

Complications after Covid-19 vaccination

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ABSTRACT

Background : Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus. Most people who fall sick with COVID-19 will experience mild to moderate symptoms and recover without special treatment. However, some will become seriously ill and require medical attention.

Objective : The aims of this study is to explore the different side effects associated with the three most common vaccines against Covid-19 in Nineveh, Iraq. Such study will aid healthcare workers and policy makers in the betterment of medical care for concerned patients, therefore, improving their quality of life.

Patients and methods: The study is a prospective case series study, included 498 participants, 48.1% of them were between the ages 18 to 30 years, 54.0% are married, Only these two characteristics were significantly different among vaccine users (p-value = .041 and .001, respectively).

Results: Frequency of Adverse Reactions Based on the Vaccine

For the first dose, the most common symptoms were body/joint pain, headache, fatigue and fever.

The frequency of these symptoms in addition to respiratory symptoms were significantly more frequent within the AstraZeneca vaccine (all p <.001).

While the Pfizer-BioNTech vaccine had significantly higher frequency of no experienced symptoms (p <.001).

For the second dose, the trends of the adverse effects did not change. However, the symptoms of joint/body pains, headache, fatigue, and fever were significantly more pronounced in the Pfizer-BioNTech vaccine (all p <.001).

Conclusions and recommendations: In conclusion, we noticed that post vaccine side effects are common with all vaccines but are more pronounced in new technology vaccines.

The application of a governmental surveillance system adverse effect severity is highly recommended.

Keywords: Covid-19, vaccination, complications, Sinopharm, Pfizer-BioNTech.

مضاعفات تلقي لقاحات كوفيد - ١٩

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الخلاصة

الخلفية : مرض الكورونا، هو مرض معدي مسبب بالفايروس اغلب المرضى الذين يقعون ضحية الفايروس يعانون اعراض بسيطة الى متوسطة الشدة ويكتسبون الشفاء بدون تدخل علاجي خاص. من جهة أخرى هنالك قلة من المرضى يعانون بشكل خطير ويتطلب شفاءهم عناية طبية.

الهدف من الدراسة: لاستكشاف الآثار الجانبية المختلفة المصاحبة لاستخدام لقاحات كوفيد-١٩ الثلاث التي استخدمت في محافظة نينوى. مثل هذه الدراسة تساعد المرضى , والرعاية الصحية من اجل سياسة صحية جيدة وسليمة وتحسين مدى جودة الحياة.

المرضى وطرق العمل: الدراسة هي دراسة مستقبلية لسلسلة حالات طبية , ضمت هذه الدراسة ٤٩٨ مشارك, ٤٨.١ % أعمارهم ما بين ١٨ و ٣٠ سنة, ٥٤% متزوجين وهذين العاملين ذوا اختلاف معنوي بين مجاميع المتلقي للقاح.

النتائج: الاعراض الأكثر تواترا حسب نوع اللقاح

مع الجرعة الأولى كانت أكثر الاعراض الالام الجسم/المفاصل، الصداع، الاعياء والحمى . تكرر هذه الاعراض بالإضافة الى الاعراض التنفسية أكثر توترا بشكل معنوي ضمن مجموعة المتلقين للقاح استرا زينكا، اما مع لقاح فايزر كانت هنالك أكثرية معنوية في عدم مصاحبة اللقاح لاية اعراض. بالنسبة للجرعة الثانية لم يكن اتجاه الاعراض الجانبية مختلفا، ولكن كانت الالام الجسم/المفاصل، الصداع والاعياء والحمى أكثر اعلانا من قبل المتلقين للقاح فايزر.

الاستنتاج: لاحظنا ان الاعراض الجانبية التي تظهر بعد تلقي اللقاح المعطى واردة الحدوث ولكنها أكثر مع اللقاحات المصنعة بطرق تكنولوجيا حديثة، مقترح ان يوضع جدول جهاز مراقبة حكومي للاعراض الجانبية.

الكلمات المفتاحية: كوفيد-19 ، اللقاحات ، المضاعفات ، سينوفارم ، فايزر- بايونتك .

INTRODUCTION

Vaccines are the most effective preventive measure in face of pandemics throughout history¹. The ongoing COVID-19 pandemic pushed the world in a vaccine production race in which 259 vaccine projects are started, of which 11 are in phase III clinical trials².

