and Moderna vaccine, 10 candidates (or 5%) had gotten the AstraZeneca and CanSino bio vaccine, and 6 candidates (or 3%) who had received the Sputnik V vaccination. Figure 1 shows that the age range of the people who have gotten vaccinations is from 20 to over 65.

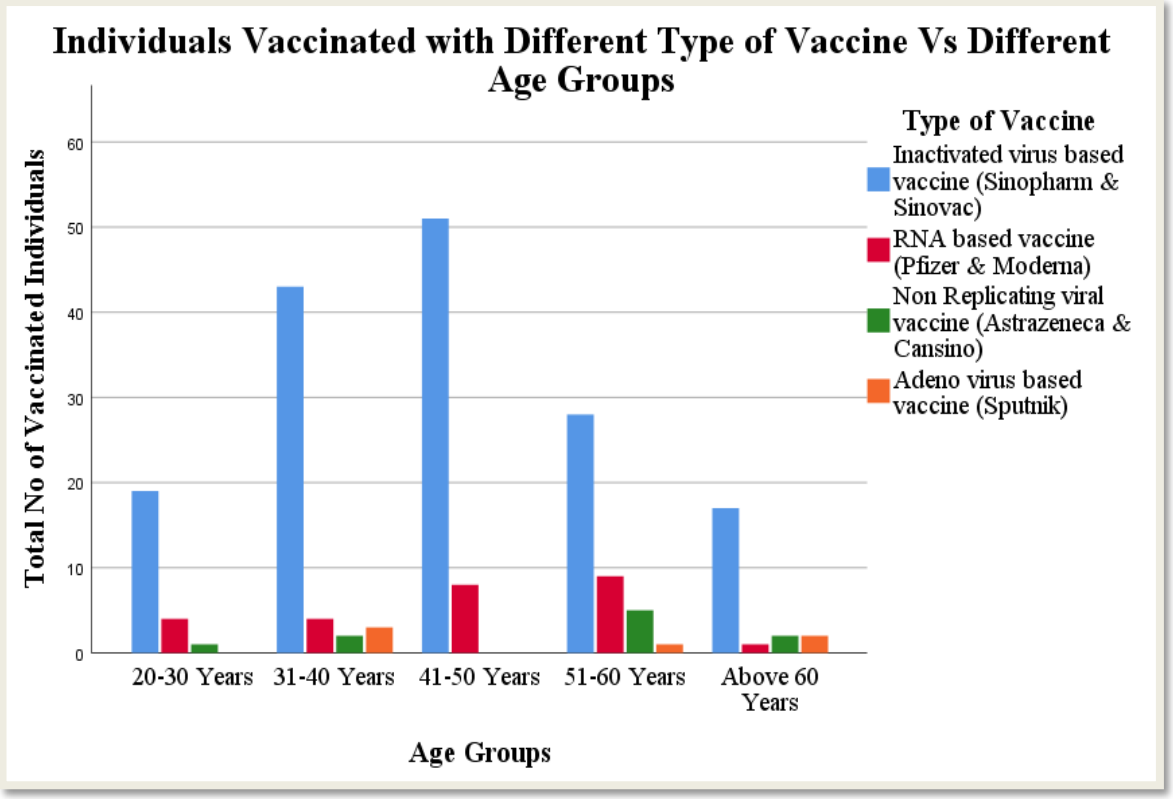

Fig 4.1: Individuals with Different Age Group Administered with Different Type of COVID-19 Vaccine

Table 2: Independent sample t-test to compare the means of two groups (N=200)

Variables	Groups		M	SD	t	df	Sig	CI = 95% LL	CI = 95% UL	Cohen's d
Total no of symptoms appeared	Gender	Male	4.00	4.66	0.309	198	.75	-1.0	1.50	0.04
		Female	3.79	4.67						
	Cancer vs Normal	Control	7.09	4.62	13.26	115.0	.00	5.42	7.33	1.87
		Case	.71	1.32						

Table 2 shows that for N = 200, the control group (normal individuals) had a high score with several symptoms as compared to the case group (cancer patients), However, the difference is 6.38 was statistically significant and represents a large effect size, calculated by Cohen's d. Moreover, the table above also indicates that on average females had less scores with the number of symptoms as compared to males. However, the difference is 0.2041 was statistically not significant and represents a very small effect size, calculated by Cohen's d.

Table 3: The Chi-Square test of independence shows the relationship of side effects with the Control and Case group (N=200)

