Side effects of AZD 1222 COVISHIELD vaccine among front-line health care workers in a tertiary care hospital: A descriptive cross-sectional study

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ABSTRACT

Introduction: Coronavirus disease vaccination has been accepted as a global health measure to prevent severity, transmission and mortality. Vaccine frequently cause adverse effects which is supposed to be due to protective immune response induced by the vaccine. The study aimed to find out the prevalence of side effects of first dose of AZD 1222 COVISHIELD vaccine among front line health care workers receiving vaccination in a tertiary care hospital. **Methods:** This was a descriptive cross-sectional study among front line health workers who received the first dose of COVISHIELD vaccine. The study was conducted from February 2021 to March 2021 in a tertiary care hospital after receiving ethical approval from the Institutional Review Committee. Convenience sampling was used for data collection and data was analyzed using SPSS version 17 was used for analysis. Point estimate at 95% confidence interval was calculated along with frequency and proportion for binary data. **Results:** Among 629 participants, 344(54.7%) participants reported one or other side effects following vaccination. The major side effects reported were fever 152(19.6%), myalgia 144(22.9%), pain at injection site 123(19.6%), headache 75(11.9%) and in one reactivation of Herpes Zoster. **Conclusions:** After the first dose of COVISHIELD vaccine, mild symptoms were seen which resolved within few days. Some cases of reactivation of Herpes Zoster was found. The adverse effects were seen more in patients who had history of COVID-19 infection.

Keywords: COVID-19, COVISHIELD, vaccination, Nepal.

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INTRODUCTION

The health system, economy, and lifestyle were affected globally by coronavirus disease with more than 168 million infections and three-million mortalities as reported to WHO till last week of May 2021.[1] The burden of the disease was expected to decrease with development of herd immunity through acquiring natural immunity via infections or vaccines.[2] The death toll will be overwhelming if we expect natural herd immunity.[2,3]

The development of vaccines have opened possibility of herd immunity.[4] The Oxford-AstraZeneca's COVID-19 vaccine AZD 1222 was developed in Serum Institute of India as COVISHIELD vaccine,[5] which was vectored with adenovirus.[5,6] The average efficacy of the vaccine was 70.4%,[7] and was safe.[8] This vaccine is logistically feasible for distribution as it can be stored in 2 to 8^{0}C. The vaccine was made available on January 27, 2021 by the Nepal Government for front line health worker.[9]

The study aimed to find out the prevalence of side effects of first dose of AZD 1222 COVISHIELD vaccine among front line health care workers receiving vaccination in a tertiary care hospital.

METHODS

This was a descriptive cross-sectional study among front line health workers who received the first dose of COVISHIELD vaccine. The study was conducted from February 2021 to March 2021 in a tertiary care hospital after receiving ethical approval from the Institutional Review Committee (IRC number 0102202101). Convenience sampling was used for data collection. Frontline health care workers were enrolled into the study after taking written informed consent. The patients younger than 18 years old, breast-feeding women, pregnancy, one with previous history for anaphylaxis, COVID-19 infection within one month and having fever were excluded from the study. By taking 95% confidence interval, prevalence taken as 50% for maximum sample size by taking 4% margin of error. Sample size was calculated by using following formula $(1.96)^2$ x 0.5 x 0.5 / $(0.04)^2$= 600. However, we took sample size of 629. Sample size was calculated using formula, n= Z^2 x p x q / e^2= $(1.96)^2$ x 0.5 x 0.5 / $(0.04)^2$= 600. The COVISHIELD vaccine was administered in the deltoid muscle. After vaccination, they were asked to stay in the hospital observation room for at least half an hour. During the stay, they were asked regarding the adverse spectrums of the vaccine. After 24 hours and on seven days, questions regarding adverse effect and measures taken to get relieved from it were asked via telephonic conversation. The data were collected in semi-structured questionnaire format regarding demographics, adverse spectrum like fever, myalgia, pain at the injection site, headache, dizziness, chills and rigors, fatigue, tingling sensation, rashes and medical history of diabetes, hypertension, hypothyroidism, arthritis, chronic obstructive pulmonary disease and asthma. The data collected were entered in Microsoft Excel and were analyzed in the Statistical Package of the Social Sciences (SPSS) version 17.0. Demographic data and clinical variables were analyzed by descriptive analysis. The results were expressed as mean ± standard deviation for quantitative variables and percentage for qualitative data. The chi-square test was used to measure the association of side effects reported with different independent variables.

