

COVID-19 vaccine side effect: age and gender disparity in adverse effects following the first dose of AstraZeneca COVID-19 vaccine among the vaccinated population in Eastern Ethiopia: a community-based study

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Abstract

Objective: The pandemic of coronavirus disease 2019 (COVID-19) is a major threat to community health, and vaccinations are a safe and effective way to reduce disease loads around the world. This study aimed to assess the age and gender disparity in adverse effects following the first dose of the AstraZeneca COVID-19 vaccine among the vaccinated population in Eastern Ethiopia.

Methods: A community-based cross-sectional study design was conducted among 832 randomly selected individuals from December 1st to 20th, 2021, in eastern Ethiopia. Data were collected by face-to-face interviews using a pretested structured questionnaire. Data were analyzed using the SPSS V26. Descriptive summary statistics were done. A chi-square test statistic was computed to assess the difference in adverse effects between age groups and both genders.

Result: Out of 832 study participants who had taken the first dose of AstraZeneca vaccine, 96.3% of them felt at least one adverse effect. The magnitude of adverse reactions was higher among male participants. The reported adverse reactions were significantly higher in the age group of 50–60 years with comorbidity than those of <50 and >60 years of age.

Conclusion: Overall, there is a significant age and gender difference in adverse effects following the first dose of the AstraZeneca COVID-19 vaccine. In addition, adverse reactions were higher among people with comorbidity in the age group of 50–60 years. The Harari Regional Health Bureau should provide training for frontline healthcare workers on early recognition and response to adverse effects of the COVID-19 vaccine. In addition, information and education should be provided to the community as a whole regarding recognition and the appropriate measures to be taken.

Keywords

COVID-19 vaccine, adverse effects, gender disparity, age disparity

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Introduction

The pandemic of coronavirus disease is a major threat to community health and has had a substantial impact on various aspects of society.¹ Million cases of illness and deaths had been confirmed.² In addition to its health consequences, coronavirus disease 2019 (COVID-19) has a major economic impact that should not be neglected.³

Given the disease's worrisome rate of spread and the enormous expense of depending solely on non-pharmaceutical measures,⁴ the world urgently requires safe and effective vaccines to protect vulnerable populations and restore people's lives to their original state.⁵ Vaccinations are a safe and effective way to reduce disease loads around the world.⁶ Vaccination is widely acknowledged as having made the highest impact on global health of any human effort.⁷

Public concerns about vaccine safety and side effects may play a role in vaccine safety as scientists throughout the world work on a potential COVID-19 vaccine.¹ Several safe and effective vaccines prevent people from getting seriously ill or dying from the COVID-19 infection.⁸ One of these is the AstraZeneca vaccine which protects people from the extremely risky dangers of COVID-19, such as death, hospitalization, and severe sickness.⁹

Vaccines, like all drugs, can have negative effects. The majority of these are mild to moderate in nature and are just temporary.¹⁰ Studies have reported COVID-19 vaccines side effects including severe reactions, such as deep vein thrombosis, transverse myelitis, and even anaphylactic shock.^{11,12} Center for Disease Control and Prevention (CDC) and other studies had reported COVID-19 vaccination side effects like local reactions such as pain, swelling, and redness at the injection site; as well as systemic effects including joint pain, tiredness, back pain, muscle pain, headache, chills, fever, and nausea.¹³⁻¹⁷

However, the United Kingdom Health Security Agency advises that those who have received the first dose of the AstraZeneca vaccination and have experienced no major side effects should be administered the second dosage to finish the course.¹⁰ Potential adverse effects of AstraZeneca include rash, swelling of face, lips, and throat, feeling light-headed, changes in heartbeat, wheezing, shortness of breath, stomach pain, nausea, and vomiting.¹⁸

Some preliminary studies have indicated that there are gender and age differences in the manifestation of COVID-19 vaccination side effects.¹⁹ Gender differences have been observed in the severe acute respiratory syndrome coronavirus-2 infectivity and the frequency of severity of COVID-19.²⁰ In addition, there is a gender difference in the frequency of adverse effects after COVID-19 vaccination.²¹

There are no studies that addressed age and gender disparity in adverse effects following the first dose of AstraZeneca COVID-19 vaccine in Ethiopia. Therefore, this study assessed age and gender disparity in adverse effects

following the first dose of the AstraZeneca COVID-19 vaccine among the vaccinated population in Eastern Ethiopia.