Control and Case Group						
Variable	**Group**	**No**	**Yes**	***X* 2 (Value)**	***p***	**V**
Pain at the site of injection	Control group	22(22.0%)	78(78.0%)	127.86	.00*	0.800(0.00)
	Case group	100(100%)	0(0.0%)			
Swelling at the site of injection	Control group	35(35.0%)	65(65.0%)	82.332	.00*	0.642(0.00)
	Case group	96(96.0%)	4(4.0%)			
Fever	Control group	38(38.0%)	62(62.0%)	38.365	.00*	0.438(0.00)
	Case group	81(81%)	19(19%)			
Headache	Control group	42(42.0%)	58(58.0%)	59.282	.00*	0.544(0.00)
	Case group	93(93.0%)	7(7.0%)			
Nausea	Control group	27(27.0%)	73(73.0%)	100.538	.00*	0.709(0.00)
	Case group	96 (96%)	4(4.0%)			
Tiredness	Control group	30(30.0%)	70(70.0%)	86.927	.00*	0.659(0.00)
	Case group	94(94.0%)	6(6.0%)			
Muscle Pain	Control group	43(43.0%)	57(57.0%)	36.264	.00*	0.426(0.00)
	Case group	84 (84%)	16(16.0%)			
Joint Pain	Control group	39(39.0%)	61(61.0%)	70.918	.00*	0.595(0.00)
	Case group	95 (95%)	5(5.0%)			
Stress	Control group	49(49.0%)	51(51.0%)	49.687	.00*	0.498(0.00)
	Case group	94 (94%)	6(6.0%)			
Gastritis	Control group	40(40.0%)	60(60.0%)	85.714	.00*	0.655(0.00)
	Case group	100(100%)	0(0.0%)			
Sugar Level	Control group	47(47.0%)	53(53.0%)	62.004	.00****	0.557(0.00)
	Case group	97 (97%)	3(3.0%)			

Note: *X2= Chi Square; p= Significance, *p<.05.*

Table 3 shows the chi-square test results in order to find the association of side effects of COVID-19 vaccination with normal individuals and cancer patients. Results revealed a statistically significant association with Pain at the site of injection, injection site swelling, Fever, headache, nausea, fatigue, joint pain, and muscle pain, Stress, Gastritis, and Sugar level. The effect size of these variables lies in the medium to large range (Pallant, 2020). Hence the result shows that all the symptoms have appeared in non-cancer individuals as well as cancer patients.

3.2 Trends of Side Effects in Control and Case group:

Figure shows that 70% of the control group and 7% of patients in the Case group had negative effects after vaccination., 93% of patients in our research sample reported no negative effects following immunization. The control group therefore significantly contributes to the significance of side effects.

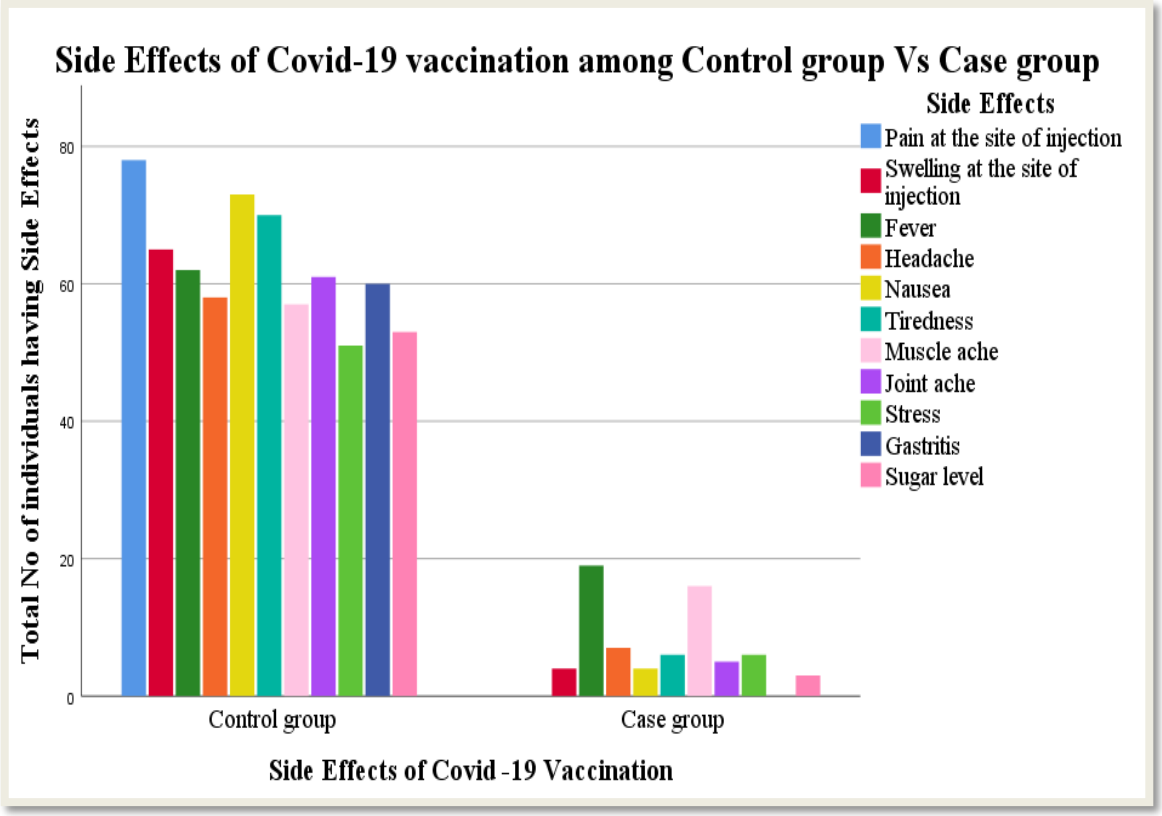

Fig 4.2: Different Side Effects After COVID-19 Vaccination Among Control and Case group

