Eurasian Medical Percent Periodical		Estimation of the complications of the COVID-19 vaccine on the Iraqi population		
Dr. Ali Has	san Ismaeel	M.B.Ch.B \ F.I.C.M.S. \ (Internal Medicine)		
AISIIa	illari *	of Medicine, College of Medicine, Kufa University, Al-Naiaf, Iraq.		
		* Corresponding Author: - <u>alihasan200872@yahoo.com</u>		
Dr. Amal Abdul Mahdi Kadhim *		M.B.Ch.B. \ D.O.G. \ C.A.B.O.G. \ (Obstetrics and Gynecology) Ministry of Higher Education and Scientific Research, Jabir ibn Hayyan Medical University, College of Medicine, Al-Najaf, Iraq. <u>amal.alrahimi@jmu.edu.iq</u>		
Dr. Anwer Hameed Rashid		M.B.Ch.B \ F.I.B.M.S \ (Family Medicine) Iraqi Ministry of Health, Karbala Health Directorate, Center Sector for Primary Health Care, Karbala, Iraq. <u>Dr.anwerh@gmail.com</u>		
Thi Ira A r und div wit this 27 Th par in a As qua vac In t fati foll As for and cor	is study aims to t qi population etrospective study derwent the vacc ided into two gro hout any effects for s study was design days (4-5-2021 to e questionnaire of t was designed to addition to comor for the second p antity of doses ar ccine. this study, patient igue, which inclue owed by fever for for the least prev 17 patients with a d statistically sign <u>nplications with A</u>	o the estimation of the complications of the COVID-19 vaccine on the udy was conducted in Iraq, where 400 patients with coronavirus who accine were collected from different hospitals, and the patients were groups (G1 with negative effects for 200 patients and the second group ts for 200 patients signed based on a questionnaire distributed to patients for a period of l to 1-6-2021). 'e distributed to patients was divided into two parts. Where the first d to collect information and demographic data such as age and gender, norbidities and the status of infection with sars CoV-2. d part, which was concerned with the vaccine, in addition to the and the study of the negative effects associated with the Covid 19 ents were informed of the presence of several complications, including cluded the most common complications for 160 patients with 80%, for 120 patients with 60 patients, and chill for 89 patients with 44.5%. revalent complications in our study, We find the pain at site reaction th 8.5 and loss of sense for ten patients with 5% significant relationship was found between the prevalence of these h AstraZeneca vaccine more than other vaccines used in this study).		
Keywords:		Astrazeneca, Pfizer-BioNTech, Sinopharm, COVID-19, vaccine, complications, immune, questionnaire, chronic.		
Introduction		vaccination, side effects are possible because a		

At the beginning of 2021, vaccination against the Coronavirus began in Iraq, and with any vaccination, side effects are possible because a drug is introduced into the body that has antigenic properties that affect the immune system. Talked about the problem of side effects with an immunologist and a therapist who specializes in coronavirus infection and heard their opinions and recommendations [1,2,3].

Scientific studies confirm that all medications, including vaccines, can have side effects, but not all people experience them [4,5]. To provide protection against the coronavirus, Covid-19 vaccines stimulate the vaccinated patient immune system [6,7]. As a result, some people, due to the characteristics of their body, may experience expected reactions or side effects. However, the presence or absence of these reactions does not indicate how strong the protection the body receives as a result of vaccination [8,9,10].

Through scientific studies, we note that the most common side effects of the Covid-19 vaccine, such as fever (sometimes more than 38 ° C), fever, headache, fatigue, muscle, and joint pain, and any flu-like symptoms, can occur 8-10 hours after Take the vaccine. It usually disappears on its own after 2-3 days [11,12,13]. Basically, it can still be argued that vaccination has more benefits than risks, and this is also evident from the current report on vaccination complications. Accordingly, the vast majority of side effects are transient local and systemic reactions, which were already observed in pre-approval clinical trials [14].

According to a retrospective study, people infected with SARS-CoV-2 who were vaccinated between six months and two weeks before contracting the coronavirus were less likely to develop venous thrombosis, strokes, or sepsis, and they also required less intensive care [15].

Material and method Patient sample

A retrospective study was conducted in Iraq, where 400 patients with coronavirus who

underwent the vaccine were collected from different hospitals, and the patients were divided into two groups (G1 with negative effects for 200 patients and the second group without any effects for 200 patients

Study design

A retrospective study was conducted, and this study was designed based on a questionnaire distributed to patients for a period of 27 days (4-5-2021 to 1-6-2021).

