MOSUL JOURNAL OF NURSING
Online ISSN: 2663-0311 - Print ISSN: 2311-8784
Website: https://mjn.mosuljournals.com

RESEARCH ARTICLE

Determination of Immunological Response among Vaccinated Individuals with Pfizer COVID-19 Vaccine in Garmian District, Iraq

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Abstract

Background: Worldwide, a coronavirus disease called COVID-19 has affected sizable populations. Although there has been a lot of excitement about vaccines, little is known about their negative effects or how antibody titters change following injections. The objective of the study is to evaluate post-vaccine IgG titters, WBCs count after Pfizer COVID-19 Vaccine and side effects in the Garmian District.

Materials and Method: The data were collected from Sherwana primary health center in Kalar, Kurdistan region, Iraq, from September 25th to December 23rd 2021, which included 120 unvaccinated controls and 115 general population participants were enrolled in a COVID-19 vaccination campaign. A questionnaire form was used which included is socio-demography, clinical history, vaccine side effects. All 115 participants underwent two Pfizer COVID-19 vaccines and blood samples were collected 4 weeks after the 1st dose and 6-8 weeks after the 2nd dose of vaccination, and then the laboratory tests for the immunological (IgG) and white blood cells were performed.

Result: The level of antibodies increased significantly after the 2nd dose of vaccines compared to the 1st dose. Younger age, non-chronic disease participant, COVID-19 positive, smoking, and AB blood group type, significantly associated with higher IgG titres after Pfizer COVID-19 vaccination. The non-vaccinated severe infected group had significantly higher antibody titters and WBC counts than the mild and moderate infected groups. Individuals with the 1st dose vaccinated have a higher level of side effects compared to vaccinated individuals with the 2nd dose at vaccine.

Conclusion: After receiving two doses of the Pfizer COVID-19 vaccine, all research participants developed antibodies. The research population appears to be at no risk from the Pfizer COVID-19 vaccine, and the antibody titer rose following the two rounds of immunization. The participants' aging and the presence of non-chronic conditions are blamed for the rise in antibody titter.

Keywords: COVID-19, Pfizer vaccine, antibodies, side effects Garmian district, andIraq

Received: 13 May 2022, Accepted: 21 August 2022, Available online: 28 August 2022.

INTRODUCTION

SARS-CoV-2 is the cause of COVID-19 (Severe Acute Respiratory Syndrome Coronavirus 2). It was discovered in Wuhan, China, in December 2019. The global pandemic was declared by the World Health Organization (WHO) in March 2020, and it has persisted ever since (Zhou et al., 2020).

Since new strains of COVID-19 have evolved and are potentially more dangerous, the disease's global spread is almost unstoppable (. Lippi G, 2021).

Individuals' responses to SARS-CoV-2 infection vary widely and rely on a variety of factors, primarily concomitant conditions like diabetes and obesity, age, sex, and ethnicity. The effects of infection might range from asymptomatic conditions to serious illnesses with a high likelihood of dying (Hodgson, 2021).

There was a scramble to develop vaccines around the world to prevent the epidemic from getting worse (Adam, 2021).

The Pfizer COVID-19 vaccine can be used in an emergency, according to US Food and Drug Administration (FDA) approval dated December 11, 2020. Two doses of the vaccination must be administered, at least 21 days apart. According to some reports, the maximum effectiveness, or about 95%, can be attained one week following the second dosage. Those who are 16 years of age and older can be eligible for the immunization (F. B. 2021).

SARS-CoV-2 immunity can be developed through infection with the virus or vaccination; it offers defence against re-infection or lowers the likelihood of experiencing clinically severe symptoms (Khoury, 2021). Since these antibodies are the most efficient in preventing the disease, levels of anti-spike protein receptor-binding domain (anti-S-RBD) immunoglobulin G (IgG) levels are a good indicator of acquired immunity to SARS-CoV-2 (Lo Sasso, 2021). The vaccine causes an IgG antibody response to the spike protein of SARS-CoV-2 when administered intramuscularly. The method of administering vaccinations has been demonstrated to be essential (I.M. Belyakov, (2009)).