Table 4: The Chi-Square test of independence shows the relationship of side effects with the type of vaccine (N=200)

Type of Vaccine						
Variables	**Group**	**NO**	**YES**	χ^2 **Value**	***P***	**V**
Pain at the site of injection	Inactivated viral vaccine	90(57.02%)	68(43.0%)	9.763	**.015***	0.220(0.02)
	RNA based Vaccine	21(80.8%)	5(19.2%)			
	Non replicating viral vaccine	5(50.0%)	5(50.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Swelling at the site of injection	Inactivated viral vaccine	100(63.3%)	58(36.7%)	5.856	.116	0.174(0.10)
	RNA based Vaccine	20(76.9%)	6(23.1%)			
	Non replicating viral vaccine	5(50.0%)	5(50.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Fever	Inactivated viral vaccine	91(57.6%)	67(42.4%)	6.820	.06	0.186(0.07)
	RNA based Vaccine	18(69.2%)	8(30.8%)			
	Non replicating viral vaccine	4(40.0%)	6(60.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Headache	Inactivated viral vaccine	107(67.7%)	51(32.3%)	8.798	**.02***	0.220(0.02)
	RNA based Vaccine	19(73.1%)	7(26.9%)			
	Non replicating viral vaccine	3(30.0%)	7(70.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Nausea	Inactivated viral vaccine	93(58.9%)	65(41.1%)	6.164	.09	0.177(0.10)
	RNA based Vaccine	19(73.1%)	7(26.9%)			

	Non replicating viral vaccine	5(50.0%)	5(50.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Tiredness	Inactivated viral vaccine	90(57.0%)	68(43.0%)	11.256	**.00***	0.235(0.01)
	RNA based Vaccine	22(84.6%)	4(15.4%)			
	Non replicating viral vaccine	6(60.0%)	4(40.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Muscle Pain	Inactivated viral vaccine	96(60.8%)	62(39.2%)	4.897	.17	0.159(0.16)
	RNA based Vaccine	19(73.1%)	7(26.9%)			
	Non replicating viral vaccine	6(60.0%)	4(40.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Joint Pain	Inactivated viral vaccine	100(63.3%)	58(36.7%)	7.729	**.04***	0.198(0.05)
	RNA based Vaccine	22(84.6%)	4(15.4%)			
	Non replicating viral vaccine	6(60.0%)	4(40.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Stress	Inactivated viral vaccine	110(69.6%)	48(30.4%)	4.068	0.25	0.149(0.22)
	RNA based Vaccine	21(80.8%)	5(19.2%)			
	Non replicating viral vaccine	6(60.0%)	4(40.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Gastritis	Inactivated viral vaccine	106(67.1%)	52(32.9%)	6.092	.09	0.178(0.09)
	RNA based Vaccine	22(84.6%)	4(15.4%)			
	Non replicating viral vaccine	6(60.0%)	4(40.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			
Sugar Level	Inactivated viral vaccine	113(71.5%)	45(28.5%)	4.588	.20	0.159(0.16)
	RNA based Vaccine	20(76.9%)	6(23.1%)			
	Non replicating viral vaccine	5(50.0%)	5(50.0%)			
	Adenovirus based	6(100.0%)	0(0.0%)			

Note: *X2= Chi Square; p= Significance, *p<.05.*

Table 4 shows the chi-square test results in order to find the association between different types of COVID-19 Vaccines with their side effects. Results revealed statistically significant association of different type of vaccines with injection site pain, Headache, Tiredness, Joint Pain. The effect size of these variable lie in the small range (Pallant, 2020). Moreover, the table above also indicates that there was no significant association of different type of vaccines with injection site swelling, Cold, Nausea, Muscle Pain, Stress, Gastritis, and sugar level. Hence the result shows that appearance of symptoms including pain of muscles at injection site, Headache, Tiredness and joint pain are more prevalent among side effects of different type of vaccines.

3.3 Prevalence of Adverse Effects Among Various COVID-19 Vaccines:

Figure displays the prevalence of adverse responses among those who received various vaccination types. Of the 158 people vaccinated with SinoVac and Sinopharm, 68 individuals (43%) reported injection site pain, 58(36.7%) reported swelling at the injection site, 67 (42.5 %) reported fever, 51 (32.3%) reported headaches, 68 (43.0%) reported tiredness, 65 (41.1%) reported nausea, 62 (39.2%) reported muscle pain, 58 (36.7%) reported joint pain, 48 (30.4%) reported stress due to vaccine, 52 (32.9%) reported Gastritis, 45(28.5%) reported increase in sugar. Individuals vaccinated with Pfizer, Moderna, AstraZeneca, and CanSino reported extremely little negative effects. No negative effects were noticed with Sputnik V due to the limited study size of only six participants. In our study group, 87 (43.5%) individuals with most of them being cancer patients reported no symptoms, 49 (24.5%) individuals had all the aforementioned side effects, and 64 (32%) individuals had five or six of these reactions. None of the observed adverse effects required hospitalization or special treatment.

