Side Effects of Pfizer-BioNTech COVID-19 Vaccine among medical staff

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ABSTRACT:

Background: A key public health intervention strategy to stop the spread of infectious diseases, such as the present COVID-19 pandemic, is vaccination. Nearly 190 COVID-19 vaccines are now being developed at various phases of pre-clinical and clinical testing, with a few vaccines recently receiving Emergency Use Authorizations (EUA) and being accepted by the WHO in several regions of the world.
Patients and Methods: A cross-sectional design was adopted to conduct the study which involve all medical staff who attends to Covid-19 vaccination center at Al-Mosul General Hospital during the period from 1st July 2021 to 31st November 2021. The study sample was 200 participants of different specializations who attend to take the 1st or the 2nd dose of the Covid-19 vaccine. The interview was done by the researchers directly through a checklist. The statistical analysis was done with IBM-SPSS-26.
Results: The mean age of the study sample is 34.8 years, 56.5% of them are males and 43.5% are females, fever is the most frequent side effect representing 49.0%, and the inflammatory reaction at the site of injection whether mild or severe represents 35.0%, pain at the injection site occurs in 28.5%, and headache occurs in 9.5%, shows that 69.7% are females and 30.3% are males. The Pfizer vaccine of batch no. FJ8198, FM3444, and FJ1966 were associated with side effects more than others.
Conclusion: COVID-19 vaccine showed that the safety of the vaccine with no major side effects emerging and females were more prone to experience side effects. The Pfizer vaccine of batch no. FJ8198, FM3444, and FJ1966 were associated with side effects more than others.

Keywords: COVID-19, Iraqi Medical staff, Pfizer-BioNTech vaccine, Side effects.

الآثار الجانبية للقاح كوفيد 19 نوع فايزر وسط الوسط الطبي

الخلاصة:

الخلفية: تتمثل إستراتيجية التدخل الرئيسية في مجال الصحة العامة لوقف انتشار الأمراض المعدية ، مثل جائحة كوفيد-19 الحالي ، في التطعيم. يتم الآن تطوير ما يقرب من 190 لقاحًا من لقاح كوفيد-19 في مراحل مختلفة من الاختبارات قبل السريرية والسريرية ، مع تلقي عدد قليل من اللقاحات مؤخرًا تصاريح استخدام الطوارئ وقبولها من قبل منظمة الصحة العالمية في العديد من مناطق العالم.
المرضى والطرق: تم اعتماد تصميم مقطعي لإجراء الدراسة التي تشمل جميع الطاقم الطبي الذي يحضر إلى مركز التطعيم كوفيد-19 في مستشفى الموصل العام خلال الفترة من 1 يوليو 2021 إلى 31 نوفمبر 2021. الدراسة كانت العينة 200 مشاركًا من تخصصات مختلفة حضروا لأخذ الجرعة الأولى أو الثانية من لقاح كوفيد-19. أجرى الباحثون المقابلة مباشرة من خلال قائمة مرجعية. تم إجراء التحليل الإحصائي باستخدام الحزمة الاحصائية للعلوم الاجتماعية 26.
النتائج: بلغ متوسط عمر عينة الدراسة 34.8 سنة ، 56.5٪ منهم ذكور و 43.5٪ إناث ، والحمى هي أكثر الأعراض الجانبية شيوعاً بنسبة 49.0٪ ، ورد الفعل الالتهابي في موقع الحقن سواء كان خفيفاً أو خفيفاً. حاد يمثل 35.0٪ ألم في موضع الحقن

28.5٪ والصداع 9.5٪ يظهر أن 69.7٪ إناث و 30.3٪ ذكور. ارتبط لقاح فايزر من الدفعات رقم FJ8198 و FM3444 و FJ1966 بآثار جانبية أكثر من غيرها.
الخلاصة: أظهر لقاح كوفيد-19 سلامة اللقاح مع عدم ظهور آثار جانبية كبيرة وأن الإناث كن أكثر عرضة لتجربة الآثار الجانبية. ارتبط لقاح فايزر من الدفعات رقم FJ8198 و FM3444 و FJ1966 بآثار جانبية أكثر من غيرها.

