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Research paper

Prevalence of adverse effects from COVID-19 vaccine among Iraqi adults: A retrospective cross-sectional study

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ABSTRACT

Background: The production of a successful vaccine has become a global dream since the declaration of coronavirus disease 2019 (COVID-19) as a global pandemic by the World Health Organization. However, doubts abound about vaccine safety. In this study, we aimed to estimate and compare the prevalence of adverse effects in Iraqi adults from the COVID-19 vaccines used in Iraq.

Methods: The study was a retrospective, cross-sectional study conducted in August 2021. An online-based questionnaire was applied randomly and distributed to individuals (≥18 years).

Results: Among the 1000 vaccinated participants from different regions in Iraq, 66.0% were from middle Euphrates, 61.3% were women, and 62.2% were in their third to fifth decade of life. Approximately, 68.4% of the participants received Pfizer vaccine, and 42.5% had a previous history of COVID-19 infection Figure 1. Most of the participants (84.1%) suffered general adverse effects after vaccination, including (in sequence of appearance) fatigue, fever, headache, injection site signs, and axillary pain. Most studied factors have no significant correlation with post-vaccine adverse effects ($P \leq 0.05$) such as age, sex, history of COVID-19 infection, and chronic disease. There was a significant correlation between adverse effects from the vaccine dose and age of recipients. Those with a history of comorbidities had a two-fold risk of developing adverse effects.

Conclusion: Fatigue, fever, headache, injection site signs, and axillary pain were the most registered adverse effects, which were mostly mild to moderate. All the vaccines revealed an encouraging safety profile. Younger age, second vaccine dose, and presence of comorbidities were considered minor risk factors for more adverse effects.

Keywords: adverse effects, Pfizer, vaccine, Sinopharm, AstraZeneca, COVID-19

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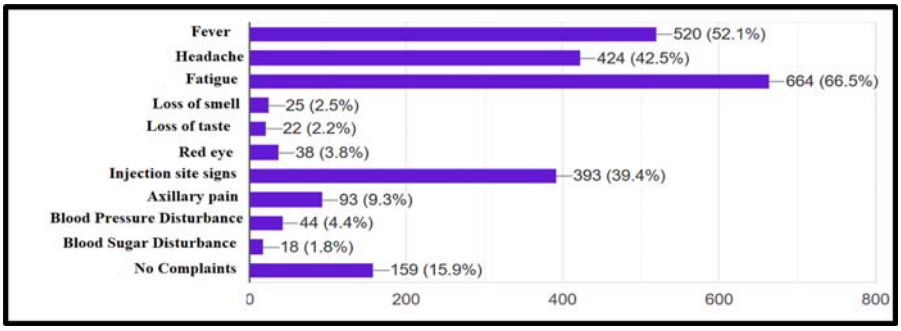

Figure 1. Prevalence of general adverse effects in the participants after vaccination with three types of COVID-19 vaccines (N = 1000).

INTRODUCTION

In December 2019, a novel coronavirus was identified as the etiology for an epidemic of possible lethal strange pneumonia, ultimately called "coronavirus disease 2019 (COVID-19)", in Wuhan, China[1,2]. Later, multiple pathogenic strains of the virus were recorded globally[3]; and there was a imperative demand to develop vaccines by the scientific society. Although the COVID-19 vaccine is the only hope for controlling the pandemic, there are still frequent questions raised about the efficacy and safety of the vaccine, allergic reactions, and long-term side effects; and could the vaccine itself cause COVID-19 infection; does the vaccine cause heart problems, blood clots, impair fertility, menstrual problems, and so forth[4,5].

After being vaccinated against COVID-19, individuals have reported different responses ranging from nil to severe side effects after the initial or the second dose or both doses of the vaccine. Several reports have shown that the second dose usually causes stronger reactions than the initial dose. This variation may be attributed to the fact that all human bodies trigger immune responses; however, they vary in strength depending on the amounts of certain chemicals released. Certain individuals may release more chemicals causing a stronger response, while others may release only what is required causing an acceptable response, also known as the "Goldilocks phenomenon". Post vaccine reactions do not indicate an error, but rather the development of an immune response; although the absence of post vaccine reactions does not necessarily mean the absence of an immune response[6–9].