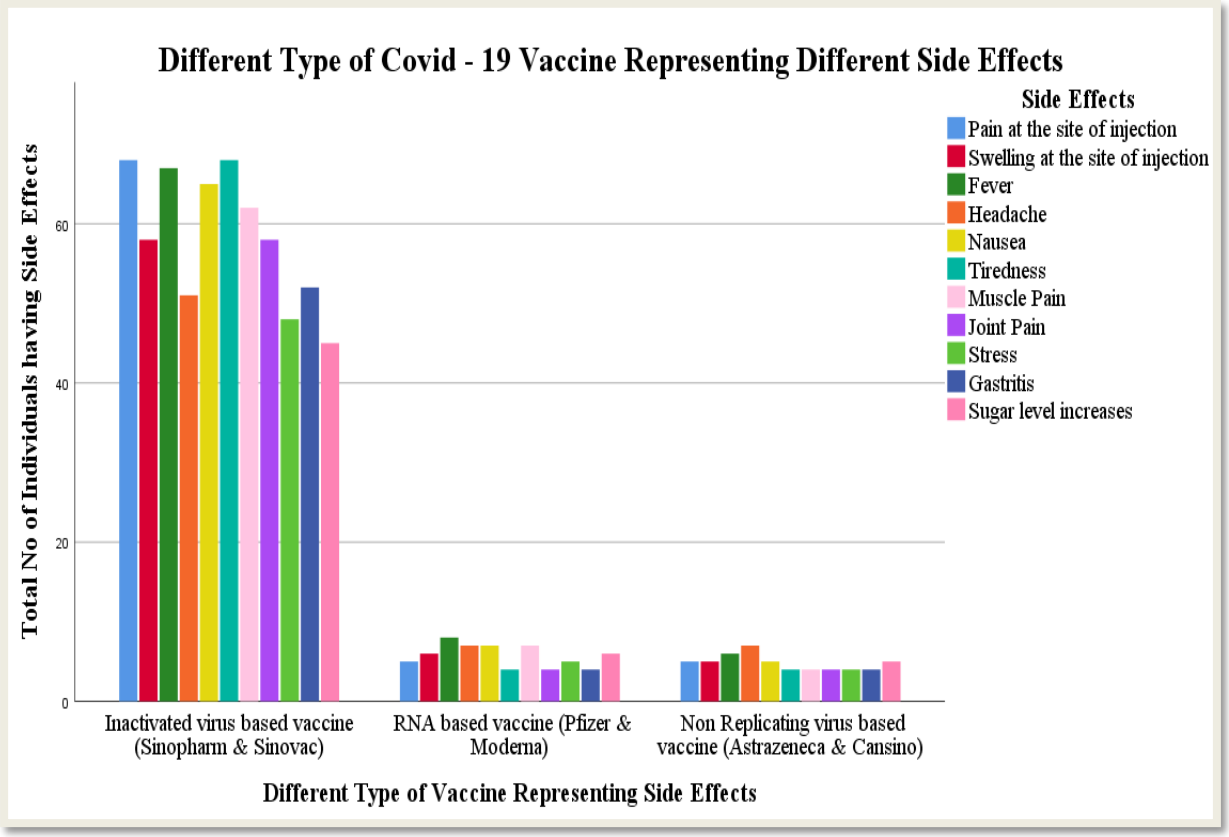

Fig 4.3: Different Side Effects with a Different Type of Vaccine for COVID-19

Table 5: The Chi-Square test of independence/fisher exact shows the relationship of side effects within the type of cancer (N=200)

Type of Cancer (Within group)						
Variables	**Group**	**NO**	**YES**	**Fisher exact**	**sig**	**V**
Pain at the site of injection	Carcinoma	66(100.0%)	0(0.0%)			
	Sarcoma	14(100%)	0(0.0%)			
	Blood cancer	20(100.0%)	0(0.0%)			
Swelling at the site of injection	Carcinoma	62(64.6%)	4(100%)	1.012	.767	0.147(0.450)
	Sarcoma	14(14.6%)	0(0.0%)			
	Blood cancer	20(20.8%)	0(0.0%)			
Fever	Carcinoma	52(64.2%)	14(73.7%)	1.302	.560	0.123(0.521)
	Sarcoma	13(16.0%)	1(5.3%)			
	Blood cancer	16(19.8%)	4(21.1%)			
Headache	Carcinoma	64(68.8%)	2(28.6%)	8.922	**.008***	0.35(0.005)
	Sarcoma	14(15.1%)	0(0.0%)			
	Blood cancer	15(16.1%)	5(71.4%)			
Nausea	Carcinoma	64(66.7%)	2(50.0%)	1.37	.419	0.07(1.00)
	Sarcoma	13(13.5%)	1(25.0%)			
	Blood cancer	19(19.8%)	1(25.0%)			
Tiredness	Carcinoma	61(64.9%)	5(83.3%)	.651	.831	0.11(0.72)
	Sarcoma	14(14.9%)	0(0.0%)			
	Blood cancer	19(20.2%)	1(16.7%)			
Muscle Pain	Carcinoma	57(67.9%)	9(56.3%)	2.04	.390	0.13(0.45)
	Sarcoma	10(11.9%)	4(25.0%)			
	Blood cancer	17(20.2%)	3(18.8%)			
Joint Pain	Carcinoma	63(66.3%)	3(60.0%)	.741	.809	0.04(1.00)

