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RESEARCH ARTICLE

A SURVEY OF THE SIDE EFFECTS OF PFIZER/BIONTECH COVID-19 VACCINE AMONG VACCINATED ADULTS IN IRAQ

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ABSTRACT

BACKGROUND:

Pfizer-BioNTech vaccine was one of the first vaccines developed for COVID-19 to be used in Iraq. While the benefits of the vaccine outweigh the risks, potential side effects remain major concerns for people and can increase vaccine hesitancy despite usually being short-lasting and mild. This study aimed to evaluate the side effects of Pfizer-BioNTech vaccination among vaccinated adults in Erbil city, Iraq.

METHODS:

A cross-sectional study was carried out with a convenience sample of 401 subjects who received the Pfizer vaccine in nine public healthcare centres in Erbil, Iraq, on February 20th, 2022, and April 17th 2022. Data were collected through interviews with the patients using a questionnaire designed by the researchers. A p-value ≤ 0.05 was considered statistically significant.

RESULTS:

The prevalence of side effects was 84.4%. Among participants who experienced side effects, the most common was pain at the injection site (93.1% for the first dose and 88% for the second dose). For the first dose, the onset of side effects on the vaccination day (day zero) was reported by 78.9% of those experiencing side effects, and the duration was one day for 45.4% of participants. Severity was rated as mild by 54.3%, and similar results were found for the second dose. Analgesics were used following the first dose by 47% of participants, which resulted in good relief for 96.6% of patients using them, and similar results were found for the second dose.

CONCLUSIONS:

Most participants who received the Pfizer-BioNTech vaccine experienced side effects, the most common of which was pain at the injection site, which was reported for both the first and second doses.

KEYWORDS

COVID-19, vaccine uptake, vaccine effects, Kurdistan, Iraq

INTRODUCTION

SARS-CoV-2 virus (COVID-19) is a viral infectious disease categorised by the World Health Organization as a global pandemic on March 11th, 2020 [1]. To date, over 490 million cases of COVID-19 infection have been recorded by WHO worldwide, along with roughly 6 million death cases [2]. COVID-19 can cause various clinical symptoms ranging from fever, cough, and loss of taste and smell to chest pain [3] and dyspnoea in moderate to severe cases [4]. An important public health intervention to control the spread of COVID-19 infections is vaccination. Massive vaccination campaigns have been carried out all over the world to fight the pandemic [5]. Nearly 190 COVID-19 vaccines are in various stages of preclinical and clinical development, and a cluster has received Emergency Use Authorization (EUA) and are approved by WHO in different states worldwide. The most famous include Moderna mRNA-1273 and Pfizer-BioNTech (BNT162b2), which depend on messenger RNA (mRNA) technology, and Janssen Ad26.CoV2.S and Oxford-AstraZeneca AZD1222, which depend on non-replicatable viral vector platforms [6].

Pfizer-BioNTech's BNT162b2 vaccine is an mRNA-based COVID-19 vaccine invented by Pfizer and the German company BioNTech during a collaborative effort, which was approved for emergency use in many countries in late 2020. There are two generations of this mRNA vaccine, BNT162b1 and BNT162b2, both of which were invented by PfizerBioNTech collaboration. BNT162b1 is a lipid-nanoparticle (LNP)-delivered mRNA vaccine that express the RBD (trimer) of the "S" protein bound by T4 foldon (the natural domain of T4 fibritin trimerisation) (NCT04368728) [7]. In accordance with a report in the New England Journal of Medicine (NEJM), the efficacy of Pfizer and BioNTech vaccines increases significantly from 52% after the first dose to 95% after the second dose; thus, a double dose regimen for COVID-19 is recommended for people aged 16 years and older [8]. Most Pfizer–BioNTech COVID-19 vaccine side effects are mild to moderate in severity and usually go away within a couple of days [9].