الكلمات المفتاحية: كوفيد-19 ، الطاقم الطبي العراقي ، لقاح فايزر-بايوتك ، الآثار الجانبية

INTRODUCTION:

By November 30, 2020, there had been more than 60 million instances of COVID-19 and 1.5 million fatalities globally as a result of the SARS-CoV-2 pandemic, which poses an enormous threat to global health. Over 13 million cases have been documented in the United States, according to the Centers for Disease Control and Prevention (CDC), there have been over 260,000 deaths, confirmed worldwide, and the number of illnesses and deaths keeps increasing. The American Health Secretary will announce on January 31, 2020, a COVID-19 public health emergency, according to the Department of Health and Human Services (HHS). The operational divisions of HHS were mobilized [(1)].

Before the development of the vaccination, several preventative measures have been implemented to stop this pandemic, including lockdown, social withdrawal, facemask use, and travel restrictions [(2)].

The Pfizer-BioNTech COVID-19 vaccine can now be used in an emergency, according to the US Food and Drug Administration (FDA) on December 11, 2020. Two doses must be administered, at least 21 days apart, for the vaccine. According to reports, the 95 percent maximal efficacy can be attained one week after the second dose. Those 16 years of age and older could use the vaccine. The Moderna COVID-19 vaccine, which has an efficacy rate of 94.1 percent and is approved for use in adults 18 and older, has also been permitted for emergency use. Additionally, the Moderna vaccination requires two shots that are spaced apart by 28 days[(3)].

A key public health intervention strategy to stop the spread of infectious diseases, such as the present COVID-19 pandemic, is vaccination [(4)].

Nearly 190 COVID-19 vaccines are now being developed at various phases of pre-clinical and clinical testing, with a few vaccines recently receiving Emergency Use Authorizations (EUA) and being accepted by the WHO in several regions of the world[(5, 6)].

Based on mRNA technology to express the SARS-CoV-2 spike (S) gene, the Pfizer-BioNTech vaccine (BNT162b2) protects against SARS [(7)]. The use of mRNA vaccines in the manufacturing of vaccines has just recently been made possible, and some are currently undergoing clinical testing, including those against the HIV and ZIKA viruses [(8)]. The Pfizer-BioNTech vaccine (BNT162b2) is thought to be the first mRNA-based vaccine for infectious diseases to be authorized for use in humans, nonetheless[(9)].

Every component of the COVID-19 vaccine is secure. The majority of the components in COVID-19 vaccinations are salts, sugars, and fats, which are present in a wide variety of meals. Also included in the Pfizer-BioNTech COVID-19 vaccine is a harmless messenger RNA fragment (mRNA). The COVID-19 mRNA instructs body cells on how to mount an immunological defense against the COVID-19 virus. Your resistance to COVID-19 infection is boosted by this reaction. All of the vaccine's components are eliminated when the body mounts an immune response, just as it would with any chemical that the body's cells no longer require. This procedure is necessary for the body to function normally[(10)].

The first emergency use authorization (EUA) for vaccination to prevent COVID-19, a condition brought on by the severe acute respiratory syndrome coronavirus 2, was issued by the U.S. Food and Drug Administration (FDA) on December 11, 2020. (SARS-CoV-2) [11]. A week later, a second COVID-19 vaccination was approved. These approvals mark a public health milestone by offering the first preventative measures against the worst pandemic to hit the world in over a century. They also mark the beginning of a vaccine development process comparable in scale and urgency to the storied Manhattan Project. These two vaccines are particularly noteworthy for being the first FDA-approved medications that use synthesized mRNA as a unique therapeutic platform (mRNA) [12].

Every cell in our body uses messenger RNAs, which act as a major hub for the communication between the genome's instructions and the synthesis of proteins. Synthetic mRNAs use this similar natural process, but they are made specifically to encode proteins that have therapeutic properties. The COVID-19 mRNA vaccines generate a full-length SARS-CoV-2 spike protein that has two mutations (K986P and V987P) that guarantee it stays in an antigenically advantageous perfusion conformation [13]. mRNA is injected into the muscle, where it is absorbed by immune cells and used to create the spike protein. The spike protein is presented on the cell surface by a trans-membrane anchor, making it visible to the immune system. As a result, antibodies and T cells are produced, defending the body against external infections and averting major illnesses. Synthetic mRNAs cannot create COVID-19 because they only produce one part of the SARS-CoV-2 genome [14, 15].