	Sarcoma	13(13.7%)	1(20.0%)			
	Blood cancer	19(20.0.0%)	1(20.0%)			
Stress (due to fear of vaccine)	Carcinoma	62(66.0%)	4(66.7%)	1.18	.681	0.12(0.57)
	Sarcoma	14(14.9%)	0(0.0%)			
	Blood cancer	18(19.1%)	2(33.3%)			
Gastritis	Carcinoma	66(100.0%)	0(0.0%)			
	Sarcoma	14(100%)	0(0.0%)			
	Blood cancer	20(100%)	0(0.0%)			
Sugar Level	Carcinoma	64(66.0%)	2(66.7%)	1.54	.45	0.12(0.73)
	Sarcoma	13(13.4%)	1(33.3%)			
	Blood cancer	20(20.6%)	0(0.0%)			

Note: *X2= Chi Square; p= Significance, *p<.0.5.*

Table 5 shows the chi-square test results to find the association of different types of cancer with the side effects of COVID-19 Vaccination. Results revealed only a statistically significant association with Headache, and the reason of non-significance of other variables is due to the small sample size i.e. less than 30.

3.4 Prevalence of Side Effects in Different Types of Cancer:

In our research population, 70% of the control group experienced all the side effects of vaccination, whereas only 7% of the case group (carcinoma, sarcoma, and blood cancer) reported side effects. No patients complained of pain at the injection site or gastritis. Fewer individuals with carcinoma reported fever and muscle pain more frequently than other side effects; sarcoma patients more frequently simply reported muscle pain, and patients with blood cancer more frequently reported fever and headache when paired with other side effects.

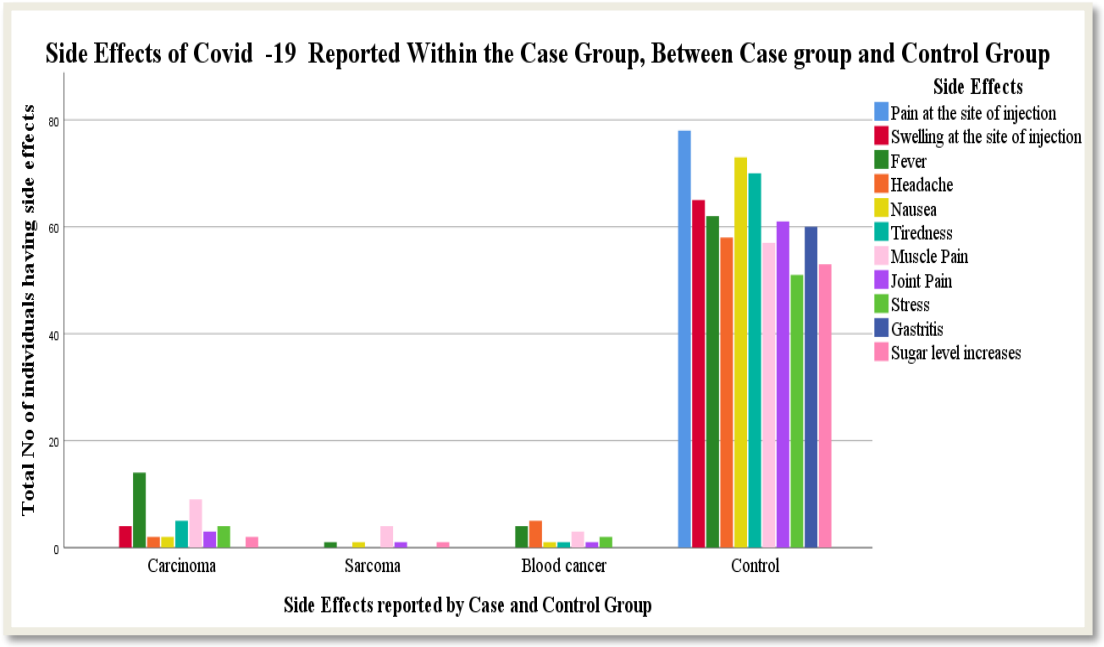

Fig 4.4: Different Types of Cancer Reported Different Side Effects of COVID-19 Vaccination

Table 6: The Chi-Square test of independence/fisher exact shows the relationship of side effects with the type of cancer treatment (N=200)

Type of treatment (For N = 200)						
Variables	**Group**	**NO**	**YES**	**Fisher exact**	**Sig**	**V**
Pain at the site of infection	Chemotherapy	50(50.0%)	0(0.0%)			
	Radiotherapy	9(9.0.0%)	0(0.0%)			
	Hormonal Therapy	6(6.0.0%)	0(0.0%)			
	CCRP	26(26.0%)	0(0.0%)			
	Surgery & Chemotherapy	9(9.0%)	0(0.0%)			
Swelling at the site of injection	Chemotherapy	49(51.0%)	1(25.0%)	4.98	.21	0.21(0.29)
	Radiotherapy	9(9.4%)	0(0.0%)			
	Hormonal Therapy	5(5.2%)	1(25.0%)			
	CCRP	25(26.0%)	1(25.0%)			
	Surgery & Chemotherapy	8(8.3%)	1(25.0%)			
Fever	Chemotherapy	43(53.1%)	7(36.8%)	4.59	.29	0.21(0.32)
	Radiotherapy	5(6.2%)	4(21.1%)			
	Hormonal Therapy	5(6.2%)	1(5.3%)			
	CCRP	21(25.9%)	5(26.3%)			
	Surgery & Chemotherapy	7(8.6%)	2(10.5%)			
Headache	Chemotherapy	45(48.4%)	5(71.4%)	1.77	.80	0.15(0.64)
	Radiotherapy	8(8.6%)	1(14.3%)			
	Hormonal Therapy	6(6.5%)	0(0.0%)			

