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Side-Effects of Oxford-Astra Zeneca (Covishield) Vaccine Reported by Medical Doctors in Bangladesh

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Abstract

Objective: The aim of this study was to determine self-reported side effects (local and systemic) after 1st dose of ChAdOx1-S recombinant COVID-19 (Covishield) vaccine among medical doctors in Bangladesh.

Materials and Methods : A cross sectional online survey was conducted among medical doctors who received 1st dose of ChAdOx1-S recombinant COVID-19 vaccine and willingly volunteered to take part were included in the study using non probability sampling. Responses were received using semi structured questionnaire through Google form link. Logistic regression analysis was done to investigate the association between different parameters in the development of side effects of the vaccine.

Result: During March-April 2021, 1265 Bangladeshi doctors who have received one dose of the vaccine participated in the survey. More than 95% (1203) of participants experienced some side effects after vaccination. Over 80% (1077) of participants experienced pain and 12.8% reported swelling at injection site. Above half of the participants experienced malaise, fever, and headache. However, most of the symptoms were mild to moderate in intensity. Adjusted multivariable logistic regression analysis showed that the risk of developing side effects after vaccination was associated with respondents increasing age (OR: 1.1; CI: 1.0-1.1; p = 0.001) and gender (OR for female: 2.2; CI: 1.2-4.0; p = 0.013).

Conclusions: Our findings suggest that the Oxford AstraZeneca vaccine was well tolerated by Bangladeshi doctors, which may encourage doctors to promote the vaccine to their patients and increase COVID-19 vaccine uptake in the general population.

Keywords: Side effects, COVID-19, Doctors, AstraZeneca vaccine

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection , mostly known as COVID-19, has evolved as a global health threat [1]. According to the World Health Organization's (WHO) data from 29 December 2021, there were 281,808,270 confirmed cases of COVID-19 worldwide, with 5,411,759 deaths, including 1,584,518 confirmed cases and 28,063 deaths in Bangladesh [2].

Apart from the primary preventative measures including maintaining a physical distance (1 meter), covering cough or sneeze, proper hand sanitizing, wearing face masks, a safe and efficient vaccine is one of the most important public health interventions to prevent severe illness or death due to

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COVID-19 [3–5]**.** The world is in a race to manufacture and deliver safe and effective vaccines. In 2020, some vaccines against SARS-CoV-2, which were in clinical trials, exhibited more than 90% efficacy [6]. By June 3 2021, several vaccines including AstraZeneca/Oxford vaccine (ChAdOx1 nCoV-19 [AZD1222]), Johnson and Johnson, Moderna, Pfizer/ BioNTech, Sinopharm, Sinovac were considered to meet safety and effectiveness standards of WHO's [5].

ChAdOx1-S recombinant vaccine was developed by AstraZeneca and Oxford University by integrating the spike gene from SARS-CoV-2 into non-pathogenic adenovirus [7]. The ChAdOx1-S vaccine manufactured by the Serum Institute of India is known as Covishield [8]. The phase 2/3 trials of the Oxford-AstraZeneca vaccine for determining the safety and efficacy, was done in the UK, Brazil, India and South Africa [9,10] and demonstrated 76% efficacy against symptomatic disease at 22–90 days after at least one standard dose [10,11]. Although vaccine is thought to be safe, their side effects aren't entirely understood. Given the importance of the vaccine in tackling this public health problem, knowing its side effects is vital [4].

After receiving the first dosage of the AstraZeneca vaccine, various symptoms such as pain, fever, chills, muscle pain, headache, diarrhea, vomiting, tiredness, palpitation, hypotension, and others have been reported in several cases [12–14].

AstraZeneca vaccine was authorized by Directorate General of drug administration of Bangladesh to be used from January 2021. It was the only vaccine available for administration in Bangladesh at that time. Soon after authorization, Bangladesh undertook a nationwide vaccination program against COVID-19. Like other vaccine against infectious disease COVID-19 vaccine was prioritized for healthcare workers not only for self-protection but also for preventing transmission of the infection to high-risk patients [15–17].