During clinical experiments, the most common side effects (found among more than 1 in 10 of patients receiving the vaccine doses) are (in sequence of frequency): pain and swelling at the site of injection, fatigue, headache, muscle aches, chills, joint pain, and fever. Fever is more prevalent after the second dose [10]. Serious hypersensitivity reaction has been noted in nearly eleven cases per million doses of vaccine given. In accordance with an announcement published by the US Centres for Disease Control and Prevention, 71% of the hypersensitivity reactions occurred within 15 minutes after vaccination, and most frequently (81%) within people with a recorded history of hypersensitivity or hypersensitivity reactions [11]. The majority of side effects disappear on their own after a few days. It is recommended by WHO that side effects are handled with rest, sufficient non-alcoholic liquids, and medication to minimise pain and fever, if necessary. WHO does not recommend taking any pain medication before getting vaccinated, as it is unknown how this might influence vaccine efficacy [12].

Research has shown that the side effects of COVID-19 vaccination were most prevalent (about 80%) among individuals who received Pfizer-BioNTech and Moderna vaccines and were least common among those who received Sinopharm and Sinovac vaccines (21%-28%) [13]. Although the side effects after the Pfizer-BioNTech vaccine are common, they are usually mild and self-limited. Local reactions like pain at the injection site are the most common. Other common side effects include fever and headache. Anaphylactic shock or severe reactions are rare [13, 14]. For example, a systematic review has shown that the most frequent side effects of Pfizer-BioNTech were injection site pain (77%), followed by fatigue (43%), muscle pain (40%), local swelling (34%), and headache (33%). Other less common side effects were also reported, including joint pain, chills, fever, itching, lymph nodes swelling, nausea, dyspnoea and diarrhoea. These side effects were more common after the second dose compared with the first dose (84% vs. 79%) and in females compared with males (69.8% vs. 30.2%) [14].

The acceptability of COVID-19 vaccination might be based on the perceived susceptibility to and severity of COVID-19, concerns about vaccine efficacy and safety, and the influence levels of information from various sources [15]. This study is based on the Health Belief Model, which postulates that the likelihood of an individual adopting specific health behaviour is determined by the belief in a personal threat of illness or disease, together with a belief in the effectiveness of the recommended health behaviour. The main constructs targeted by the theoretical model include attitudes toward the perceived threat of infection and attitudes regarding perceived expectations of vaccination. The latter include perceived risks, benefits, and barriers [15, 16]. This study focuses on the perceived risks of vaccination, particularly the side effects.

In general, people have major concerns about the side effects of COVID-19 vaccines, and these concerns made some people refuse to get vaccinated and even adopt stringently anti-vaccine attitudes [17]. It is the responsibility of the scientific community and healthcare providers to educate people with an evidence-based approach about the vaccine's side effects and explain that the benefits of vaccination outweigh the risks, along with the fact that the side effects are generally temporary [10]. Basic information about common side effects can prepare people and minimise interference with daily activities. This study aimed to evaluate the side effects of Pfizer and BioNTech vaccine among vaccinated adults in Erbil City, Iraq.

SUBJECTS AND METHODS

STUDY DESIGN: CROSS-SECTIONAL STUDY.

Study setting: Across nine public vaccination centres in Erbil City, the Capital of the Kurdistan Region, Iraq. Those who attended for vaccination at these centres did so voluntarily.

Time of the study: The study was conducted between January 2022 and June 2022. The data was collected between February 2022 and March 2022.

Study sample (size): The calculated sample size was 384.16, estimated through Cochrane's formula, which we rounded up to 385, adding an additional 30 to the target sample size to overcome non-response. Fourteen individuals with Pfizer-bioNTech refused to participate; thus, the non-response rate was 3.37%. In the end, 401 samples were collected and analysed.

Sampling method: The data was collected through the convenience sampling method.

Data collection and questionnaire: Data was collected through a questionnaire designed by the researchers comprising three parts: (1) sociodemographic characteristics (age, gender, ethnicity, residence, monthly income, occupation, education level); (2) knowledge and medical history; and (3) questions about the participant reported side effects in two different sections, concerning first and second dose experiences. The list of potential side effects was based on the lists reported by the clinical experiments of the vaccine and previous research studies. It included pain and swelling at the injection site, fatigue, headache, muscle aches, chills, joint pain, and fever. Fever is more prevalent after the second dose [10]. The questionnaire was designed in the Kurdish and Arabic languages and was administered according to the participant's native language or preference.