	CCRP	25(26.9%)	1(14.3%)			
	Surgery & chemotherapy	9(9.7%)	0(0.0%)			
Nausea	Chemotherapy	47(49.0%)	3(75.0%)	3.95	.31	0.22(0.23)
	Radiotherapy	9(9.4%)	0(0.0%)			
	Hormonal Therapy	5(5.2%)	1(25.0%)			
	CCRP	26(27.1%)	0(0.0%)			
	Surgery & chemotherapy	9(9.4%)	0(0.0%)			
Tiredness	Chemotherapy	47(50.0%)	3(50.0%)	8.568	**.03***	0.38(0.01)
	Radiotherapy	6(6.4%)	3(50.0%)			
	Hormonal Therapy		0(0.0%)			
	CCRP	26(27.7%)	0(0.0%)			
	Surgery & chemotherapy	9(9.6%)	0(0.0%)			
Muscle Pain	Chemotherapy	40(47.6%)	10(62.5%)	1.208	.94	0.11(0.89)
	Radiotherapy	8(9.5%)	1(6.3%)			
	Hormonal Therapy	5(6.0%)	1(6.3%)			
	CCRP	23(27.4%)	3(18.8%)			
	Surgery & chemotherapy	8(9.5%)	1(6.3%)			
Joint Pain	Chemotherapy	48(50.5%)	2(40.0%)	4.45	.253	0.25(0.17)
	Radiotherapy	7(7.4%)	2(40.0%)			
	Hormonal Therapy		0(0.0%)			
	CCRP	25(26.3%)	1(20.0%)			
	Surgery & chemotherapy		0(0.0%)			

0(0.0%)

0(0.0%)

0(0.0%)

Stress	Chemotherapy	47(50.0%)	3(50.0%)	6.67	**.07***	0.27(0.09)
	Radiotherapy	7(7.4%)	2(33.3%)			
	Hormonal Therapy	5(5.3%)	1(16.7%)			
	CCRP	26(27.7%)	0(0.0%)			
	Surgery & chemotherapy	9(9.6%)	0(0.0%)			
Gastritis	Chemotherapy	50(50.0%)	0(0.0%)			
	Radiotherapy	9(9.0%)	0(0.0%)			
	Hormonal Therapy	6(6.0%)	0(0.0%)			
	CCRP	26(26.0%)	0(0.0%)			
	Surgery & chemotherapy	9(9.0%)	0(0.0%)			
Sugar Level	Chemotherapy	48(49.5%)	2(66.7%)	4.22	.25	0.23(0.22)
	Radiotherapy	9(9.3%)	0(0.0%)			
	Hormonal Therapy	5(5.2%)	1(33.3%)			
	CCRP	26(26.8%)	0(0.0%)			
	Surgery & Chemotherapy	9(9.3%)	0(0.0%)			

Note: *X2= Chi Square; p= Significance, *p<.05.*

Table 6 shows the chi-square test results to find the association of different types of cancer treatment with the side effects of COVID-19 Vaccination. Results revealed only a statistically significant association with tiredness, and the reason for non-significance of other variables is due to the small sample size i.e. less than 30.

3.5 Prevalence of Side Effects with Different Types of Cancer Treatment:

Patients with cancer had been receiving various cancer treatments, and none of them had a history of allergies that would have prevented them from becoming vaccinated. Under any cancer therapy, no patient complained of pain at the injection site or gastritis. Fever and muscle pain were the most common side effects reported by individuals receiving chemotherapy plus CCRP treatment (current chemo and radiotherapy). Patients getting radiation experienced fever, tiredness, joint pain, and stress. Individuals who received hormone treatment have experienced some negative effects, swelling of muscles at injection site, Cold, nausea, muscle pain, stress, and an increase in sugar level while patients having surgery and chemotherapy experienced relatively few side effects including swelling of muscles at injection site, Headache, Cold muscle, and joint pain.

