Adverse Events Following COVISHIELD and VERO CELL Vaccination Campaigns Against COVID-19

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ABSTRACT

Background: Vaccination against COVID-19 for Nepalese was initiated in January 2021 for various age groups. People were anxious about receiving the vaccines and were concerned about the safety profile of the vaccine they received. In this study, we have tried to observe the Adverse Events Following Immunization of two different vaccines namely COVISHIELD (ChAdOx1 nCOV-19) and VERO CELL (CZ02 strain), used in different phases of vaccination by the government of Nepal.

Methods: We conducted a cross-sectional study among people who received COVID-19 vaccines in this study using a self-administered questionnaire. Data was cleaned and then exported to IBM SPSS v.20 for analysis, Chi-square test was used to see the association between different variables and a p-value<0.05 was considered statistically significant.

Results: Out of 303 respondents, all had received the first and 270 participants had received the second dose of the COVID-19 vaccine, among which, 133 (43.89%) reported at least one side effect after the first dose of vaccination while 58 (21.48%) had self-reported side effects after the second dose of vaccination. Seventeen percent of the respondents had COVID-19 infection within the past 3 months before receiving COVID-19 vaccine. Three percent of participants had re-infection with COVID-19 after receiving the first or the second dose of the COVID-19 vaccine. Among participants who experienced adverse events, 42% and 62.1% of participants experienced mild adverse events following the first dose and second dose of the vaccine, respectively.

Conclusions: The adverse events following immunization for both vaccines after both doses of vaccination were quite low, with 43.89% of participants reporting side effects after the first dose and 21.48% of participants reporting side effects after the second dose. Adverse events were most frequently reported within 24 hours of vaccination and were mostly mild. There was no statistical significance of adverse events between both vaccines.

Keywords: Adverse events following immunization (AEFI); COVID-19; COVISHIELD; VERO CELL.

INTRODUCTION

The COVID-19 was declared a pandemic by the World Health Organization on 11 March 2020, and first case reported in Nepal on 24 January 2020. [1-3] Less data regarding the safety of the available vaccines caused apprehension regarding vaccination.[4]

In Nepal, the COVID-19 vaccination program was initiated on January 27, 2021, and as of January 16, 2022, Nepal has fully vaccinated 40% of its total population of nearly 31 million thoug.[5,6] Frontline health workers and security personnel were vaccinated in first phase with COVISHIELD, VERO CELL.[7-11] Many clinical trials regarding vaccine and adverse events are ongoing and as of Feb 2022. [6]

In Nepal, comparisons of AEFI among the two vaccines as well between two doses were sparse. This study aimed to calculate the incidence of adverse events following immunization (AEFI) observed after the first and second doses of the COVISHIELD and VERO CELL vaccines.

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METHODS

This was a cross-sectional study conducted after administering the first and second doses of the COVISHIELD and VERO CELL vaccine. Ethical clearance was obtained from IRB, Kanti Hospital (Ref No.1062). We developed a questionnaire on Google Forms. The questionnaire was validated by a group of five people, including three doctors and two nurses. Then this questionnaire was tested on 20 people before circulating to the participants. The questionnaire was shared on various public forums like Viber group, Facebook, and WhatsApp group of medical professionals as well as the printed Performa was given to the participants who were not active on social media. Participants who showed a willingness to enroll in the study had to go through the questionnaire and fill out the form regarding past COVID-19 infection and note adverse events after each dose of vaccination. Information regarding sociodemographic and past history of COVID-19 were collected and whether or not the second dose of vaccination was taken was also asked. The adverse events noted in vaccine clinical trials and the vaccination product information booklet were used for reference in the questionnaire.

There are anticipated and few non-anticipated problems experienced after vaccination which are defined as Adverse events followed by Immunization (AEFI) as well some adverse events which can happen immediately after vaccination known as Adverse Events of Special Interest (AESI). The AEFI after COVID 19 vaccination were classified as mild (There was no need of medication to relieve the problems), moderate (There was need of medicine to relieve problem) and Severe (There was need of hospital admission for the problems).

The data obtained were entered in the Excel sheet, and data cleaning was done. The data were analyzed using IBM SPSS version 20.0. Descriptive analysis was done using mean, percentage, standard deviation, and chi-square. p-value <0.05 was considered statistically significant.