Although the side effects may affect daily activities, they generally do not last more than a few days. Moreover, treating the side effects is easier than treating the symptoms and complications of COVID-19. The Center for Disease Control and Prevention (CDC) and WHO have summarized the side effects of COVID-19 vaccines including fatigue, fever, chills, nausea, headache, and muscle pain; along with pain, blushing, and swelling at the injection site[6,10].

A shortage of independent studies on vaccine protection may undesirably influence vaccine acceptance, which has to be enhanced in the succeeding few months for the world to emerge out of this vicious circle of the COVID-19 virus and its mutants[4].

In this study, our primary aim was to estimate the prevalence of adverse effects from Pfizer–BioNTech, AstraZeneca, and Sinopharm vaccines in the Iraqi population from the middle Euphrates trigon in Iraq. The secondary aim was to compare the potential adverse effects of the three COVID-19 vaccines.

METHODS

The study was a retrospective, survey-based, and cross-sectional study conducted in August 2021 to collect data on the adverse reactions from the available three COVID-19 vaccines among randomly selected Iraqis. The study used an online-based questionnaire that was self-directed and generated as "Google forms", which was randomly distributed to individuals (≥18years) on different social media sites (Facebook, Messenger, E-mail, Viber, and WhatsApp). Probable applicants (volunteers) were directed to a link on Google that included a short introduction to the objective and drive of the survey. The attentiveness of the survey was elevated by advertisements on the websites and social media profiles of the College of Pharmacy. Of the 1055 forms received from different regions and cities, 1000 were included,. The study sample included participants who were vaccinated one week prior with the

first or second dose of any available COVID-19 vaccine from Pfizer-BioNTech, AstraZeneca-Oxford, and Sinopharm. The researchers did not communicate with the subjects participating in the study.

Survey and data collection

The study was conducted after searching through a wide-range of literature and guidelines of WHO, CDC, and NHS on the predictable adverse reactions from the three COVID-19 vaccines. The questions included in the questionnaire were a panel of multiple choice and checkbox type of queries that covered the respondents' demographic data; medical history; COVID-19 related history; and general, systemic, and skin-related adverse effects. The language of the questionnaire was Arabic, confirmed by a team of professionals who delivered feedback on multiple surveillance items. The study questionnaire involved several main sections, in sequence: The first section included demographic questions such as (sex, age, education level, and the city of residence). The second section comprised the history of COVID-19 infection, method of diagnosis, and number of infections. The third section reviewed the clinical profile and comorbidities (diabetes, hypertension, hepatic or renal disease, joint disorders, and others) and the type/number of administered vaccine doses. The last section was related to the COVID-19 vaccine adverse effects and whether these effects were noticed after the first or second dose. The survey form was pre-tested for suitability. Initially, two experts evaluated all the requests separately, and minor adjustments were made based on their feedback.

Ethical issues

Permission for the study was obtained from the research ethics and scientific committee of the College of Pharmacy at the University of Babylon. Informed consent already included declarations on voluntary sharing and privacy, which was obtained from all the respondents before data assortment using a uniform universal invitation letter with the questionnaire link, through which an individual could either agree or refuse to enroll in the survey.

Statistical analysis

The Statistical Package for Social Sciences version 23.0 was used to complete the descriptive data. The statistics of adverse effects was exhibited with counts/percentages and means/standard deviations. The 95% confidence interval (CI) and a $P \leq 0.05$ were considered significant.

RESULTS

Until August 31, 2021, the four types of vaccines administered in Iraq, included Oxford/AstraZeneca, Pfizer/BioNTech, Sinopharm/ Beijing, and Sputnik V. Despite diverse ways to encourage vaccination, the rate of vaccination in Iraq was much lower than the required level, perhaps owing to the fear of vaccination for multiple reasons, the most prominent of them being post vaccine adverse effects and unscientific common beliefs about it. This situation prompted the authors to conduct this study to obtain a realistic and clear picture of the most common post-vaccine adverse effects and relay them in a simplified manner to enhance health awareness among the Iraqis to encourage them to get vaccinated.