The fact that these vaccinations are non-replicating mRNAs that naturally break down and do not integrate into genomes is also significant. The original literature covering these vaccines contains thorough descriptions of their development and characterization, as well as multiple top-notch reviews [16–18].

The objective of this study was to assess any short-term side effects following the administration of the first, second, or both doses of the Pfizer-BioNTech COVID-19 vaccine.

PATIENTS AND METHOD:

A cross-sectional design was adopted to conduct the study which involves all medical staff who attends to Covid-19 vaccination center at Al-Mosul General Hospital during the period from 1st July 20121 to 31th November 2021.

The study sample was 200 participants of different specializations who attend to take the 1st or the 2nd dose of the Covid-19 vaccine.

The inclusion criteria included the administration of at least one dose of the Pfizer-BioNTech COVID-19 vaccine. While the medical staff who were not vaccinated against COVID-19 for any reason or who had received a vaccine other than one made by the Pfizer Company were excluded.

The interview was done by the researchers directly and verbal consent was taken before starting the data collection which was carried out through a checklist constructed for this purpose including age, gender, residence, batch no. of vaccine, and the dose. The follow-up period continues for 6 months to record the side effects. The statistical analysis was done with IBM-SPSS-26.

RESULTS:

Table (1) demonstrates the statistical characteristics of the study sample and shows that the mean age is 34.8 years; among the

males is 33.5 years while among the female is 36.5 years

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Table (1): The statistical characteristics of the study sample.

Statistical characteristics for age		Sample	Males	Females
Mean		34.8	33.5	36.5
Std. Deviation		11.07	10.8	11.2
Range		43.0	43.0	43.0
Minimum		19.0	19.0	19.0
Maximum		62.0	62.0	62.0
Percentiles	25	25.0	23.0	27.0
	50	33.0	30.0	36.0
	75	44.0	43.0	45.0

Figure (1) shows the distribution of the study sample according to gender and illustrates that 56.5% of the sample are males while 43.5% are females.

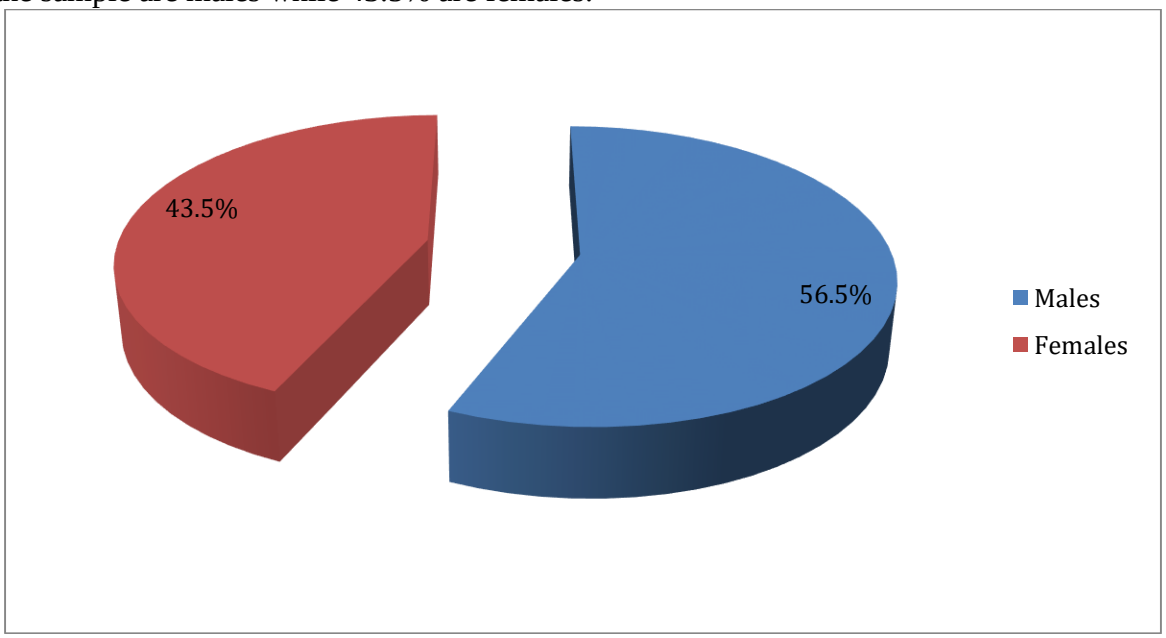

Figure (1): The distribution of the study sample according to gender.