Ten experts in the field evaluated the content and face validity of the study questionnaire. The calculated content validity index was 0.87, and the content validity ratio was 0.89. The study questionnaire was pilot tested on 12 participants to assess its clarity, comprehensibility, acceptance, and internal consistency. The reliability was assessed using a test-retest approach. Kappa statistic was calculated, which showed a reliability coefficient of 0.77.

Techniques to ensure data quality control and reduce potential biases include having a large sample size, data on a number of confounders, and minimal missing data. Responses with significant missing data were excluded from the analysis to reduce bias caused by missing data.

Statistical analysis: Data entry and analysis were done using SPSS (version 26) software. Data was presented in the form of frequencies and percentages for categorical data. Associations between categorical variables were measured using the Chi-square test. When the expected count for more than 20% of the cells in the contingency table was less than 5, Fisher's exact test was used instead. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

SOCIOECONOMIC CHARACTERISTICS OF PARTICIPANTS

The largest cohort of participants were aged between 20 and 34 (45.5%), and only 0.49% were above or equal to 80 years. Most participants were male (69.1%), and 90.5% were of Kurdish ethnicity. Over a third (34.2%) were public employees, while 4.2% were retired. Around 34% were graduates or postgraduates, while 7.9% were illiterate. Most (87.8%) were residents in urban areas. Most participants were married (65.8%), and a single subject was a widow (0.24%). The majority considered their monthly income sufficient (86%), while 4.3% considered it more than sufficient monthly income (Table 1).

TABLE 1. SOCIODEMOGRAPHIC CHARACTERISTICS OF THE STUDY PARTICIPANTS

Variable	No.	(%)
Age group		
< 20	24	(5.9)
20 – 34	183	(45.6)
35 – 49	110	(27.4)
50 – 64	62	(15.4)
65 – 79	20	(4.9)
≥80	2	(0.49)
Gender		
Male	277	(69.1)
Female	124	(30.9)
Ethnicity		
Kurd	363	(90.5)
Arab	27	(6.7)
Turkmen	11	(2.7)
Occupation		
Student	67	(16.7)
Not employed	28	(7)
Public employee	137	(34.2)
Private sector employee	105	(26.2)
Housewife	47	(11.7)
Retired	17	(4.2)
Educational level		
Illiterate	32	(7.9)
Read and write/Primary	68	(16.9)
Secondary	76	(18.9)
Undergraduate	90	(22.4)
Graduated / postgraduate	135	(33.6)
Residence		
Urban	352	(87.8)
Suburban	49	(12.2)
Marital status		
Single	136	(33.9)
Married	264	(65.8)
Widow	1	(0.24)
Monthly income		
Insufficient	39	(9.7)
Sufficient	345	(86)
More than sufficient	17	(4.3)
Total	**401**	**(100)**

KNOWLEDGE OF PARTICIPANTS ABOUT THE VACCINE AND THEIR MEDICAL HISTORY

The majority (62.6%) of participants considered themselves knowledgeable about the vaccine's side effects. In Regard to reasons why they preferred the Pfizer-bioNtech vaccine over the other types of COVID-19 vaccines, 33.9% stated that they considered it to have better efficacy and fewer side effects, while 7.5% stated this was due to mandatory vaccination from their employers (Table 2).

TABLE 2. REASONS FOR CHOOSING PFIZER-BIONTECH VACCINE

Reasons	No.	(%)
Efficacy and less side effects	136	(33.9)
Popularity	95	(23.6)
Travelling	59	(14.7)
Imposed by employer	30	(7.4)
No specific reason	81	(20.1)
Total	401	(100)

In regard to the medical history of participants,19.5% had a current chronic disease (including hypertension, diabetes, asthma, cardiovascular, and respiratory conditions), and 8.7% had a positive history of allergy to common allergic agents. Almost half of the participants (49.4%) reported having had a COVID-19 infection before the vaccination (Table 3).

