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Adverse consequences Following COVID-19 Vaccination

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ABSTRACT

Background: Employing a potent preventive measure stands as the sole recourse against COVID-19. The global scale of the COVID-19 pandemic has propelled an unparalleled rush in vaccine development. This pressing demand has spawned a diverse range of approaches in vaccine development considerations. Any potential adverse events from the COVID-19 vaccine are typical indicators that the body is building protection. **Objectives:** To identify the prevalence, types and to investigate the possible attributed factors for the adverse events associated with COVID-19 vaccines. **Method:** A descriptive cross-sectional study that was conducted in the Iraq / Baghdad / Al-Resafa Directorate of Health (DOH) from the 7th of April to the 5th of August 2021. A total of 420 participants were enrolled in the study. **Results:** The most prevalent adverse events were injection site tenderness and joint pain /lethargy. There was a significant association between the adverse event, time of disappearance, and the type of vaccine, the highest percentage was associated with Pfizer BioNTech. The adverse events were significantly higher in females. There was a significant association between the first and second doses regarding the prevalence of injection site tenderness, joint pain, fever, and other adverse events. **Conclusion:** Most vaccinated people developed mild adverse events, pain at the site of injection was the most prevalent adverse event. The gender and type of vaccine significantly affected the development of the adverse events.

Keywords: COVID-19, vaccine, Adverse, Iraq, consequences

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INTRODUCTION

The novel coronavirus is the agent responsible for causing coronavirus disease 2019 (COVID-19). It belongs to the category of single-stranded RNA viruses within the β-coronavirus genus (Huston et al., 2021). The present lack of an efficacious antiviral medication exacerbates the situation significantly. According to a statistical surveillance report from the WHO, the implementation of a robust preventive measure remains the sole recourse to combat COVID-19. Preventive measures led to a notable 30% in infections (Pradhan et al., 2020). The efficacy of preventive measures hinges entirely on the potency of surface detergents, the formulation of sanitizers, and the suitable choice of materials for manufacturing personal protective equipment (PPE) (Obaid et al., 2022).

COVID-19 pandemic has made the development of vaccines unprecedented urgency. This pressing demand has resulted in a variety of vaccine development methodologies. Unconventional vaccination platforms like nucleic acid vaccines and viral vector vaccines are emerging as dominant contenders in the race to develop a COVID-19 vaccine (Li et al., 2020).

Various types of vaccines operate through distinct mechanisms to provide protection, the body retains a reservoir of "memory" T-lymphocytes and B-lymphocytes. These cells retain the knowledge of how to combat the virus in case of future encounters (Understanding How COVID-19 Vaccines Work, 2021).

By February 15, 2021, a total of 175.3 million vaccine doses had been given, once vaccines are proven to be both safe and effective, they must undergo authorization by national regulatory bodies, adhere to precise manufacturing standards, and be systematically distributed (Coronavirus disease (COVID-19), 2021).

On March 2, 2021, Iraq has received an initial allocation of 50,000 doses of the Sinopharm COVID-19 vaccine, a generous donation that came from China. This aid comes at a crucial time for Iraq, as the nation grapples with a fresh surge of the disease (Iraq receives first batch of COVID-19 vaccines from China, 2021). On March 25, 2021, Iraq acquired a shipment of 336,000 doses of the AstraZeneca COVID-19 vaccine. This influx of vaccines makes a significant step in Iraq's efforts to combat the ongoing pandemic (Al Sa'ady et al., 2022). As of May 10th, a cumulative total of 441,121 individuals have already received the vaccine across various parts of Iraq, with an average of 15 thousand people being vaccinated every day (WHO, 2021).

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This study has been established to identify the prevalence, types, and potential attributed factors for the side effects of COVID-19 vaccines among a selected sample in Baghdad /Al-Rusafa.

METHODOLOGY

A descriptive cross-sectional study. The study was conducted in the Iraq / Baghdad / Al-Resafa Directorate of Health (DOH) from the 7th of April to the 5th of August 2021. AL-Resafa DOH comprises ten primary healthcare districts including 114 PHCs and 24 hospitals (general or specialized). All individuals who were immunized by the COVID-19 vaccine and agree to participate. One hospital and two districts in AL-Rusafa DOH were selected to conduct the study, then two PHCs from each of the selected districts were selected conveniently. Convenience samples from the vaccinated persons in these institutions who registered were enrolled in this study. The selected institutions were:

- Al-Sader district of primary healthcare (First PHC and Seventh PHC)
- Al-Baladiat-1 district of primary healthcare (Al-Baladiat PHC and Mualmen PHC) both these for BIBP (Sinopharm) and ChAdOx1-S (AstraZeneca) COVID-19 vaccines.
- Fatima Al-Zahraa specialized hospital for BNT162b2 (Pfizer BioNTech) COVID-19 vaccine.