Method and materials

Study area and period

The study was carried out in the Harari region from December 1st to 20th, 2021, in eastern Ethiopia. The total estimated population of Harar was 246,000, and approximately 150,060 (61%) of the population live in urban areas. There are nine districts in total. Of these, six of them are in urban areas, and the rest of them are in rural areas. The total dose of AstraZeneca COVID-19 vaccine administered in the regional states of Harari as of December 10, 2021, was 26,800, among these 16,130 and 10,670 were from urban and rural, respectively. This study assessed age and gender disparity in adverse effects following the first dose of the AstraZeneca COVID-19 vaccine among the vaccinated population in Harar, Eastern Ethiopia, in 2021.

Study design and population

A community-based cross-sectional study design was used. Our source population was the whole population who had taken the first dose of the AstraZeneca COVID-19 vaccine in Harari Regional State. The study population consists of all participants randomly chosen from each stratum.

Sample size determination and sampling technique

To calculate the required samples, we used a single proportion formula with a 95% confidence interval, a 5% margin of error, and the assumption of a 50% proportion. Then, it was multiplied by 2 (design effects), and finally, a 10% non-response rate was added.

$$n = \frac{Z\alpha^2 p(1-p)}{d^2} = n = \frac{(1.96)^2 0.5(1-0.5)}{0.05^2}$$

$$= 384, 384 \times 2 = 768, \text{ by adding } 10\% (77) \approx 845$$

The complete list of individuals who had taken the first dose of the AstraZeneca COVID-19 vaccine was taken from the Regional Health Bureau. The participant's home addresses and telephone numbers were taken from vaccine registry books to trace and recruit subjects. Then study participants who volunteered during the data collection period to engage in the study were included. The study participants were selected using a stratified sampling technique, which was classified into two strata based on their residence areas (urban and rural). The total sample size was proportionally allocated for urban (16,130) and rural (10,670) populations

who had taken the AstraZeneca COVID-19 vaccine, which is 509 for urban and 336 for rural. Then, the study participants were randomly selected from each stratum.

Data collection tool and procedure

Data were collected using face-to-face interviews with a pre-tested structured questionnaire. The questionnaire was prepared in the English language and translated into the local languages (Afan Oromo and Amharic), which was adapted, after reviewing relevant literature^{20,22,23} and the World Health Organization COVID-19 vaccine report.⁹ The questionnaire consisted of two parts: the first part was sociodemographic-related variables (age, sex, marital status, occupational status, level of education, average monthly income, and family members), and the second part included COVID-19 vaccine-related variables (adverse effects, onset of symptoms, duration of adverse effect, and types of treatment taken) as an outcome variable. Data were collected by ten 4th-year public health students.

Data quality control

To assure the quality of the data, a 3-day training was given for data collectors on how to interview and collect data. A pretest was done on 5% of the questionnaire in Fedis district. Close supervision of the data collectors was conducted by the authors. The reliability of the questionnaire was calculated, and the value of Cronbach's alpha was found to be 0.769. The collected data were checked both in the field, at the end of each day after data collection, and before data entry for completeness and missing values. Double data entry was performed.

Statistical analysis

The data were examined for completeness, clarity, and consistency after it was collected. The data were coded and entered into Epidata v.3.0, and SPSS v.26 was used to analyze it. To summarize the results, summary statistics were produced in the form of percentages. A chi-square test analysis was computed to assess the association between the dependent and independent variables and the difference in adverse effects between age groups and both genders. Then, those variables with a p value < 0.05 were declared as having a statistically significant association. We have used the STROBE checklist for cross-sectional study design for writing the finding of the study.

