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## Epidemiology of Adverse Effects following COVID-19 Vaccination among Subjects visiting Tikrit Teaching Hospital Outpatients Clinics

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### ABSTRACT

**Back ground :** Coronavirus disease 2019 (COVID-19) was first identified in China leading to out break of respiratory illness . there are many vaccination used for prevention of the disease. Many side effects appeared with taking theses vaccine as pain, redness, swelling at site of injection and systemic effects (e.g, fever , fatigue, headache, muscle or joint pain, with rare serious adverse events.

**Patients and methods:** The current study was descriptive one ,it was conducted among persons vaccinated with Covid-19 vaccines from the period 14th November 2021 -18th march 2022 in Tikrit city . The sample was taken from people attending Tikrit teaching hospital out patient clinics and those previously taken the vaccines. The information was obtained according to a designed questionnaire which included all information regarding certain demographic characteristics and common adverse effects as a result of COVID-19 vaccination according to vaccine type.

**Results :** The most frequent adverse effects was among subjects given AstraZeneca vaccine , followed among those given Pfizer vaccine and the last among those given Sinopharm vaccine. The more frequent cases with adverse effect with AstraZeneca and Pfizer vaccine was among age group (35 -45 years )(63%,70.2% respectively) while those among those given Sinopharm was among age group less than 35 years (38.2%).The commonest adverse effect of COVID-19 vaccination was pain/tenderness at site of injection (76.3%) followed by fever/chills (70.6%) and muscle weakness/tiredness (66.6%) .

**Conclusion:** The most frequent adverse effects of COVID-19 vaccination was pain/tenderness at site of injection and the highest frequency of adverse effects were among those given AstraZeneca vaccine.

## **Introduction:**

Corona virus 2019 (COVID-19) infection is pandemic disease which may lead to severe acute respiratory syndrome 2 (ARS-CoV-2)(1). These COVID-19 vaccines are either (messenger RNA (mRNA), adenovirus vector, or inactivated SARS-CoV-2 genes (2). mRNA (tozinameran) first used in 2020 (3). There are 252 COVID-19 vaccine candidates around the world (4) .

The documented adverse reactions of COVID-19 vaccination included pain at injection, fever, chills, tiredness , myalgia , headache and other respiratory signs and symptoms([5-10). The injection site pain was the most common local side effect, also headache/fatigue, muscle pain, malaise, chills, and joint pain were the most common systemic side effects (11),the fever normally happens within 48 hours of the vaccination (12)

It has been reported in Jordan that adverse effects after COVID-19 vaccination differed according to type of vaccination. The highest

frequency was among those who given AstraZeneca vaccine (88.9%) followed among those who given Pfizer vaccine (70.6%)and finally among those who given Sinopharm vaccine(54.3%). The highest frequency of adverse effect was tiredness and fatigability (58.2%),followed by pain at injection site (53.45%) (13). In Saudi Arabia it was documented that the more frequent adverse effect after Pfizer and vaccination was fever/chills(43.4%,70.3% respectively ) followed by pain at site of injection (Pfizer 31.3% and Astrazeneca 30.3% (14). In another study in Saudi Arabia it was reported that commonest adverse effect of COVID-19 vaccination was pain at site of injection followed by fever (15).

Aim of the study : To determine the frequency of adverse effects as a result of COVID-19 vaccinations according to some demographic factors, vaccine type .

## **Objectives :**

1-To determine the frequency of side effects according to dose and type of vaccine.

2- To determine the frequency of side effects according to certain demographic features of patients according to type of vaccine.

3- To determine the frequency of side effects according to common signs and symptoms effects and type of vaccine.

### **Patients and methods:**

The current study was descriptive one( cross sectional study ) it was conducted among persons vaccinated with Covid-19 vaccines from the period 14th November 2021 -18th march 2022 in Tikrit city . The sample was taken from people attending Tikrit teaching hospital out patient clinics and those previously taken the vaccines

The sample was a convenient sample including all those will attend out patient clinic

Inclusion criteria : the sample include all those given vaccination .

Exclusions criteria : Exclude who those admitted to hospital during the time of sampling process.

Ethical considerations: After taking permission from Tikrit health care center and manger of Tikrit teaching hospitals in addition to inform the study group about this information and their agreements.

Pilot study was done to test the time needed for collection of data and to over come any obstacles for conducting the study. The response was very high from patients and data was valid and reliable. The information was obtained according to a designed questionnaire, which included all information regarding certain demographic characteristics(gender ,age ) and common adverse effects as a result of COVID-19 vaccination according to vaccine type

Statistical Analysis: Frequencies, per cent and Chi square test was used to assess association. Statistical analysis at p-value < 0.05 was considered significant.

