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Evaluation of Post–vaccination Symptoms of COVID 19 Vaccines among People in Basrah- Iraq Society

Aseel k. Thamer

Researcher, Al Fayhaa teaching hospital, Samer S. Aziz., Higher Dip. audiologist, Al Basrah teaching hospital, Basrah- Iraq.

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Abstract

Introduction: Vaccines are one of the most effective interventions for destroying COVID-19. Many organizations have worked to establish an efficient and safe preparation in the minimum time possible. Currently, several products that different in form and effectiveness are approved for sale.

Objectives: The goal of this study was to obtain evidence on COVID-19 vaccination adverse effects.

Methodology: A cross-sectional study was made between October and December 2021 to obtain data on the influence of the COVID-19 vaccine among people in the Iraq- Basrah. There were two types of questions listed. The first one covers the subject's background information, such as nationality, gender, age, educational level, and past COVID 19 infection. The second set of questions focused on information about the COVID-19 vaccines and their side effects.

Result: Local site adverse reaction, Hypersensitivity reaction, bone and muscle pain, headache and fever were more common in persons received second dose than in participant received first dose. There was a significant difference in the number of people those under 60 years of age who reported fever, headache, bone and muscle pain compared to those 60 years old and over.

conclusion: The COVID-19 vaccine's side effects are similar to those seen with earlier immunizations, and the most of them are tolerable.

Keywords: COVID 19 vaccine; sinopharm; pfizer BioNTech; astraZeneca vaccines; side effects

Introduction

COVID19 vaccinations have been the most wanted item on the market for the past year. Many organizations have worked to establish an efficient and safe preparation in the minimum time possible. Currently, several products that different in form and effectiveness are approved for sale.

Moderna and Pfizer are two companies that make products based on mRNA technology. Others are vector vaccines include AstraZeneca and Sputnik-V.[1]

Sinopharm COVID-19 vaccine is an inactivated vaccine that uses to inject a dead copy of SARS-CoV-2 into the body.[2]

Corresponding Author: Aseel k. Thamer, Researcher, Al Fayhaa teaching hospital, Samer S. Aziz., Higher Dip. audiologist, Al Basrah teaching hospital, Basrah- Iraq.

E-mail: kadhemaseel@gmail.com

Sometimes there is growing public-health issue fueled by misconceptions about vaccine effectiveness and safety and that's called "vaccine hesitation (VH)" which is defined as "a delay in accepting or refusing vaccines despite vaccine services being available. Aversion to vaccines' potential side effects was the most common reason for vaccine hesitancy in all population groups in the United Kingdom. In the case of COVID-19 vaccines, this finding was confirmed by the fact that fear of adverse effects was the most common reason for healthcare workers and students to be less ready.[3]

Recently, all available data on COVID-19 vaccine adverse effects has been published by manufacturer-funded studies that have been approved by the authorities. COVID-19 vaccines are subjected to post-marketing examination by drug regulators and cooperating academic and clinical institutes, just like any other innovative pharmaceutical products.(4)

Methodology

This cross-sectional survey-based study was conducted out from October 2021 to December 2021 to determine the prevalence of COVID-19 vaccination adverse effects among the people. The Arabic language was used to create a Google Forms questionnaire (the scientific terms for the symptoms were written and explained in the public language) and distributed via social media (mainly Facebook and WhatsApp) to participants. Furthermore, the value of the study in informing the public about the vaccine's negative effects was emphasized.[2]

After weighing the acceptable side effects against the disease's severity, participation may encourage everyone else to get the vaccine. The setting were adjusted such that each participant may only send one response.

There were two types of questions listed. The first one covers the subject's background information, such as nationality, gender, age, educational level, and past COVID 19 infection. The second set of questions focused on information about the COVID-19 vaccines and the adverse effects that related with the vaccination, as well as when these side effects first appear. The questionnaire asks if the individual received one or two doses of COVID-19 vaccination, as well as what type of vaccine they received.

