Side Effects of mRNA (Pfizer/BioNTech) COVID-19 Vaccines among Individuals Attending PHC Centers in Najaf province/Iraq

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Abstract
Background: The use of vaccines is still a crucial defence against the COVID-19 outbreak. Pfizer-BioNTech One of the first vaccinations to reach Iraq was the COVID-19 vaccine, which has grown immensely popular due to its great efficiency. The World Health Organization announced the release of various COVID-19 vaccinations in September 2020. The Pfizer mRNA vaccine was given emergency approval on December 31, 2020. According to the study, the Pfizer vaccination had a 95% success rate. The prevalence of local side effects was higher with the mRNA-based vaccinations (e.g., injection site pain). However, a significant obstacle in the fight against the spread of the coronavirus is the public's vaccination scepticism of the current vaccines. Methods: This cohort study was done between October 2021 and May 2022 to determine the prevalence of COVID-19 vaccine (Pfizer-BioNTech) side effects among individuals who visited primary health care centres in Najaf. Participants were Iraqis from the Governorate of Al-Najaf Al-Ashraf. After the first and second doses of the COVID19 vaccine administered by Pfizer, individuals aged 18 to 50 or older who got the vaccine were monitored at varying intervals. Results: In this study, regarding the side effects of people vaccinated with the Pfizer / BioNTech vaccine, some side effects were found, the most common of which are injection site pain after the first dose, but after the second dose, the symptoms decreased and seemed to be less than the first dose the temperature became the most common. Conclusions: The most often reported side effects included injection site reactions, myalgia, fever, headache tiredness, and chills. Most symptoms ranged in severity from mild to moderate.
Keywords: COVID-19, BNT162 vaccine, vaccine-induced adverse reactions.

1. 1.Introduction

The World Health Organization (WHO) first deemed the recently discovered coronavirus virus 2019 (COVID-19) illness a Public Health Emergency of International Concern on January 30, 2020. Then on March 11, 2020, it was deemed a pandemic (1). For the majority of individuals, the condition is asymptomatic or mild. A significant portion of people suffers more severe pneumonia, which can develop into hypoxemic respiratory failure, shock, organ dysfunction, and even death. Men, older ages, lung, cardiovascular, obesity, diabetes, and hypertension-related diseases are risk factors for severe COVID-19 (2).

As immunisation is one of the most successful and cost-effective health strategies for preventing infectious diseases, COVID-19 vaccines are regarded as crucial for its prevention and control (3). Therefore, it is crucial to vaccinate the majority of the population against COVID-19, as failure to do so can have significant effects on the success of a vaccination programme, with potentially significant health and economic ramifications (4).

On 11 December 2020, the Food and Drug Administration of the United States issued the first emergency permission for the BNT162b2 COVID-19 vaccine manufactured by Pfizer and BioNTech for individuals aged 16 and older. The Pfizer-BioNTech COVID-19 vaccine belongs to a new type of vaccination termed messenger ribonucleic acid (mRNA) vaccines. mRNA vaccines provide segments of mRNA that code for a protein, which in the case of the COVID-19 mRNA vaccines is the spike protein present on the surface of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. These mRNA vaccines are meant to safeguard the mRNA material by delivering it within liposomes due to mRNA's rapid rate of degradation. These liposomes, which include polyethylene glycol and a variety of other excipients, are extremely immunogenic and are believed to be the cause of the severe local and systemic adverse effects experienced by patients. SARS-CoV-2 accesses host airway mucosal cells by attachment of its spike protein to the host's ACE-II receptor; therefore, antibodies against the spike protein are generated by the vaccine, providing for future infection protection (5,6).

By the 7th of August 2022, 18,982,116 Iraqis had received the vaccine, which was broken down as follows: those who had received at least one dosage were 11,014,427 (27.3%), and those who had received persons fully vaccinated 7,741,261 (19.2%) (7).

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Given that mRNA vaccines are relatively new on the market, there have been public and even professional worries regarding their safety profile. In the clinical trials of Pfizer-BioNTech COVID-19 vaccines, the most often reported side effects were injection-site soreness, weariness, and headache, which were typically transient (8). Therefore, The aim of this study was to investigate the short-term side effects after reported COVID-19 vaccines, and their frequency, after receiving the first and/or second dose by individuals attending primary health care centers to receive the Pfizer/BioNTech covid 19 vaccine in Najaf city.

2. 2. Methods

2.1. Study design

This Cohort study was conducted from October 2021 to May 2022, to estimate the prevalence of COVID-19 vaccine (Pfizer-BioNTech) side effects among those who attended primary health care centers in Najaf city. A standardized questionnaire sheet was used to collect information from the participants. The questionnaire included 3 major parts, in sequence: demographic data including (age, gender, residency and occupation); clinical profile (comorbid conditions, drug history and previous COVID19 infection); vaccine data (type of vaccine, side effects in term of duration and severity).

