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# 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:** In January 2021, cases affected by the coronavirus epidemic are constantly increasing, the Libyan Ministry of Health provides the vaccine to the people 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 was 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 genders aged more than 18 years old. The preliminary data were 54.0% who developed post-vaccination symptoms. The participants aged 60 years and older with chronic diseases were more likely to have adverse effects after receiving the first dose of the vaccine. In conclusion, the 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 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 the 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, and 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, and fatigue but these normally go away within a couple of days. To the best of our knowledge, there is no study that investigated adverse event following the first dose of AstraZeneca vaccine among Libyan individuals. Thus, a cross-sectional study is conducted in part of Libya, Aljmail city, in order to investigate any adverse effect that could arise in adult Libyan participants post-vaccination by AstraZeneca.

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## Materials and methods

*Study design:* The study was a randomized cross-sectional observation method and conducted by including subjects who were vaccinated with the first dose of the AstraZeneca vaccine in the western part of Libya, Algmail. The study was carried out at the Aljmail unit of the National Center for 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, and 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 participants as telephone number, age, weight, gender and clinical profile including co-morbid condition, and anticoagulant drug 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 the COVID-19 vaccine. Twelve symptoms were listed in the survey including severe headache, fever, pain at the injection site, myalgia, seizure, sore throat, blurred vision, shortness of breath, abdominal pain, chest pain, swelling and redness in a limb, and coldness in the 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:* The participants were Libyan citizens from the west (Aljmail city). Individuals aged more than 18 years who received AstraZeneca COVID-19 vaccine. Exclusion criteria were people who had been vaccinated by manufacturer companies other than the one included company and vaccination to who they did not respond.

*Ethical considerations:* This study was reviewed and approved by the scientific and ethical committee of the Faculty of Pharmacy at the University of Sabratha, Sabratha, Libya (4/2021) whereas participants provided verbal consent prior to 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 statistics. The linked risk effects 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, reflecting the status of vaccines within the community from which they were taken. Of a total of 300 participants, 167 were excluded from 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 were of in 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 had obvious adverse effects, most of the adverse effects appeared between one and three days after vaccine intake as shown in **Table 1** and **Figure 1**.

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**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 |

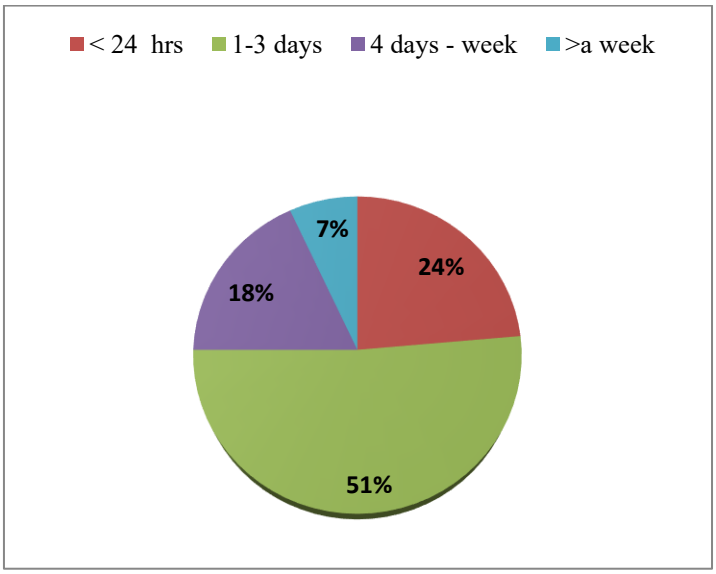


**Figure 1:** Duration of symptoms after vaccination

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**, participants aged more than 60 years old and males were more likely porn to have symptoms after the 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). Participants with the co-morbid conditions was more than participants with no disease (p=0.595). Participants suffered 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**).

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**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 complaints of adverse effects 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 such as a significant high-risk factor for adverse effects. This is in line with other reports and finds a parallel of the 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 the 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

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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 inconsistent 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 the most adverse effects of the AstraZeneca COVID-19 vaccine in Libyan adults. Ther a variety of adverse effects and most of them occur within the first 24 hours following vaccination and usually last for a few days. Severe symptoms were uncommon, the recipients should be advised and aware of the most popular adverse effects that may be occurring after the first dose of vaccination and how to seek additional guidance if necessary.

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**Conflict of interest:** The authors declare the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.
**Ethical issues:** Including plagiarism, informed consent, data fabrication or falsification and double publication or submission completely observed by the 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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