Operational definition

Adverse effects: If the participants experienced at least one of the following symptoms (local pain, local swelling, redness at injection site, fatigue, fever, headache, muscle pain chills, and nausea) after taking the AstraZeneca COVID-19 vaccine.¹⁵

Ethical consideration

The protocol of this study for the subject recruitment process and participation in the study adhered to the Declaration of Helsinki's guidelines and an ethical approval letter was obtained from the Harar Health Science College Institutional Health Research Ethics Committee with reference No. IHREC 02/595/254/2/14.

Results

Sociodemographic characteristics of study participants

A total of 832 study participants participated in the study, with a response rate of 98.5%. The majority, 75%, of them were between 50 and 60 years of age, with a mean age of 56.2 (± 8.4 SD). Fifty-eight percent of them were married, and 61% had a monthly income of less than 5000 Ethiopian Birr (ETB) on average (Table 1).

Prevalence of adverse effects following the first dose of AstraZeneca COVID-19 vaccine

Out of 832 study participants who had taken the first dose of AstraZeneca vaccine, 801 (96.3%) of them felt at least one adverse effect. Of these, the most commonly reported adverse effects were local pain, fatigue, fever, and headache, at 80.4%, 70.7%, 57.1%, and 44.3%, respectively, and less commonly or rarely reported adverse reactions were nausea (2.9%) and vomiting (1.9%) (Table 2).

Gender disparities in adverse effects following the first dose of AstraZeneca COVID-19 vaccine

The severity of adverse reactions was slightly higher in male individuals overall. Out of 389 male study participants, 98.2% of them had felt at least one adverse effect, whereas of a total of 443 females, 94.6% had felt adverse effects (χ^2 -test, $p=0.006$). There is a significant difference between males and females in adverse effects following the first dose of the AstraZeneca COVID-19 vaccine. Regarding the reports of adverse reactions, local pain and local swelling were significantly higher among males than females, which was local pain: 80.7% for males, 74.5% for females, $p=0.032$, and local swelling: 33.9% for males, 27.5% for females, $p=0.046$. The analysis of chi-square revealed that there is a significant gender difference in adverse effects (Table 2).

Adverse effects duration and measures taken to get relief based on gender

Regarding the reported adverse effects, overall, 57.6% and 25.7% of adverse effect symptoms started within 12–17h and 6–11 h, respectively, after taking the vaccine. The majority, 62.3%, of reported adverse effects lasted for 2 days.

Table 1. Sociodemographic characteristics of study participants who had taken the first dose of AstraZeneca COVID-19 vaccine in Harar, Eastern Ethiopia, 2021.