RESULTS

Among 629 health-workers, 344(54.7%) participants reported one or the other side effects following the vaccination with the first dose of AZD 1222 COVISHIELD vaccine (Figure 1).

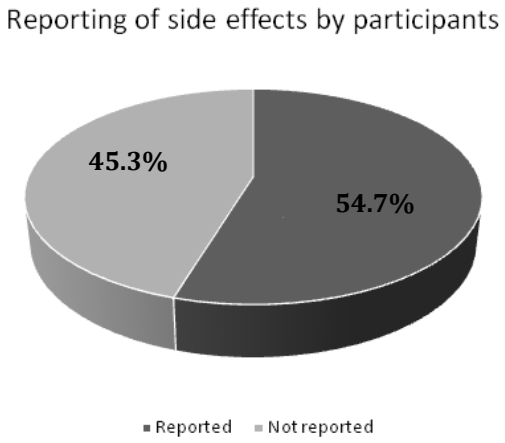

Figure 1: Pie-chart showing percentage of participants who reported side effects following immunization

The major side effects reported were fever 152(24.3%), myalgia 144(22.9%), pain at the injection site 123(19.6%) and headache 75(11.9%) (Table 1).

Table 1: Major side effects of the COVID-19 vaccine reported (N=629)

Side effects	Frequency n(%)
Fever	152(24.3%)
Myalgia	144(22.9%)
Pain at the injection site	123(19.6%)
Headache	75(11.9%)
Dizziness	69(11.0%)
Chills and Rigors	56(8.9%)
Fatigue	13(2.1%)
Tingling sensation	4(0.6%)
Rashes	4(0.6%)
Others	56(8.9%)

*Multiple responses

Participants reported arthralgia, nausea, vomiting, cough, diarrhea, flushing, chest pain, ocular pain. Reactivation of herpes zoster was seen in one patient. One female respondent came to medicine outpatient department with pain and tenderness at the vaccine injection site with difficulty to move the upper limb and to make fist which resolved with analgesics. The mean age of the participants was 36.6±11.8 years. Among the total participants, 356(56.6%) were female. There was history of hypertension in 41(6.5%) participants and diabetes mellitus in 16(2.5%) participants. There was prior COVID-19 infection in 87(13.8%) participants (Table 2).

Table 2: Socio-demographic profile of study participants (N=629)

Socio-demographic determinants	Frequency n(%)
Gender	
Male	273(43.4%)
Female	356(56.6%)
Age (years)	
<20	10(1.6%)
20-29	189(30.0%)
30-39	222(35.3%)
40-49	50(20.0%)
50-59	21(7.9%)
≥60	32(5.0%)
Ethnicity	
Brahmin	232(36.9%)
Chhetri	135(21.5%)
Newar	137(21.8%)
Others	125(19.9%)
Body Mass Index (kg/m²)	
<18.5	34(5.4%)
18.5-24.9	325(51.7%)
25.0-29.9	228(36.2%)
30.0-34.9	36(5.7%)
35.0-39.9	3(0.5%)
≥40	3(0.5%)
Co-morbidities*	
Hypertension	41(6.5%)
Diabetes Mellitus	16(2.5%)
Hypothyroidism	17(2.7%)
Arthritis	5(0.8%)
COPD/Asthma#	3(0.5%)
Others	10(1.6%)
Previous COVID-19 Infection	
Yes	87(13.8%)
No	542(86.2%)

*Multiple responses; COPD: Chronic Obstructive Pulmonary Disease

A total of 202(56.7%) female one of the other side effects. About two-third of the participants 64% of the age group 20 to 29 years experienced side effects, however only 37% of the population of age group 60 years or above experienced side effects. Age was found to be statistically significant with the reporting of side-effects (p-value= 0.017). Almost three-fourth of the participants with prior history of the COVID-19 infection had side effects following vaccination (p-value<0.001). Similarly, 29(20.7%) hypertensive participants had reported side effects (p-value=0.03). (Table 3)