This study included 1000 vaccinated participants from different regions of Iraq with different demographic characteristics as detailed in Table 1. Of the participants, 660 (66.0%) were from middle Euphrates; and women constituted 61.3% (613). Two age groups (21–30 and 41–50 years) recorded the highest vaccination rate (262 [62.2%]) for each.

Interestingly, the vaccination rate recorded in this study increased in conjunction with the rise in the level of education where the highest rates of 44.5% and 52.1% were recorded in undergraduates and holders of higher degrees, respectively.

Of the total participants, 83.2% had no past medical history, 8.3% had hypertension, 8.3% had renal disease, while the other chronic diseases constituted 0.2%–3.35%. However, there was no history of COVID-19 infection in most (57.5%) of the participants.

Although Iraqi health institutes have adopted three vaccines, the results of this study showed that the Pfizer vaccine was the most preferred with 68.4% of the participants receiving it; and furthermore, 65.2% of them had two doses. As detailed in Table 1, post vaccination symptoms appeared in 86.2% of the participants and mostly after the first vaccine dose (55.7%).

Table 1. Basal demographic characteristics of the study participants (N = 1000).

Variables		Frequency	Percentage
Gender	Males	387	38.7%
	Females	613	61.3%
Ages categories/years	18-20	111	11.1%
	21-30	262	62.2%
	31-40	210	21.0%
	41-50	262	62.2%
	> 50	156	15.6%
Levels of Education	Primary	1	0.1%
	Intermediary	2	0.2%
	Secondary	32	3.2%
	Under Graduate	445	44.5%
	Higher Education	521	52.1%
Residence of Respondents	Middle-Euphrates	660	66.0%
	Other Regions	340	34.0%
History of COVID infection	Yes	425	42.5%
	No	575	57.5%
Times of Infections	Once	376	36.7%
	Twice	58	5.8%
Chronic Diseases	Hypertension	83	8.3%
	Diabetes Mellitus	33	3.35%
	Liver Diseases	2	0.2%
	Renal Diseases	83	8.3%
	Rheumatic Diseases	6	0.6%
	Mixed Diseases	25	2.5%
	No History	832	83.2%
Types of Vaccine	Pfizer	684	68.4%
	AstraZeneca	170	17%
	Sinopharm	147	14.7%
Doses of Vaccines	First Dose	348	34.8%
	Second Dose	652	65.2%
Symptoms after vaccination	Yes	862	86.2%
	No	138	13.8%
Symptoms Appear after which Dose of Vaccine	First Dose	557	55.7%
	Second Dose	226	22.6%
	First & Second Dose	218	21.8%

The general adverse effects after vaccination with the three types of vaccines are shown in . Most participants (84.1%) suffered from more than one different adverse effect, whereas 15.9% had no complaints. The results indicated that fatigue was the most common complaint (66.5%), followed by fever (52.1%), headache (42.5%), injection site signs (39.4%), and axillary pain (9.3%); while blood sugar disturbances were the least common (1.8%).

Table 2 shows the most common risk factors associated with post vaccination adverse effects. Most of the factors had no significant correlation with adverse effects ($P \leq 0.05$), whereas type and dose of vaccines had a significant correlation with post vaccination symptoms; where of the 684 participants who received Pfizer vaccine, 618 had symptoms. Only 170 participants were symptomatic after the AstraZeneca vaccine and 146 after the Sinopharm vaccine.

The individuals who had two doses were, in general, associated with a higher incidence of adverse effects. Of the 652 participants who received two doses, 574 had symptoms, and 78 were asymptomatic. Of the 348 participants who received only one dose, 288 had symptoms.

The general adverse effects according to the doses of the three vaccines among the 1000 participants are shown in Table 3. Higher instances of fatigue, musculoskeletal pain, injection site signs, headache, and axillary pain appeared mostly after the first dose than after the second-dose, regardless of the vaccine type. Participants who were vaccinated with the Pfizer vaccine suffered from higher rates of fever, either after the first dose (48.1%) or the second dose (50.6%) or after both the doses (58.8%); whereas with the AstraZeneca or Sinopharm vaccines, the fever appeared mostly after the first dose.

