

Al-Azhar International Medical Journal

Volume 4 | Issue 9

Article 16

9-1-2023

Section: Chest, Clinical Multidisciplinary, General Medicine, Internal Medicine, Public health

Study of Efficacy, Safety and Complications of COVID 19 Vaccine on Adults and Elderly with and without Chronic Diseases

Nasser Alhamshary Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.

Abdullah Hendawy El Shahat Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.

Mohamed Gharib Mohamed Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.

Abdel Kareem Mohammad Abdel Rahim Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty

Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt., aaaamm111990@gmail.com

Follow this and additional works at: https://aimj.researchcommons.org/journal

Part of the Medical Sciences Commons, Preventive Medicine Commons, and the Pulmonology Commons

How to Cite This Article

Alhamshary, Nasser; Shahat, Abdullah Hendawy El; Mohamed, Mohamed Gharib; and Rahim, Abdel Kareem Mohammad Abdel (2023) "Study of Efficacy, Safety and Complications of COVID 19 Vaccine on Adults and Elderly with and without Chronic Diseases," *Al-Azhar International Medical Journal*: Vol. 4: Iss. 9, Article 16.

DOI: https://doi.org/10.58675/2682-339X.2019

This Original Article is brought to you for free and open access by Al-Azhar International Medical Journal. It has been accepted for inclusion in Al-Azhar International Medical Journal by an authorized editor of Al-Azhar International Medical Journal. For more information, please contact dryasserhelmy@gmail.com.

ORIGINAL ARTICLE

Study of Efficacy, Safety and Complications of Coronavirus Disease 2019 Vaccine on Adults and **Elderly With and Without Chronic Diseases**

Abdel Kareem Mohammad Abdel Rahim*, Nasser Alhamshary, Abdullah Hendawy El Shahat, Mohamed Gharib Mohamed

Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Abstract

Background: Anti-coronavirus 2 (anti-CoV-2) vaccines were developed in a much shorter time than previous vaccines. The aim of this work was to assess the efficacy of coronavirus disease 2019 (COVID-19) vaccine on adults and elderly with and without chronic diseases and evaluate the safety, side effects, and complications of COVID19 vaccine on adults and elderly with and without chronic diseases.

Methods: A prospective observational cohort study was carried out on 100 participants who received COVID-19 vaccine. Participants were divided into three groups: group (1): 30 healthy young persons aged 18-45 y old, who received COVID-19 vaccine (5 participants received Pfizer vaccine, 9 received AstraZeneca, and 16 received Sinopharm. Group (2): 35 persons, aged greater than 50 y without chronic diseases received COVID-19 vaccine (6 participants received Pfizer vaccine, 11 received AstraZeneca, and 18 received Sinopharm. Group (3): 35 persons, aged greater than 50 years with chronic diseases (diabetes mellitus (DM), hypertension (HTN), ischemic heart disease (IHD), bronchial asthma (BA), chronic obstructive pulmonary disease (COPD), hypothyroidism) received COVID19 vaccine (6 participants received Pfizer vaccine, 10 received AstraZeneca, and 19 received Sinopharm).

Results: As regards first and second dose side effects, highly significant (P value less than 0.05) increased percentage of myalgia, diarrhea, nausea, pain at the injection site, and dyspnea in AstraZeneca group when compared with the Pfizer group and Sinopharm group.

Conclusions: Adverse effects of all vaccines are moderate in frequency, mild in severity, and short-lived. Statistically significant increased percentage of side effects in the AstraZeneca group when compared with Pfizer group and Sinopharm group. Serum levels of severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) spike IgG antibody at 21 days after the second vaccine dose were similar in all groups without significant difference between different vaccines.

Keywords: Adults, Chronic diseases, Coronavirus disease 2019 vaccine, Elderly, Side effects

1. Introduction

I n December 2019, a cluster of patients with pneumonia of undetermined etiology was recognized in Wuhan, Hubei, China.¹ Subsequently, a novel coronavirus severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) was identified from lower respiratory tract samples obtained from affected patients.²

The clinical manifestation of COVID-19 is broad and ranges from asymptomatic and mild upper respiratory tract symptoms to severe illnesses with multiorgan failure and death.³ Furthermore, it is challenging to predict the clinical course or determine patients at risk of deterioration.⁴

Importantly, significant differences have been noted in the clinical and demographic features of COVID-19 patients in different regions of the world.⁵ People with co-morbidities are at risk for COVID-19 pneumonia. Furthermore, blood biomarkers differ significantly among COVID-19 patients with different disease severities.⁶

Accepted 26 February 2023.

https://doi.org/10.58675/2682-339X.2019 2682-339X/© 2023 The author. Published by Al-Azhar University, Faculty of Medicine. This is an open access article under the CC BY-SA 4.0 license (https://creativecommons.org/licenses/by-sa/4.0/).