Figure (2) demonstrates the frequencies of the Covid-19 side effects among the study sample and shows that fever is the most frequent symptom among the sample representing 49.0%, the inflammatory reaction at the site of injection whether mild or severe represents 35.0%, pain at the injection site occurs in 28.5%, headache occurs in 9.5%, fatigue in 7.0%, body pain 5.0%, bleeding 5.0%, nasal congestion 4.0%, cough 4.0%, tiredness 3.0%, flu and tonsil 2.0%, vomiting 2.0%, anorexia 1.0%, shoulder pain 1.0%, HT 1.0%, diarrhea 1.0%, nausea 0.5%, SOB 0.5%, back pain 0.5%, fit 0.5%, and LN enlargement 0.5%.

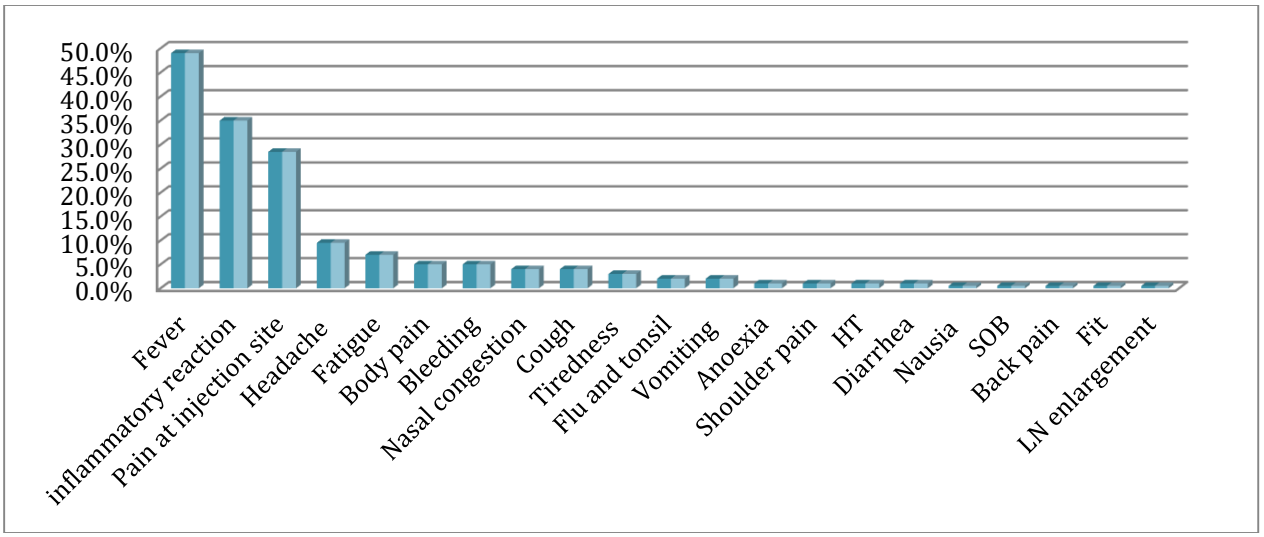

Figure (2): Frequencies of the Covid-19 side effects among the study sample.

Figure (3) displays the distribution of the vaccinated study sample according to gender and shows that 69.7% are females and 30.3% are males.

