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Original article

Evaluation of adverse effects of AstraZeneca COVID-19 vaccine after the first dose in Libyan adults: a cross-sectional study

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Abstract: On January 2021, cases affected by coronavirus epidemic are constantly increasing, Libyan Ministry of Health provides the vaccine to the people those who are most at risk. The purpose of this study was to assess and verify the adverse effects of the first dose of the AstraZeneca COVID-19 vaccine. The study conducted at the Aljmail city, west region of Libya. The study was cross-sectional study during the period of August 31st and November 5th, 2021. The method involved 133 adult Libyan participants of both gender ageing more than 18 years old. The preliminary data were 54.0% who developed post-vaccination symptoms. The participant's aged 60 years and more with chronic diseases were more likely to have adverse effects after receiving the first dose of vaccine. In conclusion, AstraZeneca vaccine was good and effective but this study indicates a need for a large and long period study to confirm the safety of the vaccine use in the adult people.

Introduction

Multiple research organizations had developed viable COVID-19 vaccines as early as December, 2020. Vaccination is the most efficient strategy to prevent COVID-19 deaths and serious illness. The Oxford-AstraZeneca vaccine for COVID-19 infection is a chimpanzee adenovirus encoding the SARS-CoV-2 spike glycoprotein (ChAdOx1-S). It was approved for use throughout the European Union (EU) by European Medicines Agency (EMA) on January 29, 2021 following approval by the European Commission [1]. World Health Organization (WHO) has identified a COVID -19 known as severe acute respiratory syndrome corna-virus 2 (SARS-CoV-2) as the cause of COVID-19 outbreak [2]. Within a short period of time the coronavirus had spread internationally, the WHO declared the coronavirus pandemic on March 11, 2020 [3]. In persons aged 18 years and above, an AstraZeneca vaccine is authorized for active immunization against COVID-19 caused by SARS-CoV-2 [4]. The vaccine can create mild side effects such as headache, fever, injection site pain, fatigue but these normally go away within a couple days. To the best of our knowledge, there is no study investigated adverse event following the first dose of AstraZeneca vaccine among Libyan individual. Thus, a cross-sectional study is conducted in part of Libya, Aljmail city, in order to

investigate any adverse effect that could be arise in adult Libyan participants post-vaccination by AstraZenica.

Materials and methods

Study design: The study was randomized cross-sectional observation method and conducted by including subjects who were vaccinated with the first dose of AstraZeneca vaccine in western part of Libya, Algmail. The study was carried out at Aljmail unit of National Center of Disease Control.

Data collection: Data were collected during the period of August 31 and November 5, 2021 and were gathered through a semi-structured and self-designed questionnaire, face-to-face interview, and - or telephone survey. The questionnaire included two major parts, in sequence: demographic data, clinical profile and vaccine data. Data were collected by trained investigators working at the health centers (NCDC). The investigators were authorized to give vaccines, then an oral interview of the vaccinated participants in order to collect data.

The structured survey: The first part of the survey included information about the demographic data of the participant as telephone number, age, weight, gender and clinical profile including co-morbid condition, anticoagulant drugs use. The second part of the survey included information about the specific symptoms that were experienced by each participant after getting the first dose of COVID-19 vaccine. Twelve symptoms were listed in the survey including severe headache, fever, pain at injection site, myalgia, seizure, sore throat, blurred vision, shortness of breath, abdominal pain, chest pain, swelling and redness in a limb, coldness in limb. Participants were asked about any side effects they had within the 1 - 28 days after their vaccines. In addition, the participant may provide any other symptoms that were not stated in the preceding alternatives. In addition, participants were asked to describe the intensity of each symptom in the first three days after receiving the vaccination. The severity scale varied from no symptoms to severe symptoms. Participants were also asked when their symptoms started on average and how long they lasted.