Available online 8 December 2023

Corresponding author at: Department of Hepatology, Gastroenterology and Infectious Diseases, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt. E-mail address: aaaamm111990@gmail.com (A.K.M. Abdel Rahim).

High risks of severity and mortality have been widely reported in older persons infected with COVID-19, a finding that has been consistent in several countries.⁷

Challenges in vaccine development, protective immune monitoring, and toxicity are common to the infectious disease research field. These challenges involve mainly the preparation of vaccines or novel and efficacious therapies to induce an early protective response in individuals. During the last century, vaccines proved their efficacy to eradicate once widespread life-threatening and debilitating diseases such as smallpox and polio. The anti-CoV-2 vaccines were developed in a much shorter time than previous vaccines: past vaccines took ~8 to 10 y before being used in humans, whereas the anti-SARS-CoV-2 vaccines were ready in eight to ten months.⁸

Monitoring the safety of COVID-19 vaccines is an important and ongoing process that should also be accurate. In the US, Vaccine Adverse Event Reporting System has been implemented as an active surveillance system, during the initial implementation phases of the COVID-19 national vaccination program.⁹ A similar system is being adopted in Europe by individual national authorities, in collaboration with the European Centre for Disease Prevention and Control and European Medicine Agency (EMA).¹⁰

Vaccine manufacturers provide a list of postvaccination side effects with their preparations. Adverse vaccine reactions are evidence of the effectiveness of the vaccine and of increasing immunity against this disease. The list of these reactions includes injection site pain and swelling, fatigue, headache, chills, fever, muscle and joint pain, nausea, delayed swelling, redness or a rash at the injection site, swollen lymph nodes (typically manifests as a lump in the armpit or above the collarbone). Most of these reactions should resolve within a few days, according to the U.S. Center for Disease Control and Prevention (CDC).¹¹

The aim of this work was to assess the efficacy of COVID-19 vaccine on adult and elderly with and without chronic diseases and evaluate safety, side effects and complications of COVID19 vaccine on adult and elderly with and without chronic diseases.

2. Patients and methods

This prospective observational cohort study was carried out on 100 participants aged 18 years or more who received COVID-19 vaccine. Of all 100 participants, 17 received Pfizer (BioNTech) vaccine, 30 received AstraZeneca (AZD1222), and 53 received Sinopharm (BBIBP-CorV). This study took place in the period from June 2021 to December 2021 in Egyptian Ministry of health centers of vaccination in Sohag.

The study was approved by the local Ethics Committee, Faculty of Medicine, and Al-Azhar University. An informed written consent was obtained from each participant.

Exclusion criteria were patients less than 18 years, had any contraindications against COVID-19 vaccination and pregnant women.

Subjects were divided into three groups: group (1): 30 young healthy persons aging 18-45 y old, who received COVID-19 vaccine (5 participants received Pfizer (BioNTech) vaccine, 9 received AstraZeneca (AZD1222), and 16 received Sinopharm (BBIBP-CorV). Group (2): 35 old healthy persons aged greater than 50 years old without chronic diseases received COVID-19 vaccine (6 participants received Pfizer (BioNTech) vaccine, 11 received AstraZeneca (AZD1222), and 18 received Sinopharm (BBIBP-CorV). Group (3): 35 old persons aged greater than 50 years with chronic diseases (diabetes mellitus, hypertension, ischemic heart disease (IHD), bronchial asthma (BA), chronic obstructive disease (COPD), hypothyroidism) pulmonary received COVID19 vaccine (6 participants received Pfizer (BioNTech) vaccine, 10 received AstraZeneca (AZD1222), and 19 received Sinopharm (BBIBP-CorV).