Sociodemographic variables	Urban (n=509)	Rural (n=323)	Total (N=832)	Percentage (%)
Age in years				
<50	46 (38.7%)	73 (61.3%)	119	14.3
50–60	425 (67.5%)	205 (32.5%)	630	75.7
>60	38 (45.8%)	45 (54.2%)	83	10
Sex				
Male	274 (58.5%)	194 (41.4%)	468	56.3
Female	235 (64.6%)	129 (35.4%)	364	43.7
Marital status				
Single	197 (68.4%)	91 (31.6%)	288	34.6
Married	278 (57.2%)	208 (42.8%)	486	58.4
Divorced	19 (63.3%)	11 (36.7%)	30	3.6
Widow	11 (64.7%)	6 (35.3%)	17	2
Separated	4 (36.4%)	7 (63.6%)	11	1.3
Occupational status				
Housewife	92 (60.5%)	60 (39.5%)	152	18.3
Marchant	161 (76.3%)	50 (23.7%)	211	25.4
Civil servant	157 (78.9%)	42 (21.1%)	199	23.9
Labor work	87 (60.8%)	56 (39.2%)	143	17.2
NGOs	13 (9.8%)	120 (90.2%)	133	16
Driver	20 (100%)	0 (0.0%)	20	2.4
Level of educational				
Unable to read and write	21 (18.9%)	90 (81.1%)	111	13.3
Primary education	125 (69.4%)	55 (30.6%)	180	21.6
Secondary education	141 (61.8%)	87 (38.2%)	228	27.4
Above secondary education	222 (70.9%)	91 (29.1%)	313	37.6
Average monthly income				
<5000 ETB	304 (59.1%)	210 (40.8%)	514	61.8
5000–9999 ETB	163 (65.5%)	86 (34.5%)	249	30
10000–14999 ETB	32 (68.1%)	15 (31.9%)	47	5.6
≥15,000 ETB	10 (45.4%)	12 (54.5%)	22	2.6
Family size				
<5	303 (64.2%)	169 (35.8%)	472	56.7
5–9	188 (58.6%)	133 (41.4%)	321	38.6
≥10	18 (46%)	21 (53.8%)	39	4.7
Had chronic disease				
Yes	436 (64.2%)	243 (35.8%)	679	81.6
No	73 (47.7%)	80 (52.3%)	153	18.4
Types of chronic disease				
Hypertension	177 (64.1%)	99 (35.9%)	276	40.6
Diabetes	157 (66.2%)	80 (33.8%)	237	34.9
Asthma	2 (40%)	3 (60%)	5	0.7
Both hypertension and diabetes	91 (61.9%)	56 (38.1%)	147	21.6
Heart disease	9 (64.3%)	5 (35.7%)	14	2.1

COVID-19, coronavirus disease 2019; NGOs, non-government organizations.

Among the participants, early onset of symptoms of adverse effects was reported among males more than females. On the other hand, late onset of symptoms was observed among females than males (Table 3). Among the total of 489 participants who had taken analgesics for relieving symptoms, 52.1% were males (Figure 1).

Age disparities in adverse effects following the first dose of AstraZeneca COVID-19 vaccine

Overall, the prevalence of reported adverse reactions was significantly higher in the age group of 50–60 years than <50 and >60 years, which was 89.5%, 99.7%, and 70.1%

Table 2. Adverse effects of AstraZeneca COVID-19 vaccine reported by participants who had taken the first dose vaccine and disparities in gender, Harar Eastern Ethiopia, 2021.

Adverse reaction	Total (N=832)	Male (n=389)	Female (n=443)	χ^2 -test
	n (%)	n (%)	n (%)	p-Value
Had any adverse effect	801 (96.3)	382 (98.2)	419 (94.6)	0.006*
Headache	355 (44.3)	161 (41.4)	194 (43.8)	0.484
Fever	457 (57.1)	220 (56.6)	237 (53.5)	0.377
Local pain	644 (80.4)	314 (80.7)	330 (74.5)	0.032*
Local swelling	254 (31.7)	132 (33.9)	122 (27.5)	0.046*
Fatigue	566 (70.7)	264 (67.8)	302 (68.2)	0.925
Chills	305 (38.1)	134 (34.4)	171 (38.6)	0.215
Nausea	23 (2.9)	14 (3.6)	9 (2)	0.169
Vomiting	13 (1.9)	9 (2.3)	4 (0.9)	0.102

n, sub-group sample; χ^2 , chi-square; *Bold number, statistically significant at p value <0.05. COVID-19, coronavirus disease 2019.

Table 3. Reported adverse effects illness duration and measures taken to get relief by their gender in Harar population, Eastern Ethiopia, 2021.