Table 2. Univariate analyses of associated risk factors with symptoms after COVID-19 vaccines.

Variables		Symptomatic	Asymptomatic	Total	OR	P-value
Ages	18-50 years	735	109	844	0.926 (0.846-1.014)	0.07
	> 50 years	127	29	156		
Gender	Females	537	76	613	1.193 (0.973-1.463)	0.11
	Males	325	62	387		
Residence	Middle-Euphrates	566	94	660	1.037 (0.916-1.174)	0.62
	Other regions	296	44	340		
History of COVID-19	Yes	481	93	574	1.027 (1.059-1.375)	0.37
	No	381	45	426		
Comorbidities	Yes	718	113	831	0.983 (0.904-1.069)	0.41
	No	144	25	169		
Doses of vaccines	Once	288	60	348	1.277 (1.030-1.583)	0.04
	Twice	574	78	652		
Types of vaccines	Pfizer	618	66	684		0.0001
	AstraZeneca	154	16	170		
	Sinopharm	90	56	146		

Appearance of local adverse-effects at the site of injection with the three types of vaccines

Types of Vaccine	Total	Local adverse-effects		P-value
		Yes	No	
Pfizer	684 (68.4%)	409 (69.2%)	> 0.05	> 0.05
AstraZeneca	170 (17.0%)	97 (16.4%)	73 (17.8%)	
Sinopharm	147 (14.7%)	86 (14.5%)	61 (14.9%)	
total	1000	592	409	

Table 3. Distribution of the general adverse effects according to the doses of the three vaccines (Pfizer, AstraZeneca, and Sinopharm) among the study participants (N = 1000).

Vaccines types	Vaccines Doses	Fever	Headache	Fatigue	Loss of smell or taste	Injection site adverse-effects	Disturbed BP	Axillary findings	Dysglycemia	Musculoskeletal pain	Red eyes	No any complaints
Pfizer N=684 No (%)	1st dose N=364	175 (48.1)	137 (37.6)	234 (64.3)	18 (4.9)	148 (40.7)	20 (5.5)	32 (8.8)	5 (1.4)	160 (44.0)	10 (2.7)	41 (11.3)
	1st&2nd doses N=160	84 (50.6)	71 (44.4)	101 (63.1)	5 (3.1)	54 (33.8)	4 (2.5)	16 (10.0)	2 (1.3)	82 (51.2)	7 (4.4)	6 (3.8)
	2nd dose N=160	94 (58.8)	77 (48.1)	111 (69.4)	5 (3.1)	73 (45.6)	7 (4.4)	18 (11.3)	2 (1.3)	86 (53.8)	5 (3.1)	19 (11.9)
AstraZeneca N=170 No (%)	1st dose N=117	63 (53.8)	53 (45.3)	78 (66.7)	3 (2.6)	49 (41.9)	4 (3.4)	9 (7.7)	0	54 (46.2)	7 (6.0)	11 (9.4)
	1st&2nd doses N=34	15 (44.1)	12 (35.3)	25 (73.5)	2 (5.9)	15 (44.1)	2 (5.9)	2 (7.9)	2 (5.9)	16 (47.1)	0	0
	2nd dose N=19	11 (57.9)	8 (42.1)	13 (68.4)	0	9 (47.4)	1 (5.3)	2 (10.5)	0	11 (57.9)	0	5 (26.3)
Sinopharm N=147 No (%)	1st dose N=	38 (50.0)	32 (42.1)	48 (63.2)	3 (3.9)	34 (44.7)	3 (3.9)	9 (11.8)	3 (3.9)	28 (36.8)	3 (8.3)	22 (39.3)
	1st&2nd doses N=	12 (50.0)	11 (45.8)	15 (62.5)	0	9 (37.5)	3 (12.5)	1 (4.2)	2 (8.3)	14 (58.3)	2 (8.3)	7 (29.2)
	2nd dose N=	27 (57.4)	19 (40.4)	35 (74.5)	0	18 (38.3)	1 (2.1)	4 (8.5)	1 (2.1)	23 (48.8)	2 (4.3)	27 (57.4)

There was no significant correlation among adverse effects, history of COVID-19 infection, and age categories ($P \leq 0.05$) (Table 4). However, a significant correlation was recorded between adverse effects and the doses of vaccinations with age categories, where it was more evident after the second dose among three vaccines ($P = 0.01$). Those with a history of comorbidities had approximately a two-fold chance to develop adverse effects than those without comorbidities (Odds ratio: 1.84, 95% CI: 1.578 – 2.145, $P = 0.001$).