Of the vaccines that made it past phase III trials, Sinopharm, Pfizer-BioNTech, and AstraZeneca were among the first to be available and to be disseminated worldwide³⁻⁵. None of which were labeled as side-effect free vaccines. Due to their rapid use, the Centers for Disease Control and Prevention has developed V-safe, a real time vaccine adverse event reporting system to track the vaccines' side effects⁶. Most reported vaccine side effects are either preventable or conservatively managed the most prevalent of which were fever and different forms of pain⁷.

In light of what's above, this study aimed to explore the different side effects associated with the three most common vaccines in Iraq. Such study will aid healthcare workers and policy makers in the betterment of medical care for concerned patients, therefore, improving their quality of life.

Methodology

The study approved by Medical Research Ethical Committee ref.no.UOM/COM/MREC/21-22(70) , It included 498 participants, of which ,Participants were stratified based on received COVID-19 vaccine. Nearly 45.0% received 2 doses of AstraZeneca, 43.0% receiver the Pfizer-BioNTech vaccine, while only 13.0% received the Sinopharm vaccine. Most of the included participants were male (60.8%), within the ages between 18 to 30 years (48.1%), married (54.0%), and were classified of normal weight (38.4%). Moreover, about 70.0% of all participants had an undergraduate degree, while 96.2% of the entire sample lived in urban residence. Of the included sample, 45.5% had been previously infected with COVID-19 while only 2.4% had multiple COVID-19 infections. Only age and marital status were

significantly different among vaccine users (p -value = .041 and .001, respectively).

Statistical Analysis

All statistical analysis was conducted on the statistical package for social sciences (SPSS) version 23.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were reported as frequencies for categorical data [n (%)] and as means and standard deviations for continuous data ($n \pm SD$). Associations were made using Chi-Square testing. ANOVA and student's t -test were utilized to detect significant mean differences between categories. A p -value equal or less than 0.05 is considered statistically significant.

RESULTS

The study included 498 participants, of which characteristics are shown in table A. Participants were stratified based on received COVID-19 vaccine. Nearly 45.0% received 2 doses of AstraZeneca, 43.0% receiver the Pfizer-BioNTech vaccine, while only 13.0% received the Sinopharm vaccine. Most of the included participants were male (60.8%), within the ages between 18 to 30 years (48.1%), married (54.0%), and were classified of normal weight (38.4%). Moreover, about 70.0% of all participants had an undergraduate degree, while 96.2% of the entire sample lived in urban residence. Of the included sample, 45.5% had been previously infected with COVID-19 while only 2.4% had multiple COVID-19 infections. Only age and marital status were significantly different among vaccine users (p -value = .041 and .001, respectively).

Table B ,demonstrates the presentations of those infected with COVID-19. Most common symptoms included fatigue (78.4%), anosmia (66.5%), fever (64.4%) aches/pains (54.7%), and headaches (50.4%). Most of the participants experienced to at least 4 COVID-19 symptoms (21.2%). The most common complication due to COVID-19 was arrhythmias (14.0%). Most COVID-19 infections lasted within the 8 to 14 days range (44.6%).

Frequency of Adverse Reactions Based on the Vaccine

Table C ,portrays the frequency of adverse reactions as stratified by vaccine and number of dosages. For the first dose, body/joint pain, headache, fatigue and fever were the most common symptoms. The aforementioned adverse effects in addition to respiratory symptoms ($p = .028$) were significantly more frequent within the AstraZeneca vaccine (all $p < .001$). On the other hand, the Pfizer-BioNTech vaccine had significantly higher frequency of no experienced symptoms ($p < .001$). For the second dose, the adverse effects trends did not change. However, the symptoms of joint/body pains, headache, fatigue, and fever were significantly more pronounced in the Pfizer-BioNTech vaccine (all $p < .001$).

DISCUSSION

Our results demonstrate that fatigue, anosmia, fever, and different kinds of pain were the most prevalent side effects after COVID-19 vaccination irrespective of type. The side effects of vaccines were more pronounced in the group taking the AstraZeneca vaccine as their first dose. On the other hand, vaccine adverse effects were more prevalent in the group taking the Pfizer-BioNTech vaccine as their second dose. The prevalence of symptoms among all groups did not significantly change with age, sex, educational status or BMI.