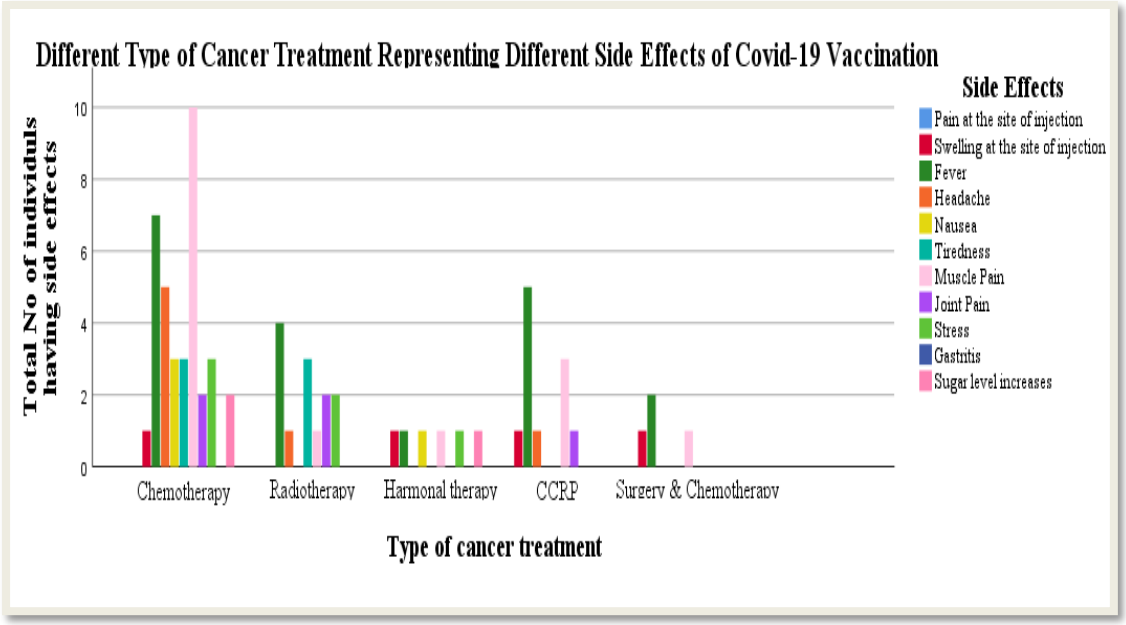

Fig 4.5: Type of Cancer Treatment Representing Different Side Effects of COVID-19 Vaccination

Table 7: Chi-square test shows the occurrence of symptoms along with controlled group and case and type of vaccine. (N=200)

Occurrence of Symptoms (Controlled vs Case)						
Duration	**Controlled**		**Case**	χ^2 ***value***	**Sig**	**Phi**
After few hours	73(73%)		24(24.0%)	74.88	.00	.612(.00)
After a day	11(11.0%)		0(0.0%)			
Not appeared	16(16.0%)		76(76.0%)			
Occurrence of Symptoms (Type of vaccination)						
Duration	**Inactivated viral vaccine**	**RNA based vaccine**	**Non replicating viral vaccine**	**Adenovirus based vaccine**		
After few hours	87(55.1%)	8(30.8%)	2(20.0%)	0(0.0%)	31.47	.00	.36(.00)
After a day	6(3.8%)	0(0.0%)	5(50.0%)	0(0.0%)		
Not appeared	65(41.1%)	18(69.2%)	3(30.0%)	6(100%)		

Note: *X2= Chi Square; p= Significance, *p<.05.*

Table 7 shows the chi-square test results in order to find the association between the occurrence of Symptoms along with normal individuals and cancer patients, and the type of vaccine. Results revealed statistically significant association with occurrence of Symptoms The effect size of these variables lies in the medium range (Pallant, 2020). Hence the result shows that symptoms appeared in normal individuals and cancer patients under treatment, vaccinated with different type of vaccines.

4.6 Prevalence of Adverse Effects Among Control and Case Groups:

Figure shows the side effects prevalence among control and case groups. It shows that the control group has only 16 participants and the 76 participants in the case group had no adverse effects. After a few hours of vaccination, 73 individuals from the control group and 24 individuals from the case group reported adverse responses among those inoculated with different types of vaccine. After one day, eleven members of the control group and none in the case group reported side effects. After a week, neither group reported any side effects.