Numerous organ systems within its host may be impacted by COVID-19. Studies have shown that haematological profiles change over the course of SARS-CoV-2 infection. In the beginning stages of the antiviral defence, neutrophils play a role. However, in severe pneumonia, neutrophils degranulate and lyse to become cytotoxic (A.K. Haick et al., 2014) a Recent study has shown that severe COVID-19 patients tend to have increased NLR (C. Qin, 2020). As with the Pfizer COVID-19 vaccine, side effects such as discomfort, fatigue, fever, and headaches are possible, and in some cases, allergic reactions to some of the vaccine components have been reported (Khurana, 2021). the objective of the study is to evaluate post-vaccine IgG titers and WBCs count in 4 weeks after the1s dose of Pfizer COVID-19 Vaccine and 6–8 weeks after the 2nd dose of Pfizer COVID-19 Vaccine, and also to identify the main side effects of the vaccine in the Garmian District.

Materials and Method

Study setting and population

A cross-sectional study from September 25th to December 23rd, 2021, was conducted at Sherwana primary health center in Kalar, Kurdistan region, Iraq. The target population includes those people over the age of 20 years old who were vaccinated with the Pfizer COVID-19 vaccine. The total sample size of the study was (235), which involved 115 volunteer vaccinated and 120 volunteer non-vaccinated participants.

Epidemiological data

After conducting ethical and validation approval, the questionnaire form was constructed. After four weeks following the 1st dose of vaccination, the questionnaire form was filled in with the participants by face-to-face inter-view, which includes demographic characteristics, such as age, gender, education level, blood type, COVID-19 diagnosis, chronic illness history, and smoking. The frequency of infection rates among the vaccinated population, as well as their desire to have the 2nd dose after 6–8 weeks, was also reported. The adverse effects of the two COVID-19 vaccines under research were the focus of the study's second segment. There were two categories of side effects: systemic and local. Before they completed the questionnaire, participants gave their permission.

Blood sample collection

Blood samples were taken 4 weeks after the 1st dose of vaccine and 6 - 8 weeks after the 2nd dose was administrated. Blood aspiration was performed by using disposable syringes and sterile test tubes for extracting 2 ml of venous blood and then the blood was kept at room temperature for 20-30 minutes the clotted blood samples were centrifuged at (1500) rpm to (5) min for serum prepared, and 2 ml venous blood gentle mix method was used for WBC account.

Laboratory Diagnosis

Participants signed informed consent before recruitment into neutralizing antibodies (NAbs) was assessed on a subset of 115 participants after getting the 1st and 2nd dose of the Pfizer COVID-19 vaccine. At different time points. 120 participants with natural immunity were not vaccinated.

Antibody Test: Serum samples were analysed for IgG antibodies to SARS-CoV2 Spike protein receptor-binding domain after 4 weeks 1st dose and 6-8 weeks after 2nd dose of PfizerCOVID-19 vaccine, the test was performed according to the manufactured prediction in the laboratory using (ELx800) BIO-TEK INSIRUMENT, INC.ELISA test. the IgG titer is measured in(unit/ml). Normal range: > 0.5 unit/ml.

Complete Blood Counts: For determination of the changes in WBCs account between the1st and 2nd doses of the Pfizer COVID-19 vaccine among the participants, ALFA SWELAB SWEDEEN BRAND MACHINE LABORATORY was used

Statistical Analysis: The Statistical Package for Social Science (SPSS) version 21.0 (IBM Statistics.inc) for Windows and Microsoft Excel2020 were used to computerize and analyse the data. As for continuous variables, mean, median, and St-deviation values, as well as frequency and percentage values for qualitative variables, were provided as descriptive statistics. For continuous variables, a one-way analysis of variance or independent samples T-test was employed, and for qualitative variables, the T-test was utilized. P <0.05 was indicated as the statistically significant value.

Results

Demographics Characteristics

For demographic characteristics of the participants, the findings revealed that 71(62.1%) and 44(37.9%) of the participants were male and female for gender, respectively, and there was no significant association for IgG titer after the 2nd dose of the vaccination for gender groups.

For age groups, there was a higher number for (36-50) and (20-35) age groups, 47 (40.5%) and 34 (29.3%) respectively, and a lower number for (51-65) and (over 65) age groups, 22(19.9%) and 12 (10.3%) respectively.

For IgG titer, there was a significant interaction between age group of participants and IgG titer, younger age group produced a higher IgG titer than those of older age groups (20–35) age groups had a (15.87) IgG titer and (>65) age groups had an (8.94) IgG titer.

For blood groups, a greater frequency was recorded with O+,A+,B+ 40(34.8%), 31 (26.8%), and 20(17.8%) respectively, and a smaller frequency was recorded with other blood groups, and there was a non-significant relationship between blood groups of participants and IgG titer.