2.2. Participants

Participants were Iraqi citizens from the Al-Najaf Al-Ashraf Governorate. Individuals aged 18-50 and more who received Pfizer COVID19 vaccines were followed up after the first and second doses at different periods after vaccination. Exclusion criteria were people who had been vaccinated from other manufacturer companies, Autoimmune and immune deficiency diseases, patients Diagnosed with Cancer, pregnant women, People who have a temperature of (37 ℃) or more or have low oxygen levels, Chronic renal disease, Cardiovascular diseases, who have allergies to certain substances, as well as medications, foods (such as eggs), latex, or any component of a vaccination, Who has a brain-related neurological condition or has had a problem brought on by a vaccine, Who uses steroids, cancer-fighting medications, or have you had radiation therapy, Regarding occupation, both healthcare workers (HCWs) and non-healthcare workers were included.

2.3. Statistical Analysis

After testing the normal distribution of data, A nova test was applied for the difference between means of their finding of vaccinated cohort study by SPSS program version 25.

2.4. Approval of the Ethical Committee

The approval was taken by the Research Ethics Committee after presenting the research project to the committee at the College of Medicine, University of Kufa, numbered (009647801241456) ,date 2/3/2022.

3. 3. Results

3.1. Prevalence of clinical side effects of vaccinated individuals during the first dose and the second dose

In this study, the side effects of 75 volunteers after taking the first dose was, Injection site pain 54 (72.0%), myalgia 50 (66.7%), Fever 45 (60.0%), Headache 45 (60.0%), Fatigue 40 (53.3%), Chill 14 (18.7%), Joint pain 8 (10.7%), Cough 6 (8.0%), Runny nose 5 (6.7%), Nausea 4 (5.3%), Shortness 3 (4.0%), Diarrhea 3 (4.0%), Hypotension 3 (4.0%), Loss of smell and taste and sense 2 (2.7%), Lymphedema 2 (2.7%) respectively. While the second dose was 48 (64.0%), 40 (53.3%), 37 (49.3%), 30 (40.0%), 27 (36.0%), 4 (5.3%), 2 (2.7%), 0 (0.0%) respectively in the table (1).

Table (1): Prevalence of clinical signs of vaccinated individuals during the first dose and the second dose (No. of cases =75)

Side effects	First dose of vaccine		Second dose of Vaccine	
	1st dose No=75	%	2nd does No=75	%
Fever	45	**60.0%**	48	**64.0%**
Fatigue	40	**53.3%**	30	**40.0%**
Headache	45	**60.0%**	27	36.0%
Chill	14	18.7%	4	5.3%
Injection site pain	54	**72.0%**	40	**533%**
Myalgia	50	**66.7%**	37	**49.3%**
Joint pain	8	10.7%	0	0.0%
Runny nose	5	6.7%	4	5.3%
Nausea	4	5.3%	2	2.7%
Cough	6	8.0%	0	0.0%
Lymphedema	2	2.7%	0	0.0%
Shortness	3	4.0%	0	0.0%
Diarrhea	3	4.0%	0	0.0%
Loss of smell and taste and sense	2	2.7%	0	0.0%
Hypotension	3	4.0%	0	0.0%

3.2. Difference in side effects of vaccinated individuals depending on age groups

This table (2) shows the relationship between the side effects after giving two doses of Pfizer vaccine and the ages of the volunteers in the order 20, 20-29, 30-39, 40-49, and 50 years old.

Table (2): Difference in clinical signs of vaccinated individuals during the first dose and the second dose depending of age groups(No. of cases =75)

