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Original Article

The Severity of Symptoms and Thrombotic Effect of AstraZeneca Covid-19 Vaccine After the First Dose in Western Libya

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ABSTRACT

***Background and aims**. There have been numerous COVID-19 vaccines introduced with various efficacy and safety profiles. The severity and reactogenicity of the COVID-19 vaccine in our community have received very little attention to date, and many people have expressed concerns about its safety. The purpose of this study was to evaluate the severity of symptoms and thrombotic side effect after the first dose of AstraZeneca COVID-19 vaccine and the risk factors associated with severe side effects among Libyans in the west of the country. **Methods**. A randomized cross-sectional observational study among individuals who received the first dose of the AstraZeneca COVID-19 vaccine, and were aged > 18. Data were collected through semi-structured questionnaires, face-to-face interviews and\or telephone surveys. **Results**. Out of 133 participants, about 72 (54.1%) had obvious adverse effects ranging from mild to severe in terms of severity. The most reported reactions regarding the severity of symptoms include; fever, headache, injection site reaction, and myalgia. About (55.5%) of severe side effects had occurred in males, and (61.1%) occurred in those aged (>18-59). **Conclusion**. AstraZeneca COVID-19 vaccine was well tolerated and most of the symptoms were mild to moderate among people of different age groups.*

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INTRODUCTION

Coronaviruses are members of the Coronavirdiae family, coronavirus was given its name because of the crown-like spike on the virus's outer surface [1]. In late December 2019, Wuhan, Hubei Province, China, saw an outbreak of an unknown disease identified as pneumonia of unclear etiology several independent laboratories identified the primary agent of this unusual pneumonia as a novel coronavirus (nCoV)a few days later [2]. The World Health Organization (WHO) has identified a (nCoV) as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as the cause of the COVID-19 outbreak [3]. WHO declared the coronavirus pandemic on 11 March 2020 [4], the first case of COVID-19 in Libya was reported on 24 March 2020 [5].

Vaccinations are generally known to stop infections from spreading and lower the incidence of a variety of infectious diseases [6]. Because of this, it represents the only chance of ending the COVID-19 pandemic [7]. Several vaccine candidates were shown to be safe and effective in trials in December 2020, and mass vaccination (in conjunction with existing control measures) was seen as one of the key elements to controlling the pandemic [8].

A cross-sectional study was conducted among Libyan adults to investigate the severity of a symptom and Thrombotic side effect of the AstraZeneca COVID-19 vaccine following the first dose. The AstraZeneca 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. The AstraZeneca COVID-19 vaccination has been linked to rare cases of major blood clots in the brain, since 11 March 2021, according to reports from the United Kingdom, the European Union, and Scandinavian countries [9].

Since March 11, 2021, Oxford-AstraZeneca COVID-19 vaccine has been temporarily halted in various European nations (including Denmark, France, Italy, Latvia, Norway, Spain, Sweden, and The Netherlands) due to reports of blood clot occurrences and the death of a vaccination recipient [10-11].

With advanced symptoms and observation of asymptomatic carriers to serious/life-altering outcomes, the incidence and mortality of several diseases have been decreased due to the development of numerous vaccinations, which are now being used worldwide (Figure 1). Recently, uncommon but potentially fatal occurrences include thrombosis with thrombocytopenia syndrome (TTS), also known as vaccine-induced thrombocytopenia (VITT), and thrombosis, with several COVID-19 vaccinations, have been documented [12].