RESULTS

Out of 303 participants who participated in the study, there were 144 (47.52%) males and 159 (52.47%) females. The mean age was 32.77, with a median of 31.0 years (19 years - 71 years). Similarly, we had different people participating in our study, among which 224 (73.92%) were from medical backgrounds while 79 (26.07%) were from non-medical backgrounds—some 86(28.38%) who were previously infected with COVID-19.

Out of 86 participants 15 (17.44%) were infected within three months of the first dose of vaccination, while the rest were positive three months before the first dose of vaccination. Among the previously infected people 72 (83.72%) had mild symptoms, 10 (11.62%) had moderate symptoms, 2 (2.32%) had severe symptoms and 2 (2.32%) were asymptomatic.

Table 1. Demographics of the participants who were vaccinated for COVID-19.

SN	VARIABLES	FREQUENCY (%)
1	Sex	N=303
	Male	144 (47.52%)
	Female	159 (52.47%)
2	Profession	N=303
	Medical	224 (73.92%)
	Non-Medical	79 (26.07%)
3	Were you previously infected with COVID-19	N=303
	Yes	86 (28.38%)
	No	217 (71.61%)
4	Were you infected within 3 months of the first dose?	N=86
	Yes	15 (17.44%)
	No	71 (82.55%)
5	What were the symptoms when infected with COVID-19?	N=86
	Mild	72 (83.72%)
	Moderate	10 (11.62%)
	Severe	2 (2.32%)
	Asymptomatic	2 (2.32%)

We observed that 229 (75.57%) had taken COVISHIELD vaccine while 74 (24.42%) had taken VERO CELL. One hundred thirty-three (43.89%) had AEFI followed by the first dose of COVID-19 vaccination. SAEI (Severe Adverse Events of Interest) were 10 (7.51%) were noted after the first dose of vaccination while 6 (10.34%) were noted in the second dose of vaccination. AEFI mainly was seen within 24 hours of vaccination in both doses of vaccination 102 (76.69%). Most 76 (57.14%) AEFI seen were moderate in nature, where the participants self-medicated at home. None of the participants had severe grading of AEFI followed by the first dose of vaccination, while 1 (1.72%) had severe AEFI after the second dose of vaccination. (Table 2, Table 4 given below). Myalgia, a feeling of fatigue, and a general feeling of unwell were mostly seen as three adverse events following both doses of vaccination. There were 35% of participants who had some events at the injection site in the first dose, while 15% had some events in the injection site

followed by the second dose of vaccination. Pain and tenderness over the injection site are seen, followed by both of vaccinations which is shown in Table No. 2

Table 2. Adverse Events after Vaccination of COVID-19 after first dose.

SN	VARIABLES	Number (%)
1	Vaccine taken	N=303
	COVISHIELD	229 (75.6)
	VERO CELL	74 (24.4)
2	Were there adverse events after the first dose?	N=303
	Yes	132 (43.6)
	No	171 (56.4)
3	What were the Adverse Events? *	N=132
	General feeling unwell	73 (55.3)
	Feeling tired (fatigue)	81 (61.4)
	Headache	49 (37.1)
	Chills	65 (49.2)
	Fever	65 (49.2)
	Flu like symptoms such as high grade temperature	17 (12.9)
	Vomiting	2 (1.5)
	Nausea	16 (12.1)
	Cough	16 (12.1)
	Sore throat	16 (12.1)
	Muscle pain (myalgia)	94 (71.2)
	Runny nose	15 (11.4)
	Others	15 (11.4)
4	Onset time of the Adverse Events start	N=132
	Within 30 minutes (Adverse Events of Special Interest -AESI)	9 (6.8)
	Within 24 hours of vaccination	103 (78.0)
	After 24 hours of vaccination	20 (15.2)
5	Adverse Events' severity	N=132
	Mild	56 (42.4)
	Moderate	76 (57.14)
	Severe	0 (0.00)
6	Injection site symptoms	N=303
	Experienced	110 (36.3)
	Not experienced	193 (63.7)
7	Symptoms at the injection Site*	N=110
	Pain, tenderness over site of injection	108 (98.2)
	Redness over injection site	4 (3.6)
	Itching over injection site	3 (2.7)
	Swelling or bruising over injection site	4 (3.6)
	Warmth over injection site	16 (14.5)

- **multiple answers from single respondent*

In our study we observed that 5 (1.65%) tested COVID-19 positive after the first dose of vaccination while 6 (2.22%) tested positive after the second dose. Among them, 7 cases tested positive within one month of vaccination, while four tested positives after one month of vaccination. We also observed that 33 (10.89%) did not take part in the second dose of vaccination, with the most common reason 21 (63.63%) being the unavailability of the vaccine for the second dose. (Table 3)

Table3. COVID-19 infection in Participants after Vaccination.