Participants: Participants were Libyan citizens from west (Aljmail city). Individual aged more than 18 years who received AstraZeneca COVID-19 vaccine. Exclusion criteria were people who had been vaccinated from manufacturer companies other than the one included company and vaccination who they did not responded.

Ethical considerations: This study was reviewed and approved by scientific and ethical committee of Faculty of Pharmacy at University of Sabratha, Sabratha, Libya (4/2021) whereas participants provided verbal consent prior participation.

Statistical analysis: Data were analyzed by the statistical package to analyze the outcomes software version 22 (SPSS-22). Demographic factors and medical recollection were subject to descriptive statistical. The linked risk effect following vaccine dose were discovered using Fisher's exact and Chi-square testing. A probability value (P) of less than 0.05 was considered a statistically significant difference.

Results

In this study, a statistical analysis of data revealed high values of accuracy, reflect the status of vaccine within the community from which they were taken. A total of 300 participants, 167 had been excluded in the study as they had not met the study inclusion criteria. The remaining 133 were enrolled for the final analysis. Sixty two of the participants were male (46.6%) and 71 of the participants were female (53.4%) as shown in **Table 1**. With regard to the age distribution, most of the participants was of at the range of 18 - 59 years old which was 72.9%. Regarding the medical anamnesis, 49 of the participants (36.8%) had at least one co-morbid disease (hypertension, diabetes and asthma etc.). Most of the participants which were 72 (54.1%) out of 133 on had obvious adverse effects, most of the adverse effects were appeared between one and three days after vaccine intake as shown in **Table 1** and **Figure 1**.

Table 1: Demographic characteristics of the participants

Variable	Frequency	Percentage
Gender		
male	62	46.6
female	71	53.4
Age (years)		
18 - 59	97	72.9
≥ 60	36	27.1
Symptoms after vaccine		
Yes	72	54.1
No	61	45.9
Duration of symptoms		
< 24 hours	17	12.8
1 - 3 days	37	27.9
4 days - week	13	09.8
> a week	05	03.8
Co-morbid disease		
Disease		
No disease	49	36.8
Smoking	84	63.2
Yes	15	11.2
No	118	88.7

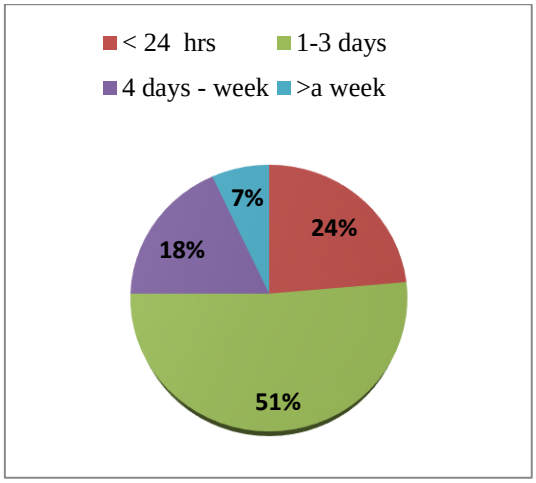

Figure 1: Duration of symptoms after vaccination

In **Table 2**, the most common post vaccine symptoms were fever (n = 46), headache (n = 45), reaction at the site of injection (pain, redness and swallowing, n = 27), myalgia and muscle pain (n =17), the less likely appeared symptoms were foot pain and bloated (n = 5) and pack pain (n = 3). In **Table 3**, participate who aged more than 60 years old and male were more likely porn to have symptoms after vaccine (58.3%, p = 0.554). Male individuals experienced adverse reactions to a slightly greater extent than female participants with no significant (p = 0.879). Participate with co-morbid condition was more than participate with no disease (p = 0.595). Participate suffer excessive obesity (60.0%) who of them were asymptom (p = 0.660). With regard to smoking, most of the participants were free of symptoms (67.0%, p = 0.086). The Chi-squared test revealed no significant difference (**Table 3**).

