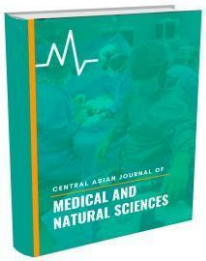

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Article

Adverse Effects of SARS-CoV-2 Vaccines on Patients Suffering from Non-Communicable Diseases

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Abstract: Vaccination side effects is one of the main social concerns in vaccination decision among population especially among adults who have non-communicable diseases. The aim of the present study is to investigate the effect of three SARS-CoV-2 vaccines presented in Iraq (Pfizer, AstraZeneca-Oxford and Sinopharm) including SARS-CoV-2 infection on the development of some post- vaccination side effects. A total of 414 individuals were included in the present study. Data was collected between January 2022 and March 2022. All individuals are vaccinated by one of the three vaccines that are available in Iraq which are Oxford-AstraZeneca vaccine, Pfizer Biontech vaccine and Sinopharm vaccine. All individuals in the present study were tested for one of the common non-communicable diseases (Hypertension, Allergy, Rheumatoid arthritis, Heart diseases, Diabetes, Kidney diseases and others). The results revealed the prevalence of moderate side effects were in two types of vaccines in Iraq which are Pfizer BioNTech Vaccine and Oxford-AstraZeneca vaccine. However; Sinopharm Vaccine show mild or asymptomatic side effects to all types of non-communicable diseases. Severity was observed in Pfizer BioNTech vaccine only. The side effects of three major SARS-CoV-2 vaccines in Iraqi patients with NCDs, differentiating between those previously infected and those who were not.

Keywords: SARS-CoV-2, Vaccines, Hypertension, Diabetes, Rheumatoid Arthritis

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1. Introduction

The effectiveness of SARS-CoV-2 vaccination, particularly concerning chronic comorbidities, has been noted in recent publications, especially regarding the Iraqi population. The need for researching the vaccine was emphasized in some of the first works, such as the one by which described the implementation of different vaccines in Iraq and discussed suspicions related to vaccination uptake. The vaccine uptake was fluctuated due to the disbelief, myths, misinformation, and distrust regarding the vaccine manufacturers, even with the demonstrated benefits of AstraZeneca and Pfizer vaccines [1].

Subsequent studies concentrated on the ramifications of vaccination for individuals receiving immunotherapy for dermatological disorders, highlighting the necessity for customized vaccination protocols. This was especially pertinent as individuals with immune-mediated disorders may have modified reactions to vaccines, but they were not identified as having an elevated risk for catastrophic COVID-19 outcomes [2].

Broadened the discussion by analyzing the interaction between COVID-19 and non-communicable diseases (NCDs), demonstrating that those with chronic disorders including hypertension and diabetes encountered increased risks of severe sickness from the virus. This systemic literature analysis revealed the feedback mechanisms through which pre-existing chronic illnesses may worsen COVID-19 outcomes, hence underscoring the need of immunization for these at-risk individuals [3].

Subsequent enquiries elucidated the varieties and frequency of side effects linked to certain vaccines among healthcare professionals and immunocompromised populations, respectively. These investigations emphasized the imperative for continuous safety assessments and stressed the requirement for more extensive data on vaccine efficacy in vulnerable populations [4,5]. The challenges to vaccine adoption were further examined, both of which revealed factors affecting vaccination uptake among the Iraqi community. The research indicated that misunderstandings regarding vaccine safety and efficacy continued to pose substantial obstacles to increasing immunization rates, especially among individuals with chronic illnesses [6,7].

Additional studies examined vaccine acceptability in patients with chronic diseases, indicating that age, previous health status, and public health education significantly influenced the desire to vaccinate. The results further validated this by illustrating the efficacy of vaccines in diminishing unfavorable outcomes in people with chronic conditions, however they advocated for longitudinal studies to evaluate the durability of these effects [8], [9], 10].

Research investigated the influence of chronic diseases on COVID-19 outcomes, revealing elevated mortality rates linked to chronic liver illness and underscoring the potential of immunization to reduce certain risks. This issue of chronic illness and vaccination was reiterated in the cross-sectional analyses, which examined determinants of vaccine uptake among individuals with chronic diseases, demonstrating the intricate dynamics of vaccine hesitation and acceptance constitute a complex topic that need significant study [11,12]. The evolving literature underscores the necessity of effectively addressing vaccination hesitancy while comprehending the special requirements and concerns of chronic disease patients. Moreover, prioritizing effective communication regarding vaccine safety and efficacy is essential for enhancing vaccination rates in Iraq and analogous countries confronting public health challenges. The comprehensive research highlights the necessity of adopting customized public health policies to increase vaccine acceptance, hence improving health outcomes in at-risk vulnerable communities. By persistently assessing and modifying these tactics, one can cultivate a more knowledgeable populace that is more amenable to vaccination and its significant advantages.