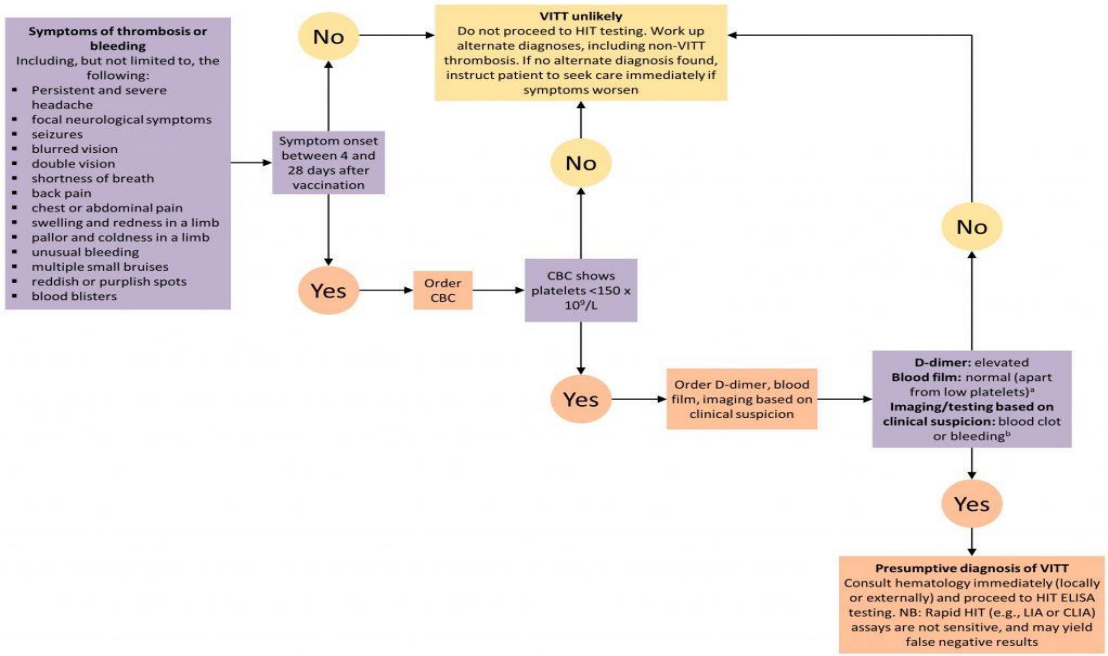

Figure 1. Presents the symptom, diagnosis, and ruling out VIPIT

In our study only two participants appear symptoms of VIPIT a male (severe headache and high blood pressure), Female has (breathless) both of them underwent the CBC count test see Table 3

METHODS

Study design and setting

The study was a randomized cross-sectional observation that included patients over the age of >18 who got their first dose of AstraZeneca COVID-19 vaccination in western Libya. The research was conducted at the National Center for Disease Control Libya.

Data collection procedure

Data were collected between August 31, 2021 and November 5, 2021. Most of the participants were Libyans from the west (Aljmail city). Data were gathered through semi-structured questionnaires, face-to-face interviews, and/or telephone surveys. The questionnaire included three major parts: demographic data including (Age, and gender); clinical profile (Co-morbid condition, previous stork or family history with stork, Anticoagulant drugs use); and vaccine data (Side effect in terms of duration and severity).

The information about the participant's demographics, including their phone number, age, weight, gender, and clinical profile, was provided in the survey's first section (Co-morbid condition, previous stork or family history with stork, Anticoagulant drugs use). The details of the precise side effects that each participant had after receiving the COVID-19 vaccine were provided in the survey's second section. Severe headache, blurred vision, shortness of breath, chest discomfort, abdominal pain, swelling and redness in a limb, and coldness in a limb were the seven symptoms identified in the poll.

Participants were asked about any symptoms and side effects they had within 1-28 days after their vaccines. In addition, the participant may provide any other symptoms that were not stated in the preceding alternatives. Furthermore, 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.

Ethical consideration

The study was reviewed and approved by the college of pharmacy at the University of Sabratha, whereas participants provided verbal consent before participation.

Statistical analysis

The data were entered into a statistical package to analyze the results (SPSS) software version 22. Descriptive statistics were applied to both demographic characteristics and medical recall. Fisher's exact and Chi-square tests were used to determine the related risk effect after vaccination. A statistically significant p-value of 0.05 was used.

RESULTS

Demographic characteristics

A total of 133 participants were enrolled for the final analysis. About 62(46.6%) were male and 71(53.4%) were female. Most of participants were aged in the group of (>18-59) which was about 72.9%. Regarding medical anamnesis, 49 (36.8%) participants had at least one co-morbid disease (high blood pressure, diabetes, asthma, etc.). Only 7(5.3%) had a previous blood clot and 22(16.5%) had a history of a blood clot. Most of the participants which were about 72(54.1%) out of 133 had obvious adverse effects ranging from mild to severe in terms of severity as shown in Table 1 and figure 2