For diagnostic COVID-19, positive PCR results 62(53.4%) had a statistically significant IgG titer of 15.71 compared to those with negative PCR results (Table 1). Furthermore, the IgG titers were (13.16) and (12.27) for smoker and non-smoker participants respectively, and there was a non-significant interaction. For education level, statically, there was a non-significant association between educational levels. Shown The IgG titers were (22.15), (9.15) and (5.70) for nan vaccinated groups that had three groups of severe, moderate, and mild participants respectively, and there was a significant interaction between in non-vaccinated groups and IgG titers. The severe infected groups produced IgG titers than those of mild and moderately infected groups (Table 1)

The results showed that the participants after 8 weeks produced a higher titer of IgG (13.9) than those participants in the 4 after the 1st dose (2.42) and the 6 weeks (11.08) after the 2nd dose. The interaction was statistically significant between doses. (Table 2)

for showing the effect of WBC count level by dose. The participant's WBC level showed that the participants after the 2nd dose produced a higher level of WBCs (8.087) than those participants after the 1st dose (7.275). The interaction was not statistically significant between doses. (Table 3)

For revealing the WBCs count among non-vaccinated participants, a greater frequency was recorded in mild infection group 48 (40%) and a lower frequency was recorded in moderate infection group 30(25%), respectively while this association was not statically significant. (Table 4)

According to the participants' responses to the questionnaires, local or systemic side effects of the first- and second-dose COVID-19 vaccines were recorded at the highest level, as seen in Figures 1 and 2.

The figures 1 and 2 display them. After the first dose and after the second dose, subjects experienced all side effects. There were noticeably more side effects with the first dose than the second dose (p 0.005; local pain,

headache, and fever were higher side effects than other side effects). Local pain after the first dose (63.5%) and after the second dose (40.0%) (p 0.005) Following the first dosage of the vaccine, the following side effects were noted: local pain (63.50%), a headache (43.5%), and a fever (41.7%) local reaction (37.3%), allergic reaction (1.7%), drowsiness (25.2%), rhinorrhoea (22.2%), general discomfort (30.4%), nausea (4.3%), vomiting (4.3%), non-side effects (0.9%), and others (digestion AL symptoms, shivering, Fu-like syndrome, anosmia, thoracic pain, abdominal pain, asthenia, dizziness, etc.) After the second vaccination dose: Local pain (40%) headache (32.2%) fever (23.5%) local reaction (13.9%) allergic reaction (0.9%) sleepiness (19.1%) rhinorrhoea (6.1%) general discomfort (13.9%) nausea (2.6%) vomiting (6.1%) non-side effects (16.5%) and others (such as digestive symptoms, shivering, full-like syndrome, anosmia, thoracic pain, abdominal pain, asthenia, dizziness, oedema swelling, and cough), comorbidity After the second, problems or non-side effects were more prevalent.

Figure 3 shows the results for the IgG titer analysis for the participants with chronic disease revealed that the healthy participants produced a higher titer of IgG (14.76) than the participants with chronic disease, such as diabetes mellitus, heart disease, hypertension, asthma, and thyroid disorder (9, 9.47, 10.65, 8, 9.59).

Demographics Characteristics shown in Table 1

Demographics Characteristics		Percentage	Frequency	IgG Mean after 2nd dose	P .value
Gender	Male	62.1	71	12.37	0.7982
	Female	37,9	44	12.66	
Age	20 - 35	29.3	34	15.87	0.0027
	36 -50	40.5	47	12.07	
	51 - 65	19.9	22	10.21	
	0ver 65	10.3	12	8.94	
Blood Group	A+	26,8	31	10.5388	0.0365
	B+	17,8	20	12.4870	
	AB+	6,9	8	14.4900	
	O+	34,8	40	11.8250	
	A-	4,3	4	12.3400	
	B-	3,4	5	12.8840	
	AB-	1,7	2	13.3500	
	O-	4,3	5	12.1860	
COVID-19 Diagnosis	COVID-19 Positive	53,4	62	15.71	0.0001
	COVID-19 Negative	43,6	54	9.67	
Smoker	Smoker	24.1	27	13.16	0.4913
	Non smoker	75,9	88	12.27	
Education	illiteracy	32,7	37	12.02	0.582
	Primary education	41,4	48	13.49	
	Higher education	25,9	30	11.62	
Non vaccinated (control)	Severe	35	42	22.15	< 0.0001
	Mild	40	48	5.70	
	Moderate	25	30	9.10	