Illness duration and measures taken	Male (n=382)	Female (n=419)	n=801 (n (%))
When did symptoms starts			
<6 h	20 (5.2%)	17 (4.8%)	37 (4.6%)
6–11 h	105 (27.5%)	101 (24.1%)	206 (25.7%)
12–17 h	227 (59.4%)	234 (55.8%)	461 (57.6%)
18–23 h	27 (7.1%)	56 (13.4%)	83 (10.4%)
>24 h	3 (0.8%)	11 (2.6%)	14 (1.7%)
Adverse effects lasted			
1 day	41 (10.7%)	38 (9.1%)	79 (9.9%)
2 days	224 (58.6%)	275 (65.6%)	499 (62.3%)
3 days and above	117 (30.6%)	106 (25.3%)	223 (27.8%)
Take any form of treatment			
Yes	377 (98.7%)	412 (98.3%)	789 (98.5%)
No	5 (1.3%)	7 (1.7%)	12 (1.5%)

with $p < 0.001$, respectively. Among the reported adverse reactions, headaches (44.5%, $p = 0.048$), fever (56.8%, $p = 0.016$), and local pain (80.7%, $p < 0.001$) were more commonly reported in the age group of 50–60 years. The chi-square analysis indicated that these adverse reactions were statistically significant differences between the age groups (Table 4).

Adverse effects duration and measures taken to get relief based on age

Regarding the reported adverse effects, overall, 57.6% and 25.7% of adverse effect symptoms started within 12–17 h and 6–11 h, respectively, after taking the vaccine. Among these, majority of them were found between 50 and 60 years of age. The majority, 62.3%, of reported adverse effects lasted for 2 days. People with age <50 years have not shown adverse symptoms during the first 11 h, whereas the majority of participants between 50 and 60 years of age started to feel

symptoms within the first 11 h (Table 5). Among the total of 489 participants who had taken analgesics for relieving symptoms, 83.2% were found in the age group of 50–60 years (Figure 2).

Discussion

This study was the first study conducted in Ethiopia that tried to assess gender and age disparities in adverse effects following the AstraZeneca COVID-19 vaccine among the population in Eastern Ethiopia. In the study, commonly reported adverse effects by participants were local pain at the injection site, fatigue, fever, and headache.

Overall, 96.3% of the study participants felt at least one adverse effect after receiving the AstraZeneca COVID-19 vaccine. This finding was consistent with similar studies from Kabul, Afghanistan,²³ where (93.5%) and Jordan²⁴ (89.9%) participants reported at least one adverse effect following the first dose of AstraZeneca COVID-19