SIDE EFFECTS OF COVID-19 VACCINE

Over a third (n=140, 35%) of participants had received one dose of the vaccine, while 261 participants (65%) had received both doses. The prevalence of side effects among those who had received only one dose was 84.4%. Among those who had received both doses, 58.8% reported side effects, including 19.9% (n=52) after the first dose, 14.2% (n=37) after the second dose, and 56.3% (n=147) after both doses (Table 4).

Results regarding differences in the occurrence of side effects in relation to demographic and medical history variables revealed no significant associations between age (p=0.406), gender (p=0.466), history of allergies(p=0.116), chronic disease (p=0.054), and previous history of COVID-19 (p=0.054) and the occurrence of side effects (Table 5).

TABLE 3. PAST MEDICAL HISTORY REPORTED BY PARTICIPANTS

Past medical history	No.	(%)
Chronic diseases (Hypertension, DM, respiratory diseases)	78	(19.5)
Allergy to common allergens	35	(8.7)
Prior COVID-19 infection	198	(49.4)
Total	311	(77.6)

TABLE 4. SIDE EFFECTS FOR SINGLE AND DOUBLE DOSED PATIENTS REPORTED BY PARTICIPANTS

No. of dose and presence of side effect	No.	(%)
Received one dose		
Had side effects	118	(84.3)
No side effects	22	(15.7)
Total	140	(100)
Received two doses		
Only in the first dose	52	(19.9)
Only in the second dose	37	(14.2)
In both doses	147	(56.3)
No side effects	25	(9.6)
Total	261	(100)

TABLE 5. DIFFERENCES IN SIDE EFFECTS OCCURRENCES RELATIVE TO SOCIOECONOMIC STATUS AND MEDICAL HISTORY

Variable	Side effects				Total		P value
	Had side effects		No side effects				
	No.	(%)	No.	(%)	No.	(%)	
Age group (years)							
< 20	21	(87.5)	3	(12.5)	24	(100)	0.406*
20 – 34	167	(91.3)	16	(8.7)	183	(100)	
35- 49	98	(89.1)	12	(10.9)	110	(100)	
50.- 64	51	(82.3)	11	(17.7)	62	(100)	
65 – 79	16	(80)	4	(20)	20	(100)	
≥ 80	1	(50)	1	(50)	2	(100)	
Gender							
Male	241	(87)	36	(13)	277	(100)	0.466
Female	113	(91.1)	11	(8.9)	124	(100)	
History of allergy							
has history of allergy	33	(94.3)	2	(5.7)	35	(100)	0.116*
no allergy	321	(87.7)	45	(12.3)	366	(100)	
Chronic disease							
has chronic disease	67	(85.9)	11	(14.1)	78	(100)	0.235
no chronic disease	287	(88.9)	36	(11.1)	323	(100)	
Prior COVID-19 infection							
has prior infection	181	(91.4)	17	(8.6)	198	(100)	0.054
no prior infection	173	(85.2)	30	(14.8)	203	(100)	
Total	354	(88.3)	47	(11.7)	401	(100)	

* Fisher's Exact Test is used (for others, Pearson Chi-Square test is used)

The common side effects after the first dose included local pain at the injection site (n=317, 93.1%), and there were two cases of allergic reactions (0.6%). Fatigue, fever, headache, and joint pains were reported less than local pain. The most common side effect after the second dose was again local pain at the injection site (n = 184, 88%), and joint pain (arthralgia) was the least experienced side effect (17.9%) (Table 6).

TABLE 6. SIDE EFFECTS OF FIRST AND SECOND DOSES OF THE VACCINE AMONG THE PARTICIPANTS

Dose	Local pain	Fatigue	Fever	Headache	Joint pain	Allergic reaction
1	295 (93.1)	147 (46.4)	101 (31.9)	101 (31.9)	34 (10.7)	2 (0.6)
2	162 (88)	85 (46.2)	88 (47.8)	69 (37.5)	33 (17.9)	0 (0)

Regarding the onset of the side effects after the first dose, the majority (78.9%) of participants reported that they experienced side effects on the day of vaccination (day zero), while only 0.6% of them reported onset three days after vaccination. For the second dose, similar results were found, with 80% of participants reporting that the onset of side effects occurred on the day of vaccination, while only 1.6% of participants reported it two days after vaccination (Table 7).