Table 1. Demographic Characteristic of study population N=133

Variable	Frequency	Percentage %
Gender		
Male	62	46.6
Female	71	53.4
Age		
>18-59	97	73
60 and above	36	27
Symptom after vaccine		
Yes	72	54.1
No	61	45.9
Severity of symptoms (N=72)		
Mild	24	18.0
Moderate	30	22.6
Severe	18	13.4
Duration of symptoms (N=72)		
< 24 hrs	17	12.8
1-3 days	37	27.9
4 days - week	13	9.8
>a week	5	3.8
Previous blood clot		
Yes	7	5.3
No	126	94.7
Family history of the blood clot		
Yes	22	16.5
No	111	83.5
Co-morbid disease		
Disease	49	36.8
No disease	84	63.2
Smoking		
Yes	15	11.2
No	118	88.7

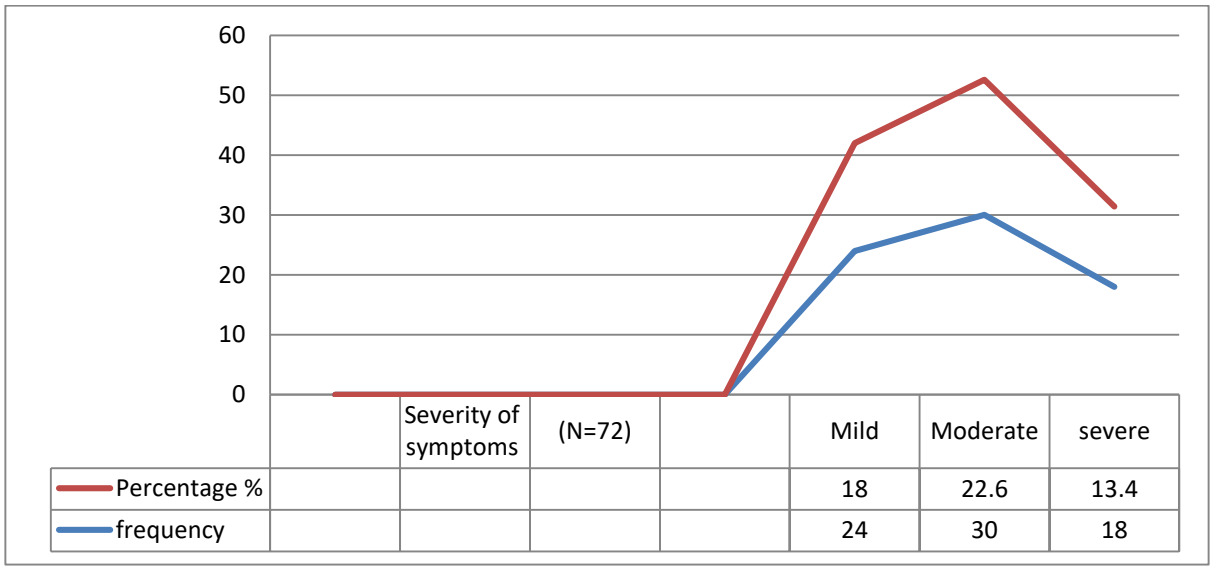

Figure 2. severity of symptoms

Associated risk factors getting severe post-vaccination adverse effect

Regarding the severity of symptoms only 18 (25%) out of 72 symptomatic participants faced severe to critical adverse effects. (55.5%) of severe side effects had occurred in males, (61.1%) occurred in those aged (>18-59). Individuals with the co-morbid disease most of them prone to the mild-moderate symptom (p-value; 0.413, 0.295, 0.259, 1.000, 0.577, respectively). The chi-squared test revealed that were no statically significance. On the other hand, a family history of the blood clot and previous blood clots do not correlate with the appearance of severe symptoms after vaccination (Table 2).

Prevalence of general side effects

The majority of post-vaccination symptoms were fever 63.9%, headache 62.3%, injection site reaction (pain, redness, and swallowing) 37.5%, myalgia and muscle pain 23.6%, the less likely appeared symptoms were dry troth and chills 1.4% (Figure 3).