All patients were subjected to complete history taking, full clinical examination, laboratory Investigations (Complete blood picture, latex agglutination slide test, C-reactive protein (CRP), serum erythrocyte sedimentation rate (ESR), D-dimer level, serum creatinine, liver function, and thyroid stimulating hormone (TSH)), assessment of serum levels of SARS-CoV-2 spike IgG Ab, and vaccination protocol.

2.1. Sampling

Blood samples randomly were collected from patients (at baseline and 6 months after 2 s dose).

Latex agglutination slide test was performed for qualitative and semiquantitative determination of CRP in nondilated serum ESR was performed by the Westergren method.

D-dimer level was measured by immune turbidimetry assay with the coagulation laboratory autoanalyzer (ACL 2000; Instrumentation Laboratory, Milan, Italy). The D-dimer level was graded according to the level of estimation Graded as normal level, when less than 200 ng/ml, slightly elevated are 200–500 ng/ml, moderate elevation is 500–1000 ng/ ml and severely elevated were 1000–2000 ng/ml. Assessment of Serum levels of SARS-CoV-2 spike IgG Ab: SARS-CoV-2 spike antigen specific IgG antibody levels 21 days after the second vaccine dose with SARS-CoV19 vaccination. Patients provided 3 cc of blood by venipuncture using vacutainer tubes, serum was separated and stored frozen at -80 °C until tested by enzyme linked immunosorbent assay (ELISA).

2.2. Vaccination protocol

All patients received Covid-19 vaccination according to protocols of WHO and ministry of health and population, Egypt. Of all 100 participants, 17 received Pfizer (BioNTech) vaccine, 30 received AstraZeneca (AZD1222), and 53 received Sinopharm (BBIBP-CorV).

2.3. Statistical analysis

Data were analyzed using Statistical Program for Social Science (SPSS) version 24. Shapiro-Wilks normality test and histograms were used to test the distribution of quantitative variables to select accordingly the type of statistical testing: parametric or

Table 1. Comparisons between studied groups as regard demographic data

nonparametric. Parametric variables were expressed as mean and standard deviation (SD) and were compared using ANOVA test among the three groups. Categorial variables were expressed as frequency and percentage and were statistically analyzed by χ^2 test. A two-tailed *P* value less than or equal to 0.05 was considered statistically significant.

3. Results

No significant difference (P statistically value > 0.05) between studied groups as regard sex, BMI, smoking and residence. Highly statistically significant (P-value <0.001) decreased age in group I when compared with group II and group III. Statistically significant difference (P value < 0.05) between studied groups as regard red blood cells (RBS), Creatinine (basal data) and RBS (after 6 months). No statistically significant difference (Pvalue >0.05) between studied groups as regard other studied laboratory data (basal data and after 6 months). (Table 1).

There was no statistically significant difference (P value > 0.05) between studied groups as regard first and second dose side effects and duration of side effects (Table 2).

	Group I ($n = 30$)	Group II ($n = 35$)	Group III ($n = 35$)	P value
Age (y)	30.3 ± 6.4	60.7 ± 4.6	67.8 ± 5.4	<0.001*
Sex				
Male	18 (60 %)	21 (60 %)	20 (57.1 %)	0.692
Female	12 (40 %)	14 (40 %)	15 (42.9 %)	
BMI (kg/m ²)	29.1 ± 3.0	30.0 ± 4.8	28.5 ± 3.0	0.236
Smoking	14 (46.7 %)	16 (45.7 %)	16 (45.7 %)	0.971
Laboratory data (basa)	1)			
WBCs	6.3 ± 1.8	6.4 ± 1.9	6.1 ± 1.9	0.765
Hb	13.1 ± 0.9	13.1 ± 0.9	13.1 ± 0.9	0.974
PLTs	219.8 ± 58.1	218.8 ± 62.8	214.0 ± 56.3	0.912
D-Dimer	291.9 ± 39.1	297.7 ± 43.6	294.2 ± 44.4	0.855
ESR	34.7 ± 7.3	34.7 ± 7.2	34.8 ± 7.0	0.997
CRP	5.8 ± 3.0	5.6 ± 3.0	5.8 ± 3.0	0.903
RBS	130.7 ± 21.7	133.4 ± 23.1	160.3 ± 37.7	0.001*
TSH	2.5 ± 1.0	2.2 ± 0.6	2.7 ± 1.1	0.09
Creat	1.00 ± 0.09	1.00 ± 0.12	1.10 ± 0.18	0.015*
O2 sat	97.1 ± 1.1	97.0 ± 1.1	97.1 ± 1.1	0.973
Laboratory data (at 6	months)			
WBCs	5.9 ± 1.7	6.0 ± 1.7	6.0 ± 1.6	0.975
Hb	13.6 ± 1.9	13.6 ± 1.8	13.6 ± 1.8	0.979
PLTs	216.2 ± 46.4	209.2 ± 41.7	215.0 ± 45.3	0.790
D-Dimer	285.4 ± 32.8	297.3 ± 46.0	308.1 ± 49.2	0.794
ESR	34.4 ± 7.6	34.6 ± 7.4	34.8 ± 7.4	0.978
CRP	5.9 ± 3.0	5.7 ± 2.8	5.8 ± 2.9	0.989
RBS	128.9 ± 25.7	134.6 ± 26.4	170.7 ± 35.3	< 0.001*
TSH	2.2 ± 1.1	2.2 ± 0.6	2.6 ± 1.2	0.334
Creatinine	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0.1	0.267
O_2 saturation	97.1 ± 1.1	97.3 ± 1.2	97.1 ± 1.1	0.706