The participants were asked to choose from a list of symptoms that included injection site adverse effect, Hypersensitivity Symptoms as "fast heartbeat, difficulty breathing, body allergy", headache, fever, bone or muscle Symptom, chills, Sore throat, GIT Symptoms like nausea, vomiting, as well as any other symptoms they had after receiving the immunization.

Sample size

The sample size for conducting this survey was 650 with a 5% margin of error and a 95% confidence level. We have hypothesized that the prevalence of the side effects in the population is 50% ± 5 (the reported side effects by FDA ranged from 14.2% to 84.1%). In this study, 650 subjects completed the COVID-19 vaccine questionnaire (Figure 1).

Statistical analysis

Descriptive statistics were performed for the collected data. The responses were displayed as (percentage). A chi-squared test was employed for statistical analysis. The data were statistically analyzed using the IBM SPSS Statistics Version 26.0.0.0 software.). The level of significance was set at $p \leq 0.05$.

Results

People have been concerned about the dangers and risks of vaccination administration since the beginning of vaccine manufacture. There is a wide range of people's faith in vaccinations, which is influenced by various reasons including vaccine awareness, potential hazards, personal experiences, religious or political factors, as well as social and economic standing.[5]

Furthermore, it has been discovered that consumers estimate vaccination-related hazards compared to other risks in different way than specialists do.[6]

Some side effects are unlikely to manifest in pre-licensure clinical investigations because of their minimal frequency, the limited numbers of respondent individuals, and other study restrictions, As a result, post-marketing surveillance of side effects after vaccine delivery is critical.[7]

For this study, 650 individuals, all of them of Iraqi descent, participated. Women were the majority of the participants (401, 61.8%), while men constituted the minority of participants (249, 38.2%). It was found that (395, 60.7%) participants were younger than 60 years of age, and (255, 39.3%) were

60 years or older. Most of the study population was made up of people with the university (494, 76%) and postuniversity (55, 8.4%) education levels, while the minority were those with pre-university (101, 15.6%) education. The study population's past medical history revealed that (351, 54%) had previously been infected with the COVID 19 virus, while (299, 46%) participants had never been infected. Participants of (16%, 104) had Sinopharm vaccine, while (484, 74.5%) received Pfizer BioNTech vaccine and (62, 9.5%) received AstraZeneca vaccine. Participants of (399, 61.5%) had received both COVID-19 vaccine doses, while (251, 38.5%) had received only one dose of their vaccines doses. Participants of (518, 79.7%) reported the presence of the side effects after receiving their doses of the vaccines (first and second dose), (132, 20.3%) of participant reported that they had no side effects after received the vaccine, see Table 1.

Table 1: The study participants' demographic characteristics, COVID-19 past infection, type of vaccine, number of vaccine doses, and the onset of side effects

Characteristics	Frequency (n and %)
	All Participants (n= 650)
Gender	
Male	249 (32.2%)
Female	401 (61.8%)
Age (year)	
< 60	395 (60.7%)
≥ 60	255 (39.3%)
Education Level	
Pre-university education	101 (15.6%)
University education	494 (76%)
Post-university education	55 (8.4%)
Previous Infection with Covid 19	
Infected	351(54%)
Not infected	299 (46%)
Type of COVID-19 Vaccine	
Pfizer-BioNTech	484 (74.5%)
AstraZeneca	62 (16%)
Sinopharm	104 (16%)
Inoculated Vaccine Dose	
1st dose	251 (38.5%)
1st and 2nd dose	399 (61.5)
Presence of Symptoms	
Presence of symptoms	518 (79.7%)
Absent of symptoms	132 (20.3%)

Side effects of the COVID-19 vaccine and their correlation to the first and second doses

The data obtained from the participants in this trial revealed that the vaccine's side effects were recognized after the two doses, with the majority coming after the second dose. The most common side effects, which include discomfort at the injection site, headaches, muscle and joint ache, and raised body temperature, could remain for days, according to the fact sheet, and were more common after the second dose than the first. See Table (2).

Chills, sore throat, hypersensitivity symptoms, vomiting, abdominal pain, and diarrhea are less common adverse effects.