A total of 420 vaccinated participants were involved in this study.

The data was obtained by an interview via questionnaire adopted after a review of similar articles, the researcher introduces himself and explains the purpose of the research. The questionnaire included close-ended questions and was divided into two parts:

Part one: Social and demographic variables

Part two: COVID-19 vaccine variables

The gathered data underwent analysis through descriptive and infential statistics and using (SPSS), version 22. A P-value below 0.05 was regarded as indicating statistical significance.

The research project was first proposed and subsequently granted approval by the scientific committee of the College of Medicine at the University of Baghdad, as well as the Baghdad/Al-Rusafa Department of Health. Patients were provided with comprehensive and

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clear explanations regarding the study's objectives, following which their full and informed consent was obtained verbally.

RESULTS

Table 1: *Social, demographic and medical characteristics of participants (N = 420)*

Characteristic		NO.	%
Gender	Male	251	59.8
	Female	169	40.2
Age group	<30	97	23.1
	30-39	87	17.4
	40-49	73	29.0
	≥50	163	38.8
Time of COVID-19 infection (N=110)	Before the first dose	95	22.6
	After the first dose	15	3.6

The range of the age was (18-87) years. The mean age was 43.9 (±15.0) years, the largest age group was (≥50) equal to 163 (38.8%). Males constituted 251 (59.8%) of the sample, and more than half of sample 236 (56.2%) were college or higher level.

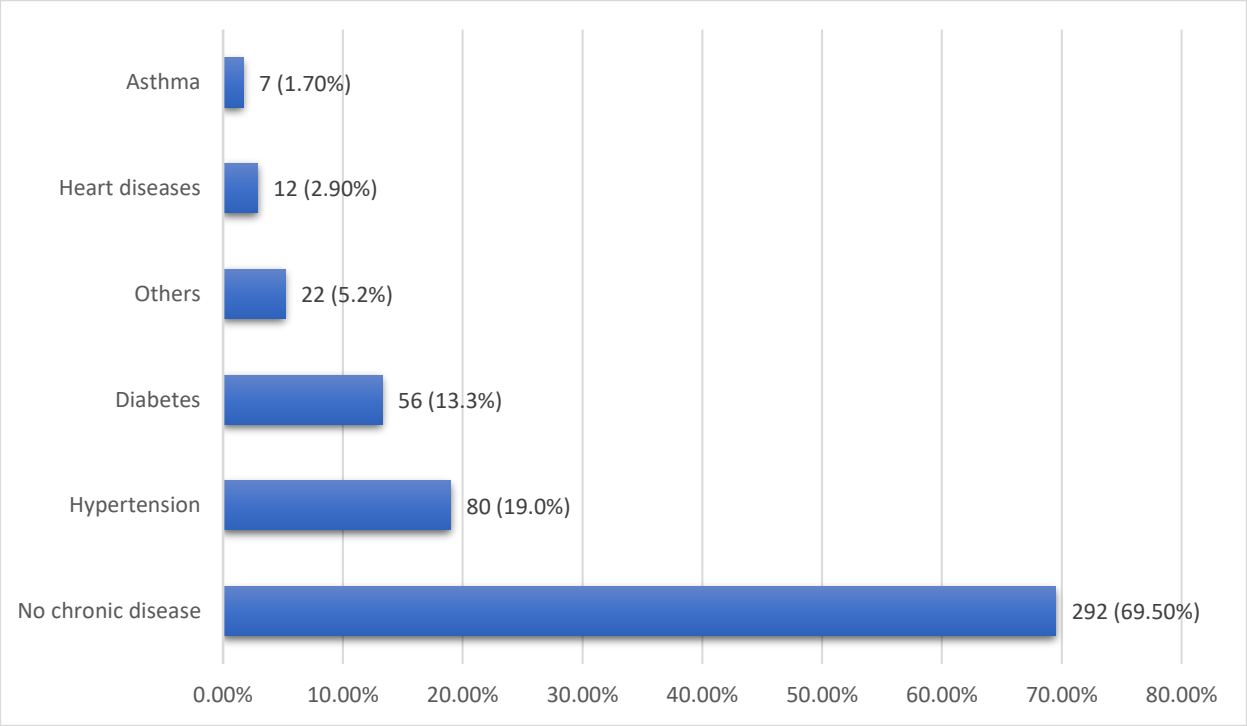

Figure 1: Prevalence of chronic diseases among the studied sample N=128.

