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Adverse events following immunization after COVISHIELD vaccination among Nepali population of eastern Nepal

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Abstract

Introduction: Vaccines require continuous monitoring to increase their compliance, quality, and safety. We conducted this study to fulfill the research gap for the adverse events following immunization (AEFIs) after COVISHIELD (ChAdOx1nCoV-19) vaccination among Nepali of eastern Nepal.

Method: A cross-sectional study was conducted from 25 Jan 2021 to Jul 2021 at Birat Medical College Teaching Hospital of Morang, Nepal. The data on COVISHIELD vaccine recipients at this center were analyzed for AEFI. Ethical clearance was obtained.

Result: Out of 167 vaccine recipients, the mean age was 28.08±7.35 y. The AEFI occurred in 122(73.1%) and 89(72.9%) who developed symptoms on the same day of vaccination. The AEFI symptoms were less common in males (OR 0.43; CI (0.19-0.96; P 0.03). In both sexes, the AEFI symptoms were reported on the same day of vaccination than the next day but it had no significant association.

Conclusion: The AEFI following COVISHIELD vaccination was reported by 2/3rd recipients mostly on the same day of the vaccine and less common in males.

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

Introduction

The novel Corona Virus disease 2019 (COVID-19) pandemic has affected all the countries in the world.¹ The post-authorization safety profile, adverse events following immunization (AEFIs), and adverse events of special interest (AESIs) are important for surveillance, and response of vaccines.^{2,3} The AEFI after COVISHIELD vaccination was reported during its vaccine trial.⁴ Study found AEFI symptoms reported were related to vaccine reactogenicity which is mediated by pyrogenic cytokines such as interleukin-1 (IL-1), IL-6, prostaglandin-E2, and tumor necrosis factor-alpha (TNF- α), which is released due to activation of immune response after vaccination.⁵

Even after approval and licensing of vaccine after phase V, the regulatory authorities continuously monitor the potency, safety, and purity of the vaccine through the vaccine adverse event reporting system (VAERS).^{6,7} Nepal government has already started vaccination of high-risk population with COVISHIELD (ChAdOx1nCoV-19) vaccine manufactured in India.^{4,8}

We did this study to assess the adverse event following COVID-19 vaccination among the Nepali population of eastern Nepal.

Method

A cross-sectional study was conducted from 25 Jan 2021 to 25 Jul 2021 at Birat Medical College Teaching Hospital of Morang, Nepal. We enrolled 167 COVISHIELD vaccine recipients at our center through the census enumeration technique. Ethical clearance was obtained from the institutional review committee of Birat Medical College Teaching Hospital. Written informed consent was taken from each participant. COVISHIELD is a recombinant ChAdOx1 nCoV-19 Corona Virus Vaccine. It is indicated for active immunization of individuals ≥ 18 y old for the prevention of coronavirus disease 2019 (COVID-19).⁴ As per the serum institute of

India, common AEFI were categorized as "Very common (may affect more than 1 in 10 people) - tenderness, pain, warmth, or itching where the injection is given, generally feeling unwell, feeling tired (fatigue), chills or feeling feverish, headache, feeling sick (nausea), joint pain or muscle ache; Common (may affect more than 1 in 10 people) - swelling or redness where the injection is given, fever, being sick (vomiting) or diarrhea, pain in legs or arms, flu-like symptoms, such as high temperature sore throat, runny nose, cough and chills; Uncommon (may affect up to 1 in 100 people) - sleepiness or feeling dizzy, abdominal pain, enlarged lymph nodes, excessive sweating, itchy skin, rash or hives; Not known (the frequency cannot be determined from the available data) -severe allergic reaction (anaphylaxis), severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing) and Rarest: Major blood clotting (venous and/or arterial thrombosis) in combination with low platelet count (thrombocytopenia) have been observed very rarely (with a frequency less than 1 in 100,000 vaccinated individuals)".⁴

Most of the adverse events following COVISHIELD vaccination occur on the same day within 6-8 h and may resolve within 2 to 3 d and uncommon within a week.⁴ A specifically designed pro forma was used to collect data on AEFI. Pro forma contains socio-demography, symptoms of adverse events, the status of previous COVID-19 infection. We asked individual participants regarding adverse events after having COVISHIELD and followed up till 7 d of vaccination. We monitored all the possible adverse events suggested by the serum institute of India and any new events as well by meeting the concerned person and also using a phone call. Investigators themselves are involved in the process of adverse event recording and follow-up. The completeness of the data was checked every day. The confidentiality and anonymity of data were maintained. The collected data was entered in Microsoft Excel 2016 and analyzed by SPSS version 23. The univariate analysis percentage, mean and standard deviation was used. For bivariate

analysis, the chi-square test and Fischer's exact test were used. The statistical significance was set at having a p-value less than 0.05.