Sign and symptom	First dose of Vaccine/ age groups per years				Scond dose of Vaccine/ age groups per years					
	< 20	20-29	30-39	40-49	< 50	< 20	20-29	30-39	40-49	50 <
Fever 1st dose No.=45 2nd does No.=48	6 (13.3) %	**20 (44.4) %**	**9 (20.0) %**	6 (13.3) %	4 (8.9) %	8 (16.7) %	**18 (86.4) %**	**16 (33.3) %**	4 (8.3) %	2 (4.2) %
Fatigue 1st dose No.=41 2nd does No.=30	1 (2.4) %	**18 (43.9) %**	**13 (31.7) %**	6 (14.6) %	3 (7.3) %	5 (16.7) %	**12 (40.0) %**	**7 (23.3) %**	4 (13.3) %	2 (6.7) %
Headache 1st dose No.=45 2nd does No.=27	1 (2.2) %	**14 (31.1) %**	**8 (17.8) %**	3 (6.7) %	1 (2.2) %	4 (14.8) %	**8 (29.6) %**	**3 (11.1) %**	1 (3.7) %	0 (0.0) %
Chill 1st dose No.=14 2nd does No.=4	1 (7.1) %	6 (42.8) %	4 (28.6) %	2 (14.3) %	1 (7.1) %	0 (0.0) %	2 (40.0) %	2 (50.0) %	0 (0.0) %	0 (0.0) %
Injection site pain 1st dose No.=54 2nd does No.=40	1 (1.9) %	**29 (53.7) %**	**16 (29.6) %**	7 (13.0) %	1 (1.9) %	5 (12.5) %	**18 (45.0) %**	**13 (32.5) %**	3 (7.5) %	1 (2.5) %
Myalgia 1st dose No.=50 2nd does No.=37	2 (4.0) %	**22 (44.0) %**	**13 (26.0) %**	11 (22..0) %	2 (4.0) %	4 (10.8) %	**15 (40.5) %**	**11 (29.7) %**	3 (8.1) %	4 (10.8) %
Joint pain 1st dose No.=8 2nd does No.=0	0 (0.0) %	2 (25.0) %	3 (37.5) %	1 (12.5) %	2 (25.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
Runny nose 1st dose No.=5 2nd does No.=4	0 (0.0) %	1 (20.0) %	2 (40.0) %	0 (0.0) %	2 (40.0) %	1 (25.0) %	1 (25.0) %	1 (25.0) %	0 (0.0) %	1 (25.0) %
Nausea 1st dose No.=4 2nd does No.=2	1 (25.0) %	2 (50.0) %	1 (25.0) %	0 (0.0) %	0 (0.0) %	1 (50.0) %	0 (0.0) %	1 (50.0) %	0 (0.0) %	0 (0.0) %
Cough 1st dose No.=6 2nd does No.=0	2 (33.3) %	1 (16.7) %	2 (33.3) %	0 (0.0) %	1 (16.7) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
Lymphedema 1st dose No.=14 2nd does No.=0	2 (14.3) %	7 (50.0) %	4 (28.6) %	0 (0.0) %	1 (7.1) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
Shortness 1st dose No.=3 2nd does No.=0	1 (33.3) %	1 (33.3) %	1 (33.3) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
Diarrhea 1st dose No.=3 2nd does No.=0	0 (0.0) %	0 (0.0) %	3 (100.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
Loss of smell and taste and sense 1st dose No.=2 2nd does No.=0	0 (0.0) %	1 (50.0) %	1 (50.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
Hypotension 1st dose No.=3 2nd does No.=0	0 (0.0) %	1 (33.3) %	2 (66.7) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %	0 (0.0) %
P-value = 0.007(P-value ≤ 0.05 was significant), x^2 = 61.681										

Table (4.10): Difference in clinical signs of vaccinated individuals during the first dose and the second dose(No. of cases =75)							
Sign and symptom	First dose of Vaccine		Total	Second dose of vaccine	Total		P-value
	Male	Female		Male	Female		
Fever	34 (82.9%)	7 (17.1%)	41 (100.0%)	37 (74.0%)	13 (26.0%)	50 (100.0%)	0.135
Fatigue	31 (75.6%)	10 (24.4%)	41 (100.0%)	25 (75.6%)	8 (24.2%)	33 (100.0)	
Headache	23 (79.3%)	6 (20.7%)	29 (100.0%)	9 (64.3%)	5 (35.7%)	14 (100.0%)	
Chill	8 (80.0%)	2 (20.0%)	10 (100.0%)	4 (80.0%)	1 (20.0%)	5 (100.0%)	
Injection site pain	46 (88.5%)	6 (11.5%)	52 (100.0%)	36 (80.0%)	9 (20.0%)	45 (100.0%)	
Myalgia	37 (90.2%)	5 (12.8%)	41 (100.0%)	32 (82.1%)	7 (17.9%)	39 (100.0%)	
Joint pain	6 (85.7%)	1 (14.3%)	7 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Runny nose	4 (66.7%)	2 (33.3%)	6 (100.0%)	4 (66.7%)	2 (33.3%)	6 (100.0%)	
Nausea	4 (66.7%)	2 (33.3%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Cough	4 (80.0%)	1 (20.0%)	5 (100.0%)	1 (100.0%	0 (0.0%)	1 (100.0%)	
Lymphedema	9 (81.0%)	2 (18.2%)	11 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Shortness	4 (100.0%)	0 (0.0%)	4 (100.0%)	2 (100.0%)	0(0.0%)	2 (100.0%)	
Diarrhea	3 (100.0)	0 (0.0)	3 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Loss of smell and taste and sense	0 (0.0%)	2 (100.0%)	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Hypotension	2 (100.0%)	0 (0.0%)	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
P-value > 0.05 (not significant), x^2 = 33.139							

3.3. General side effects of vaccinated individuals during the first dose and the second dose according to gender

This table (3) shows the general side effects of the volunteer during the first dose and the second dose according to gender, where there is no statistical significance at (P-value >0.05).