Regarding the duration of the side effects, for the first dose, the largest group of those experiencing side effects (45.4%) reported that they lasted only one day, while 3.8% reported four days and 6.3% reported five or more days. Similar figures were found for the second dose, with 45.7% of participants reporting one day of symptoms and 1.1% reporting four days (Table 7).

Regarding the severity of the side effects based on their interference with regular daily activities among those who reported side effects, following the first dose 54.3% reported

mild impacts, followed by moderate (33.1%), while over a tenth reported severe (12.6%). Following the second dose, almost half cited mild symptoms (49.5%), followed by moderate (37.5%) and then severe (13%) (Table 7).

The findings of onset, duration, and severity in regard to differences between the first and second dose were tested to determine any statistically significant difference between them; the results were only significant in duration (p=0.009), while there was no significant difference in severity (p=0.557) and onset (p=0.867 between first and second doses (Table 7).

TABLE 7. SIDE EFFECT ONSET, DURATION, AND SEVERITY WITH FIRST AND SECOND DOSE

Variable	First dose		Second dose		P value
	No.	(%)	No.	(%)	
Onset					
Same day	250	(78.9)	149	(81)	0.867*
After 1 day	60	(18.9)	32	(17.3)	
After 2 days	5	(1.6)	3	(1.6)	
After 3 days	2	(0.6)	0	(0.0)	
Duration					
1 day	144	(45.4)	84	(45.6)	0.009
2 days	94	(29.6)	73	(39.7)	
3 days	47	(14.8)	12	(6.5)	
4 days	12	(3.8)	2	(1)	
≥ 5 days	20	(6.3)	13	(7)	
Severity					
Mild	172	(54.2)	91	(49.4)	0.557
Moderate	105	(33.1)	69	(37.5)	
Severe	40	(12.6)	24	(13)	
Total	317	(100)	184	(100)	

* Fisher's Exact Test is used (for others, Pearson Chi-Square test is used)

DISCUSSION

Vaccines play major roles in preventing and controlling communicable diseases that may cause epidemics, including controlling and eliminating COVID-19. During the COVID-19 pandemic, the scientific community faced significant vaccine hesitancy among the general public [15], which reflected public fears due to the unprecedented public health measures being instituted (i.e., a general climate of fear surrounding the virus itself and lockdown policies) and the perception that novel vaccines (particularly in terms of mRNA technology) were being rushed to market as per emergency use authorisation. Consequently, there was much hesitancy concerning potential side effects, and media sensationalism in reporting rare adverse effects of vaccines such as thrombosis [18], myocarditis [19], and anaphylactic/allergic reactions contributed to vaccine hesitancy and refusal.

In the current study, the side effects were not significantly associated with the demographic and medical history variables of the participants. However, the current study included only a limited number of factors and did not assess the effect of many other potential risk factors.

Other studies have revealed several factors significantly associated with the development of side effects. For example, people not engaged in physical activity are more likely to develop side effects than those involved. The side effects were also more common among those who felt fear when vaccinated than those who did not [20]. Other studies have shown that females and those married are more likely to develop side effects than males and singles [21]. Another study showed that higher odds of side effects were associated with full vaccination dose, vaccine brand, younger age, female sex, and having COVID-19 before vaccination [22].

In this study most participants experienced at least one side effect from the Pfizer-BioNTech vaccine after the first (76.2%) and second (70.5%) doses. These findings are similar to those of a study conducted in the UK, which reported71.9% (150,023 out of 208,767) for individuals after the first dose and 68.5% (9,025 out of 13,179) after the second dose of Pfizer-BioNTech vaccine [23].

In this study, among participants who reported side effects, the vast majority reported pain at the injection site after the first (93%) and second (88%) doses, which is a universal feature of injectable vaccines [24]. Nevertheless, it is notable that 13 out of 317 subjects with side effects in the first dose did not report localised pain at the injection site, which makes 6.9%, and 22 out of 184 subjects with side effects in the second dose, which makes 12%. This may be attributable to improved vaccine administration techniques and practices among healthcare professionals, leading to fewer adverse reactions and side effects [25]. Another study undertaken in 2020 found that local pain at the site of injection was reported by 83% of the participants after the first dose and 78% after the second dose [26]. Consequently, it is recommended to administer injectable vaccines in the non-dominant arm to decrease the impact of side effects on daily activities. Other side effects, such as fever, fatigue, headache, and joint pain, were all relatively common but not as significant as local pain at the injection site. Participants usually treated their side effects with analgesics or antipyretics for relief.