Result

The mean and standard deviation of the age were 28.08 y and 7.35 y respectively. The maximum number of participants, 83 (49.7%) belonged to the 16-25 y age group.

Table 1. Baseline characteristics of participants (N=167)

Characteristics	N(%)
Age (y)	
16-25	83(49.7%)
26-35	59(35.3%)
36-45	18(10.8%)
46-55	7(4.2%)
Mean± SD	28.08±7.35
Sex	
Female	136(81.4%)
Male	31(18.6%)
Occupation	
Doctors	14(8.4%)
Nurses	52(31.1%)
Others	101(60.5%)
Department	
Emergency	11(6.6%)
Intensive Care Unit	72(43.1%)
Medicine	11 (6.6%)
Obstetrics & Gynaecology	10(6.0%)
Operation Theatre	6(3.6%)
Paediatrics	9(5.4%)
Reception	6(3.6%)
Surgery	5(3.0%)
Others	37(22.2%)
History of COVID 19	
Yes	38(22.8%)
No	129(77.2%)
Date of vaccination	
28 Jan 2021	33(19.8%)
29 Jan 2021	82(49.1%)
30 Jan 2021	28(16.8%)
31 Jan 2021	24(14.4%)

Table 2. Symptoms of adverse events following immunization after COVISHIELD vaccination (N=167)

Characteristics	N(%)
Presence of symptoms	
Yes	122(73.1%)
No	45(26.9%)
The onset of symptoms (N=122)	
Same day	89(72.9%)
Next day	33(27.1%)
Number of symptoms	
1	36(29.5%)
2	34(27.9%)
3	27(22.1%)
4	15(12.3%)
5	7(5.7%)
7	2(1.6%)
8	1(0.8%)
Mean± SD	2.48± 1.42
Symptoms distribution	
Fever	95(56.9%)
Headache	41(24.6%)
Bodyache	40(24%)
Rigors	29(17.4%)
Pain at Injection Site	18(10.8%)
Nausea	14(8.4%)
Vomiting	14(8.4%)
Chills	12(7.2%)
Weakness	12(7.2%)
Dizziness	6(3.6%)
Joint Pain	5(3.0%)
Swelling at Injection site	4(2.4%)
Back Pain	2(1.2%)
Leg Pain	2(1.2%)
Shortness of Breath	1(0.6%)
Malaise	1(0.6%)

Table 3. Association of sex with history of COVID-19 (N=167)

Sex	History of COVID-19		OR (CI)	p-value
	Yes	No		
Males	6(19.4%)	25(80.6%)	0.78(0.29-2.07)	0.62
Females	32(23.5%)	104(76.5%)		

There were more female participants 136(81.4%). We had nurses 52(31.1%), doctors 14(8.4%), and the remaining 101(60.5%) were from different sections of the hospital. The maximum number of participants working at the intensive care unit was 72(43.1%). Among them, 38(22.8%) had a history of COVID-19 infection. The majority got vaccination on the second day of the

vaccination program rolled out in the first phase of vaccination 82(49.1%), Table 1. The maximum number of participants 122(73.1%) had at least one symptom of AEFI. The majority 89(72.9%) developed those symptoms within the same day of vaccination. The maximum number of participants 36(29.5%) had at least one symptom followed by two 34(27.9%).

Table 4. Association of sex with AEFI symptoms (N=167)

	Sex		OR (CI)	p-value
	Male	Female		
AEFI Symptoms (Yes)	18(58.1%)	104(76.5%)	0.43(0.19-0.96)	0.03*
Fever (Yes)	12(38.7%)	83(61%)	0.40(0.18-0.90)	0.02*
Headache (Yes)	2(6.5%)	39(28.7%)	0.17(0.34-0.75)	0.01*
Body ache (Yes)	6 (19.4%)	34 (25%)	0.72(0.27-1.9)	0.51
Dizziness (Yes)	0	6(4.4%)	NA	0.59#
Nausea (Yes)	4(12.9%)	10(7.4%)	1.87(0.55-6.4)	0.30#
Vomiting (Yes)	4(12.9%)	10(7.4%)	1.87(0.55-6.4)	0.30#
Chills (Yes)	5(16.1%)	7(5.1%)	3.54(1.04-12.04)	0.04#*
Pain at Injection site (Yes)	2(6.5%)	16(11.8%)	0.56(0.11-2.38)	0.53#
Swelling at the Injection site (Yes)	0	4(2.9%)	1.03(1-1.06)	1#
Joint pain (Yes)	1(3.2%)	4(2.9%)	1.1(0.12-10.19)	1#
Weakness (Yes)	1(3.2%)	11(8.1%)	0.38(0.05-3.05)	0.69#
SOB (Yes)	0	1(0.7%)	1.01(0.99-1.02)	1#
Back pain (Yes)	0	2(1.5%)	1.02(0.99-1.04)	1#
Leg Pain (Yes)	0	2(1.5%)	1.02(0.99-1.04)	1#
Rigors (Yes)	4(12.9%)	25(18.4%)	0.66(0.21-2.05)	0.47
Malaise (Yes)	0	1(0.7%)	1.01(0.99-1.02)	1#