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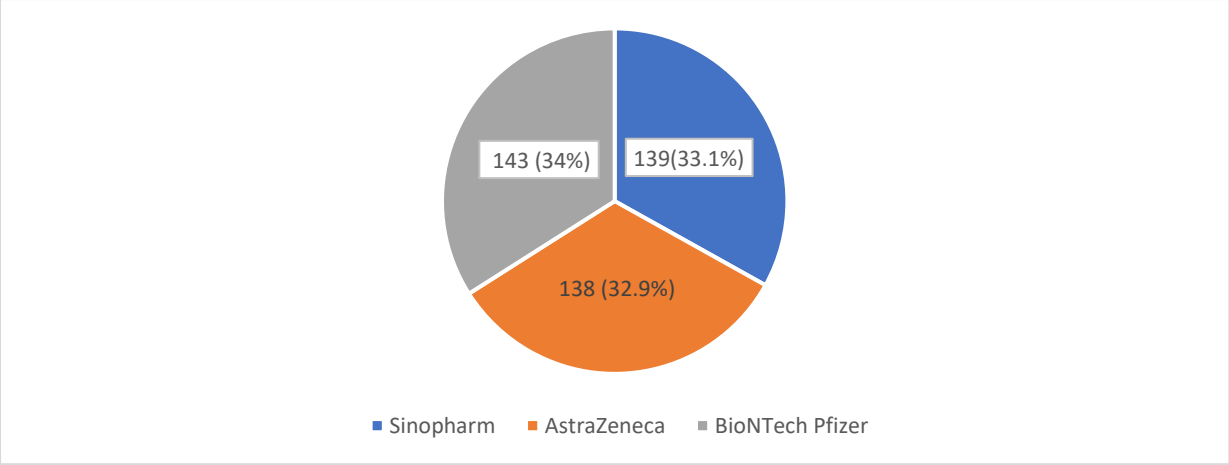

Figure 2: Distribution of the participants according to the vaccine type.

Table 2: Distribution of the adverse effects according to the type of the vaccine

Adverse event		Vaccine type								P-value
		BIBP (Sinopharm)		ChAdOx1-S (AstraZeneca)		BNT162b2 (Pfizer BioNTech)		Total		
		No.	%	No.	%	No.	%	No.	%	
Adverse events of first dose		115	30.9	126	33.9	131	35.2	372	100.0	0.030*
Time of adverse events disappearance	24 hours	39	50.0	18	23.1	21	26.9	78	100.0	<0.001*
	48 hours	54	26.5	79	38.7	71	34.8	204	100.0	
	≥72 hours	22	24.4	28	31.1	40	44.4	90	100.0	
Adverse events of second dose		73	23.6	97	31.4	139	45.0	309	100.0	<0.001*
Time of adverse events disappearance	24 hours	22	31.4	27	38.6	21	30.0	70	100.0	0.022*
	48 hours	38	20.9	55	30.2	89	48.9	182	100.0	
	≥72 hours	12	21.1	14	24.6	31	54.4	57	100.0	
Medical consultation		17	23.0	18	24.3	39	52.7	74	100.0	<0.001*

This table show that there was a significant association between the adverse events of the first and second dose, time of disappearance, and the type of vaccine (<0.05).

Table 3: *Adverse events of COVID-19 vaccines*

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Characteristic	After the first dose (N=420)		After the second dose N(=420)		P-value
	No.	%	No.	%	
Injection site pain	277	66.0	227	54.0	0.031
Joint pain/lethargy	201	47.9	166	39.5	0.015
Fever	170	40.5	116	27.6	<0.001
Headache	82	19.5	64	15.2	0.101
Shivering	19	4.5	11	2.6	0.137
Anorexia	19	4.5	10	2.4	0.089
Pharyngitis and/or flu like	12	2.9	6	1.4	0.153
Sweating	8	1.9	7	1.7	0.794
Dyspnea	6	1.4	6	1.4	1.000
*Others	23	5.5	9	2.1	0.012

The table shown significant associations between the first and second doses regarding the prevalence of pain at the site of injection, joint pain, fever, and other adverse events (p-value<0.05) (Table 3).