This study showed two cases of anaphylactic reactions to the vaccine, similar to the results found in a study conducted in Israel [27]. Although this outcome is very rare, the consequences are very serious for the individuals affected, and after vaccination, one should prepare for the potential of such cases.

The onset of most side effects in this study was reported to be on day zero for 78.9% of participants after the first dose, of whom 45.4% reported that they lasted for one day, while 29.7% cited two days. Most participants experiencing side effects after the second dose reported that onset was on day zero (80%); of these participants, 45.7% recalled that symptoms lasted for one day, while 39.7% said they lasted for two days. Of those experiencing side effects after the first dose, 54.3% rated them as mild in severity, and 12.6% reported them to be severe. For those experiencing side effects after the second dose, 49.5% reported mild, and 13% reported severe severity. These findings are similar to the results of a study conducted in Saudi Arabia, in which the onset of the symptoms was reported mostly to be within 24 hours after vaccination for the majority of those experiencing side effects (66.3%), followed by onset between 24 to 48 hours later (23.2%). The intensity was mainly mild (30%) to moderate (57.9%), with only 12.1% reporting severe symptoms [28].

Research has shown that several factors are associated with hesitancy and vaccination resistance, including side effects [29]. For example, a study showed that more than half of the respondents claimed not taking the first dose even two months after the initiation of vaccination due to fear of some reaction or side effects, safety concerns regarding the vaccine, reservations concerning the success of vaccination, and the efficiency of the vaccine [30].

COVID-19 vaccine concerns among the population should be addressed through communication campaigns to improve COVID-19 vaccine uptake [30]. Educational campaigns and efforts to raise awareness about the safety and efficacy of COVID-19 vaccines must be directed to the population. Health education and measures to prevent the harmful effects of COVID-19 vaccine misinformation could potentially improve the acceptance rate of the COVID-19 vaccine. Providing pre-awareness about the side effects to reduce observed anxiety related to the vaccine is recommended. It is also important to plan monitoring and evaluation of the post-vaccine effect using standard longitudinal study designs to measure the effects directly.

LIMITATIONS OF THE STUDY

This study is cross-sectional, so causality cannot be assessed adequately for some of the above mentioned associations. There is some potential for recall bias for various data points since they were self-reported by participants, and there were at least 21 days between the first and second vaccination doses.

CONCLUSIONS

Most participants who received the Pfizer-BioNTech vaccine experienced side effects, the most common of which was pain at the injection site, which was reported for both the first and second doses. Other symptoms, such as fever, fatigue, headache, and joint pain, were much less common than local pain. The most common time for the onset of side effects was on day zero (the day of vaccination), and in most cases, they were of mild severity and lasted only one day. These findings were similar for

both the first and second doses. Using analgesics can provide relief for the most common side effects.

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AVAILABILITY OF DATA AND MATERIALS

The questionnaire and datasets used in this study are available with the corresponding author upon reasonable request.

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AUTHOR'S CONTRIBUTIONS

AMS designed the study, collected data, interpreted the results, prepared all tables and figures, wrote the manuscript and reviewed it before submission. NPA contributed to data analysis and writing of the manuscript and reviewed, revised and finalised the manuscript.

ETHICS DECLARATIONS

Ethics approval and consent to participate: This study was approved by the Ethical Committee of the College of Health Sciences, Hawler Medical University, Erbil, Iraq (reference number 6 dated 5th January 2022). Informed consent was obtained from all participants after explaining all the study details to them and from a parent and/or legal guardian for the illiterate population included in the study. All methods were performed in accordance with the relevant guidelines and regulations.

CONSENT FOR PUBLICATION

Not applicable

COMPETING INTEREST

The author declares no competing interest.

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