Original Article

Monitoring Oxford-AstraZeneca COVID-19 vaccine Side Effects in Faridpur, Bangladesh: A Prospective Study

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Abstract:

The Oxford-AstraZeneca COVID-19 vaccine is effective in preventing illness and death from COVID-19. In this study, we aimed to evaluate the safety of the Oxford-AstraZeneca COVID-19 vaccine in a population in Faridpur, Bangladesh. The study population included individuals who received both doses of the vaccine from Bangabandhu Sheikh Mujib Medical College Hospital in Faridpur. We followed up with these individuals via phone interviews one week and one month after each vaccination to gather information about side effects. We found that the overall incidence of systemic and injection site side effects after the first and second doses was 36.5% and 34.7%, and 68.2% and 61.3%, respectively, among the 2256 studies population. The most common systemic side effects were fatigue, fever, and muscle pain, while the most common injection site symptoms were tenderness, pain, and redness. These side effects generally resolve within 24-72 hours after vaccination. Only a small percentage of individuals (1.3% after the first dose and 0.5% after the second dose) sought medical attention for their side effects. We also found that individuals with a history of chronic disease and those who had a history of COVID-19 symptoms had a significantly higher likelihood of experiencing side effects. In conclusion, the Oxford-AstraZeneca COVID-19 vaccine was generally safe in this population, with a low incidence of side effects requiring medical attention.

Key words: ICOVID-19 vaccine, Oxford-AstraZeneca, Side effects, Bangladesh.

Introduction:

COVID-19, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is a highly infectious and potentially severe respiratory illness that emerged in late 2019 and quickly spread to become a global pandemic[1-3]. The urgent need to control the spread of COVID-19 led to the rapid development and deployment of vaccines without the benefit of large-scale clinical trials, which are typically conducted before a vaccine is approved for widespread use[4-7]. As with any medication, vaccines can have side effects[8-10], and it is important to monitor and understand these side effects to ensure the continued safety and effectiveness of the vaccination programs.

Bangladesh began its COVID-19 vaccination campaign in February 2021, initially targeting healthcare workers and other high-risk groups[11,12]. As vaccine supplies have increased, the vaccination campaign expanded to include a wider range of individuals of different age groups.

The Oxford-AstraZeneca COVID-19 vaccine was developed using a chimpanzee adenovirus vector encoding the SARS-CoV-2 S protein and is effective at preventing illness and death from COVID-19[7].

Initial studies found that the Oxford-AstraZeneca

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COVID-19 vaccine had an efficacy of 62% and could be stored at 2° to 8°C for up to six months, and costs a few dollars per dose, making it suitable for use in low- and middle-income countries like Bangladesh[7, 13].

Since the initiation of the vaccination program in Bangladesh, the Oxford-AstraZeneca COVID vaccine has been a key component. Till July 2022, more than 50.8 million doses of Oxford-AstraZeneca COVID-19 vaccines have been administered among the people in Bangladesh.

Despite its widespread use, there is limited data on the safety profile of the Oxford-AstraZeneca COVID-19 vaccine in the Bangladeshi population. To address this knowledge gap, we conducted a prospective study in the Faridpur district to evaluate the safety of the vaccine in a population of approximately 2.26 million individuals. This study aimed to determine the incidences of different side effects after vaccination and to identify potential risk factors for these side effects.

Materials and methods:

This prospective observational study was conducted in Faridpur district, Bangladesh, between January 2022 to June 2022. Participants were recruited from the vaccination center at Bangabandhu Sheikh Mujib Medical College Hospital, Faridpur (BSMMCH). Eligible participants were individuals who received both 1st and 2nd doses of the Oxford-AstraZeneca COVID-19 vaccine at BSMMCH. During the initial phase of the vaccination campaign in Bangladesh, the main vaccine administered was the Oxford AstraZeneca COVID-19 vaccine.