There is significant difference ($p < 0.001$) between the number of patients experiencing side effects following the second dose of the vaccination (75%) than those reported side effect after receiving the first dose (40.2%), according to the findings of this study. The number of participants reporting injection site adverse effects following the second dosage of the vaccine (65.1%) which is nearly similar to those reporting side effect after first dose (64.5%) and this show that there is no significant difference between the two groups ($p > 0.1$).

There is significant difference ($p < 0.03$) between The number of people who reported hypersensitivity symptoms like fast heartbeat, shortness of breath and rash all over the body after getting the second dose of the vaccination (15.8%) than the number of people who reported hypersensitivity symptoms after receiving the first dose (5.3%).

Also the number of people who reported bone and muscle pain after receiving the second dose of the vaccine was significantly different) $p <0.01$) (47.5%), (40.1%) respectively than the number of people who reported bone and muscular pain after receiving the first dose (15%) (10%), according to the findings.

Furthermore, there is significant difference ($p <0.001$) between the number of people who reported fever after receiving the second dose of the vaccination (49%) than the number of people who reported fever after receiving the first dosage (26%).

There is also significant difference between individuals that develop chills ($p < 0.04$) and sore

throat ($p < 0.05$) after second vaccine dose (15%) (7.5%) respectively as compared to individuals reported chills and sore throat reported after their first vaccine doses (2%) (1.5%).

The number of participants who reported a desire to sleep after getting the second dosage of the vaccine (63.5%) which was significantly different ($p < 0.02$) than the number of participants who reported a desire to sleep after receiving the first dose (40.7%).

Besides, there was a significant difference ($p < 0.002$) in the number of participants who reported headache after receiving the second dose of the vaccine (45.5%) compared to the number of individuals who reported headache after receiving the first dose (20%).

The results also showed a significant difference in the number of persons who reported GIT symptoms: nausea ($p < 0.01$), vomiting ($p < 0.03$), abdominal pain ($p < 0.04$), and diarrhea ($p < 0.01$) after receiving the second dose of the vaccine (21.9%), (4.1%), (9.1%), (5.4%) respectively compared to the number of persons who reported GIT symptoms after receiving the first dose (5%), (0.5%), (1.5%), and (1.5%).

Table 2: The reported COVID-19 vaccine side effects and their correlation with the vaccine's first, second doses

	1st Dose (%)	2nd Doses (%)	Chi-Square p value
Presence of Symptoms Presence Absence	 (40.2%) (59.8%)	 (75%) (25%)	 0.001
Local Symptoms Arm pain, Injection site pain, Injection site swelling and redness	(64.5%)	(65.1%)	0.1
Hypersensitivity Symptoms, A fast heartbeat, Difficulty breathing, body allergy	(5.3%)	(15.8%)	0.03
Bone and Muscle Symptoms	(15%) (10%)	(47.5%) (40.1%)	0.001 0.001
Headache Fever Chills Sore throat	(20%) (12%) (2%) (1.5%)	(45%) (49%) (15%) (7.5%)	0.002 0.001 0.04 0.05
GIT Symptoms Nausea Vomiting Diarrhea abdominal pain	 (5%) (0.5%) (1.5%) (1.5%)	 (21.9%) (4.1%) (5.4%) (9.1%)	 0.01 0.03 0.01 0.04
Desire to sleep	(20%)	(63.5%)	0.002

Reported COVID-19 vaccine side effects and their correlation with participants' ages

The results of the study revealed significant differences ($p< 0.05$) between those under the age of 60 who were experiencing COVID-19 vaccination adverse effects and those at the age of 60 and older. See Table 3.

In comparison of individuals under 60 years old with those 60 years and older, noted that there is no significant difference ($p > 0.2$) following the first and second doses of the vaccine in the local symptoms. local symptoms and injection site effect in 60 years old and over is (75.8%) while under 60 years were (80%).

The results of this study revealed that injection site discomfort was reported similarly in people aged 60 and up and in younger people, also the same thing occur following first and second dose of vaccine.