**Results :**

The more frequent cases with side adverse effect (in general )was among those taken AstraZeneca vaccine in both doses the average was

(88.5%) followed those taken Pfizer vaccine (81.5%)and the last among those taken Sinopharm vaccine (79%)(fig. 1)

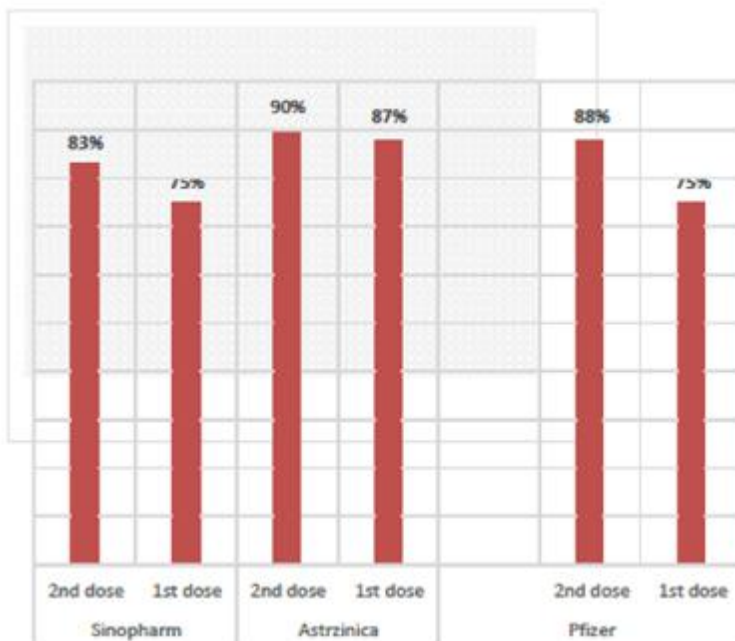


Fig (1) Distribution of adverse effects (in general)according to type of vaccine and dose .

It has been reported that more frequent cases with adverse effects of Pfizer and AstraZeneca vaccine was with age group (35-45)(70.2% ,63% respectively) while the highest frequency in Sinopharm vaccine was with age group (< 35 years) with significant difference. Adverse effects following vaccination .

In all those given vaccines there were slightly female cases with side effects more than males without significant difference. The frequency of male side effects as a result of Pfizer, AstraZeneca and Sinopharm are 48.8%,48.1% and 49.6% respectively . (Table1)

Table (1) Distribution of common adverse effects of covid -19 vaccine according to certain demographic features and type of vaccine.

Vaccine type Demographic factors	Pfizer	AstraZeneca	Sinopharm	Total	Chi square test
<b>Age group /years</b>					The chi-square statistic is 51.9031. The p-value is < 0.00001. The result is significant at p < .05.
<35	15 17.9%	10 7.4%	50 38.2%	75	
35-45	59 70.2%	85 63%	46 35.1%	190	
More than 45	10 11.9%	40 29.6%	35 26.7%	85	
<b>Total</b>	<b>84 100%</b>	<b>135 100%</b>	<b>131 100%</b>	<b>350</b>	
<b>Gender</b>					The chi-square statistic is 0.0576. The p-value is .971606. The result is not significant at p < .05.
Male	41 48.8%	65 48.1%	65 49.6%	160	
Female	43 51.2%	70 51.9%	66 50.4%	190	
<b>Total</b>	<b>84 100%</b>	<b>135 100%</b>	<b>131 100%</b>	<b>350</b>	

It has been documented that the most common adverse effect of Covid-19 vaccination was pain and tenderness at site of injection (76.3%) and the highest frequency was among those given AstraZeneca Vaccine (88.9%) followed by those given Pfizer (81%) and Sinopharm vaccines (76.3%) with significant difference. The second adverse effect of Covid-19 vaccination was fever and chills (70.6%). The frequency of subjects with fever and chills as a result of AstraZeneca vaccine (77.8%), Pfizer (72.6%) and Sinopharm (70.6%) with significant difference. Muscle weakness and tiredness appeared in (66.6%) of vaccinated subjects and the frequency according to type of

Vaccine was (AstraZeneca 72.6%, Pfizer 67.9% and Sinopharm 59.5%) without significant difference. Headache is one of the adverse effects of covid-19 vaccination, it was reported in 42% of vaccinated subjects (as a result of vaccination (AstraZeneca 75.6%, Pfizer 23.8% and Sinopharm 19%) with significant difference. The frequency of vaccinated subjects with respiratory and gastrointestinal tract adverse effects was (13.1% and 9.1% respectively) (Table 2).

Table (2) Distribution of common adverse effects as type of signs and symptoms and covid -19 vaccines type.