At the time of vaccination, the contact details of the participants were recorded. Data were collected through phone interviews with study participants at one-week and one-month intervals after each vaccination dose. During these interviews, participants were asked about any side effects they experienced using a pre-structured questionnaire, as well as about any measures they took to address these side effects.

The type of side effects (e.g., fever, headache, muscle pain, etc.), timing of side effects (e.g., within first 24 hours, 1-3 days after vaccination, etc.), duration of side effects and any measures taken to address the side effect (e.g., over-the-counter medication, seeking medical attention, etc.) were recorded.

In addition, demographic variables (e.g., age, gender, underlying health conditions), and vaccination details (dose number, date of vaccination) were noted for each participant.

Data were analyzed using descriptive statistics and logistic regression analysis to determine the incidence of side effects and identify potential risk factors for these side effects. A p-value of <0.05 was considered statistically significant for all statistical tests. The study was approved by the ethical review committee of BSMMC, and all data were collected and analyzed by ethical guidelines to ensure the confidentiality and protection of study participants.

Result:

Between January 2022 to June 2022, a total of 2256 individuals who took both 1st and 2nd doses of the Oxford-AstraZeneca COVID-19 vaccine from the BSMMCH vaccination center and consented to participate in the study were included as the study population.

Table I displays the demographic and clinical characteristics of the study participants. The majority of participants were between the ages of 31-40 years (33.5%), female (58.8%), had an undergraduate education (29%), and lived in urban areas (67.5%). Only 9.4% of participants had a history of chronic diseases, with type-II diabetes mellitus and hypertensive heart disease being the most common conditions. Additionally, 7.2% of participants had a history of diagnosed COVID-19, while 18.8% had reported symptoms of COVID-19 at some point but did not seek testing to confirm the infection.

Table I: Demographic and clinical characteristics of the study population (N = 2256)

Characteristics	Number (%)
Age (Yrs)	
18-30	288 (12.8)
31-40	756 (33.5)
41-50	612 (27.1)
51-60	389 (17.2)
>60	211 (9.4)
Sex	
Female	1327 (58.8)
Male	929 (41.2)
Educational level	
Higher secondary certificate and below	598 (26.5)
Undergraduate	655 (29.0)
Graduate	548 (24.3)
Postgraduate	348 (15.4)
No formal education	107 (4.7)

Residence	
Urban	1523 (67.5)
Rural	447 (19.8)
Semi-urban	286 (12.7)
History of chronic diseases	
Any	212 (9.4)
Asthma	58 (2.6)
Hypertensive heart disease	68 (3.0)
Type II diabetes mellitus	74 (3.3)
Others	43 (1.9)
History of diagnosed COVID-19	**163 (7.2)**
Ever had symptoms of COVID-19	**423 (18.8)**

Table II displays the incidence of systemic side effects, injection site symptoms, the timing of symptom development, duration of injection site symptoms, and measures taken for side effects after both doses of the Oxford-AstraZeneca COVID-19 vaccine. The results show that 36.5% of the study population experienced systemic side effects after the first dose, while 34.7% experienced such side effects after the second dose. Regarding injection site symptoms, 68.2% of the population experienced these symptoms after the first dose, while 61.3% experienced them after the second dose. This difference was statistically significant ($p < 0.01$).

Most injection site symptoms developed within 6 hours after vaccination, with 37.7% and 45.1% of individuals experiencing such symptoms after the first and second doses, respectively. The development of symptoms within 12-24 hours and after 24 hours decreased significantly after the second dose. The majority of symptoms after the first dose lasted between 24-72 hours (64%), while the majority of symptoms after the second dose lasted less than 24 hours (61.2%). In a few cases, symptoms lasted more than 72 hours. Only 0.5% of the population after the first dose and 0.3% after the second dose experienced allergic reactions. To address these symptoms, 15.3% of individuals after the first dose and 16.9% after the second dose took over-the-counter drugs, while only two individuals after the first dose and none after the second dose required hospitalization. The most common drugs used were paracetamol and painkillers.