Table 4: *side effects frequency and distribution after the first dose according to sociodemographic characteristics and chronic diseases*

Characteristic		Adverse events of the first dose						P-value
		Yes N=372(88.6%)		No N= 48 (11.4%)		Total 420		
		No.	%	No.	%	No.	%	
Gender	Male	216	86.1	35	13.9	251	100.0	0.048*
	Female	156	92.3	13	7.7	169	100.0	
Age group	<30	87	89.7	10	10.3	97	100.0	0.722
	30-39	76	87.4	11	12.6	87	100.0	
	40-49	67	91.8	6	8.2	73	100.0	
	≥50	142	87.1	21	12.9	163	100.0	
Chronic diseases**		112	87.5	16	12.5	128	100.0	0.648
HTN		67	83.8	13	16.3	80	100.0	
DM		52	92.9	4	7.1	56	100.0	
Asthma		6	85.7	1	14.3	7	100.0	
CHD		9	75.0	3	25.0	12	100.0	
Others		21	95.5	1	4.5	22	100.0	
COVID-19 before first dose (N=95)		83	87.4	12	12.6	95	100.0	0.675
Type of vaccine	Sinopharm	115	82.7	24	17.3	139	100.0	0.030*
	AstraZeneca	126	91.3	12	8.7	138	100.0	
	BioNTech Pfizer	131	91.6	12	8.4	143	100.0	

***The Chi-square statistic is significant at the< 0.05 level.*
*** Multiple choice question*

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Regarding the adverse events of the first dose, there was a significant association between the adverse events of the first dose and gender (P-value=0.048), and a significant association was found between the adverse events of the first dose and the type of the vaccine(P-value=0.030) (Table 4).

Table 5: *side effects distribution after the first dose and type of vaccine.*

Side effect	Type of vaccine								P-value
	BIBP (Sinopharm) N=139		ChAdOx1-S (AstraZeneca) N=138		BNT162b2 (Pfizer BioNTech) N=143		Total N= 420		
	No.	%	No.	%	No.	%	No.	%	
Injection site tenderness	81	58.3	78	56.5	118	82.5	277	66.1	<0.001*
Joint pain/lethargy	52	37.4	88	63.8	61	42.7	201	47.9	<0.001*
Fever	41	29.5	86	62.3	43	30.1	170	40.5	<0.001*
Headache	13	9.4	44	31.9	25	17.5	82	19.5	<0.001*
Anorexia	5	3.6	7	5.1	7	4.9	19	4.5	0.903
Pharyngitis and/or flu like	3	2.2	6	4.3	3	2.1	12	2.9	0.538 [a]
Sweating	3	2.2	3	2.2	2	1.4	8	1.9	0.823 [a]
Dyspnea	3	2.2	2	1.4	1	0.7	6	1.4	0.452 [a]
Shivering	2	1.4	17	12.3	0	0	19	4.5	<0.001* [a]
Other	6	4.3	7	5.1	10	7.1	23	5.5	0.689

** The Chi-square statistic is significant at the< 0.05 level.*
[a] At least one expected value is < 5, Fisher's Exact Test is used.

The BioNTech Pfizer vaccine was significantly associated with the highest percentage of Injection site tenderness (P-value= 0.001), while the AstraZeneca vaccine was significantly associated with the highest percentage of joint pain/lethargy, fever, headache, and shivering (P-value < 0.05). The highest frequency of adverse events after the second dose was in the Pfizer

DISCUSSION

The current study in table 3 found that was most participants had mild adverse effects and did not need medical consultations, the same finding was obtained by another study in the Czech Republic conducted by Riad et al. In the United Kingdom, Menni et al. found the adverse

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events of Pfizer BioNTech and the Oxford-AstraZeneca were mild. The CDC postulated that the vaccinated people may have not some adverse event, these are typical indicators of the body developing protection. While these adverse events may temporarily impact an individual's ability to carry out daily activities, they typically subside within a few days. It's worth noting that not everyone experiences adverse events, as some individuals have no such reactions. (Possible Side Effects After Getting a COVID-19 Vaccine, 2021) The Reported adverse events of COVID-19 vaccines by WHO have often been mild or moderate (Side Effects of COVID-19 Vaccines, 2021).

An important finding in the current study as illustrated in table 5 and figure 2 that most participants experience adverse events with a significant association between the types of vaccines, the higher percentage was in Pfizer BioNTech vaccinated participants while the lowest percentage was in Sinopharm vaccinated participants. In comparison to other studies, most of the AstraZeneca vaccinated participants in Jordan developed adverse events while less than half of the Sinopharm vaccinated participants developed adverse events (Abu-Hammad et al., 2021) In KSA, A study had revealed that most of the Pfizer BioNTech vaccinated participants develop adverse events (El-Shitany et al., 2021; Suleman & Rahman, 2020; Suleman & Mohamed, 2019; Suleman et al., 2023), The low incidence of adverse events associated with the Sinopharm vaccine might suggest its comparatively lower immunogenic potential. It's worth noting that inactivated vaccines, like Sinopharm, are generally considered safer but they may require a well-structured booster plan to establish robust immune memory (Side Effects of COVID-19 Vaccines, 2021).