The aim of the study was to investigate the effect of three SARS-CoV-2 vaccines presented in Iraq (Pfizer Biontech, AstraZeneca-Oxford, and Sinopharm) and SARS-CoV-2 infection on patients suffering from non-communicable diseases (NCDs).

2. Materials and Methods

Patients and sampling

A total of 414 individuals were included in the present study. Data was collected between January 2022 and March 2022. All individuals are vaccinated by one of the three vaccines that are available in Iraq which are Oxford-AstraZeneca vaccine, Pfizer Biontech vaccine and Sinopharm vaccine. All individuals in the present study were suffering from one of the common non-communicable diseases in Iraq (Hypertension, Allergy, Rheumatoid arthritis, Heart diseases, Diabetes, Kidney diseases and others). Symptoms of vaccination were recorded by a fellow up electronic form. Non-communicable diseases' patients were divided into two groups after vaccination by one of SARS-CoV-2 vaccines. The first group was COVID-19 non-infected patients and the second group was COVID-

19 infected before vaccination patients. Vaccination side effects (symptoms) were divided into (Nill, Moderate and Severe) according to severity of side effects.

Data Collection

Data was gathered via a researcher-designed questionnaire consisting of three sections: (1) sociodemographic characteristics (2) knowledge and medical history; and (3) enquiries regarding participant-reported side effects, divided into two segments addressing experiences related to the infected by SARS-CoV-2 or not infected. The enumeration of possible adverse effects was derived from the findings revealed in the vaccine's clinical trials and prior research investigations. The symptoms encompassed localized pain and swelling at the injection site, weariness, headache, myalgia, chills, arthralgia, and fever and classified to nil, moderate and severe according to European Medicines Agency [13].

Routine laboratory tests

A total of 5ml. blood samples and urine were taken from all patients to test for kidney functions, diabetes, rheumatoid arthritis and allergy while hypertension and heart diseases were diagnosed by a specialist physician. Routine lab. tests were performed to diagnose these non-communicable diseases. Kidney functions were tested by GUE test, creatinine and blood urea. For diabetes patients, random plasma glucose test, A1C test and urine analysis were done to check and confirm the disease. Allergy diagnosed by presence of IgE antibodies in the blood of patients. In addition, CBC, CRP, ESR and RF were tested for rheumatoid arthritis diagnosis. Some other additional lab tests were performed individually when the specialist physician demand for confirmation.

Statistical Analysis

The Statistical Packages of Social Sciences -SPSS (2019) program was used to detect the effect of difference factors in study parameters (percentage distribution). Chi-square test was used to significant compare between percentage (0.05 and 0.01 probability) in this study.

3. Results

Distribution of non-communicable diseases

The total number of patients included in the present study was 414. The hypertension patients were 177/414, Allergy patients were 46/414, Rheumatoid arthritis were 4/414, heart disease 46/414, Diabetes were 90/414, kidney diseases were 27/414, and other diseases show 24/414 (table 1). Results show a highly significant difference between the types of non-communicable diseases of SARS-CoV-2 vaccinated patients (P-value= 0.0001). The total number of patients vaccinated by Oxford-AstraZeneca vaccine was 99 out of 414 patients while Sinopharm vaccine demonstrate 75/414 and Pfizer BioNTech vaccine was 240/144. Oxford-AstraZeneca (OA) vaccinated-hypertension patients were 27 out of 177 hypertension patients included in the study, OA-Allergy patients were 14/46, OA-Rheumatoid arthritis were 1/4, OA-heart disease 46/414, OA-Diabetes were 20/90, kidney diseases were 8/27, and other diseases show 4/24, see table 1.

Table 1. Distribution of non-communicable diseases patients on the types of vaccines.