Table-II: Incidence, time, duration, and measures taken for side effects in both 1st and 2nd doses

Characteristics	Number	Percentage	Number	Percentage	p-value
	1st dose		2nd dose		
Systemic side effects	823	36.5%	782	34.7%	0.202
Injection site symptoms	1538	68.2%	1382	61.3%	<0.01
Time to develop injection site symptoms	n = 1538		n = 1382		
Within 6 hours	580	37.7%	623	45.1%	0.148
6 - 12 hours	543	35.3%	588	42.5%	0.122
12 - 24 hours	321	20.9%	122	8.8%	<0.01
After 24 hours	94	6.1%	49	3.5%	<0.01
Duration of injection site symptoms	n = 1538		n = 1382		
<24 hours	482	31.3%	942	61.2%	<0.01
24 - 72 hours	985	64.0%	402	26.1%	<0.01
>72 hours - 7 days	52	3.4%	31	2.0%	0.02
>7 days	19	1.2%	7	0.5%	0.018
Allergic reaction	11	0.5%	6	0.3%	
Measures taken for side-effects					
Took medication to mitigate side effects	345	15.3%	382	16.9%	
Visited a physician due to side effects	29	1.3%	12	0.5%	
Hospitalized due to side effect	2	0.1%	0	0.0%	
Types of medicines					
Antipyretic (Paraetamol)	283	82.0%	302	79.1%	
Pain killer	58	16.8%	45	11.8%	
Antihistamine	38	11.0%	20	5.2%	
ORS	43	12.5%	12	3.1%	
Others	123	35.7%	66	17.3%	

Figure 1 shows the most common systemic side effects and injection site symptoms after both doses of the Oxford-AstraZeneca COVID-19 vaccine. The most commonly reported systemic side effects were fatigue, fever, and generalized muscle pain, while the most common injection site symptoms were tenderness, pain, redness, and warmth. The data indicate that both systemic side effects and injection site symptoms were less common after the second dose of the vaccine compared to the first dose.

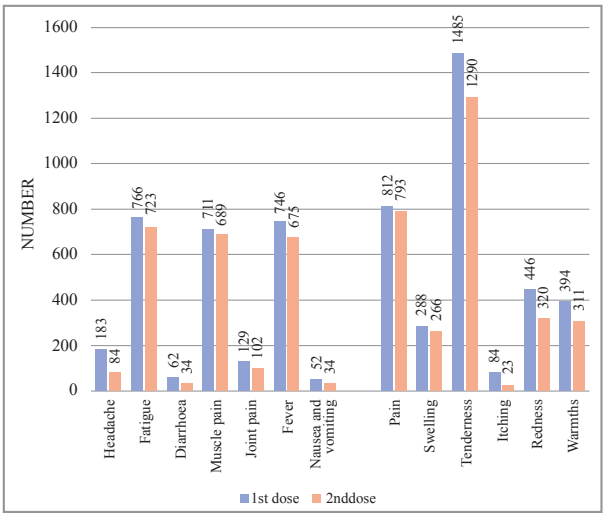

Figure 1: Bar chart showing the population experienced systemic side effects and injection site symptoms after 1st and 2nd doses of vaccination.

Table III presents the results of a binary logistic regression analysis examining the relationship between various factors and the development of side effects after either the first or second dose of the Oxford- AstraZeneca COVID-19 vaccine. The results show that individuals with a history of chronic disease or a history of COVID-19 symptoms had higher odds of experiencing side effects compared to those without these risk factors.

Table III: Risk factors of side effects after first or second doses of the Oxford-AstraZeneca COVID-19 vaccine among the population.