Fear over perceived safety of COVID-19 vaccine can negatively impact vaccine uptake among general population [18] and health professionals [19]. Additionally, doctors play an important role in promoting vaccines among general population [18]. If a vaccine is well tolerated among doctors, it is likely that doctors will have confidence in recommending the vaccine to their patients and the general population. Thus, we conducted this study with the aim to understand the real-world experience of the doctors in Bangladesh with side effects associated with COVID-19 Vaccine.

Materials and Methods

A web based cross-sectional study was performed, in 2021, on medical doctors who received the 1st dose of the available COVID-19 vaccine (Oxford-AstraZeneca (Covishield) vaccine). Responses were collected via a web-based platform (Google form) due to countrywide lockdown in Bangladesh.

Recruitment of the participants

Non-probability sampling technique was used, and participants who volunteered willingly to respond were included in the study. The participants were provided with a semi-structured questionnaire in a Google form link. Participants were recruited to the study through multiple approaches. The questionnaire link was sent to doctors through personal emails where available. Email addresses were retrieved from record book of Centre for medical research and development, an aid for post-graduation medical research. We also uploaded the link for the survey specific group for medical doctors in Bangladesh on social media platform including Facebook. In addition, link of the questionnaire was sent through WhatsApp, where phone numbers were available. Moreover, personal communication channel was also used by the research personnel to encourage doctors within their networks to participate in the study. The Google link for the survey was accessible for two months (March and April 2021).

Data collection form/ Questionnaire

The survey included 20 questions. The first section of the questionnaire included demographic information and comorbidity status. The second section primarily focused on vaccine-related data, such as side effects experienced following the vaccination as well as duration. Participants were permitted to leave the box unchecked if they had no side effects.

Participants were asked to report vaccine side effects, with response options including fever, chills, fatigue, sore/scratchy throat, nausea, vomiting, diarrhea, altered consciousness, blood pressure change, muscle pain, joint pain, headache, other pain, redness/swelling at the injection site, rash in or other than at the injection site, allergic reaction/ anaphylaxis, other, and none of the above. Participants might respond in free-text to the “other” option.

Consent

Information about the study including nature, purpose and duration of the study were displayed on the front page of the online survey. Informed consent of the participants was taken with the questionnaire link.

Data analysis

Demographic characteristics (age, sex), comorbidities (diabetes, hypertension, asthma, body mass index) and risk behaviors (smoking) were presented in frequency and percentage. Pain and swelling at the injection were considered as local side effects and rest were considered as

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systematic side effects. Later, the systematic side effects were organized under different organ system. The association of these variables on the likelihood of participants experiencing side effects was assessed using binary logistic regression. Those who reported at least one side effect, whether it was local or systemic, were included in the regression analysis. A statistically significant result was defined with a p-value of less than 0.05. Data analysis was conducted with SPSS version 22.0.

Results

A total of 1327 doctors completed the questionnaire; 52 questionnaires were partially completed and excluded from analysis. The proportion of males (53.1%) and females (46.9%) in the survey was almost similar. Among the study participants, 19.5% were aged 18–25 years, 68.5% were 26–35 years, 7.6% were between 36–45 years, and the rest were ≥ 46 years.

Table 1, displays that 74 (5.8%) of the participants were diabetic, 106 (8.4%) were hypertensive, 197 (15.6%) had asthma, 129 (10.2%) were smokers, and only 4 (0.3%) had cancer.

A total of 1203 (95.1%) participants experienced side effects following 1st dose of the Oxford-AstraZeneca (Covishield) vaccine. Local side effects were reported by 1077 (85.1%) of participants, whereas systematic side effects were experienced by 1054 (83.3%) of participants 67.2% participants experienced more than two side effects. Table 2 presents the vaccination-related side effects, where pain in the injection site was the predominant side effect followed by malaise and fever.