SN	VARIABLES	Number (%)
1	Have you been tested positive for COVID-19 after receiving COVID-19 vaccination?	
	Yes, After first dose	3 (1.0)
	Yes, After second dose	6 (2.0)
	Not infected	294 (97.0)
2	When were you tested positive after vaccination?	N=9
	Within 1 month	5 (55.5)
	After 1 month	4 (45.5)
3	Did you take part in the second dose of vaccination?	N=303
	Yes	270 (89.1)
	No	33 (10.9)
4	Reasons of not taking 2nd dose of vaccines	N=33
	Personal reasons	11 (33.3)
	Unavailability of vaccine for second dose	7 (21.2)
	Gap between subsequent dose not reached yet	6 (18.2)
	Tested covid-19 positive	2 (6.0)
	Others	5 (15.2)

Similarly, among 270 recipients of the second dose of vaccine, 58 (21.5%) had adverse events with fatigue (11.5%), myalgia (9.6%) and a general feeling of unwell (9.3%) being the most common. Seventy-four percent of AEFI occurred within the first 24 hours, 15.5% occurred after 24 hours of vaccination and 10.3% occurred within 10 minutes of vaccination. The majority of the adverse events were mild (62.1%) and 36.2% and 1.7% events were moderate and severe, respectively. Forty participants experienced injection site symptoms, with pain and tenderness over the injection site being the most common symptom.

Table4. Adverse Events after Vaccination of COVID-19 second dose.		
SN	**VARIABLES**	**FREQUENCY (%)**
1	Were there adverse events after the second dose?	N=270
	Yes	58 (21.5)
	No	212 (78.5)
2	What were the Adverse Events?*	N=270
	General feeling unwell	25 (9.3)
	Feeling tired (fatigue)	31 (11.5)
	Headache	14 (5.2)
	Fever	13 (4.8)
	Cough	4 (1.5)
	Chills	4 (1.5)
	Runny Nose	4 (1.5)
	Sore throat	4 (1.5)
	Flu like symptoms such as high-grade temperature	4 (1.5)
	Nausea	4 (1.5)
	Muscle pain (myalgia)	26 (9.6)
	Others	7 (2.6)
3	When did the Adverse Events start?	N=58
	Within 30 minutes (SAEI)	6 (10.3)
	Within 24 hour of vaccination	43 (74.1)
	After 24 hours of vaccination	9 (15.5)
4	How were the Adverse Events in severity?	N=58
	Mild	36 (62.1)
	Moderate	21 (36.2)
	Severe	1 (1.7)
5	Injection site symptoms	N=270
	Experienced	40 (14.8)
	Not experienced	230 (85.2)
6	Were there any symptoms at the injection site?*	N=270
	Pain, tenderness over the site of injection	39 (14.4)
	Redness over injection site	2 (0.7)
	Itching over injection site	1 (0.4)
	Swelling or bruising over injection site	1 (0.4)
	Warmth over injection site	6 (2.2)
	Nothing happened	230 (85.2)

- **multiple answers from a single respondent*

Table 5.Test of association.				
Association between 1st and 2nd dose vaccination and occurrence of AEFI				
	AEFI seen	AEFI not seen	X-squared, df	p-value
After 1st dose vaccine	132	171	30.43, 1	<.000001 (statistically significant)
After 2nd dose vaccine	58	212		
Association between gender of the participant and occurrence of AEFI following 1st dose vaccination				
	AEFI seen	AEFI not seen	X-squared, df	p-value