Factors	Response	Adjusted OR	CI	p-value
History of chronic disease	Yes No	1.42	1.07-1.87	0.01
Diagnosed with COVID-19	Yes No	0.78	0.56-1.07	0.12
Ever had symptoms of COVID-19	Yes No	0.77	1.09 - 1.68	<0.01
Age	<30 >30	0.90	0.75 - 1.07	0.23
Sex	Male Female	1.10	0.93 - 1.30	0.25

Discussion:

This prospective study aimed to evaluate the safety of the Oxford-AstraZeneca COVID-19 vaccine in a population in Faridpur District, Bangladesh. The results of the study showed that the overall incidence of systemic side effects after the first and second doses of the vaccine were 36.5% and 34.7%, respectively. The most common systemic side effects were fatigue, fever, and generalized muscle pain. The overall incidence of injection site symptoms after the first and second doses of the vaccine were 68.2% and 61.3%, respectively, with the most common injection site symptoms being tenderness and pain. Our results are consistent with previous studies that have found similar sets of side effects, including a study among the Bangladeshi population by Parvej et al.[14], another study of healthcare workers in Ethiopia by Yesuf et al.[15], and a study by Vallée et al[16]. However, our results differ from another study of Ethiopian healthcare workers by Solomon et al.[17], which found a higher incidence of injection site symptoms (75.8%) compared to our study.

Binary logistic regression analysis showed that individuals with a history of chronic disease or a history of COVID-19 symptoms had higher odds of experiencing side effects compared to those without these risk factors. These findings are consistent with a study by Tissot et al.[18], which found that vaccine recipients with prior COVID-19 reported more side effects than others. We did not find any significant difference in the development of side effects between male and female recipients. However, a similar study in Bangladesh by Jahan et al.[19] found a significantly higher percentage of female participants suffering from post-vaccination side effects than males.

The majority of injection site symptoms in our study developed within 6 hours after vaccination. The development of symptoms after 12 hours decreased significantly after the second dose. In a few cases, symptoms lasted more than 72 hours. To address these symptoms, 15.3% of individuals after the first dose and 16.9% after the second dose took over-the-counter medications, while only two individuals after the first dose and none after the second dose required hospitalization.

Overall, our results suggest that the Oxford-AstraZeneca COVID-19 vaccine is generally safe in the population studied, with a low incidence of side effects and a high proportion of injection site symptoms. These findings are consistent with the overall safety profile of COVID-19 vaccines, which are highly effective at

preventing illness and death from COVID-19 and have a favorable safety profile in clinical trials and real-world use[20]. Our study adds to the growing body of evidence on the safety of COVID-19 vaccines and highlights the importance of ongoing surveillance to monitor the safety profile of vaccines in real-world use. These findings can contribute to the understanding of the safety profile of COVID-19 vaccines in the Bangladeshi population. Further research is needed to assess the long-term safety of COVID-19 vaccines and to examine the safety profile of the Oxford-AstraZeneca COVID-19 vaccine in different populations.

Conclusion:

In conclusion, our study found that the Oxford-AstraZeneca COVID-19 vaccine was generally safe in the population studied, with a low incidence of side effects requiring medical attention. However, individuals who have pre-existing comorbidities or a history of COVID-19 symptoms may be at higher risk for experiencing side effects, and it is important to advise these individuals about potential vaccine symptoms and how to manage them. Our study also highlights the importance of monitoring recipients for at least the first 24 hours following vaccination, as the majority of symptoms were observed within this period. Overall, our findings contribute to the growing body of evidence on the safety of COVID-19 vaccines and highlight the importance of ongoing surveillance to monitor the safety of vaccines in real-world use. The study relied on self-reported data, which may be subject to reporting biases. Participants may have under reported or over reported side effects or may have had difficulty accurately recalling or reporting side effects that occurred sometime after vaccination. Additionally, the study only assessed the incidence of side effects within a relatively short timeframe after vaccination (e.g. 7 days and 1 month). It is possible that some side effects may have occurred outside of this timeframe or may have persisted for a longer period. Another limitation of the study is that our study population may not be representative of the general population in Bangladesh, as it was limited to individuals who received the Oxford-AstraZeneca vaccine at the BSMMCH vaccination center. Therefore, further research is needed to assess the safety of the Oxford-AstraZeneca COVID-19 vaccine and also the other vaccines against COVID-19 in other populations and settings.

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