Table 2: Advers reactions to different vaccines among reciepts of differnt vaccines N = 72

Symptoms	Frequency	Percentage
fever	46	63.9
Headache	45	62.3
Injection site reaction	27	37.5
Myalgia and muscle pain	17	23.6
Loss of smell	03	04.2
Back pain	03	04.2
Dry troth	01	01.4
Chills	01	01.4
Chest pain - shortness of breath	03	04.2
Foot pain - bloating	05	06.9

Table 3: Univariate analysis of associated risk factors with symptoms after COVID-19

Variables	Symptomatic n = 72 (54.2%)	Asymptomatic n = 61 (45.8%)	Total n = 133 (100%)	P value
Gender				
Male	34 (54.8%)	28 (45.1%)	62 (46.7%)	**0.879**
Female	38 (53.5%)	33 (46.5%)	71 (53.3%)	
Age				
>18 - 59	51 (53.0%)	46 (47.4%)	97 (73.0%)	**0.554**
60 and above	21(58.3%)	15 (41.6%)	36 (27.1%)	
Co-morbidity				
No disease	44 (52.3%)	40 (48.0%)	84 (63.2%)	**0.595**
Disease	28 (57.1%)	21(43.0%)	49 (36.8%)	
Anti-coagulants				
Yes	16 (66.7%)	08 (33.3%)	24 (18.0%)	**0.174**
No	56 (69.1%)	53 (47.0%)	109 (82.0%)	
Obesity				
Yes	02 (40.0%)	03 (60.0%)	05 (03.8%)	**0.660**
No	70 (55.0%)	58 (45.3%)	128 (96.2%)	
Smoking				
Yes	05 (33.3%)	10 (67.0%)	15 (11.3%)	**0.086**
No	67 (57.0%)	51 (43.2%)	118 (88.7%)	

Discussion

The present study shows that no obvious complains of adverse effect and serious problems associated with the AstraZeneca vaccine after the first dose in Libyan adults. The most reported adverse events on the first day were fever, headache, injection site reaction (pain, redness and swallowing), myalgia and muscle pain. The number of participants reporting adverse effects and the intensity of those side effects decreased on the second and third days. This outcome is consistent with those of other COVID-19 vaccinations, in which the first day saw the largest percentage of adverse events and the seventh saw a sharp decline was similarly, studies conducted in Saudi Arabia [5]. Co-morbidity is considered as a significant high risk factor for adverse effect. This is in line with other reports and find parallel of Food and Drug Administration which is in line with other studies conducted in Iraq [6] and in Saudi Arabia [5]. The current study indicates that the prevalence of reported adverse effects is higher in the group of people aged 60 years and above than in the younger aged group which is similar to the previous published study of Chinese group [7] and Ethiopia [8]. The younger population was shown to have a significantly higher rate of Corona vaccination side effects, according to research carried out in Bangladesh [9] and in Turkey [10]. This might be brought on by various immunological reactions to antigens, variations in innate and adaptive immune responses and host racial or ethnic background. Male participants experienced adverse reactions to a slightly greater extent than female participants. This is in consistent with a Chinese study in which more males than females were reported negative effects [7].

Conclusion: The present study indicates that fever, headache, myalgia and muscle pain are most adverse effects by AstraZeneca COVID-19 vaccine in Libyan adults. A variety of adverse effects and most of them occurring within the first 24 hours following vaccination and usually lasted for few days. Severe symptoms were uncommon, the recipients should be advised and aware about the most popular adverse effect that may be occurring after first dose of vaccination and how to seek additional guidance if necessary.

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Ethical issues: Including plagiarism, informed consent, data fabrication or falsification and double publication or submission have completely been observed by authors.
Data availability statement: The raw data that support the findings of this article are available from the corresponding author upon reasonable request.
Author declarations: The authors confirm that all relevant ethical guidelines have been followed and any necessary IRB and/or ethics committee approvals have been obtained.

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