Table 5 shows the prevalence of post-vaccination adverse effects and its correlation with sex of the participants ($P \leq 0.05$). There was no significant correlation between sex and the symptoms. In

Table 4. Correlation of appearance of adverse effects, history of previous COVID-19 infection, and doses of COVID-19 vaccinations with age categories of the study participants (N = 1000).

Variables		Age Categories		Total	OR	P-value
		< 50 years	> 50 years			
General adverse-effects	Yes	736	127	862	0.926 (0.846-1.014)	0.07
	No	109	29	138		
History of previous COVID-19 infection	Yes	360	65	425	0.993 (0.941-1.048)	0.86
	No	484	91	575		
Doses of vaccines	Once	308	40	348	1.076 (1.022-1.134)	0.01
	Twice	536	116	625		
Comorbidities	Yes	761	71	832	1.84 (1.578-2.145)	0.001
	No	84	84	168		

Table 5. Prevalence of adverse effects post COVID-19 vaccination and its correlation with sex of the study participants (N = 1000).

Adverse-effects	Males no (%)	Females no (%)	P- value
Symptomatic N=632	62 (44.9)	67 (55.1)	0.11
Asymptomatic N=138	325 (37.7)	537 (62.3)	
Fever	208 (40.3)	308 (59.7)	0.27
Fatigue	255 (38.6)	405 (61.4)	0.99
Injection site adverse-effects	144 (35.2)	265 (64.8)	0.06
Axillary pain	31 (33.3)	62 (66.7)	0.31
Headache	146 (34.8)	274 (65.2)	0.03
Loss of smell or taste	17 (47.2)	19 (52.8)	0.29
Red eyes	18 (50.0)	18 (50.0)	0.16
Dysglycemia	5 (29.4)	12 (70.6)	0.61
Disturbed blood pressure	17 (37.8)	28 (62.2)	0.99
Musculoskeletal pain	183 (38.6)	291(61.4)	0.99

addition, no significant correlation of incidence of sex with most of the symptoms, except headache in 65.2% women and in 34.8% of men ($P \leq 0.03$).

There were no significant differences in the appearance of injection site adverse effects, including pain, swelling, tenderness, and redness among the three types of vaccines (Table 6).

DISCUSSION

Most studies have evaluated primarily the adverse effects of the Pfizer, Moderna, and AstraZeneca vaccines[11–14], whereas only two studies focused on the Sinopharm vaccine[15,16]. To the best of our knowledge, this study represents the first epidemiological report that has investigated adverse effects of the three available COVID-19 vaccines from Pfizer-BioNTech, AstraZeneca-Oxford, and Sinopharm in middle Euphrates (central Iraq).

Multiple vaccines manufactured using various techniques from several different companies have been introduced within one year of the epidemic, which was an exceptional and gigantic achievement; however, they were not entirely safe or without side effects, and more than a few challenges persist. There is also a great deal of hesitancy to be vaccinated, principally in the young, who mostly tolerated COVID-19 better with insignificant symptoms or were asymptomatic.

The adverse effects caused by vaccination are not erratic and are evidence of an immune reaction[17,18]. In this study, 86.2% of the participants were symptomatic. 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. The survey reported no serious adverse reactions, an observation that failed to be repeated by other studies[12,19].

The incidence of adverse reactions in this study was parallel to the outcomes of other studies[20,21]; although all these epidemiological studies have reported variable adverse reactions ranging from mild to moderate in severity with the incidence (mostly >60% and in some studies 100%) in the vaccinated groups. Hence, our study shows a relatively similar safety profile compared with studies from different populations[13,19,22]. Nevertheless, these evaluations should be carefully interpreted given the small sample and the fact that few severe adverse events ensued.