Note/ data presented as (Freq.=frequency, n=number of cases), *Calculated by chi-square

Table 1 Comparison of antibody titer level per weeks

IgG titer	mean	median	St-deviation	frequency	percent	p. value
After4 week first dose	2.42	2.55	. 447	115	100	< 0.0001
After 6 week second dose	11.08	10.9	2.93	59	51.8	
After 8 week second dose	13.9	10.92	7.57	56	48.2	

Table 3: Comparison of WBCs count level between 1st dose 2nd dose vaccine groups

WBCs count	mean	median	St-deviation	Frequency	Percentage	P value
WBCs after 1st dose	7.275	7.400	1,7959	115	100	0.3014
WBCs after2nd dose	8.076	7.500	3.9803	115	100	

Table 4: Correlation WBCs count with the non-vaccinated group control

WBCs count	Mean	median	St-deviation	N(%)	P value
WBCs of non-vaccinated mild infection	7.82	5.95	4.74	48(40)	0.196
WBCs of non-vaccinated moderate infection	7.58	7.40	1.73	30(25)	
WBCs of non-vaccinated sever infection	8.56	8.20	3.88	42(35)	

Note/ data presented as (Freq.=frequency, n=number of cases), *Calculated by chi-square

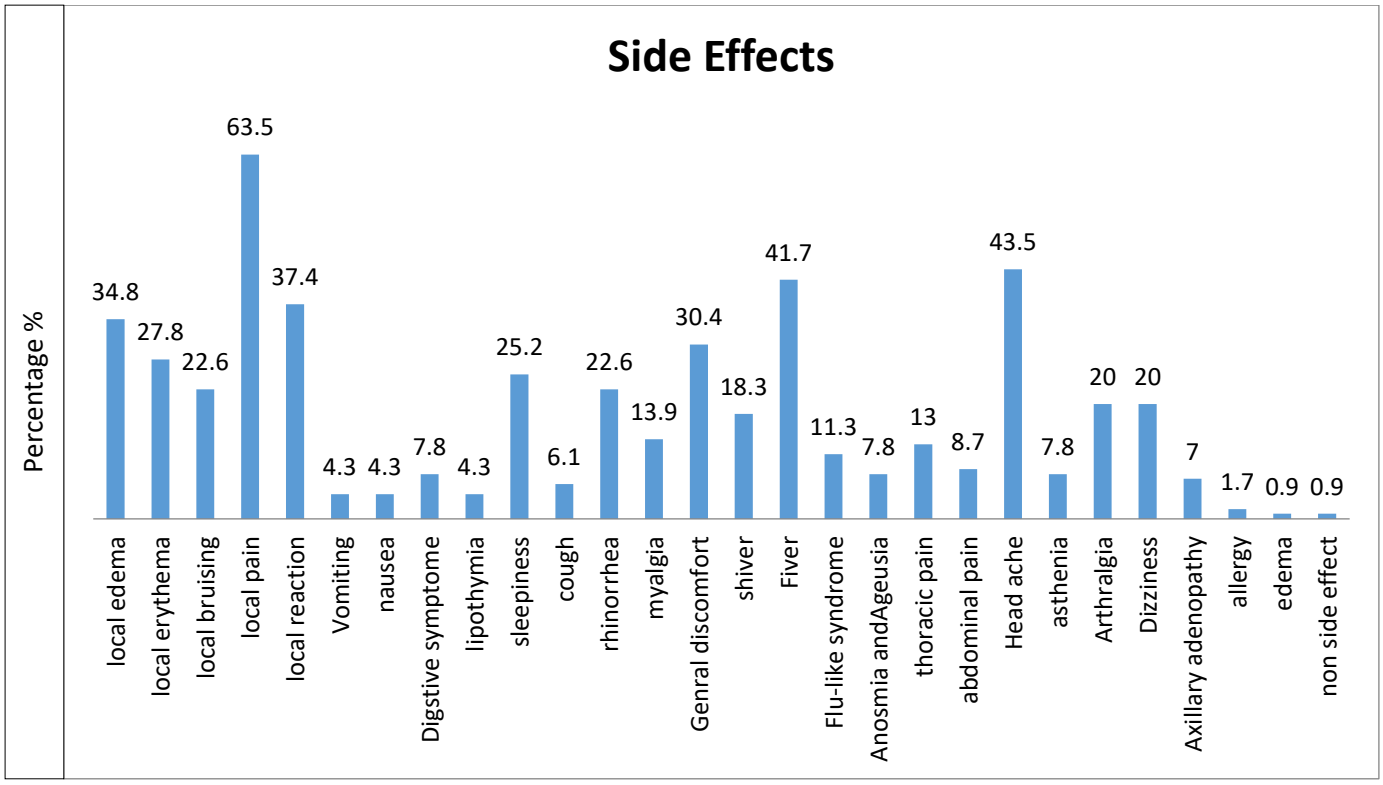

Figure 1: Side effects after taken 1st dose of vaccine.