Headache was from the most common symptom after receiving a vaccination injection. Also fever more likely to develop following the second dose in young persons.

There was a significant difference in the number of people who reported fever ($p < 0.01$) and headache ($p < 0.02$) under 60 years of age (75.5%) and (67.2%) respectively compared to those 60 years old and over (60.4%) and (52%).

Besides, there was a significant difference in the number of people who developed bone ($p < 0.01$) and muscle pain ($p < 0.03$) over 60 years of age (31.4%) and (6.4%) compared to those under 60 years old (56.2%) and (19.7%).

The study also note that there were no significant differences between the other side effects of the vaccine when comparing their incidence between participants according to their ages.

Table 3: The reported COVID-19 vaccine side effects and their correlation with the participants ages

	Frequency (n and %)		
	Age < 60 (Year)	**Age ≥ 60 (Year)**	**Chi-Square**
	(%)	**(%)**	**p value**
Local Symptoms, Arm pain, Injection site pain Injection site swelling and redness	(80%)	(75.8%)	0.2
Hypersensitivity Symptoms A fast heartbeat Difficulty breathing body allergy	(5%)	(9%)	0.1
Bone Muscle Symptoms	(56.2%) (19.7%)	(31.4%) (6.4%)	0.01 0.03
Headache Fever chills Sore throat	(67.2%) (75.5%) (8%) (4%)	(52%) (60.4%) (5%) (2%)	0.002 0.01 0.1 0.3
GIT Symptoms Nausea vomiting	 (9%) (4%)	 (6.4%) (2.5%)	 0.2 0.1
Desire to sleep	(67%)	(64%)	0.1

Correlation between presence and absence of post COVID-19 vaccine side effects and the participant's sex

According to the findings, there was a significant difference ($p< 0.05$) in the number of females who experienced COVID-19 vaccination side effects (80%) as compared to males (60%).

Discussion

The majority of the symptoms are most likely due to an overabundance of a cytokine called type I interferon, which plays an important role in potentiating early stages of the immune response (IFN-I).[8]

The data obtained from the participants in this trial revealed that the vaccine's side effects were recognized after the two doses, with the majority coming after the second dose. this is due to the fact that the immune system identifies the viral spike protein from the first vaccine dose and produces a stronger response.[9] The FDA Fact Sheet for Recipients and Caregivers confirmed these findings.

Another theory is based on the immune system's response. The immune system could release cytokines that could cause inflammation in the blood vessels, muscles, and other tissues.

Injection site tenderness as a subjectively reported symptom has a variety of confounders that should be taken into account in future vaccination side effect research, including injection method, vaccine temperature, and injection velocity. These variables are difficult to regulate and will have a major impact on one's experience. Furthermore, injection into a relaxed muscle causes less discomfort than injection into a stiff muscle, so it's best to lower the patient's arm that will be injected.[3]

The results of this study revealed that injection site discomfort was reported similarly in people aged 60 and up and in younger people, also the same thing occur following first and second dose of vaccine. This is agree with the predictions of Polack et al, who found that injection site discomfort was more common in those younger than 55 years old compared to those older.[10]

This could also explain why persons under the age of 60 are more likely to have adverse effects than older people, as younger people have stronger and more efficient immune systems. Severe allergic

response would occur within minutes to one hour after getting the vaccine dose.

Our findings are in agreement with those of Polack et al, who found that vaccine-associated systemic adverse effects were more common among younger participants and more common after the second vaccine dose in both trials.[10]

In comparison to the intensity of typical immune responses, IFN-I production is significantly higher in females than in males, and in younger people than in older people.[8]

Conclusion

In general, the COVID-19 vaccine's side effects are similar to those seen with earlier immunizations, and the most of them are tolerable.[11] Furthermore, the majority of the symptoms have been recorded by the manufacturer and the FDA Facts Sheet.[11] However, for certain people, monitoring them for a short time after receiving their vaccine doses is required.

Ethical clearance: Approval of the study design was obtained by the ethics committee at the university of basrah / medical college. The committee was very supportive of the project

Conflict of interest: the authors declare no conflict of interest

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