Discussion

In our study, almost all doctors (95%) who received a dose of the COVOD-19 vaccine reported some side effects which was comparable to finding from other study where more than 93% of health professionals experienced side effects after receiving the AstraZeneca vaccine [12]. Reassuringly about 85% of participants in our study experienced local side effects. However, Kim et al. (2021) reported a lower proportion of local side effects, after 1st dose of AstraZeneca vaccines vaccine, which ranged between 71.2%. Additionally, it was claimed that 89.4% of the study participants had suffered systemic side effects after receiving the first dose of AstraZeneca vaccines [20].

In present study, female doctors were more likely to experience side effects compared to males. Moreover, following the first dose of the vaccine, its recipients experienced pain and swelling in the injection site, fever, headache, nausea, malaise, and respiratory distress, as the most common side effects with mild to moderate intensity. In two studies in South Korea, the most prevalent symptoms following the administration of the first dose of the AstraZeneca vaccine were fatigue, muscle pain, , fever, chills and headache [12,14]. In addition, fever, headache, injection site pain, chills, and muscular pains were the most notable side effects documented by the Philippine National Adverse Effects Following Immunization Committee (NAEFIC) due to vaccination by AstraZeneca [13].

Local pain (76%), fatigue (76%), headache (65%), general myalgia (53%), chills (35%), arthralgia (33%), and nausea (26 %) were common side effects, found in a phase 2/3 trial of the AstraZeneca vaccination undertaken in the United Kingdom [11]. Whereas, in the present study, pain at the injection site (84.7%), fatigue (7.1%), headache (50.1%), myalgia (2.2%), and nausea (12.3%) were the major side effects reported by the participants. Besides, Ramasamy et al. (2020) found 42.9% of 18–55 years old participants complained fever after administration of the first dose of the Oxford-AstraZeneca vaccine, with 24.5% having documented fever (≥38.0°C) [11]. In this study, 52.6% of study participants had fever, which was greater than Ramasamy et al. (2020), approximately similar (56.8%) to the findings of Kim et al. (2021), but considerably lower than the proportion (98.7%) reported by Song et al. (2021) [11,14,20]. Nevertheless, the fever subsided within two days of vaccination. Half of the participants in this study had headache which was lower than reported from other studies (65%, 55% and 72% patients felt headache in Ramasamy et al., (2020), Kim et al. (2021) and Song et al. (2021) respectively [11,14,20]. Dyspnea/ respiratory discomfort was reported by 10.7% of this study, while only 1.9% was reported in the study of Kim et al. (2021) [20].

The study's primary weakness is that it analyzed only adverse events following the first dose of vaccination. Besides, it was a self-reported online survey where the

Table 1: Comorbidity status and risk behavior of the surveyed medical doctors

Comorbidity		Frequency (percentage)
Diabetes		74 (5.8)
Hypertension		106 (8.4)
Asthma		197 (15.6)
Cancer		4 (0.3)
Smoker		129 (10.2)
Body mass index	Underweight (<18.5 kg/m^2)	32 (2.5)
	Normal (18.5 – 24.9 kg/m^2)	552 (43.6)
	Overweight (25.0 – 29.9 kg/m^2)	534 (42.2)
	Obese (≥30.0 kg/m^2)	147 (11.6)

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Table 2: Side effects of Oxford AstraZeneca (Covishield) vaccine (1st dose) experienced by participants categorized as organ systems (Symptoms were measured in percentage with all the participants)