Data are presented as mean \pm SD or frequency (%).

BMI, Body mass index; BSA, Body surface area; CRP, C-reactive protein; Hb, hemoglobin; PLTs, platelet counts; RBS, Red blood cells; WBCs, white blood cells; ESR, erythrocyte sedimentation rate: TSH, thyroid stimulating hormone.

*: significant P value.

As regards of first dose side effects, presence of side effects was significantly higher in AstraZeneca group compared with Sinopharm and Pfizer groups with no significant difference between Sinopharm group and Pfizer group. Incidence of myalgia, diarrhea and dyspnea was significantly higher in AstraZeneca group and Pfizer group compared with Sinopharm group with no significant difference between AstraZeneca group and Pfizer group. Incidence of nausea and pain at injection site was significantly higher in AstraZeneca group compared with Sinopharm and Pfizer groups with no significant difference between Sinopharm group and Pfizer group. Incidence of arthralgia was significantly higher in Pfizer group compared with Sinopharm group with no significant difference between AstraZeneca group compared with Sinopharm group and Pfizer group. Incidence of sore throat was significantly higher in Sinopharm group compared with AstraZeneca group with no significant difference between Pfizer group compared with Astra-Zeneca group and Sinopharm group. Incidence of headache was significantly higher in AstraZeneca group compared with Sinopharm group with no significant difference between AstraZeneca and Sinopharm groups compared with Pfizer group. Incidence of fever, fatigue and thromboembolism was insignificantly different among the three vaccine groups.

As regard of second dose side effects, presence of side effects was significantly higher in AstraZeneca group compared with Sinopharm and Pfizer groups with no significant difference between Sinopharm group and Pfizer group. Incidence of fever, fatigue was insignificantly different among the three vaccine groups. Incidence of myalgia was significantly higher in AstraZeneca group compared with Sinopharm group and significantly higher in Sinopharm group compared with Pfizer group with no significant difference between AstraZeneca group and Pfizer group. Incidence of diarrhea, arthralgia, and headache was significantly higher in AstraZeneca group compared with Sinopharm group with no significant difference between Pfizer group compared with AstraZeneca group and Sinopharm group. Incidence of nausea and pain at injection site was significantly higher in AstraZeneca group compared with Sinopharm group and Pfizer group with no significant difference between Sinopharm group and Pfizer group. Incidence of dyspnea was

Table 2. Comparisons between studied groups as regard first and second dose and duration of side effects.