#Fischer's exact Test *Statistically significant

Table 5. Association of sex with the onset of AEFI symptoms (N=122)

Sex	Onset of symptoms		OR (CI)	p-value
	Same day	Next day		
Male	13 (72.2%)	5 (27.8%)	0.96 (0.31-2.93)	1#
Female	76 (73.1%)	28 (26.9%)		

#Fischer's Exact Test

Table 6. Association of sex with AEFI symptoms (n=167)

	History of COVID-19		OR (CI)	p-value
	Yes	No		
AEFI Symptoms (Yes)	28(73.7%)	94(72.9%)	1.04(0.46-2.37)	0.92
Fever (Yes)	22(57.9%)	73(56.6%)	1.06(0.51-2.19)	0.89
Headache (Yes)	12(31.6%)	29(22.5%)	1.59(0.72-3.54)	0.25
Body ache (Yes)	12(31.6%)	28(21.7%)	1.67(0.75-3.71)	0.21
Dizziness (Yes)	0	6(4.7%)	1.05(1.01-1.09)	0.34#
Nausea (Yes)	4(10.5%)	10(7.8%)	1.4(0.41-4.75)	0.53#
Vomiting (Yes)	2(5.3%)	12(9.3%)	0.54(0.12-2.53)	0.74#
Chills (Yes)	3(7.9%)	9(7%)	1.14(0.29-4.45)	1#
Pain at Injection site (Yes)	3(7.9%)	1(11.6%)	0.65(0.18-2.38)	0.77#
Swelling at the Injection site (Yes)	1(2.6%)	3(2.3%)	1.14(0.12-11.24)	1#
Joint pain (Yes)	1(2.6%)	4(3.1%)	0.85(0.93-0.79)	1#
Weakness (Yes)	4(10.5%)	8(6.2%)	1.78(0.51-6.27)	0.47#
SOB (Yes)	0	1(0.8%)	1.01(0.99-1.02)	1#
Back pain (Yes)	1(2.6%)	1(0.8%)	3.46(0.21-56.65)	0.4#
Leg Pain (Yes)	0	2(1.6%)	1.02(0.99-1.04)	1#
Rigors (Yes)	8(21.1%)	21(16.3%)	1.37(0.55-3.40)	0.5#
Malaise (Yes)	0	1(0.8%)	1.01(0.99-1.02)	1#

#Fischer's exact Test *Statistically significant

The most common symptoms reported were fever 95(56.9%), headache 41(24.6%), Table 2.

History of covid-19 was more in females compared to males but there was no significant association Table 3.

Sex had a significant association with AEFI symptoms which is less common in males (OR 0.43; CI 0.19-0.96; P 0.03). Further analysis found sex had a significant association with fever, headache, and chills (table 4). The p-value is used for the comparison of yes and no of each symptom with the sex of the participant.

AEFI symptoms were reported more on the same day of vaccination in both sex but there was no statistically significant difference, Table 5.

The history of COVID-19 has no significant association with AEFI symptoms. It has no further association with each symptom, Table 6. The p-value is used for the comparison of yes and no of each symptom with the history of COVID-19 of the participant.

Discussion

We found almost half (49.1%) received the COVISHIED vaccine on the second day of the first vaccine rollout in this health center. That might be due to hesitation to take vaccination on the first day because of different rumors related to vaccination.⁹⁻¹¹ In our study, more than one-fifth (22.8%) had a history of COVID-19 infection. It is similar to a study from central Nepal (20.2%).¹² Both studies from India reported a lower prevalence of history of COVID-19 infection than our study, which was 7.0%¹³ and 6.4%⁵.

We found at least one adverse event following COVISHIELD vaccination (73.1%) where the majority (81.4%) were female health workers in our study. The female participants were more because more nursing professionals were vaccinated in the first phase. Other studies reported 85.04%,¹²

91.6%¹⁴, 57.24%¹⁵ and 40%¹³ AEFI after COVISHIELD vaccination. These findings vary in the higher and lower range compared to what we found. The possibilities of subjective variation in symptom reporting cannot be excluded in these studies We need to cautiously interpret the findings.