Symptoms after the first dose of AstraZeneca vaccine	Number of doctors reporting symptom (n)		Total (%) N=1265
	Male (n1=672)	Female (n_2=593)	
Local side effects			**1077 (85.1)**
1. Pain in the injected site	552 (82.1)	520 (87.7)	1072 (84.7)
2. Swelling in the injected site	63 (9.4)	99 (16.7)	162 (12.8)
Systematic side effects			**1054 (83.3)**
Generalized side effects			
3. Fever	331 (49.3)	335 (56.5)	666 (52.6)
4. Headache	303 (45.1)	331 (55.8)	634 (50.1)
5. Vertigo	97 (14.4)	150 (25.3)	247 (19.5)
6. Malaise	447 (66.5)	422 (71.2)	869 (68.7)
7. Weakness/fatigue	38 (5.7)	52 (8.8)	90 (7.1)
Gastrointestinal side effects			
8. Nausea	38 (5.7)	118 (19.9)	156 (12.3)
9. Anorexia	1 (0.1)	6 (1.0)	07 (0.6)
10. Losing taste sensation	21 (3.1)	49 (8.3)	70 (5.5)
11. Diarrhea	31(4.6)	27 (4.6)	58 (4.6)
12. Vomiting	5 (0.4)	10 (1.7)	15 (1.2)
Head/ Ear/ Nose side effects			
13. Runny nose	46 (6.8)	55 (9.3)	108 (8.0)
14. Tinnitus	12 (1.8)	25 (4.2)	37 (2.9)
15. Losing smell sensation	8 (1.2)	20 (3.4)	28 (2.2)
Respiratory side effects			
16. Cough	28 (4.2)	44 (7.4)	72 (5.7)
17. Respiratory distress	62 (9.2)	73 (12.3)	135 (10.7)
18. Chest tightness	2 (0.3)	3 (0.5)	05 (0.4)
Skin manifestation			
19. Skin rash	4 (0.6)	20 (3.4)	24 (1.9)
Musculoskeletal side effects			
20. Myalgia	14 (2.1)	14(2.4)	28 (2.2)
21. Body ache	28 (4.2)	35(5.9)	63 (5.0)
Cardiovascular side effects			
22. Palpitation	3(0.4)	13 (2.2)	16 (1.3)
23. Hypotension	1(0.1)	4 (0.7)	05 (0.4)
Neurological/psychological side effects			
24. Increased sleep	7 (1.0)	6 (1.0)	13 (1.0)
25. Insomnia	3(0.4)	3 (0.5)	06 (0.5)

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Table 3: Effect of different parameters in the development of side effect of vaccine determined by logistic regression

Variable	Odds ratio (95% Confidence interval)	p-value
Age	1.1 (1.0-1.1)	0.001
Female Sex	2.2 (1.2-4.0)	0.013
Diabetes	1.1 (0.4-2.8)	0.814
Hypertension	1.3 (0.5-3.0)	0.585
Asthma	0.8 (0.3-1.6)	0.47
Smoking	0.7 (0.3-1.7)	0.483
Body mass index	1.0 (0.9-1.1)	0.754

researcher had no way to verify the side effects. Moreover, there could be a possibility of overestimation, since the study was conducted only among medical doctors, which also limit generalizability. Some side effects might be misreported, which could have been caused, imitated, or contributed by other chronic illnesses. Longitudinal surveys should be put in place to investigate long term vaccination side effects.

Conclusion

Medical doctors are generally more aware and knowledgeable about vaccine related side effects compared to general population. This study conducted among thousands of doctors who received Oxford-AstraZeneca (Covisheild) vaccine suggests that even if the vaccine was associated with mild and local side effects, it was generally well-tolerated and safe. The most notable side effects were pain and swelling at the injection site, fever, headache, nausea, loss of taste sensation, cough, and respiratory distress. Though female doctors experienced more side effects than males following vaccination, most of the side effects were mild to moderate in their intensity, well tolerable, and subsided within few days. The findings of the study can help motivate health professionals to receive the COVID-19 vaccine and promote the vaccine to their patients and general population.

Declarations

Authors' Contribution

MZA, MTKT, AHMGK and MNS**,** NM were responsible for Concept development, designing the study and drafting the manuscript. AHMGK, MTKT, MZA, SKM, MNS, MMR, MSS, ASMTI, MAI were responsible for implementation of the study or data collection. MTKT, AHMGK, MZA, SKM, FFA, and SNA were responsible for data management and data analysis.

Competing interests

All the authors declared that they have no conflicts of interest.

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Ethics approval and consent to participate

This study was carried out in accordance with the Helsinki Declaration and all procedures involving research study participants. During the data collection, all respondents provided informed consent.

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