Table 5.Test of association.				
Association between 1st and 2nd dose vaccination and occurrence of AEFI				
	AEFI seen	AEFI not seen	X-squared, df	p-value
Male	52	92	5.64, 1	.018 (statistically significant)
Female	80	79		
Association between gender of the participant and occurrence of AEFI following 2nd dose vaccination				
	AEFI seen	AEFI not seen	X-squared, df	p-value
Male	20	114	6.03, 1	.014 (statistically significant)
Female	38	98		
Association of severity-type of AEFI following 1st and 2nd dose of COVID-19 vaccines				
	Mild (does not require medication)	Moderate or severe (requires medication)	X-squared, df	p-value
After 1st dose vaccine	56	76	5.46, 1	.019 (statistically significant)
After 2nd dose vaccine	36	22		
Association of severity-type of AEFI following 1st and 2nd dose of COVID-19 vaccine: COVISHIELD				
	Mild	Moderate or severe	X-squared, df	p-value
After 1st dose vaccine	49	75	6.94, 1	.008 (statistically significant)
After 2nd dose vaccine	32	19		
Association of severity-type of AEFI following 1st and 2nd dose of COVID-19 vaccine: VEROCELL				
	Mild	Moderate or severe	X-squared, df	p-value
After 1st dose vaccine	7	1	0.55, 1	0.459
After 2nd dose vaccine	4	3		
Association of severity-types of AEFI following 1st dose vaccination and history of COVID-19 infection				
	Mild	Moderate or severe	X-squared, df	p-value
Previously Infected	21	25	0.13, 1	.716
Not infected previously	35	51		
Association of severity-types of AEFI following 2nd dose vaccination and history of COVID-19 infection				
	Mild	Moderate or severe	X-squared, df	p-value
Infected	12	5	0.32 , 1	.573
Not infected	24	17		
Association of time of onset of AEFI following 1st and 2nd dose of COVID-19 vaccine				
	within 24 hours	after 24 hours	X-squared, df	p-value
After 1st dose	112	20	0.02, 1	.877
After 2nd dose	49	9		
Association of time of onset of AEFI following 1st dose vaccination and type of vaccine taken				
	within 24 hours	After 24 hours	X-squared, df	p-value
COVIDSHIELD	107	17	1.72, 1	.190
VEROCELL	5	3		
Association of time of onset of AEFI following 2nd dose vaccination and type of vaccine taken				
	within 24 hours	After 24 hours	X-squared, df	p-value
COVIDSHIELD	45	6	2.48, 1	.116
VEROCELL	4	3		

The test of association was done between different variables. The association between the first and second doses of the vaccine and the occurrence of AEFI was tested. There was a significant relationship between the two variables, X^2(df=1, N=573) = 30.43, p = <0.000001. More participants had significantly experienced AEFI after the 1st dose of COVID-19 vaccination than after the 2nd dose.

The association between gender and the occurrence of AEFI after 1st dose of COVID-19 vaccination was tested. There was a significant relationship between the two variables, X^2(df=1, N=303) = 5.64, p = 0.18. Similarly, the association between gender and the occurrence of AEFI after 2nd dose of COVID-19 vaccination was tested. There was also a significant relationship between the two variables, X^2(df=1, N=270) = 6.03, p = 0.14. Male participants reported significantly less AEFI in both 1st dose and 2nd dose of COVID-19 vaccination compared to women.

There was a significant relationship between the dose number of the COVID-19 vaccine and the severity-type outcome of AEFI among those who experienced AEFI, X^2(df=1, N=190) = 5.46, p = 0.19. More participants have AEFI requiring medication following the 1st dose of study vaccination compared to that after the 2nd dose of study vaccination. A similar result was found for the participant following 1st and 2nd dose of COVISHIELD vaccine, but a significantly more number of people experienced AEFI requiring medication following 2nd dose of VERO CELL vaccination than 1st dose of study vaccination, X^2(df=1, N=15) = 0.55, p = 0.459.

The association of severity-type of AEFI following 1st dose and 2nd dose of COVID-19 vaccination was tested separately with their status of previous infection with COVID-19. A significantly different severity-type of AEFI was not seen in participants after 1st dose or 2nd dose of study vaccination by their status of previous COVID-19 infection.

The test of association of the time of onset of AEFI was tested with the dose number of the COVID-19 vaccine, type of vaccine (COVISHIELD or VERO CELL) was tested separately. A significantly different result was not obtained with regard to the time of onset of AEFI (within or after 24 hours of vaccination) and those variables.