Within a regional context, a Jordanian study on the general populace demonstrated that fatigue, headache, muscle pain, arthralgia and fever were the most prevalent symptoms post vaccination and were significantly more prevalent in mRNA vaccines irrespective of number of dose⁸.

Similarly, a study conducted on Jordanian healthcare workers demonstrated comparable trends in which pain at site of injection was the most frequent reported symptom⁹. An Iraqi retrospective investigation reported that fatigue, local injection site reactions, fever, and muscle pain were the most prevalent symptoms among a randomized sample of over 1000 Iraqi participants¹⁰.

Moreover, none of the aforementioned studied reported any serious side effects that required emergent treatment or advanced medical care, in fact all of the reported local or systemic side effects were in the expected range associated with vaccines. Our results are consistent with the above.

To our surprise, pain at site of rejection was infrequently reported across our cohort. So infrequent that a proper statistical analysis could not be conducted based on the low numbers. What could explain such a phenomenon is the cross-sectional nature of the study which extracted participants' experiences with post-vaccination side effects in a retrospective manner through questionnaires. Therefore, while consistent with the literature, all results or rather the defects within them fall prey to recall bias which could have underestimated the prevalence of short-lived adverse effects such as that of pain at injection site.

Additionally, the frequency of side effects was significantly higher in mRNA vaccines, being higher in AstraZeneca in the first dose, and in Pfizer-BioNTech in the second. Such results are consistent with the previous literature as many reports demonstrated that vaccine related side effects in terms of frequency or severity were influenced by vaccine type and composition¹⁰⁻¹³.

Our study aimed to systematically describe and compare the side effects associated with the most common vaccines in Iraq. The value of such efforts lies in their ability to counter rumors contributing to hesitancy towards taking the vaccine among the community . The United States is monitoring the vaccine through the Vaccine Adverse Event Reporting System (VAERS) and V-safe¹⁴. Additionally, Jordan is using a governmental hub formulated for the surveillance of side effects reported by the vaccinated public⁸. Iraq did not design similar surveillance programs nor issued any campaigns regarding such a pertinent topic.

CONCLUSIONS AND RECOMMENDATIONS

In sum, our results are in concordance with that reported in the literature. Post vaccine side effects are common to all vaccines but are more pronounced in new technology vaccines. The implementation of a governmental surveillance system that accounts for adverse effect severity is highly recommended.

Table A: The characters of the participants

		Total	AstraZeneca	Pfizer	Sinopharm	P-value
Age (years)		32.5 ± 9.4				
	18 – 30	239 (48.1%)	93 (18.7%)	120 (24.1%)	26 (5.2%)	.041
	31 – 40	178 (35.8%)	89 (17.9%)	61 (12.3%)	28 (5.6%)	
	41 – 50	54 (10.9%)	28 (5.6%)	20 (4.0%)	6 (1.2%)	
	51 – 60	20 (4.0%)	10 (2.0%)	8 (1.6%)	2 (0.4%)	
	61 – 70	5 (1.0%)	2 (0.4%)	2 (0.4%)	1 (0.2%)	
	+70	1 (0.2%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	
Gender						
	Male	303 (60.8%)	144 (28.9%)	118 (23.7%)	41 (8.2%)	.099
	Female	195 (39.2%)	78 (15.7%)	95 (19.1%)	22 (4.4%)	
Marital Status						
	Single	224 (45.0%)	81 (16.3%)	121 (24.3%)	22 (4.4%)	.001
	Married	269 (54.0%)	139 (27.9%)	90 (18.1%)	40 (8.0%)	
	Divorced	2 (0.4%)	1 (0.2%)	1 (0.2%)	0 (0.0%)	
	Widowed	2 (0.4%)	0 (0.0%)	1 (0.2%)	1 (0.2%)	
	Engaged	1 (0.2%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	
Educational Level						
	Illiterate	1 (0.2%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	.318
	Primary	1 (0.2%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	
	Elementary	4 (0.8%)	2 (0.4%)	2 (0.4%)	0 (0.0%)	
	Secondary	14 (2.8%)	10 (2.0%)	3 (0.6%)	1 (0.2%)	
	Undergraduate	342 (68.7%)	150 (30.1%)	154 (30.9%)	38 (7.6%)	
	Postgraduate	136 (27.3%)	59 (11.8%)	53 (10.6%)	24 (4.8%)	
Area of living						
	Urban	479 (96.2%)	8 (1.6%)	6 (1.2%)	5 (1.0%)	.172
	Rural	19 (3.6%)	214 (43.0%)	207 (41.6%)	58 (11.6%)	
BMI						
	Underweight	13 (2.7%)	4 (0.8%)	7 (1.5%)	2 (0.4%)	.545
	Normal	185 (38.4%)	73 (15.1%)	93 (19.3%)	19 (3.9%)	
	Overweight	176 (36.5%)	80 (16.6%)	72 (14.9%)	24 (5.0%)	
	Obese	108 (22.4%)	59 (12.2%)	22 (6.8%)	16 (3.3%)	