The questionnaire distributed to patients was divided into two parts. Where the first part was designed to collect information and demographic data such as age and gender, in addition to comorbidities and the status of infection with sars CoV-2.

As for the second part, which was concerned with the vaccine, in addition to the quantity of doses and the study of the negative effects associated with the Covid 19 vaccine.

Study period

The necessary and required licenses to conduct this study were obtained by relying on a questionnaire distributed to patients to find out the negative effects of the vaccine. The study period was 27 days (4-5-2021 to 1-6-2021).

Aim of study

This study aims to the estimation of the complications of the COVID-19 vaccine on the Iraqi population

Statistical analysis

The data and demographic information of the nursing mother were analyzed by relying on the statistical analysis program SPSS IBM SOFT 18 in addition to the use of Microsoft Office Excel 2013, and the standard regression value was applied, which represented (S. D.).

The logistic regression value was calculated for complications and negative effects of Vaccines on patients

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Results

Table 1- Demographic results of patient

Р	Value		
Age (Mean±SD)	29±8.8		
Age female	27.5±5.7		
Age male	30±7.3		
Sex			
male N (%)	301 (75.25)		
female N (%)	99 (24.75)		
History of COVID-19, n (%)			
Male	50 (12.5%)		
female	15 (3.75)		
History of chronic diseases, N (%)	55 (13.75)		
vaccine			
AstraZeneca	250 (62.5)		
Pfizer-BioNTech	100 (25)		
Sinopharm BBIBP vaccine	50 (12.5)		
Received two doses, N (%)	44 (11)		

Table 2- Study analysis according to side effects of the vaccine

P	G1 Patient with side effect N=200	G2 without side effects N=200
Age (Mean±SD)	26±5.5	29.9±6.9
Sex		
male N (%)	130 (32.5)	171 (42.75)
female N (%)	70 (17.5)	29 (7.25)
History of COVID-19, N (%)		

Male	35 (8.75%)	15 (3.75)
female	10 (2.5)	5 (1.25)
History of chronic diseases, N (%)	39 (9.75)	16 (4)
vaccine		
AstraZeneca	175 (43.75)	75 (18.75)
Pfizer-BioNTech	50 (12.5)	50 (12.5)
Sinopharm BBIBP vaccine	28 (7)	23 (5.5)
Received two doses, N (%)	25 (6.25)	19 (4.75)

Figure 1- Histogram P-Value of the participants who presented with side effects compared to those without side effects



Table 3- Results of patients according to Participants with Side Effects

	Frequency	Percentage	
Duration of symptoms			
< 24 hs	90	22.5	
1–3 days	50	12.5	
4 days – a week	30	7.5	
> week	30	7.5	
Severity of symptoms			
Mild	100	25	
Moderate	75	12.5	
Sever	25	6.25	

Table 4- Prevalence of general adverse effects

Parameter	N (%)
Fatigue	160 (80)
Fever	120 (60)
Chill	89 (44.5)
Nausea & vomiting	82 (41)
Cough	55 (27.5)
Shortness of breath	25 (12.5)
pain at site reaction	17 (8.5)
Loss of smell and taste	10 (5)

Table 5- Prevalence of adverse effects according to the type of vaccine

	AstraZeneca N=250	Pfizer-BioNTech	Sinopharm
		N-100	N=50
Fatigue	130	20	10
Fever	60	40	20
Chill	55	15	19

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Nausea & vomiting	39	22	21
Cough	19	21	15
Shortness of breath	10	10	5
pain at site reaction	7	8	2
Loss of smell and taste	5	3	2

Table 3- Univariate analysis with side effects due to COVID-19 vaccination.

Variable	Odd Ratio (95% CI) with side effects	P value
Age	1.44 (0.98–2.2)	0.88
sex	0.45 (0.2–0.87)	0.52
History with Covid 19	1.234 (0.8–2.12)	0.03
Vaccine type		
AstraZeneca	3.3 (2.1-5.6)	0.001
Pfizer-BioNTech	2.55 (1.5-3.8)	0.055
Sinopharm	1.1 (0.8-1.5)	0.088
Fatigue	3.9 (1.6-6.9)	0.001
Fever	2.2 (1.1-3.8)	0.001
Chill	1.8 (0.9-2.5)	0.073
Nausea & vomiting	1.5 (0.8-2.5)	0.06
Cough	0.8 (0.4-1.2)	0.9
Shortness of breath	0.7 (0.3-1.5)	0.82
pain at site reaction	0.66 (0.25-0.88)	0.65
Loss of smell and taste	0.54 (0.1-0.9)	0.01

Discussion

A retrospective study was conducted in which 400 patients from different hospitals were included. The patients were divided into two groups, but based on the presence of negative effects on patients, where the group 1, Participants with Side Effects, included 200 patients, and group 2, Participants without Side Effects, 200 patients and was relied on a program Statistical analysis SPSS in the analysis of data and demographic information about the disease, where it was mean value + sd to patients' ages (29 ± 8.8) and the patients.