Vaccine types	Pfizer		AstraZeneca		Sinopharm		Total		Chi square test
<b>Adverse effects</b>									
<b>Pain /tenderness at site of injection</b>									The chi-square statistic is 31.3569. The p-value is < 0.00001. The result is significant at p < .05.
Yes	68	81%	120	88.9%	79	60.3%	267	76.3%	
No	16	19%	15	11.1%	52	39.7%	83	13.7%	
Total	84	100%	135	100%	131	100%	350	100%	
<b>Fever /chills</b>									The chi-square statistic is 7.5876. The p-value is .02251. The result is significant at p < .05.
Yes	61	72.6%	105	77.8%	82	62.6%	248	70.6%	
No	23	27.4%	30	22.2%	49	36.4%	102	29.1%	
Total	84	100%	135	100%	131	100%	350	100%	
<b>Muscle weakness /tiredness</b>									The chi-square statistic is 5.1705. The p-value is .075378. The result is not significant at p < .05.
Yes	57	67.9%	98	72.6%	78	59.5%	233	66.6%	
No	27	32.1%	37	27.4%	53	40.5%	117	33.4%	
Total	84	100%	135	100%	131	100%	350	100%	
<b>Headache</b>									The chi-square statistic is 102.0508. The p-value is < 0.00001. The result is significant at p < .05.
Yes	20	23.8%	102	75.6%	25	19%	147	42%	
No	64	76.2%	33	24.4%	106	81%	203	58%	
Total	84	100%	135	100%	131	100%	350	100%	
<b>Respiratory</b>									The chi-square statistic is 6.115. The p-value is .047006. The result is significant at p < .05.
Yes	10	11.9%	25	18.5%	11	8.4%	46	13.1%	
No	74	88.1%	110	81.5%	120	91.6%	304	86.9%	
Total	84	100%	135	100%	131	100%	350	100%	
<b>GIT</b>									The chi-square statistic is 4.2251. The p-value is .120929. The result is not significant at p < .05.
Yes	8	9.5%	17	12.6%	7	5.3%	32	9.1%	
No	76	90.5%	118	70.4%	124	94.7%	318	90.9%	
Total	84	100%	135	100%	131	100%	350	100%	

**Discussion :**

In the current study general speaking the frequency of adverse events as a result of COVID-19 vaccination varied according to vaccine type , certain demographic and common signs and symptoms associated with vaccination . The highest frequency of adverse effects was among those given AstraZeneca vaccine (89%) which is similar to that found in Jordan then followed with those given Pfizer vaccine (81.5%) which is lower to that found in Jordan (70.6%) and the last frequency was

among those given Sinopharm vaccine (54.3%)(13). Adverse effects in 2nd dose is more frequent than the 1st dose in all type of vaccines which agree with other studies (13,16) while in agreement with other studies in which adverse effects in 1st dose is more frequent (17-19). Pfizer vaccination averse effects was more than that reported as a result of Sinopharm vaccination (5,16,20).

In this study the adverse effects were more frequent with age group 35-34 years in cases of Pfizer and AstraZeneca vaccination (70.2%,

63% respectively ) while among those given Sinopharm vaccine were common with less than 35 years( 38.2%). Other studies reported that more frequent Adverse effects following pfizer vaccination was among age group more than 55 years, and Sinopharm vaccination among age group less than 35 years (16).

It has been reported that adverse effects were more among females than males without significant difference . this results were similar to that reported in other studies (5,16,18,20).

The frequency of adverse effects among females given Pfizer ,AstraZeneca and Sinopharm vaccination was( 51.2% , 51.9% and 50.4% respectively) while in Jordan the results among females given Sinopharm and Pfizer vaccination was 66.6% and 69.3% respectively(5,16,20)

Pain/tenderness at site of vaccine injection is the commonest adverse effect as a result of COVID-19 vaccination(76.3%) .This result is agreement with other studies results

(15,16,18,19,22,23), even the frequency was lower than that found by current study. Other studies found the commonest adverse effects was fever, fatigability (14,16).

According to the type of vaccines the frequency of pain/tenderness at site of injection in the current study was (Pfizer 81%, AstraZeneca 88.9% and Sinopharm 60.3%) of vaccinated subjects. Other studies revealed that pain/tenderness represented (Pfizer 31.3%, AstraZeneca 30.5%)(14), (Pfizer 41,1%, Sinopharm 40%)(16).

Regarding fever in the current study , it was (Pfizer 72.6%, AstraZeneca 77.8% and Sinopharm 62.6.3%) of vaccinated subjects while other studies reported the frequency of fever was (Pfizer 43.4%, AstraZeneca 70.3%)(14), (Pfizer 24%, Sinopharm 5.2%)(16).

In current study muscle weakness /tiredness represented (Pfizer 67.9%, AstraZeneca 72.6% and Sinopharm 59.5%) of vaccinated subjects, while other studies results were (Pfizer 50.9%, AstraZeneca 65%)(14),

(Pfizer 30.3%, Sinopharm 25.3%)(16).

Headache adverse effects reported in (Pfizer 23.8%, AstraZeneca 75.6% and Sinopharm 19%) of vaccinated subjects while other studies results were (Pfizer 28.3, AstraZeneca 40.3%)(Alfaleh 2022), (Pfizer 17.2%, Sinopharm 17.3%)(Gansan 2022).

Respiratory and GIT adverse effects among vaccinated subjects were (13.1%,9.1% respectively) .this result was agreement with other study in Jordan (Hatmal 2021)

Conclusion :The most frequent adverse effects of COVID-19 vaccination was pain/tenderness at site of injection and the highest frequency of adverse effects were among those given AstraZeneca vaccine.

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