We found almost three-fourth (72.9%) reported AEFI symptoms within the same day. A study from another sentinel site of central Nepal reported 84.4% had onset of symptoms within 24 h.¹² Both these studies had similar findings. More AEFI symptoms on the day of vaccination were also suggested by the vaccine manufacturer during their vaccine trial.⁴ This is also supported by another phase 2/3 clinical trials.¹⁶ This might be immediate vaccine reactogenicity within the same day of vaccination.

We found 29.5% had at least one symptom followed by two (27.9%) symptoms. A study from another sentinel site of central Nepal reported an almost similar finding where 25.6% males and 19.4% females had one symptom.¹²

More than half of the participants had a fever as a major symptom in our study. Other symptoms experienced were headache, body ache, rigors, pain at the injection site respectively from our study participants. A study from another sentinel site of central Nepal reported pain at the injection site (55%) followed by fever (37.1%), myalgia (30.1%), lethargy (27.6%), and headache (26.3%).¹² Another study also reported pain at the injection site, weakness, fever, headache, joint/muscle pain as major AEFI symptoms.¹⁴ Further another study found fever, headache, and dizziness were the commonly reported AEFIs, seen respectively in 15.2%, 6.2%, and 3.7% individuals.¹³ Other studies found feeling unwell (19%), headache (17.4%), fever (12.5%), fatigue (12.3%), and muscle ache (11.2%).^{17,18} Solicited injection-site pain was the most common local reaction, and fatigue and headache were the most common systemic reactions.¹⁸ Reporting rates of adverse events from post-authorization

observational studies were similar to results from clinical trials.¹⁸ Other studies also reported a similar type of AEFI symptoms.¹⁹

In this study, more females had a history of COVID-19 infection but sex has no significant association with the history of COVID-19 within this study population. It means COVID-19 transmission has no sex preference. We found sex had a significant association with AEFI symptoms which is less common in males in our bivariate analysis. This association is not proved by the causal hypothesis. We need further research with an appropriate method. Further analysis also found sex had a significant association with fever, headache, chills. A study from another sentinel site of central Nepal reported no statistically significant difference in the percentage of AEFI seen between males and females.¹² Similar to our study, another study found age and gender had a significant effect on AEFI severity.¹⁴ Similarly, female gender, hypothyroid status, and history of allergy were observed as significant predictors of high risk of AEFI occurrence.¹⁰ In our further analysis, we found AEFI symptoms were reported more on the same day of vaccination in both sexes but there was no statistically significant difference. It means a day of onset of AEFI has no preferences over the sex of study participants. We found the history of COVID-19 has no significant association with AEFI symptoms. A study from another sentinel site of central Nepal reported a similar result.¹² This study found no significant association of the history of COVID-19 with each symptom of AEFI. In contrast, a study from central Nepal found AEFIs like chills, dizziness, running nose, cough, and abdominal pain were observed more frequently in the COVID group and the difference was statistically significant.¹²

The findings from this study may help health experts in formulating plans and policies to improve the vaccine response in the mass vaccination campaigns against COVID-19. The reactogenicity of the vaccine products of different companies with different ethnic groups or populations might change the

occurrence of the number and severity of AEFI symptoms. We had no encounter with severe AEFI but continuous vigilance should be taken for the possibilities. In line with other studies²⁰ AEFI reported in our study were mild and self-resolving resulting in good vaccine safety of COVISHIED. It was suggested to do further research on the issue of more AEFI in women and young age.²¹ Because vaccine hesitancy in women is the challenge for effective vaccination programs.²² We recommend strict monitoring of AEFI after vaccination. A multicentric study on this research question is recommended. Further, systematic review and meta-analysis would be a great help to conclude.

We are limited not to include some variables such as underlying chronic illnesses, smoking status, alcohol use, use of tobacco, and history of allergies. There might be a subjective variation in the symptoms reporting. As our study participants have no elderly population, this might restrict the generalization of findings in this age group.

Conclusion

At least one adverse event following COVISHIED vaccination was reported by 2/3rd recipients. The AEFI was more in females but was not associated with the history of COVID-19 infection.

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Conflict of Interest

None

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Author Contribution

Concept, design, planning: SBP, HKC, AS, PK;
Literature review: SBP, HKC; Data

collection/analysis: SBP, AS, SPK, HKC; Draft manuscript: SBP, HKC, AS; Revision of draft: ALL; Final manuscript: ALL; Accountability of the work: ALL.

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