The most common side effects reported increased after the second dose[23]. This remark can be understood on an immunological basis. The pro-inflammatory cytokines could induce an inflammatory response in the vessels, muscles, and other body tissues[24-26] as well as initiating flu-like illness a few days after the vaccine dose[19]. The overall rate of local adverse-effects at the injection site was 39.4%, with non-significant differences among the three-vaccines. This rate was lower than the rate reported by the Kurdish[19], Emirati[27], and Polish studies[28]. In contrast, the Pfizer vaccine was described to have a higher rate of adverse effects at the injection site (83.1%); whereas, an equivalent rate was reported with the adenoviral vector vaccine (54%)[29-31].

In this study, some associated risk factors to develop adverse effects post vaccines were documented, particularly Sinopharm vaccines ($P = 0.001$), second dose ($P = 0.04$), comorbidity ($P = 0.001$), and younger age ($P = 0.01$). The number of women who developed side effects were greater than men, although did not reach statistical significance. Alternatively, older people were less likely to develop symptoms. This result was similar to that recorded by the FDA, which stated that individuals aged >55 years were less expected to complain of adverse effects[31]. Another Iraqi study conducted in the northern provinces revealed similar outcomes[19]. Likewise, a Czech survey reported that youngsters were more prone to have adverse effects with the Pfizer vaccine[13], which was also supported by a UAE study[27]. A survey on the safety of the AstraZeneca vaccine from the UK, South Africa, and Brazil demonstrated a lower severity of adverse effects among older individuals[32]. Generally, younger people and women tend to develop robust immunity than older individuals and men[32]. A Saudi study revealed no significant variations in the rate of adverse effects with different ages and a higher number of women who developed adverse effects than men[14]. Henceforth, both sexes are expected to have frequent and more severe adverse effects.

The information about what ensues after a vaccination in the real state among the general population is still modest. In this study, the participants who received the second dose were more prone to develop systemic adverse effects ($P = 0.04$) in concordance with other studies[14,27]. In contrast, consistent with the CDC, adverse effects manifested more after the first dose[6], a finding that was supported by a Polish study that showed that systemic effects post the first dose of the AstraZeneca vaccine were more common than post the first and second doses of the Pfizer vaccine, with an overall incidence rate more after the second dose[28]. Given these results, it is not unexpected that many individuals reject the vaccine, not only in Iraq, but also in other countries. Longstanding investigation regarding COVID-19 immunity in people who have delayed their second doses of the vaccine compared with those getting their second doses in time (21 days post the first dose) will be vital to decide whether this primary immunity continues.

Most of the post vaccine allergy is not induced by its active constituents, but rather the inactive ingredients, such as egg proteins, thimerosal, gelatins, formaldehyde, and neomycin that stimulate specific IgE-mediated immunity. According to "European Medicines Agency", excipients that are mixed with vaccines to preserve the effects of the vaccine during injection, shipping, and storing could be the basis for several allergic responses[33,34].

In this study, there was no impact of age on the incidence of adverse effects. The same is true for gender, residence, and the presence of different comorbidities ($P > 0.05$). Unlike our results, the female sex is a risk factor for the adverse effects according to another Iraqi study[19], which was in line with several other studies[12,13,29].

CONCLUSIONS

COVID-19 vaccine adverse effects are undeniable and has occurred in around 84.1% of vaccine recipients; however, all the three vaccines have revealed an encouraging safety profile. The most common adverse effects of the COVID-19 vaccine among the respondents were fatigue, fever, headache, and pain at the injection site. The distribution of adverse effects among Iraqis agreed with the manufacturer's data expressly, regarding their relationship with the younger age group, the second dose, and presence of comorbidities, which were associated risk factors for developing vaccination adverse effects.

In general, the incidence of some local and/or systemic adverse-effects was more than the manufacturer's reports although were typical manifestations of most preceding reports and the FDA and were well-tolerated. However, it may be required to monitor certain individuals closely for a short time after vaccinations. Additional studies with larger population sizes and longer duration of follow-up will help aid community confidence in the vaccine in terms of its safety.

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