 DOI: 10.33899/mjn.2022.175559

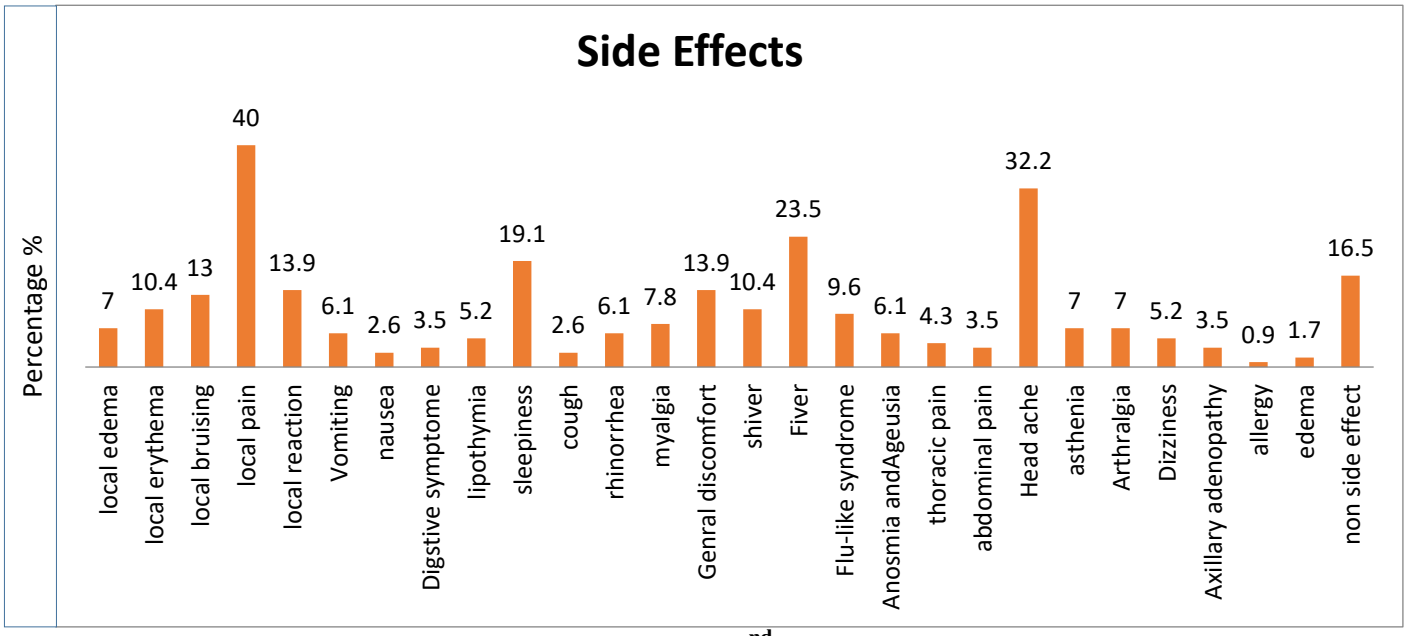

Figure 2: Side effects after taken 2nd dose of vaccine

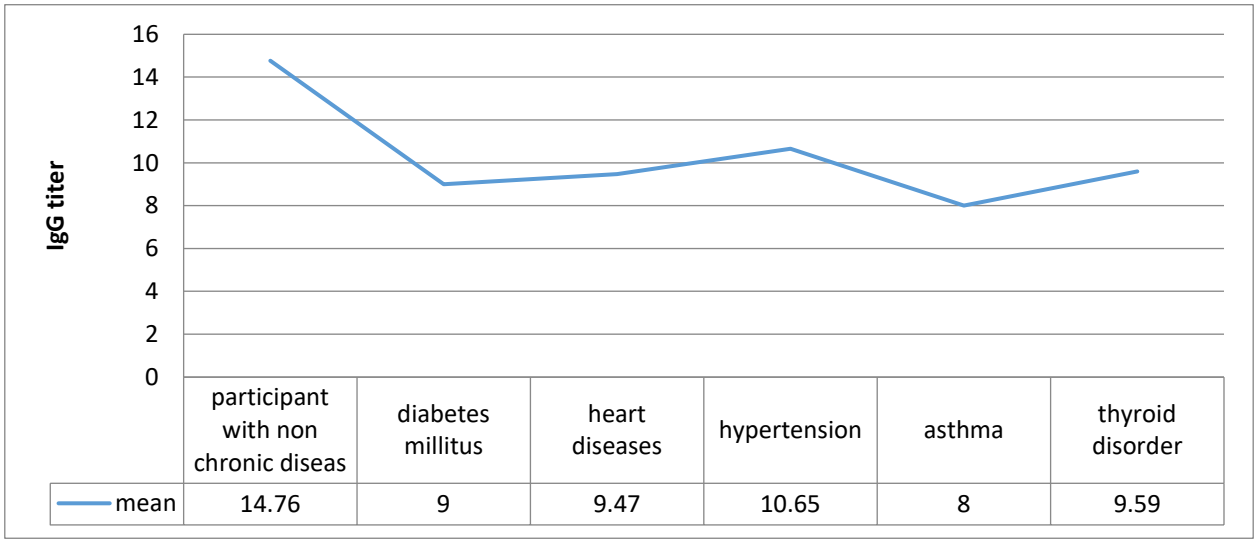

Figure3: Comparison IgG titer after 2nd d dose between particpante with chronic and non chronic diseaes.

Discussions

In our study, 63.5% of participants had local pain, which was the highest rate at the time of the 1st vaccinated dose, followed by 43.5% of participants with severe headaches, and 41.7% had a strong fever, while only 0.9% had no side effects. Local pain is the most common side effect. Other studies in 2021 were done in the Kurdistan region, Iraq, Turkey, and Iran to support our findings. This similarity may be due to the same environment, culture, and injected local vaccination. (A. I. T. et, 2021) (H. B. A. et, 2021) ((b. A. R. et, 2021) (Farhang Babamahmoodi, 2021).

In our study, side effects such as (local pain, fever, headache, etc.) were decreased after getting the 2nd dose of Pfizer COVID-19. This may be due to increased immunity after the 1st dose of the vaccine. Other research by Babamahmoodi F, et al and Hatmal MmMa, et al backed up our findings (Babamahmoodi et al., 2021; Hatmal et al., 2021).

In our study, side effects of negative and positive COVID-19 after the 1st and 2nd doses were observed in individuals. COVID-19 negative individuals experienced more side effects than COVID-19 positive individuals. Those who are infected with COVID-19 have immunity against