More specifically, the first dose was more associated with a higher incidence of side effects in comparison to the second dose except for the Pfizer-BioNTech reverse this result as shown in table 3 and 4. Another study was done in the Czech Republic revealed that the second dose was associated with a higher occurrence of adverse events (Riad et al., 2021), In the United Kingdom, a study was done there that revealed that systemic side-effects were reported by a higher number of individuals after the second dose of Pfizer BioNTech than after the first dose. While local side-effects were reported by a lower percentage of individuals after the first dose of Pfizer-BioNTech than the second dose, also the younger age developed more adverse events after the first dose than older age (Menni et al., 2021; Suleman et al., 2023; Suleman et al., 2021; Suleman, Mohamed & Ahmmed, 2020) this may explain the discrepancy as the participants of the current study had lower mean age.

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Regarding the duration of adverse events as recorded in table 2; usually started within the first 12 hours after vaccination, most patients are relieved within 48 hours with a significant association between the type of vaccine, about half of those vaccinated by Sinopharm relieved within 24 hours, while about two-thirds of those vaccinated by Pfizer BioNTech had symptoms for more than 72 hours. The same finding was obtained by another study in Jordan that revealed that the Sinopharm was significantly associated with fewer adverse events with a short duration (Abu-Hammad et al., 2021).

Injection site tenderness was the main side effect observed in the current study as documented in table 5; followed by lethargy and fever, while dyspnea was the least frequent. This agrees with WHO which postulated that injection site pain and tenderness are the most common side effect. In comparison, the same results were obtained by other studies (Riad et al; Menni et al, 2021), While Abu-Hammad et al concluded that fatigue, chills, headache, myalgia, and pain at the injection site were the commonest adverse events. This is related to the different types of vaccines used in these studies.

There was no significant association between age and the appearance of adverse events in both doses. Another study in the UAE revealed that the frequency of adverse events was significantly higher in those older than 49 years (Saeed et al., 2021) ,In the UK, there was increasing in the risk of adverse events in those older than 55 years as obtained by a study that was done there ,In concordance to the current study, another study was done in the Kingdom of Saudi Arabia (KSA) revealed no significant associations between those older and younger than 60 years old (Alhazmi et al., 2021). This discrepancy may be related to the prevalence of underlying comorbidities and the types of vaccines used in each study.

There was no significant association between the underlying chronic diseases that were more prone to develop adverse events of COVID-19 vaccines as displayed in figure 1. In comparison, the same results were observed in another study (Riad et al., 2021). In concordance with these results, alhazemi et al concluded no significant association between chronic diseases and the development of adverse events (Alhazmi et al., 2021) According to the CDC, COVID-19 vaccines are generally deemed safe for administration to individuals with underlying medical conditions. (CDC, 2021), a higher percent of the smoker developed adverse events compared to nonsmokers without significant association, this could be related to the prevalence of underlying chronic diseases among smokers. In contrast, another study concludes that

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central obesity, hypertension, and smoking are associated with lower antibody titers following COVID-19 vaccination and fewer adverse event (Watanabe et al., 2021).

There was no significant association between COVID-19 infection and the development of the adverse event. The same results were obtained by other results, in the Czech Republic studies (Riad et al., 2021), and UK, In contrast, there were significant associations between previous infection and the development of adverse events in Sinopharm vaccinated participants in the UAE, this could be related to the vaccine type and other personal factors. The WHO postulated that even the person has already had COVID-19, he must be vaccinated when it is available (Coronavirus disease (COVID-19), 2021).

The males form the largest percentage of the participants as shown in table 1, while females were predominant in a study in UAE (Saeed et al., 2021) Jordan and UK (Menni et al., 2021). Vaccination reduces the morbidity and mortality rate (Obaid et al., 2023).

CONCLUSION

Most vaccinated people developed mild adverse events and did not need medical consultations. Injection site tenderness and Joint pain/lethargy were the most prevalent adverse events. The gender and type of vaccine significantly affected the development of adverse events. The first dose is significantly associated with a higher percentage of adverse events.

RECOMMENDATIONS

1. Increase health education by MOH through mass media about the safety of all types of vaccines.
2. Strong strategies are needed to strengthen infection control and prevention measures for all people even those who received the COVID-19 vaccine.

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