	Group I ($n = 30$)	Group II ($n = 35$)	Group III ($n = 35$)	P-value
First dose side effects				
Presence of side effects	21 (70 %)	23 (65.7 %)	24 (68.6 %)	0.930
Fever	8 (26.7 %)	8 (22.9 %)	9 (25.7 %)	0.933
Fatigue	15 (50 %)	15 (42.9 %)	16 (45.7 %)	0.846
Myalgia	13 (43.3 %)	15 (42.9 %)	16 (45.7 %)	0.968
Diarrhea	4 (13.3 %)	5 (14.3 %)	5 (14.3 %)	0.992
Nausea	4 (13.3 %)	4 (11.4 %)	5 (14.3 %)	0.937
Arthralgia	4 (13.3 %)	5 (14.3 %)	6 (17.1 %)	0.902
Sore throat	2 (6.7 %	2 (5.7 %	2 (5.7 %	0.893
Headache	5 (16.7 %)	5 (14.3 %)	5 (14.3 %)	0.954
Pain at injection site	7 (23.3 %)	8 (22.9 %)	8 (22.9 %)	0.999
Dyspnea	4 (13.3 %)	5 (14.3 %)	5 (14.3 %)	0.992
Thromboembolism	0	0	1 (2.8 %)	0.391
Second dose side effects				
Presence of side effects	22 (73.3 %)	23 (65.7 %)	26 (74.3 %)	0.692
Fever	7 (23.33 %)	6 (17.14 %)	9 (25.71 %)	0.933
Fatigue	14 (46.67 %)	16 (45.71 %)	13 (37.14 %)	0.684
Myalgia	13 (43.33 %)	16 (45.71 %)	14 (40 %)	0.889
Diarrhea	3 (10 %)	4 (11.43 %)	5 (14.29 %)	0.862
Nausea	3 (10 %)	5 (14.29 %)	4 (11.43 %)	0.862
Arthralgia	3 (10 %)	4 (11.43 %)	5 (14.29 %)	0.862
Sore throat	1 (3.33 %)	2 (5.71 %)	2 (5.71 %)	0.882
Headache	4 (13.33 %)	4 (11.43 %)	5 (14.29 %)	0.937
Pain at injection site	5 (16.67 %)	6 (17.14 %)	7 (20 %)	0.928
Dyspnea	3 (10 %)	4 (11.43 %)	4 (11.43 %)	0.978
Thromboembolism	0	0	1 (2.86 %)	0.391
Duration of side effects (days)				
After first dose	$2.9 \pm 1.4 (1-6)$	$2.9 \pm 1.1 \ (1{-}5)$	$3.3 \pm 1.3 (2-7)$	0.613
After second dose	$3.1 \pm 1.4 (1-7)$	$3.4 \pm 1.3 (2-7)$	$3.4 \pm 1.3 (2-7)$	0.713

Data are presented as mean \pm SD (range) or frequency(%).

· · ·	A 1 7	<u> </u>	DC	<u>,</u> р 1	6: :C 1 /
	AstraZeneca	Sinopharm	Pfizer	P value	Significance between groups
	(n = 30)	(n = 53)	(n = 17)		
First dose side effects					
Presence of side effects	30 (100 %)	27 (50.9 %)	11 (64.7 %)	< 0.001*	$P1 < 0.001^* P2 < 0.001^* P3 = 0.322$
Fever	10 (33.3 %)	15 (28.3 %)	1 (5.6 %)	0.102	_
Fatigue	19 (63.3 %)	21 (39.6 %)	6 (35.3 %)	0.071	_
Myalgia	20 (66.7 %)	13 (24.5 %)	11 (64.7 %)	<0.001 *	$P1 < 0.001^* P2 = 0.892 P3 = 0.002^*$
Diarrhea	6 (20 %)	3 (5.7 %)	5 (29.4 %)	0.026*	P1 = 0.044* P2 = 0.464 P3 = 0.007
Nausea	11 (36.7 %)	2 (3.8 %)	0	< 0.001*	$P1 < 0.001^* P2 = 0.004^* P3 = 0.416$
Arthralgia	5 (16.7 %)	4 (7.5 %)	6 (35.3 %)	0.02 *	P1 = 0.199 P2 = 0.147 P3 = 0.004*
Sore throat	0	7 (13.2 %)	0	0.036*	$P1 = 0.038^* P2 = -P3 = 0.144$
Headache	9 (30 %)	3 (5.7 %)	3 (17.6 %)	0.011*	P1 = 0.002* P2 = 0.351 P3 = 0.124
Pain at injection site	23 (76.7 %)	0	0	< 0.001*	$P1 < 0.001^* P2 < 0.001^* P3 = -$
Dyspnea	11 (36.7 %)	0	3 (17.6 %)	< 0.001*	$P1 < 0.001^* P2 = 0.171 P3 = 0.002^*$
Thromboembolism	1 (3.3 %)	0	0	0.308	_
Second dose side effects					
Presence of side effects	30 (100 %)	30 (56.6 %)	11 (64.7 %)	< 0.001*	$P1 < 0.001^* P2 < 0.001^* P3 = 0.555$
Fever	8 (26.67 %)	13 (37.14 %)	0	0.064	_
Fatigue	13 (43.33 %)	11 (31.43 %)	6 (17.14 %)	0.085	_
Myalgia	18 (60 %)	10 (28.57 %)	9 (25.71 %)	< 0.001*	$P1 < 0.001^* P2 = 0.638 P3 < 0.006^*$
Diarrhea	6 (20 %)	1 (2.86 %)	2 (5.71 %)	0.02*	P1 = 0.004* P2 = 0.470 P3 = 0.08
Nausea	8 (26.67 %)	2 (5.71 %)	0	0.001*	$P1 = 0.002^* P2 = 0.019^* P3 = 0.41$
Arthralgia	4 (13.33 %)	0	1 (2.86 %)	0.027*	P1 = 0.006* P2 = 0.426 P3 = 0.075
Sore throat	0	5 (14.29 %)	0	0.097	_
Headache	7 (23.33 %)	2 (5.71 %)	2 (5.71 %)	0.024*	P1 = 0.006* P2 = 0.333 P3 = 0.217
Pain at injection site	20 (19 %)	0	0	< 0.001*	$P1 < 0.001^* P2 < 0.001^* P3 = -$
Dyspnea	9 (30 %)	0	2 (5.71 %)	< 0.001*	$P1 < 0.001^* P2 = 0.156 P3 = 0.011^*$
Thromboembolism	0	0	0	_	_
Duration of side effects (da	ys)				
After first dose	$3.7 \pm 1.4 (2-8)$	$2.4 \pm 1.0 (0-4)$	$2.6 \pm 0.7 (0-3)$	< 0.001*	$P1 < 0.001^* P2 < 0.01^* P3 = 0.447$
After second dose	$3.8 \pm 1.2 (2-7)$	$2.9 \pm 0.5 (0-3)$	$3.2 \pm 1.0 (1-5)$	0.032*	$P1 < 0.001^* P2 = 0.087 P3 = 0.104$