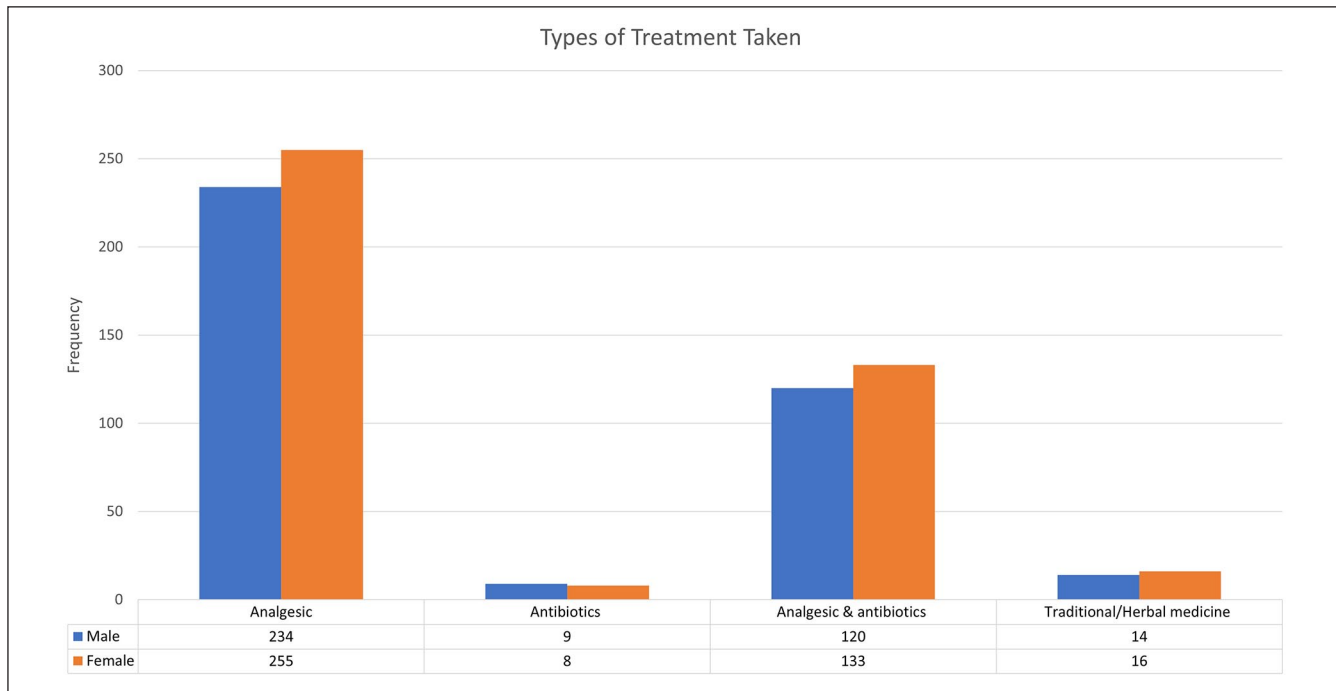


Figure 1. Types of treatment taken by participants to subside adverse effects of AstraZeneca COVID-19 vaccine based on their gender among the population in Harar, Eastern Ethiopia, 2021. COVID-19, coronavirus disease 2019.

Table 4. Adverse effects of AstraZeneca COVID-19 vaccine reported by participants who had taken the first dose vaccine and disparities in age, Harar Eastern Ethiopia, 2021.

Adverse reaction	Total (N=832)	Age < 50 (n=86)	Age 50–60 (n=679)	Age > 60 (n=67)	χ^2 -test
	n (%)				p Value
Had any adverse effect	801 (96.3)	77 (89.5)	677 (99.7)	47 (70.1)	<0.001*
Headache	355 (44.3)	33 (38.4)	302 (44.5)	20 (29.8)	0.048*
Fever	457 (57.1)	45 (52.3)	386 (56.8)	26 (38.8)	0.016*
Local pain	644 (80.4)	60 (69.8)	548 (80.7)	36 (53.7)	<0.001*
Local swelling	254 (31.7)	29 (33.7)	212 (31.2)	13 (19.4)	0.107
Fatigue	566 (70.7)	58 (67.4)	470 (69.2)	38 (56.7)	0.111
Chills	305 (38.1)	29 (33.7)	251 (37)	25 (37.3)	0.835
Nausea	23 (2.9)	2 (2.3)	21 (3.1)	0 (0.0)	0.326
Vomiting	13 (1.9)	2 (2.3)	11 (1.6)	0 (0.0)	0.496

COVID-19, coronavirus disease 2019; n, sub-group sample; χ^2 , chi-square.

*Bold indicates statistically significant at $p < .05$.

vaccination. However, this finding is higher than studies from Debre Markos, Ethiopia,²⁵ Turkey,²⁶ and Bangladesh²⁷ where 75%, 62.5%, and 55% of participants reported at least one adverse reaction following vaccination, respectively. These observed variations could be due to differences in study population demographic data such as age, race-based pain threshold, and psychological differences in symptoms reporting behavior.