4. 4. Discussion

4.1. Prevalence of clinical side effects of vaccinated individuals during the first dose and the second dose

According to the data collected from the participants of this study, which included 75 subjects who received two doses of the vaccine (30 g of mRNA); they were followed up after C2 (21-45 days) and C3, most of the effects occur after the first dose because this dose is more effective at stimulating the immune response and merely sets up the immune system to launch a more potent response when it is time for the next dose (21-120 days). This result was consistent with a Saudi Arabian study (9). The most frequent side effects were local reactions (pain at the injection site and seldom lymphadenopathy); these results are consistent with two trials carried out in Saudi Arabia and the European Union (10,11). Following these were non-specific systemic effects, which were regarded as the most common vaccine typical reactions and appeared 1-3 days after vaccination and continued for 1-2 days. These included myalgia, fever, headache, weariness, chills, and joint discomfort. These systemic symptoms were comparable to and in agreement with a study conducted in Iraq, Jordan, and Egypt (12–14). The side effects that were most frequently reported after receiving the initial dosage were discomfort at the injection site (72.0%), myalgia (66.7%), fever and headache (60.0%), tiredness (53.3%), and chill (18.7%). These results are consistent with research done in the Czech Republic, Slovakia, and the US (8,15,16).

The most frequent side effects following the second dosage were fever (64.0%), discomfort at the injection site (53.3%), myalgia (49.3%), fatigue (40.0%), headache (36.0%), and chills (5.3%). This study's findings regarding the temperature and the remaining symptoms following the second dosage were comparable to those of a Polish study and a Saudi inquiry (2,9).

Although vaccine side effects are often mild, they can occasionally be severe and even fatal (17). Excipients (the inactive components included in the mRNA vaccine to stimulate a greater immune

response) are principally accountable for the rapid and focused IgE-mediated reactions to vaccines (6). The potential of adverse reactions following immunisation is evidence that the immune system is working as it should. One of many intramuscular vaccines notorious for causing patients to experience muscle soreness is Pfizer-BioNTech BNT162b2. Following vaccination, the triggered immune reaction creates an arm ache right away. IM vaccines draw local macrophages and dendritic cells that release cytokines such IL-1, IL-6, TNF-, and PGE2, as well as neutrophils, lymphocytes, and monocytes that secrete prostaglandins. Although there is a robust immunological reaction, nociception is increased by cytokines and prostaglandins, which, once it reaches a certain threshold, manifests as muscular pain (18). The creation of different soluble substances (cytokines and vasodilators) and their circulation entry are most likely what cause systemic effects (fever, myalgia, headache, etc.). Immunological blood cells or distant organs (such the liver) may produce systemic substances that lead to the emergence of these symptoms (19).

4.2. Difference in side effects of vaccinated individuals depending on age groups

In this study, we found that young adults (20-29) had a higher risk of unfavourable consequences compared to individuals of other ages (less than 20, 30-39, 40–49, and older than 50) This result corroborates findings from research conducted in Germany and Singapore demonstrating that young people are more prone to experience adverse reactions following vaccines (1,20).

We claimed that the proximity of the health centre to schools and colleges, as well as its proximity to universities, are the reasons why this age group takes vaccinations. We also linked the fact that this age group followed technology, global health, and scientific research websites more closely than other age groups to the fact that they are more knowledgeable and perceptive. As a result, their desire was greater than that of other age groups. Without hesitation or apprehension, he received the immunisation. Due to the synthesis of type 1 interferon (IFN-I) required to stimulate a strong immune response, young people may have more adverse consequences (21), which explains the occurrence of the majority of their symptoms.

4.3. General side effects of vaccinated individuals during the first dose and the second dose according to gender

According to the findings of the study, there were no significant gender differences in the severity of side effects. This conclusion may explain a number of factors, including the fact that women are less likely than men to want to be vaccinated; another factor for women not receiving the vaccine during pregnancy and breastfeeding is consistent with recent Canadian research; and a Arab study explains why women do not receive the vaccine during pregnancy and breastfeeding (22,23).

5. Conclusions:

1-In this study , that following people for signs and symptoms appear of them after vaccination with two doses, it was proven that these symptoms are temporary and resolve after a few days and do not require special medical care.

2-In this study showed not significant effect of gender or age on the severity of the vaccine's side effects.

6. Recommendations:

1-For a safe society and the return of life to normal, it is necessary to vaccinate the largest possible population group. This is done by administering the vaccinations well.

2-Medical education programs should educate the population about the benefits of vaccinations compared to the few side effects of raising awareness and fighting rumors about vaccination.

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