Table 3. Comparisons between used vaccines as regard first and second dose side effects and duration of side effects.

Data are presented as mean \pm SD (range) or frequency (%), *: significant *P* value.

Table 4. Comparisons between studied groups and vaccines as regard Anti-spike IgG levels.

	Group I ($n = 30$)	Group II ($n = 35$)	Group III ($n = 35$)	P value
Anti-spike IgG levels				
Range	232-1866	216-1412	224-1872	0.697
Mean \pm SD	754.9 ± 430.7	725.8 ± 261.3	745.1 ± 444.8	
AstraZeneca ($n = 30$)	Sinopharm ($n = 53$)	Pfizer ($n = 17$)		
Anti-spike IgG levels	L			
Range	224-1872	232-1684	216-720	0.460
Mean \pm SD	852.5 ± 491.1	697.6 ± 299.5	681.2 ± 375.02	

significantly higher in AstraZeneca group and Pfizer group compared with Sinopharm group with no significant difference between AstraZeneca group and Pfizer group. Incidence of sore throat and thromboembolism was insignificantly different among the three vaccine groups. Duration of side effects after first dose was significantly longer in AstraZeneca group compared with Sinopharm and Pfizer groups with no significant difference between Sinopharm group and Pfizer group. Duration of side effects after second dose was significantly longer in AstraZeneca group compared with Sinopharm group with no significant difference between Pfizer group with no significant difference between Pfizer group compared with Sinopharm and AstraZeneca groups (Table 3). There was no statistically significant difference (*P*-value >0.05) between studied groups and vaccines as regard Anti-spike IgG levels (Table 4).

4. Discussion

The clinical manifestation of COVID-19 is broad and ranges from asymptomatic and mild upper respiratory tract symptoms to severe illnesses with multiorgan failure and death.³ Furthermore, it is challenging to predict the clinical course or determine patients at risk of deterioration.⁴

Importantly, significant differences have been noted in the clinical and demographic features of COVID-19 patients in different regions of the world (Lippi et al., 2020). People with co-morbidities are at risk for COVID-19 pneumonia. Furthermore, blood biomarkers differ significantly among COVID-19 patients with different disease severities.⁶

In our study, patients were followed-up for 6 months and revealed that none of them infected with COVID-19 again. As our methodology was designed to evaluate safety for 6 months and efficacy for 2 weeks, we monitored patients' symptoms for all the study period and tested SARS-CoV-2 IgG Ab only after 2 weeks from the second dose as mentioned by Dennis and Ogden¹² who followed the efficacy of the vaccines for 2 weeks.