In our study, fatigue, headache, pain at the injection site, and fever were adverse effects commonly reported by participants. This is similar to an experimental study on the

ChAdOx1 nCoV-19 vaccine, which identified fatigue (53.1%), headache (52.6%), pain at the site of injection (54.2%), and tenderness at the site of injection (63.7%) as frequently reported adverse effects. Furthermore, this is similar to the adverse reactions reported after taking the AstraZeneca nCoV-19 vaccine in Debre Markos, Ethiopia,²⁵ Turkey,²⁶ Afghanistan,²³ and Bangladesh.²⁷

In this study, gender disparity was observed in reporting side effects following the first dose of the AstraZeneca vaccine and the magnitude of adverse reactions was slightly higher in male participants than females. This is congruent

Table 5. Reported adverse effects illness duration and measures taken to get relief by their age in Harar population, Eastern Ethiopia, 2021.

Illness duration and measures taken	<50 Age (n=77)	50–60 Age (n=677)	>60 Age (n=47)	n=801 (n (%))
When did symptoms starts				
<6h	0 (0.0%)	19 (2.8%)	18 (38.3%)	37 (4.6%)
6–11 h	0 (0.0%)	182 (26.9%)	24 (51.1%)	206 (25.7%)
12–17 h	68 (88.3%)	388 (57.3%)	5 (10.6%)	461 (57.6%)
18–23 h	9 (11.7%)	74 (10.9%)	0 (0.0%)	83 (10.4%)
>24h	0 (0.0%)	14 (2.1%)	0 (0.0%)	14 (1.7%)
For how many days adverse effects lasted				
1 day	0 (0.0%)	62 (9.2%)	17 (36.2%)	79 (9.9%)
2 days	44 (57.1%)	429 (63.4%)	26 (55.3%)	499 (62.3%)
3 days and above	33 (42.9%)	186 (27.4%)	4 (8.5%)	223 (27.8%)
Did you take any form of treatment				
Yes	77 (100%)	668 (98.7%)	44 (93.6%)	789 (98.5%)
No	0 (0.0%)	9 (1.3%)	3 (6.4%)	12 (1.5%)