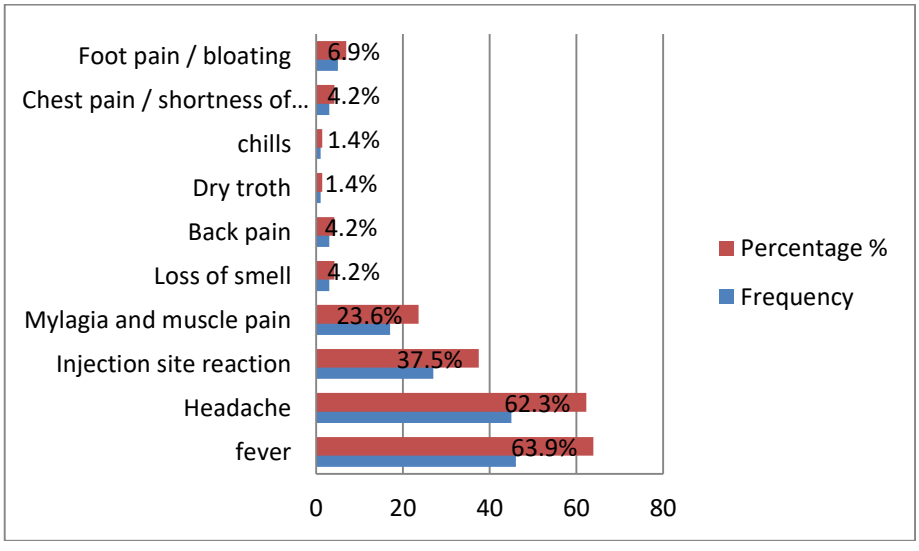

Figure 3. The type of negative reaction.

Table 2. Variable correlation with severity of symptoms N = 72

Variables	Mild-Moderate Symptoms N = 54	Severe symptoms N = 18	P-Value
Male **Female**	24 (70.5%) 30 (78.9%)	10 (29.4%) 8 (21.1%)	0.413
Age >18-59 60 and above	40 (78.4%) 14 (66.7%)	11 (21.6%) 7 (33.3%)	0.295
Previous blood clot Yes No	2(50%) 52(76.5%)	2 (50%) 16 (23.5%)	0.259
Family history of the blood clot Yes No	10 (77%) 44 (75%)	3 (23.1%) 15 (25.4%)	1.000
Co-morbid diseases Diseases No diseases	20 (71%) 34 (77.3%)	8 (29%) 10 (23%)	0.577
Smoking Yes No	4 (80%) 50 (75%)	1 (20%) 17 (25.3%)	1.000

As we mentioned in the introduction only 2 participants appear symptoms of VIPIT Associated variables CBC show platelets < 150 ×10∗ 9
Two of the study underwent the CBC count test, male age 57 has a severe headache and high blood pressure, Female has breathless age 23. results show there is no low platelet level (<150) (Table 3).

Table 3: Variables correlated with Platelets (CBC show platelets < 150 ×10∗ 9) N = 2

Variable		Result (Platelets not elevated)
Sex	Age	
Male	57	192
Female	23	286

DISCUSSION

In the current trial, there were no reports of complications or significant difficulties related to the AstraZeneca vaccine. On the first day, the most common symptoms were fever (46) participants, headache (45) participants, injection site reaction (pain, redness, and swallowing) (27) participants, and myalgia and muscular soreness (17) participants. Regarding the severity of symptoms most symptoms were mild-moderate (75%), and only (25%) reported severe symptoms This result is consistent with a Wuhan study that found that the majority of symptoms were mild to moderate in severity [13].
The study showed 2 participants underwent the CBC count test, male age 57 has a severe headache and high blood pressure, Female breathless age 23. Results show there is no low platelet level. Patients who experience blood clotting symptoms during the past 4 to 20 days and have a platelet count below 150 x 10*9/L should be assessed for VIPIT at the closest emergency department. This study did not show an increase in VIPIT in an individual with a family history of the blood clot, or a personal history of the venous or arterial clot, this was in line with other literature [8].
The current study has some limitations. First, it was conducted in Aljmail City with convenience sampling which may limit the generalizability of the findings.

CONCLUSION

The study showed that severe symptoms were infrequent, and no one of the participants had thrombotic events linked to the AstraZeneca vaccine. Most of the symptoms were mild to moderate in terms of severity. Additionally, those who had co-morbidities, male gender, and the ages 60 and above show more correlation with severity symptoms.

Prospective studies with higher sample size, longer follow-up, and inclusion of clinical laboratory parameters such as CBC blood count test and D-dimer elevation are advisable.

Conflict of Interest

There are no financial, personal, or professional conflicts of interest to declare.

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