Were distributed even according to gender (301 male patients with 75.25% and 99 female patients with 24.75), and the vaccines used in this study were (AstraZeneca for 250 patients with 62.5%, Pfizer-BioNTech for 100 patients with 25%, and Sinopharm for the 50 patients with 12.5%) as it is. Shown in Table 1.

In Table 3, results of patients according to Participants with Side Effects, through which the symptoms were identified and their severity, and we note that the duration of symptoms was < 24 hs for 90 patients with 22.5% and 1-3 days for 50 patients with 12.5% followed by four days-a weeks for 30 patients with 7.5% and for the severity of symptoms it was mild for 100 Sick and moderate for 75 patients and severe for 25 patients.

In this study, patients were informed of the presence of several complications, including fatigue, which included the most common complications for 160 patients with 80%, followed by fever for 120 patients with 60 patients, and chill for 89 patients with 44.5%.

As for the least prevalent complications in our study, we find the pain at site reaction for 17 patients with 8.5 and loss of sense for ten patients with 5%, as shown in Table 4

It was observed a higher prevalence of complications in patients who were vaccinated with the Oxford-AstraZeneca vaccine than in patients who were vaccinated with the Pfizer and Sinopharm vaccine, such as fatigue and fever, and it would be interesting to include a larger sample of participants with the second dose to evaluate their experience of severe side effects compared to the first dose. However, with the current sample, we found a significant difference between the participants who experienced side effects of Fatigue (CI, 95% with 3.9(1.6-6.9) and P-value 0.001 and Fever 2.2(1.1-3.8) with 0.001).

Conclusion

In this study, we aim to evaluate the side effects of the coronavirus vaccine and to study complications.

Patients reported that complications that included (fatigue, fever caught, Nausea & vomiting were the most prevalent among patients, and a statistically significant relationship was found between the prevalence of these complications with the AstraZeneca vaccine more than other vaccines used in this study).

Most of the symptoms were mild to moderate in severity and tolerable. Thus, COVID-19 vaccines are safe, and our community is encouraged to receive the vaccination.

Recommendations

- The medical community has a unified position regarding vaccination against the novel coronavirus infection. The vaccine is currently considered the most effective and efficient way to prevent coronavirus. Although there are side effects mentioned above, but they usually go away on their own. Nonsteroidal anti-inflammatory drugs are rarely used.
- Side effects of the coronavirus vaccine can appear immediately after vaccination, then they are interpreted as acute reactions after vaccination, and after some time, it can be 3, 5, 7, 10, 14 days

References

- 1. Ledford, H., Cyranoski, D., and Van Noorden, R., 2020. The UK has approved a COVID vaccine—here's what scientists now want to know. Nature, 588 (7837), pp. 205-206.
- Baden, L.R., El Sahly, H.M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S.A., Rouphael, N., Creech, C.B. and McGettigan, J., 2020. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. New England journal of medicine.
- 3. Polack, F.P., Thomas, S.J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S.,

Perez, J.L., Marc, G.P., Moreira, E.D., Zerbini, C. and Bailey, R., 2020. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. New England Journal of Medicine.