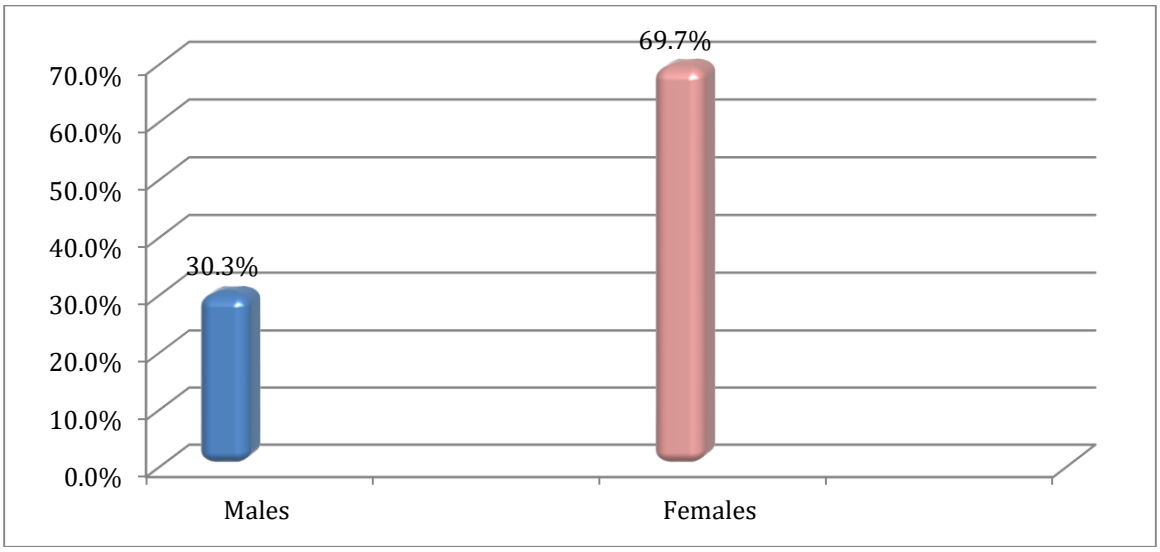

Figure (3): The distribution of the vaccinated study samples according to gender.

Table (2) demonstrates the distribution of side effects according to Batch no. of the vaccine and depicts that fever occurs in 31 participants given the FJ8198 vaccine, five persons with FJ1966, and four person with FM3444, while high fever mostly occurs in two persons with F51966. Pain at the injection site, body pain, headache, fatigue, and tiredness occur in 16, 4, 5, 2, and 2 persons respectively who were vaccinated with FJ8198.Fatigue and tiredness are found in two persons for each in addition to 5 persons developing bleeding with FM3444. Inflammatory reaction develops mainly in 15 participants and severe reaction occurs in 17 persons seen with FJ8198. Flu and tonsil in 2, diarrhea in 2, cough in 6, nasal congestion in 3, HT in 2, vomiting, back pain, fit, dizziness, SOB, and anorexia each present in one participant. Enlargement of LN is found with FN1455 in one person only.

Table (2): Distribution of side effects according to Batch no. of the vaccine.

Batch No.	Fever	High fever	Pain at injection site	Body pain	Headache	Fatigue	Tiredness	Severe IR	Inflammatory reaction	Flu and tonsil	Diarrhea	Cough	Nasal congestion	HT	Vomiting	LN enlargement	Back pain	Fit	Dizziness	Anorexia	SOB	Bleeding
ET0384	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EY4825	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F51965	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F51966	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FA5742	2	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FA5843	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
FC8289	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FC9001	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FD3613	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FD3613	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FD5613	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FD7220	1	0	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FD8813	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FE1510	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FE6014	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
FE8087	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
FF5109	2	0	0	1	1	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
FF8111	2	0	0	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

FF8838	1	0	3	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FJ1966	5	0	2	0	0	0	1	0	4	0	0	1	1	1	0	0	0	0	0	0	0	0
FJ4182	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FJ4188	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FJ8198	31	0	16	4	5	2	2	17	15	2	2	6	3	2	1	0	1	1	1	1	1	2
FJ8798	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FL7309	2	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
FM3444	4	0	1	0	2	2	2	12	0	0	0	1	1	0	0	0	0	0	0	0	0	5
FM3496	3	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FN1455	2	0	0	0	1	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FY8198	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

DISCUSSION:

Vaccination is still an important tool for managing COVID-19 in a healthy way. Iraq was the first country to provide the Pfizer-BioNTech COVID-19 vaccine an interim authorization. The current study described the adverse effects of Pfizer-BioNTech COVID-19 immunization in light of international studies that have been published regarding the safety and side effect profiles of mRNA COVID-19 vaccines.