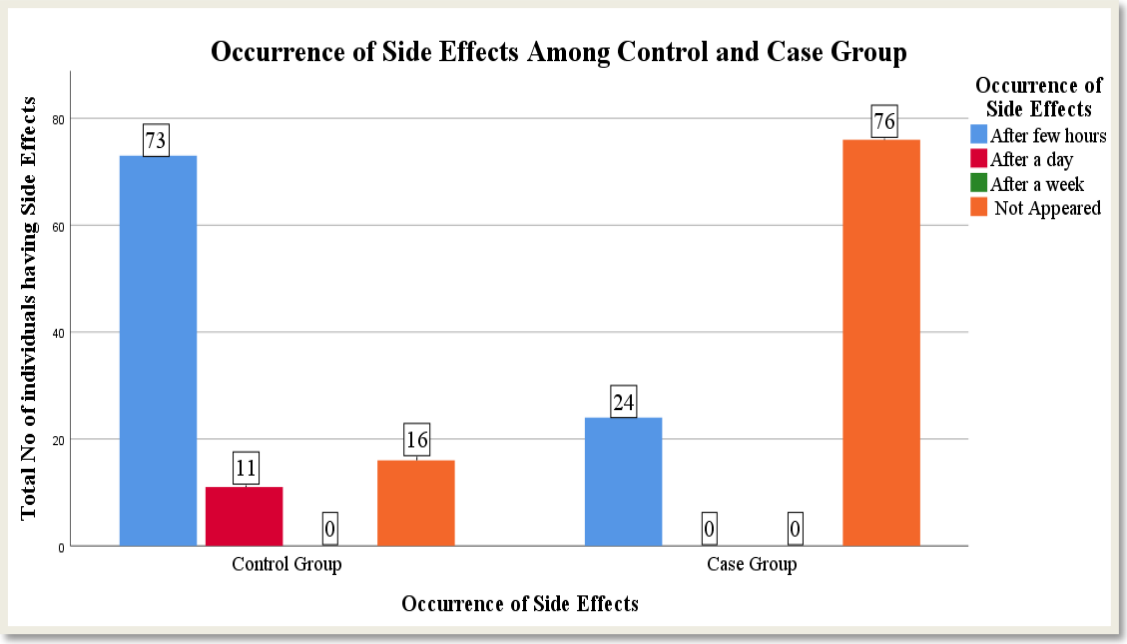

Fig 4.6: Occurrence of side effects after COVID-19 vaccination among control and case groups.

CHAPTER # 4

Discussion

At the beginning of the COVID-19 outbreak, the vaccination was the only available treatment for this pandemic because no alternative medical strategy existed. Vaccines promote the inflammatory response and also have systemic and local side effects. Depending on the host factors (age, gender, and disease severity), the type of vaccine, and its composition, different post-vaccination consequences may occur. Our model suggests that certain people would probably react negatively to the COVID-19 vaccine after getting it. Patients in our research were more likely to refuse the vaccine if they thought it might interfere with their medical care or alter the course of their illness. The majority of patients did not view cancer as a severe disease that needed to be first avoided by vaccination. In both outpatient and inpatient sessions, oncologists must actively engage in teaching their patients about these difficulties.

In our study, adverse reactions to the COVID-19 vaccination were reported by just 7% of cancer patients. This is a result of systemic anticancer therapy being administered to immunocompromised cancer patients. In some cancer patients, compared to people without the disease or their treatment, immunosuppression raises the risk of infection. Immunosuppression may put cancer patients at risk for serious infection issues, delaying treatment and necessitating additional hospital stays that could be detrimental to the prognosis of the disease. Compared to the general population, cancer patients had a weaker immune response to the Sinovac and Sinopharm vaccines. Jackson et al. found that 86.9% of cancer patients who received the Sinopharm inactivated vaccine tested positive for the antibody; they also found that older cancer patients, those who are receiving active therapy, and people with hematologic malignancies are more likely to have low seropositivity rates. [22]. 90% of patients getting systemic anticancer treatment after receiving the Pfizer vaccination exhibited a sufficient immune response but had

noticeably lower antibody titers in comparison to a healthy control group, according to Massarweh et al. The lowest antibody titers were seen in patients receiving immunotherapy and chemotherapy together [23].

Both the case and control groups experienced adverse effects that eventually went away. Vaccination side effects are frequent and show that the immune system is responding [24]. According to a meta-analysis evaluating COVID-19 vaccination safety in cancer patients, the mild to moderate side effects predominated. In any of the included investigations, there were no serious adverse events reported [25].

When compared to other types of vaccines, the incidence of side effects in those getting the Sinovac and Sinopharm immunization was lowest in cancer patients and greatest in non-cancer patients. The majority of people were immunized with Sinovac and Sinopharm, while a small number were immunized with Pfizer and Moderna and very few with AstraZeneca, CanSino, and Sputnik V. Tenforde et al. found that vaccine effectiveness was significantly lower in people with immunocompromising illnesses (59.2%) than in healthy individuals (91.3%) [26].

Six persons, two from the case group (patients with breast and bladder cancer) and four from the control group, experienced COVID-19 symptoms following vaccination and recovered in a week. There is not much information on vaccine tolerance for this population because cancer patients were excluded from vaccination clinical studies [27].

The limitation of our study was that it was a cross-sectional study that provided only a snapshot at the time of the survey. Even though cancer patients from across Pakistan are treated there, the procedure was only performed at one institution. When reporting adverse effects, the included respondents did have some memory impairments, and cancer patients also confused the side effects of their medication with the side effects of vaccinations. Our study's approach to patient enrollment, which relied on their voluntary completion of the questionnaire during their routine visits, was another disadvantage. We

can conclude that a subgroup of individuals who had poor COVID-19 results did not attend regular check-ups and hence did not form part of the analyzed population in our study.

4.1 Conclusion & Future Prospects

Our study suggests that due to their immunocompromised state, cancer patients in Compared to the broader population, Pakistan showed a better acceptance of the COVID-19 vaccination. The negative effects of vaccinations are mild and do not significantly slow down the course of cancer treatment. The COVID-19 vaccination offers the same protection to cancer patients as it does to the general public. More research is needed to determine the efficacy and the safety in cancer patients, of COVID-19 vaccines. A thorough understanding of how immunizations affect cancer patients is necessary. On the basis of the available data, we recommend cancer patients to receive the inactivated viral-based COVID-19 vaccine. An effort to strengthen efficient communication between multiple government databases is necessary to improve the quality and consistency of information.

CHAPTER # 5

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