Study Parameters	Hypertension	Allergy	Rheumatoid arthritis	Heart disease	Diabetes	Kidney disease	Others	Total	P-value
Male + Female Patients %	177 42.75%	46 10.14%	4 0.96%	46 11.11%	90 21.73%	27 6.52%	24 5.79%	414 100%	0.0001 **

AstraZeneca vaccine	42	14	1	8	20	8	6	99	0.0001 **
Sinopharm	29	7	1	10	17	7	4	75	0.0001 **
Pfizer BioNTech	106	25	2	28	53	12	14	240	0.0001 **

Oxford-AstraZeneca vaccine

SARS-CoV-2-non infected patients vaccinated by Oxford-AstraZeneca vaccine show that hypertension patients revealed highly significant moderate symptoms (16/27), (P≤0.01); allergy patients demonstrate (5/6) and diabetes present (10/14) of moderate symptoms of the vaccine. The infected before vaccination group show non-significant differences among the vaccine side effects in most of non-communicable diseases. Diabetes shows nil symptoms on 4 of 6 cases. Allergy patients demonstrate severe symptoms in 50% of the cases. Significant differences appeared among the symptoms categories of the present group (P≤0.05), see Table 2.

Table 2. Oxford-AstraZeneca vaccine side effects and symptoms of some non-communicable diseases' patients.

Study Parameters		**Hypertension**	**Allergy**	**Rheumatoid arthritis**	**Heart disease**	**Diabetes**	**Kidney diseases**	**Others**	**Total**	**P-value**
Non-infected patients		27	6	0	8	14	6	4	65	0.0001 **
Symptoms	Nil	8	0	0	1	2	1	0	12	0.0085 **
	Moderate	16	5	0	5	10	3	4	43	0.0001 **
	Severe	3	1	0	2	2	2	0	10	0.094 NS
P-value		0.0001 **	0.038 *	NS	0.043 *	0.0062 **	0.378 NS	0.0262 *	0.0001 **	--
Infected before vaccination		15	8	1	0	6	2	2	34	0.0001 **
Symptoms	Nill	6	0	1	0	4	0	1	12	0.0094 **
	Moderate	4	4	0	0	1	0	1	10	0.037 *
	Severe	5	4	0	0	1	2	0	12	0.033 *
P-value		0.673 NS	0.033 *	0.872 NS	NS	0.0498 *	0.325 NS	0.866 NS		--

*** (P≤0.05), ** (P≤0.01).**

Sinopharm Vaccine

Both non-infected patients and infected before vaccination by Sinopharm vaccine show a highly significant differences (P≤0.01) among nil and significant differences among moderate symptoms (P≤0.05) while severe symptoms are non-significant in this vaccine. In non-infected patients' group, nil symptoms showed 14/17 of hypertension patients while moderate showed only 3/17. In addition, heart diseases patients revealed nil side effects in 5/6 of all patients, see table 3. In infected patients before Sinopharm vaccination also show prominent moderate side effects in most of the non-communicable diseases.

Highly significant differences appeared among hypertension and diabetes patients (P≤0.01).

Table 3. Distribution of Sinopharm vaccination in some non-communicable diseases' patients.

Study Parameters		Hypertension	Allergy	Rheumatoid arthritis	Heart disease	Diabetes	Kidney disease	Others	Total	P-value
Non-infected patients		17	3	1	6	9	4	3	43	0.0001 **
Symptoms	Nil	14	1	1	5	4	1	3	29	0.0001 **
	Moderate	3	1	0	1	4	3	0	12	0.0394 *
	Severe	0	1	0	0	1	0	0	2	0.782 NS
P-value		0.0001 **	1.00 NS	0.871 NS	0.037 *	0.0976 NS	0.327 NS	0.062 NS	--	--
Infected before vaccination		12	4	0	4	8	3	1	32	0.0001 **
Symptoms	Nil	7	2	0	2	5	3	0	19	0.0078 **
	Moderate	5	2	0	2	2	0	1	12	0.0274 *
	Severe	0	0	0	0	1	0	0	1	0.893 NS
P-value		0.0098 **	0.326 NS	NS	0.326 NS	0.0497 *	0.062 NS	0.871 NS	0.0001 **	--

*** (P≤0.05), ** (P≤0.01).**

Pfizer BioNTech Vaccine

Severe symptoms appeared in this type of vaccine in both groups of the present study. Among hypertension patients of non-infected group, highly significant differences appeared. The moderate symptoms presented in the highest number of patient (36/49) while severe symptoms were (4/49) in non-infected patients' group. In addition, moderate symptoms also record a highly significant differences among diabetes and kidney diseases patients (19/26 and 4/5 respectively). Infected before vaccination group show prominent moderate side effect of the vaccination by Pfizer BioNTech among patients of most of non-communicable diseases. Hypertension, allergy, heart diseases, diabetes, and other diseases demonstrate a highly significant difference (P≤0.01), see table 4.

Table 4. COVID-19 symptoms after Pfizer BioNTech vaccination of some non-communicable diseases' patients.