The results of current study showed that the most common local side effect was injection site pain (23.3 %, 22.9, 22.9 in group I, II, and III, respectively). The most common systemic side effects were fatigue (50, 42.9, and 45.7 % in group I, II, and III, respectively), followed by Myalgia (43.3, 42.9, and 45.7 % in group I, II, and III, respectively).

In accordance with our results, Andrzejczak-Grządko et al.¹¹ showed that among AstraZeneca vaccinated patients, (52.6 %) reported injection site pain, (50.5 %) reported muscle aches, (56.4 %) reported headaches, (56.6 %) reported fever, (55.6 %) reported chills, and (60.9 %) reported weakness. In Pfizer vaccinated cases, (63.3 %) reported injection site pain, (73 %) reported shoulder pain, (10.7 %) reported muscle aches, (15.8 %) reported headaches, (6.6 %) reported fever, (6.6 %) reported chills, and (24 %) reported weakness.

In another nationwide cross-sectional survey evaluated the postvaccination side effects among healthcare workers received Pfizer vaccine (El-Shitany et al., 2021)¹⁴ showed that 77 % were females, 55.7 % were aged between 31 and 54 years. The most common local side effect was injection site pain (85.2 %), followed by injection site swelling (10.2 %) and injection site redness (8.4 %). The most common systemic side effects were fatigue (54.2 %), followed by headache (34.3 %), muscle pain (28.4 %), chills (26.4 %), and malaise (20.5 %).

Our results showed statistically significant increased percentage of side effects in AstraZeneca group (100 %), Pfizer group (64.7 %) and Sinopharm group (50.9 %) (*P* value < 0.001). Results of current study showed statistically significant (P = 0.029) increased percentage of fever, myalgia, arthralgia, diarrhea, nausea, in AstraZeneca group when compared with Pfizer group and Sinopharm group. Moreover, one case in the AstraZeneca group showed thromboembolism that was associated with partial recovery.

In accordance with our results, Al Khames Aga et al.¹³ observed that the median participants' age

was 49 years; males formed 51.61 % of the total number of the participants and 19.64 % received two doses of vaccines. The percentage of participants who did not report any signs and symptoms represented by 40 % for those who received Sinopharm vaccine, 25.71 % who received Pfizer vaccine, and 18.39 % who had AstraZeneca vaccine. Signs and symptoms after the first dose of AstraZeneca vaccine were more prevalent compared with other vaccines, followed by Pfizer and less adverse reaction associated with Sinopharm vaccine.

Results of current study showed no statistically significant difference between studied groups as regard prevalence and severity of side effects (P < 0.05).

In accordance with our results, El-Shitany et al.¹⁴ reported that women were the majority of the participants (64.2 %). It was found that (65.7 %) participants were younger than 60 years of age. Patients had received Pfizer-BioNTech COVID-19 vaccine and found that the most common symptoms were injection site pain, headaches, flu-like symptoms, fever, and tiredness. Less common side effects were a fast heartbeat, whole body aches, difficulty breathing, joint pain, chills, and drowsiness. The study results showed no significant difference between those who were under the age of 60 years and those over the age of 60.

In contrast to our results, Alghamdi et al.¹⁵ noted that the less than or equal to 50-year-old group showed more frequent side effects which included myalgia, headache, fever, palpitation, sore throat, and gastrointestinal symptoms (P < 0.05). This study concluded that the COVID-19 vaccine was safe and well-tolerated. The less than or equal to 50-year-old group was more prone to side effects compared with the greater than 50-year-old group. But there was no significant difference between the two groups concerning the mean duration of the side effects.

In our study, serum levels of SARS-CoV-2 spike IgG antibody at 2 weeks after the second vaccine dose were similar in all groups without significant difference between different vaccines.

Wisnewski et al.¹⁶ showed that the Spike antigen specific IgG levels rose exponentially and plateaued 21 days after the initial vaccine dose. After the second vaccine dose IgG levels increased further, reaching a maximum ~7–10 days later, and remained elevated (average of 58 % peak levels) during the additional greater than 100 day follow-up period.