COVID-19 and this immunity has fewer side effects. While those who are not infected do not have any immunity and suffer more side effects, other studies will be conducted in Mexico in 2021 In our study, female side effects were higher than male side effects. However, a recent finding from a study conducted in Malaysia between May and July 2021 (Elnaem et al., 2021) In the Japanese smeller study, this may be due to the sample size of females rather than males (Izumo et al., 2021).

The younger people participating in the study had more side effects than older people. That's because each person's immune system is unique. which is also supported by other studies in Iran, Malaysia, and Japan (Babamahmoodi et al., 2021; Elnaem et al., 2021; Izumo et al., 2021).

All of the side effects were more severe in the first dose than in the second, this may be due to increase the immunity after 1st dose of the vaccine. Loannis et al. 2021 support our findings (20).

In our finding, allergies developed in participants after receiving the 2nd dose of vaccination, because almost every vaccine worldwide may be susceptible to making allergies. Other studies support our finding (" "Expanded Practice Standards" (PDF). Iowa Administrative Code. 2019.," ; Ronen Shavit, 2021).

Our findings indicate a significant difference in IgG antibody levels by age following the 2nd dose of the Pfizer COVID-19 vaccine, with younger people producing a higher antibody response than older people. This may be due to higher physical activity at a younger age than at an older age. This is a recent finding of studies by Niki Vassilak et al 2021) and , Salvagno, G.L et al(G. L. S. a. e. al, 2021) and Terpos et al(E. T. e. al, 2021)such as Lisa Müller et al (Lisa Müller, 2021) .