DISCUSSION

In this study, we aimed to find the rate of AEFI following the administration of two different vaccines, COVISHIELD and VERO CELL. Two hundred and twenty-four (74%) of vaccine receivers were from medical backgrounds. This may indicate hesitancy in people from nonmedical backgrounds due to a lack of awareness or concern about vaccine adverse effects. Eighty-six (17.44%) people in our study reported having a previous COVID-19 infection, with 72 participants having a mild infection, 10 with moderate symptoms, 2 with severe infection, and 2 with no symptoms. Among the enrolled participants, 229 (75.57%) had received the COVISHIELD vaccine and the rest received VERO CELL. This discrepancy may have been due to the availability of the vaccine at that time.

Eighty-six participants (28.38%) were previously infected with COVID-19, out of which fifteen participants were infected within three months of the first dose of vaccination, while the rest were positive three months before the first dose of vaccination. Among the previously infected, most participants 72 (83.72%) had only mild symptoms. It is similar to a study from central Nepal (20.2%). [13] We found 43.6% of participants had at least one symptom following the first dose of the vaccine. A study from another sentinel site in central Nepal reported a lower finding where 25.6% of males and 19.4% of females presented with one symptom. [13]

AEFI was mostly seen within 24 hours of vaccination in both doses of vaccination in 103 (78%) participants which is similar to other studies. [13,14] Fifty-seven percent of participants had moderate AEFI, and they self-medicated at home. None of the participants had severe grading of AEFI followed by the first dose of vaccination, and one participant had severe AEFI after the second dose of vaccination. Myalgia, a feeling of fatigue, and a general feeling of unwell were mainly seen as three adverse events following both doses of vaccination. Thirty-five percent of participants had some events at the injection site in the first dose, while 15% had some events in the injection site followed by the second dose of vaccination. Pain and tenderness over the injection site were seen, followed by both vaccinations. A study from another sentinel site in central Nepal reported pain at the injection site (55%) followed by fever (37.1%), myalgia (30.1%), lethargy (27.6%), and headache (26.3%). [13] Another study in Western Nepal reported pain on the injection site, generalized weakness, fever, headache, joint and muscle pain, dizziness, and loss of appetite as the most common adverse events. [15]

Our study also shows that more participants had significantly experienced AEFI after the 1st dose of COVID-19 vaccination than after the 2nd dose. A study on AEFI after COVAXIN use showed a similar finding with

higher rates of adverse events after first dose than the second dose of vaccine. [16]

In our study, male participants reported significantly less AEFI in both 1st dose and 2nd dose of COVID-19 vaccination compared to women. This is similar to another study done in Eastern Nepal[14] and another study done in Central and Western Nepal. [17] Similar to our study, another study found gender had a significant effect on AEFI severity. [18]

The number of participants requiring medications following AEFI is more compared to that after the 2nd dose of study vaccination. A similar result was found for the participant following 1st and 2nd dose of the COVISHIELD vaccine, but a significantly more number of people experienced AEFI requiring medication following the 2nd dose of VERO CELL vaccination than 1st dose of the study vaccination.

The association of severity-type of AEFI following 1st dose and 2nd dose of COVID-19 vaccination was tested separately with their status of previous infection with COVID-19. A significantly different severity-type of AEFI was not seen in participants after 1st dose or 2nd dose of study vaccination by their status of previous COVID-19 infection.

This is a self-administered questionnaire, so some recall bias may be there.

We could have done it in larger samples to make the power of statistics strong.

The randomization couldn't be made as it is an open and voluntary survey to those who took part in governmental vaccination programs.

CONCLUSIONS

The adverse events following immunization after COVID-19 vaccines after both doses of vaccine in our study were quite low, with 43.89% of participants reporting side effects after the first dose and 21.48% of participants reporting side effects after the second dose. Injection site symptoms were more frequently seen following the first dose of vaccine in comparison to the second dose (36.3% of participants' vs 14.8%). Females reported a significantly higher incidence of AEFI and adverse events were most frequently reported within 24 hours of vaccination and were mostly mild. There was no statistically significance in the adverse events caused by both vaccines. The severity type of AEFI was similar following the first and second dose of vaccination.

CONFLICT OF INTEREST

None

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