- 4. Voysey, M., Clemens, S.A.C., Madhi, S.A., Weckx, L.Y., Folegatti, P.M., Aley, P.K., Angus, B., Baillie, V.L., Barnabas, S.L., Bhorat, Q.E. and Bibi, S., 2021. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. The Lancet, 397 (10269), pp. 99-111.
- 5. Menni, C., Klaser, K., May, A., Polidori, L., Capdevila, J., Louca, P., Sudre, C.H., Nguyen, L.H., Drew, D.A., Merino, J. and Hu, C., 2021. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: а prospective observational study. The Lancet Infectious Diseases, 21 (7), pp. 939-949.
- Bernal, J.L., Andrews, N., Gower, C., Robertson, C., Stowe, J., Tessier, E., Simmons, R., Cottrell, S., Roberts, R., O'Doherty, M. and Brown, K., 2021. Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on Covid-19 related symptoms, hospital admissions, and mortality in older adults in England: a test-negative casecontrol study. bmj, 373.
- Haas, Eric J., Frederick J. Angulo, John M. McLaughlin, Emilia Anis, Shepherd R. Singer, Farid Khan, Nati Brooks, et al. "Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data." The Lancet 397, no. 10287 (2021): 1819-1829.
- 8. Graham, M.S., Sudre, C.H., May, A., Antonelli, M., Murray, B., Varsavsky, T., Kläser, K., Canas, L.S., Molteni, E., Modat, M. and Drew, D.A., 2021. Changes in symptomatology, reinfection, and

transmissibility associated with the SARS-CoV-2 variant B. 1.1. 7: an ecological study. The Lancet Public Health, 6 (5), pp. e335-e345.

- 9. Cherian S, Potdar V, Jadhav S, Yadav P, Gupta N, Das M, Rakshit P, Singh S, Abraham P, Panda S, NIC team. Convergent evolution of SARS-CoV-2 spike mutations, L452R, E484Q, and P681R, in the second wave of COVID-19 in Maharashtra, India. bioRxiv 2021. https://doi.org/10.1101/2021.04.22.44 0932 10.1101/2021.04.22.440932
- 10. Shen X, Tang H, McDanal C, Wagh K, Fischer W, Theiler J, Yoon H, Li D, Haynes BF, Sanders KO, Gnanakaran S, Hengartner N, Pajon R, Smith G, Dubovsky F, Glenn GM, Korber B, Montefiori DC. SARS-CoV-2 variant B.1.1.7 is susceptible to neutralizing antibodies elicited by ancestral Spike vaccines. bioRxiv 2021. https://doi.org/10.1101/2021.01.27.42 8516 10.1101/2021.01.27.428516
- 11. Garcia-Beltran WF, Lam EC, St Denis K, Nitido AD, Garcia ZH, Hauser BM, Feldman J, Pavlovic MN, Gregory DJ, Poznansky MC, Sigal A, Schmidt AG, Iafrate AJ, Naranbhai V, Balazs AB. Circulating SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity. medRxiv 2021. https://doi.org/10.1101/2021.02.14.21 251704 10.1101/2021.02.14.21251704
- 12. Madhi SA, Baillie V, Cutland CL, Voysey M, Koen AL, Fairlie L, Padayachee SD, Dheda K, Barnabas SL, Bhorat OE, Briner C, Kwatra G, Ahmed K, Aley P, Bhikha S, Bhiman JN, Bhorat AE, du Plessis J, Esmail A, Groenewald M, Horne E, Hwa SH, Jose A, Lambe T, Laubscher M, Malahleha M, Masenya M, Masilela M, McKenzie S, Molapo K, Moultrie A, Oelofse S, Patel F, Pillay S, Rhead S, Rodel H, Rossouw L, Taoushanis C, Tegally H, Thombrayil A, van Eck S, Wibmer CK, Durham NM, Kelly EJ, Villafana TL, Gilbert S, Pollard AJ, de Oliveira T, Moore PL, Sigal A, Izu A, NGS-SA Group Wits - VIDA COVID Group.

Efficacy of the ChAdOx1 nCoV-19 Covid-19 vaccine against the B.1.351 variant. N Engl J Med 2021; 20:384:1885-98. https://doi.org/10.1056/NEJMoa21022 14 10.1056/NEJMoa2102214

- Lustig Y, Nemet I, Kliker L, Zuckerman N, Yishai R, Alroy-Preis S, Mendelson E, Mandelboim M. Neutralizing response against variants after SARS-CoV-2 infection and one dose of BNT162b2. N Engl J Med 2021; NEJMc2104036. https://doi.org/10.1056/NEJMc210403
 6 10.1056/NEJMc2104036
- 14. Moore JP. Approaches for optimal use of different COVID-19 vaccines: issues of viral variants and vaccine efficacy. JAMA 20216; 325:1251-52. https://doi.org/10.1001/jama.2021.34 65 10.1001/jama.2021.3465
- 15. Noh JY, Jeong HW, Shin EC. SARS-CoV-2 mutations, vaccines, and immunity: implication of variants of concern. Sig Transduct Target Ther 2021;6 (203). https://doi.org/10.1038/s41392-021-00623-2 10.1038/s41392-021-00623-