Moreover, we found that women had an increase in IgG titer response compared to men after the 2nd vaccine dose, but it was not significant, although this discrepancy could be affected by genetic and also non-genetic local factors and requires further investigation. while other studies in 2021 were done in Athens, Greece (E. T. e. al, 2021).

When compared to COVID-19 negative people without a history of prior infection in the current investigation, COVID-19 positive individuals exhibited considerably greater IgG titers. This might be as a result of increased immunity brought on by COVID-19 infection (Elizabeth Fraley, 2021; reserved., 2021; Saman Saadat, 2021) .

Smokers in our study had non-significantly greater levels of smoking-habit antibodies than non-smokers. Smoking weakens the immune system and might make it harder for the body to fight off illness. The immune system is the body's defence against illness and infection. While another research was conducted in Italy in 2021 (A. M. e. al, 2021). However, which have different result with our study (Y. N. e. al, 2021) This trend might be brought on by the study's small sample size and larger proportion of people without chronic diseases (N. N. M. S. E. AL, 2022; Y. N. e. al, 2021) (M. W. e. al, 2022; Y. e. al, 2021).

The IgG titers in the severe case group were substantially greater than those in the mild group and moderate group in the % trial with 120 (non-vaccinated) subjects. This is because severe instances have stronger immune systems that can combat viruses than do mild and moderate cases (S. Y. e. al, 2021).

In comparison to the vaccinated group after the 2nd dose, and when the vaccinated group after 2nd dose vaccination had a higher IgG titer than the non-vaccinated groups that were not severely infected (Emel AZAK 2021).

To our knowledge, the correlation of IgG titers with the blood type groups of the population from the study after vaccination with the Pfizer COVID-19 vaccine after calculating (P value 0.05), the significance of the difference between blood groups. This result was significant between the AB group and the A group. The resulting group (Ab+) was higher than all other blood groups in the study. This result may be due to the small sample size in the present study being AB blood type or due to the age of participants.

In our study, we compared WBC count levels in non-vaccinated groups of mild, moderate, and severe infected people. The WBC count was highest in the severely infected, but this was not statistically significant. While other studies prove this finding (Y. S. e. al, 2021; Kumar12345, 2020).

To the best of our knowledge, this is the first study in the Garmian country to provide data on the comparison level of WBCs between the "1st dose" group and the "2nd dose" group after getting Pfizer COVID-19 vaccination.

The main strengths of the study are that the first study was done in Garmian Distract, Kalar City, and COVID-19 disease. The emerging disease at the time did not have a specific treatment. People are concerned about the vaccine prevention requirement for immunity now, following vaccination.

The limitation of our study is that ten participants did not return to receive a second blood sample examination within the specified time window, so we excluded them from the analysis.

CONCLUSIONS

After receiving the Pfizer mRNA COVID-19 vaccine in two doses, all trial participants developed antibodies. After receiving the first and second doses of the Pfizer COVID-19 vaccine, there were greater disparities in antibody responses. Reduced frequency of neutralizing antibodies, particularly in chronically ill patients, men, the elderly, and those who test negative for COVID-19. In addition, the antibody

titer and WBC count in the non-vaccinated severe cases were higher than those in the mild and moderate groups, and the side effects in the first dose were greater than in the second dose..

ETHICAL CONSIDERATIONS COMPLIANCE WITH ETHICAL GUIDELINES

The study has been approved by the Research Ethics Committee of the University of Sulaimani Polytechnic .college of health and medical Technology by ethical code (Chooo52).

FUNDING
Self-fund

AUTHOR'S CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual Contribution to the work, and approved it for publication.

DISCLOSURE STATEMENT:

I hereby declare that, except where specific reference is made to the work of others, the contents of this thesis are original and have not been submitted in whole or in part for consideration for any other degree or qualification in this or any other university.

ACKNOWLEDGEMENTS

First of all, I want to thank Technical College Health & Medical Technology for giving me the chance to study for my Master's in Community Health.

We are also grateful to the Garmian General Directory of Health and the Sherwana health center in Kalar town, especially the Vaccine department, for their permission to collect data.

Finally, we thank all the participants in the study

Abbreviations

WBC; Wight blood cell, IgG; immunoglobulin G, WHO; Word health organization, FDA; Food and Drug Administration, SD; Standard deviation, SPSS; Statistical package for Social Sciences

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