The present study showed that fever was the most frequent symptom among the study sample accounting for 49.0%, while the inflammatory reaction at the site of injection was reported by 35.0%, and pain at the injection site occurred in 28.5%. These results were much lower than the findings of the Alamer *et al.,* study [19] which found that the most frequently reported side effects were pain or redness at the site of injection (90%), fatigue (67%), fever (59%), headache (55%), nausea or vomiting (21%), and chest pain and shortness of breath (20%). Joint or bone pain was reported less frequently among our participants (2%). In addition, the data from the present study are in support of the data from clinical trials as well as other real-world studies [20-23]. In phase 3 clinical trials done by Skowronski and De Serres [24] on the BNT162b2 vaccine, the three most common events after the first dose were injection-site pain (71–83%), fatigue (34–47%), and headache (25–42%). Also found that only 14% of the participants needed to see a doctor due to vaccine side effects, and only 8% of individuals were admitted to the hospital following vaccination. While the reported side effects were commonly associated with the COVID-19 vaccine, physician visits and hospitalizations after vaccination in this age group could be driven by more worrisome parents about their children.

The data sheet states that the most typical side responses, which include discomfort at the injection site, fatigue, headaches, muscle and joint pain, chills, and an elevated body temperature, might linger for days and are more likely to occur after the second shot

than the first. The immune system's reaction could be used to interpret this observation. Cytokines that the immune system may create may cause inflammation in the muscles, blood vessels, and other tissues. Additionally, it has been known to cause flu-like symptoms days following vaccination [25].

It has been suggested that the Pfizer-BioNTech COVID-19 vaccination may cause a serious allergic reaction. After getting the vaccine dose, an acute allergic reaction will eventually occur within a few minutes to an hour. Dyspnea, swelling of the face and throat, a rapid heartbeat, a body rash, dizziness, and weakness can all be symptoms of an acute allergic reaction. Bell's palsy has also been listed as a relatively uncommon adverse reaction to the vaccination [26, 27].

Al Sa'ady*et al.*,[28] study reported that the most common symptoms were fatigue (66.5%), fever (52%), headache (42.4%), and complications at the injection site (34.3%) which were trivial and self-limiting.

Although all of these epidemiological studies have reported variable adverse reactions ranging from mild to moderate in severity with the incidence (most commonly.60 percent and in some studies 100%) in the vaccinated groups, the incidence of adverse reactions in the present study was parallel to the findings of other studies [29, 30].

Although males were more frequently vaccinated in the present work, the females showed more side effects than the males. Since the results of earlier experiments were not disclosed in a gender-sensitive manner, information on sex or gender differences is still lacking. Despite receiving just 61 percent of the immunizations, women reported 79 percent of all adverse effects to the Centers for Disease Control and Prevention, based on an examination of 13.7 million doses of the COVID-19 vaccine provided in the USA [31]. Additional research based on actual data revealed a similar trend towards higher reactogenicity in females [32, 33].

According to published research, adverse symptoms were more common in women than men and persons under age of 55 compared to those over 55 years [20-22]. Similar to this, another study revealed that female participants experienced higher side effects than male participants. It is thought that the physiologic differences imposed by gender differences are related to the diversity in immunogenicity toward vaccines [34]. Moreover, a study done by Alamer *et al* [20] reported that the female participants developed more side effects when compared to male participants 52.0% and 48.0% respectively. Similarly, the study conducted by El-Shitany *et al.*,[35] showed a significant difference between the number of males and females who suffered from COVID-19 vaccine side effects. There was a significant increase ($p < 0.001$) in the number of female participants who reported different side effects after they receive the vaccine (264, 58%) compared to males (128, 28.1%).Saita *et al.*,[36] study also found that females have reported more side effects than others.

To our knowledge, no previous study conducted to find the Pfizer vaccine side effects concerning batch no., the current work found that different batch no. of vaccine are associated with different side effects, and the most of participants who receive the vaccine of batch no. FJ8198 experienced the most different side effects among the study sample. The FM3444 and FJ1966 were associated with lesser frequent side effects.

CONCLUSION:

COVID-19 vaccine showed that the safety of the vaccine with no major side effects emerged and females were more prone to experience side effects. The Pfizer vaccine of batch no. FJ8198, FM3444, and FJ1966 were associated with side effects more than others.

LIMITATIONS OF THE STUDY:

The cohort resulted from convenience sampling, which limits the representativeness of the results. The decision as to whether or not to participate this survey might have depended on several reasons; persons who suffered from stronger vaccine reactions might have been more prone to share their experiences, leading to an overestimation of reactogenicity. Also, the recommended interval varied between vaccines; the vaccine program was an ongoing process. The time between vaccinations and the survey might have varied substantially between participants, potentially influencing the memories of reactions.

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CONFLICTS OF INTEREST:

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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