Table B: The signs and symptoms of those participants infected with Covid-19

Number of times contracting COVID-19		
	0	256 (52.0%)
	1	224 (45.5%)
	2	12 (2.4%)
Vaccine		
	AstraZeneca	222 (44.6%)
	Pfizer	213 (42.8%)
	Sinopharm	63 (12.7%)
Symptoms due to COVID-19		
	Fever	152 (64.4%)
	Dry Cough	92 (39.0%)
	Fatigue	185 (78.4%)
	Sore Throat	82 (34.7%)
	Headache	119 (50.4%)
	Anosmia	157 (66.5%)
	SOB	45 (19.1%)
	Aches and pains	129 (54.7%)
	Conjunctivitis	11 (4.7%)
	Diarrhea	53 (4.7%)
	Chest pain	44 (18.6%)
Number of symptoms		
	1	21 (8.9%)
	2	18 (7.6%)
	3	30 (12.7%)
	4	50 (21.2%)
	5	45 (19.1%)
	6	27 (11.4%)
	7+	41 (17.4%)
Complications due to COVID-19		
	Pneumonia	12 (5.1%)
	Arrhythmia	33 (14.0%)
	Secondary bacterial infections	5 (2.1%)
	ARDS	8 (3.4%)
Duration		
	≤ 7 days	65 (30.5%)
	8 – 14 days	95 (44.6%)
	≥ 15 days	53 (24.9%)

Table C: The frequency of the adverse effects after vaccination according to the vaccine type

Post vaccination symptoms	First Dose			P-value	Second Dose			P-value
	AstraZeneca	Pfizer	Sinopharm		AstraZeneca	Pfizer	Sinopharm	
None	20 (4.0%)	72 (14.5%)	17 (3.4%)	<.001	60 (12.0%)	30 (6.0%)	29 (5.8%)	<.001
Joint or body pain	132 (26.5%)	69 (13.9%)	15 (3.0%)	<.001	29 (5.8%)	65 (13.1%)	5 (1.0%)	<.001
Headache	109 (21.9%)	64 (12.9%)	18 (3.6%)	<.001	31 (6.2%)	60 (12.0%)	14 (2.8%)	.001
Fatigue	164 (32.9%)	93 (18.7%)	28 (5.5%)	<.001	62 (12.4%)	94 (18.9%)	14 (2.8%)	<.001
Diarrhea	9 (1.8%)	6 (1.2%)	4 (0.8%)	.424	1 (0.2%)	1 (0.2%)	0 (0.0%)	--
Respiratory Symptoms	14 (2.8%)	3 (0.6%)	2 (0.4%)	.028	2 (0.4%)	5 (1.0%)	2 (0.4%)	--
Fever	143 (28.7%)	54 (10.8%)	14 (2.8%)	<.001	30 (6.0%)	67 (13.5%)	3 (0.6%)	<.001
Nausea	32 (6.4%)	19 (3.8%)	5 (1.0%)	.130	6 (1.2%)	12 (2.4%)	2 (0.4%)	.279
Pain at site of injection	1 (0.2%)	4 (0.8%)	1 (0.2%)	--	0 (0.0%)	1 (0.2%)	1 (0.2%)	--
Abdominal pain	4 (0.8%)	5 (1.0%)	2 (0.4%)	--	6 (1.2%)	12 (2.4%)	2 (0.4%)	.279

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