Study Parameters		Hypertension	Allergy	Rheumatoid arthritis	Heart disease	Diabetes	Kidney disease	Others	Total	P-value
Non-infected patients		49	10	0	14	26	5	3	107	0.0001 **
Symptoms	Nil	9	5	0	6	6	1	1	28	0.0043 **
	Moderate	36	5	0	7	19	4	2	73	0.0001 **
	Severe	4	0	0	1	1	0	0	6	0.0376 *
P-value		0.0001 **	0.0216 *	NS	0.0279 *	0.0001 **	0.0488 *	0.692 NS	0.0001 **	--
Infected before vaccination		57	15	2	14	27	7	11	133	0.0001 **

Symptoms	Nil	23	4	0	6	9	2	5	49	0.0001 **
	Moderate	31	10	2	7	17	4	6	77	0.0001 **
	Severe	3	1	0	1	1	1	0	7	0.0001 **
	P-value	0.0001 **	0.0087 **	0.362 NS	0.0279 *	0.0001 **	0.0956 NS	0.0226 *	0.0001 **	--

*** (P≤0.05), ** (P≤0.01).**

4. Discussion

COVID-19 vaccines have proven great efficacy and solid safety profiles across several platforms, including mRNA, viral vector, and inactivated virus technologies. Clinical trials and real-world investigations repeatedly reveal that mRNA-based vaccines, such as Pfizer-BioNTech and Moderna, achieve effectiveness rates surpassing 90% in preventing symptomatic SARS-CoV-2 infection [14,15]. Adenovirus-vectored vaccines, like AstraZeneca and Johnson & Johnson, also offer excellent protection, notably against severe sickness and hospitalization [16]. Safety studies suggest that while moderate side effects—such as fatigue, headache, and injection site pain—are prevalent, major adverse events are rare and occur at rates comparable to placebo groups [17]. Inactivated viral vaccinations tend to have the lowest frequency of systemic side effects. Importantly, vaccine effectiveness may change with new variations and with time, prompting recommendations for supplementary doses to maintain immunity [18]. COVID-19 vaccinations continue to be fundamental to public health initiatives aimed at decreasing transmission, morbidity, and mortality.

COVID-19 vaccinations, although extremely efficacious, may induce various side effects, the most of which are moderate and temporary. Typical responses encompass discomfort or erythema at the injection site, weariness, cephalalgia, myalgia, chills, and mild fever [19]. These symptoms generally subside after few days and indicate the immune system's response to the immunization. Infrequent yet more severe adverse effects have been documented, including myocarditis and pericarditis, especially among adolescent and young adult males [20]. Individuals with non-communicable diseases (NCDs)—including cardiovascular disease, diabetes, chronic renal disease, and autoimmune disorders—may have distinct side effect profiles post-COVID-19 immunization. Although the majority of side events are moderate and temporary, research indicates that persons with non-communicable diseases may be more vulnerable to the worsening of pre-existing disorders following vaccination [21].

The present study aimed to investigate the effect of three SARS-CoV-2 vaccines presented in Iraq (Pfizer BioNTech, AstraZeneca-Oxford, and Sinopharm) and SARS-CoV-2 infection on the development of vaccine side effects. The study specifically focused on patients suffering from non-communicable diseases (NCDs). The results revealed the prevalence of moderate side effects were in two types of vaccines in Iraq which are Pfizer BioNTech Vaccine and Oxford-AstraZeneca vaccine. However; Sinopharm Vaccine show mild or asymptomatic side effects to all types of non-communicable diseases. Severity was observed in Pfizer BioNTech vaccine only. Adverse Effects of the Pfizer-BioNTech Vaccine in Iraq also recorded in many studies. A cross-sectional study conducted in Erbil revealed that 84.4% of participants reported experiencing side effects, with injection site discomfort being the most prevalent. The severity was predominantly mild to moderate; however, the prevalence was significantly elevated [22]. A comparison analysis indicated that receivers of AstraZeneca exhibited a statistically significant risk of experiencing more severe symptoms, particularly among younger populations and persons with comorbidities. Prevalent adverse effects encompassed weariness, pyrexia, cephalalgia, and arthralgia [23]. Numerous investigations, including one conducted in Baghdad, consistently indicate that recipients of Sinopharm experienced less and less severe adverse effects. It had the

lowest incidence of post-vaccination symptoms among the three vaccinations analyzed [24,25]. These studies agreed with the present results.

5. Conclusion

In summary, the study investigated the side effects of three major SARS-CoV-2 vaccines in Iraqi patients with NCDs, differentiating between those previously infected and those who were not.

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