Table 3: Relation between reported side effects and socio-demographic variables (N=629)

Variables	Side effects reported n (%)	Side effect not reported n (%)	p-value*
Gender			
Male	142(52.0%)	131(48.0%)	0.238
Female	202(56.7%)	154(43.3%)	
Age (years)			
<20	6(60.0%)	4(40.0%)	
20-29	121(64.0%)	68(36.0%)	
30-39	119(53.6%)	103(46.6%)	0.017*
40-49	59(46.8%)	47(53.2%)	
50-59	27(54.0%)	23(46.0%)	
≥60	12(37.0%)	20(62.5%)	
Body Mass Index (kg/m²)			
<18.5	16(47.1%)	18(52.9%)	
18.5-24.9	179(55.1%)	146(44.9%)	
25.0-29.9	123(53.9%)	105(46.1%)	0.541
30.0-34.9	24(66.7%)	12(33.3%)	
35.0-39.9	1(33.3%)	2(66.7%)	
≥40.0	1(33.3%)	2(66.7%)	
Previous COVID-19 infection			
Yes	64(73.6%)	23(26.4%)	<0.001*
No	280(51.7%)	262(48.3%)	
Co-Morbidities Hypertension			
Yes	29(70.7%)	12(29.3%)	0.03*
No	315(53.6%)	272(46.4%)	
Diabetes Mellitus			
Yes	11(68.8%)	5(31.3%)	0.252
No	333(54.3%)	280(45.7%)	

Chi-square test; *p<0.05 signifies statistical significance

DISCUSSION

The present study has explored the adverse effect following immunization among the health care workers following the first dose of COVISHIELD vaccination in the middle of the pandemic in the context of Nepal. The commonly reported adverse effects following immunization with COVISHIELD vaccination were fever, myalgia, pain at the injection site, headache, dizziness, chills and rigors. There were no serious adverse effects requiring hospital admission. Anaphylaxis and deaths were not observed. In the study, the mean age of the participant was 36.6±11.8 years. A total of 344(54.7%) participants reported one or the other side effects

following the vaccination with the COVISHIELD vaccine. However, in a survey conducted in India among 5396 people, 66% had reported at least one adverse effect after vaccination.[10] The major side effects reported were fever (19.6%), myalgia (22.9%), pain at the injection site (19.6%), headache (11.9%), fatigue (2.1%), tingling sensation (0.6%) and rashes (0.6%). The adverse effects like fever and chills, rigors were seen within 12 to 24 hours. The adverse effects like body ache used to subside in three days. Compared to our study, a higher incidence of adverse effects was reported in other study.[11] The difference in occurrence of adverse effects might be due to ethnic differences. Reactivation of herpes zoster was seen in one patient. A total of 202(56.7%) females had one or the other side effects. The participants with age group 60 years or above experienced fewer side effects as compared to young participant in the study. Age was found to be statistically significant with the reporting of side effects (p-value=0.017). In another study conducted in the Republic of Korea, systemic and local adverse effects were seen more frequently below 35 years of age than among above 50 years of age, which has similar trend as compared to our study.[12] The adverse effect following immunization was seen in 70.7% of the participant with prior history of COVID-19 which was statistically significant (p-value<0.001). Our findings was similar to the ZOE COVID symptoms study which found that people with a previous COVID-19 infection experience adverse effects twice likely than to those without past COVID-19 infection from a Pfizer/BioNTech vaccine dose.[13] In another study, a significantly higher incidence of adverse effects were observed among prior COVID-19 infection following SARS COV-2 mRNA vaccination.[14] The higher adverse effects reported in hypertensive patient was statistically significant (p-value=0.03).

CONCLUSIONS

More than half of the front-line workers experienced one or more side effects after first dose of AZD 1222 COVISHIELD vaccine. The most common adverse effect following immunization were fever, myalgia, pain at the injection site, headache, dizziness, chills and rigors which resolved in few days. Reactivation of Herpes Zoster was seen in a participant which resolved in one week. The adverse effects were more common in elderly and in patients who have prior COVID-19 infection. The COVISHIELD vaccine is found to be safe for vaccination against COVID-19 infection in context of Nepal.

CONFLICTS OF INTEREST: None declared

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