In another study, antibody testing was performed on sera available from 259 fully vaccinated subjects. No significant differences in age, sex, or vaccine product received were observed between fully vaccinated controls. Among fully vaccinated Moderna controls, median of anti-spike IgG levels among persons with sera collected 14–119 days after the second vaccine dose was 759 BAU/ml.¹⁷

4.1. Conclusions

Injection site pain, fatigue and Myalgia were observed to be the most common side effects of the vaccine. Adverse effects of all vaccines are moderate in frequency, mild in severity, and short-lived. Statistically significant increased percentage of side effects in AstraZeneca group when compared with Pfizer group and Sinopharm group. Serum levels of SARS-CoV-2 spike IgG antibody at 21 days after the second vaccine dose were similar in all groups without significant difference between different vaccines.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article.

Sources of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Financial support and sponsorship

Nil.

Conflicts of interest

The authors declared that there were no conflicts of Interest.

References

1. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395:497–506.

- 2. Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. *N Engl J Med.* 2020; 382:727-733.
- 3. Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirusinfected pneumonia in Wuhan, China. *JAMA*. 2020;323: 1061–1069.
- Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet (London, England)*. 2020;395:1054–1062.
- Lippi G, Henry BM, Bovo C, Sanchis-Gomar F. Health risks and potential remedies during prolonged lockdowns for coronavirus disease 2019 (COVID-19). *Diagnosis (Berl)*. 2020;7: 85–90.
- Guan WJ, Liang WH, Zhao Y, et al. Comorbidity and its impact on 1590 patients with COVID-19 in China: a nationwide analysis. *Eur Respir J.* 2020;55(5):2000547. Published 2020 May 14. https://doi.org/10.1183/13993003.00547-2020.
- Docherty AB, Harrison EM, Green CA, et al. Features of 20 133 UK patients in hospital with covid-19 using the ISARIC WHO Clinical Characterisation Protocol: prospective observational cohort study. *BMJ*. 2020;369:m1985.
- Mascellino MT, Di Timoteo F, De Angelis M, Oliva A. Overview of the main anti-SARS-CoV-2 vaccines: mechanism of action, efficacy and safety. *Infect Drug Resist.* 2021;14:3459.
- Gee J, Marquez P, Su J, et al. First month of COVID-19 vaccine safety monitoring - United States, december 14, 2020january 13, 2021. MMWR Morb Mortal Wkly Rep. 2021;70: 283-288.
- Cavaleri M, Enzmann H, Straus S, Cooke E. The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines. *Lancet*. 2021;397:355–357.
- Andrzejczak-Grządko S, Czudy Z, Donderska M. Side effects after COVID-19 vaccinations among residents of Poland. *Eur Rev Med Pharmacol Sci.* 2021;25:4418–4421.
- 12. Dennis A, Ogden J. Nostalgia, gratitude, or optimism: the impact of a two-week intervention on well-being during COVID-19. J Happiness Stud. 2022;23:2613–2634.
- Al Khames Aga QA, Alkhaffaf WH, Hatem TH, et al. Safety of COVID-19 vaccines. J Med Virol. 2021;93:6588–6594.
- El-Shitany NA, Harakeh S, Badr-Eldin SM, et al. Minor to moderate side effects of Pfizer-BioNTech COVID-19 vaccine among Saudi residents: a retrospective cross-sectional study. *Int J Gen Med.* 2021;14:1389–1401.
- Ibrahim Amer FH, Alzayyat R, Alzayyat N, et al. Side effects of COVID-19 vaccines (Pfizer, AstraZeneca) in Saudi Arabia, Eastern Province. *Cureus*. 2022;14(7):e27297. Published 2022 Jul 26. https://doi.org/10.7759/cureus.27297.
- Wisnewski AV, Campillo Luna J, Redlich CA. Human IgG and IgA responses to COVID-19 mRNA vaccines. *PLoS One*. 2021;16:e0249499.
- Bajema KL, Dahl RM, Evener SL, et al. Comparative effectiveness and antibody responses to Moderna and Pfizer-Bio-NTech COVID-19 vaccines among hospitalized veterans - five veterans affairs medical centers, United States, february 1-september 30, 2021. MMWR Morb Mortal Wkly Rep. 2021;70: 1700–1705.