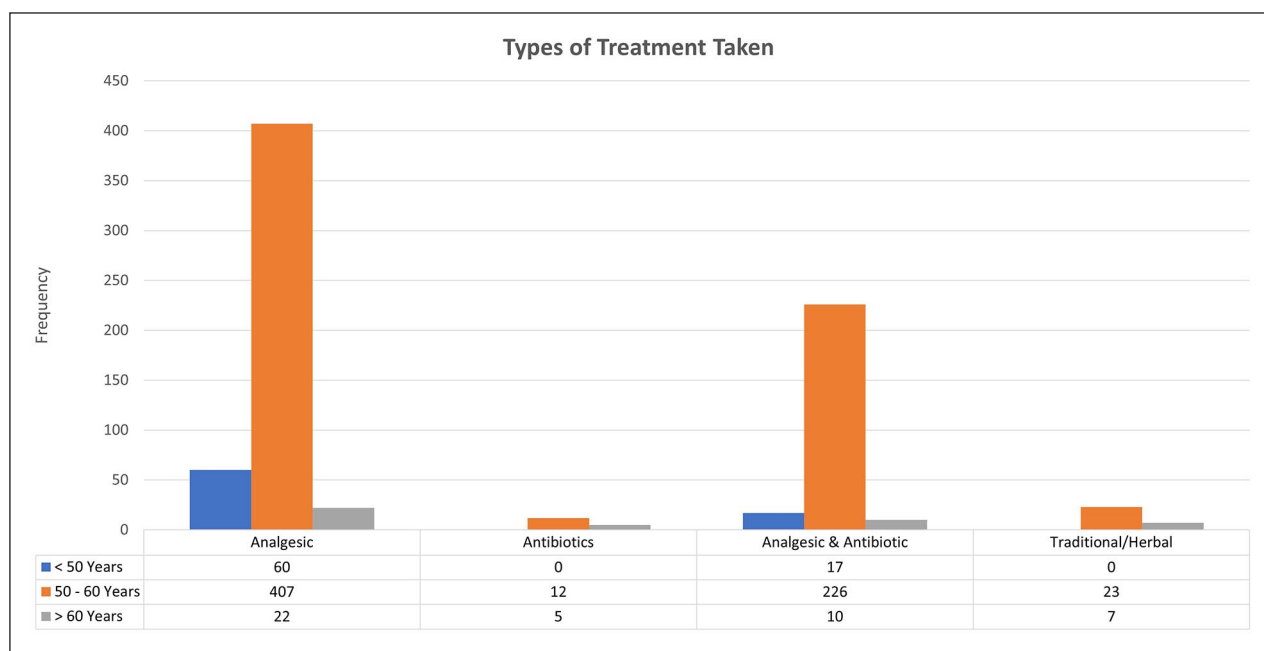


Figure 2. Types of treatment taken by participants to subside adverse effects of AstraZeneca COVID-19 vaccine based on their age among the population in Harar, Eastern Ethiopia, 2021. COVID-19, coronavirus disease 2019.

with a study from China where higher proportions of males reported adverse effects than females.²² On the contrary, other similar studies from Saudi Arabia,²⁸ Turkey,²⁶ and Bangladesh²⁷ have reported that a higher percentage of female participants suffered from post-vaccination side effects compared to males.

In our study, the observed gender disparities in adverse effects following COVID-19 vaccines might be related to the different immune responses between gender.²⁹ Immunological responses to antigens differ between males and females, as do innate and adaptive immune responses. When males are

compared to females, the cellular immunological response of the particular immune system is suppressed.³⁰

Overall, the prevalence of reported adverse reactions was significantly higher among 50–60 years age group individuals than among people <50 years and >60 years of age. However, other similar studies reported variable results related to age disparity on side effects following COVID-19 vaccination. For instance, a study from China indicated that older people greater than 65 years are more likely to have adverse reactions than those between 18 and 64 years.²² On the other hand, an Afghanistan²³ study reported that the

frequency of adverse reactions was higher in participants aged 40 years or less than in older participants. Similarly, studies conducted in Bangladesh²⁷ and Turkey²⁶ revealed that corona vaccine side effects were found to be significantly more prevalent in the younger population. This could be due to different immune responses to antigens, differences in innate and adaptive immune responses in different age groups,^{31,32} and host race or ethnicity.³³

Limitation of the study

The study used a cross-sectional study design. Therefore, there is a temporal issue and also more prone to recall bias. There is a lack of similar studies for comparison. As the study was addressing side effects after the first dose, information regarding adverse effects after the second dose may be limited.

Conclusion

Overall, 96.3% of the study participants felt at least one adverse effect after receiving the AstraZeneca COVID-19 vaccine. The magnitude of COVID-19 vaccine adverse effects was higher among male participants and those in the age group 50–60 years with comorbidity.

The government should provide training for frontline healthcare workers on early recognition and response to adverse effects of the COVID-19 vaccine as per the recommendation of the CDC. In addition, information and education should be provided to the community as a whole regarding recognition and the appropriate measures to be taken.

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Author contributions

AA, MY, and AD participated in the study from inception to design, acquisition of data, analysis, and interpretation of the results. LO, YA, RA, and DF participated in the methods, analysis, interpretation, and writing of the manuscript of the results. Finally, all authors approved the manuscript for publication and the journal to which it has been submitted.

Data availability

At any time, the corresponding author provides an additional resource on request.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethics approval

The protocol of this study for subject recruitment process and participation in the study adhered to the Declaration of Helsinki's guidelines and an ethical approval letter was obtained from Harar Health Science College Institutional Health Research Ethics Committee with reference No. IHREC 02/595/254/2/14.



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Consent to participate

Oral informed consent was obtained from participants before collecting data. All participants provided their consent prior to participating in the study. Participation was completely voluntary, and the participants were free to withdraw from the study at any time without any consequence. Confidentiality of all information has been maintained. This form of obtaining consent was approved by the IEC.

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Trial registration

Not applicable.

Supplemental material

Supplemental material for this article is available online.

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