

## Assessment of Booster Dose's Adverse Effects of Covishield and Vero Cell Vaccine among The Staff and Medical Students of Nepalgunj Medical College

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### **ABSTRACT:**

The Coronavirus disease 2019 (COVID-19) started as an outbreak in China and affected millions of people around the globe. The massive spread of this disease caused thousands of casualties and vaccines came as a ray of hope. The majority of people got vaccinated with Covishield and Vero cell vaccines. Among those who are vaccinated, many are experiencing side effects. There are few studies done regarding Covishield and Vero cell Vaccines. However, there are no studies to our knowledge assessing the adverse effects of booster doses of those vaccines among the people of Nepal. The aim of this study is to assess the adverse effect of Covishield's and Vero cell's boosters among staff and medical students of Nepalgunj Medical College. This is a descriptive observational study conducted among the Staff and medical students of Nepalgunj medical college with a cross-sectional design. The adverse effects of Covishield's and Verocell's boosters were similar to the other two doses of the vaccines but the pain at the injection site was present in a higher number of participants vaccinated with boosters. Local site pain, bodyache, and fever were more in people vaccinated with Verocell's boosters than in Covishield's boosters.

**Keywords:** Covishield, Verocell, Side Effects, Vaccine, COVID-19

### **INTRODUCTION:**

Coronavirus disease 2019 (COVID-19) started as an outbreak in China and affected millions of people around the globe within three months after which the world health organization (WHO) declared it a pandemic on 12<sup>th</sup> of March in 2020.<sup>1-3</sup> Nepal reported its first case on a student returned from China in January 2020.<sup>4</sup> The cases started increasing tremendously after the second case in Nepal was detected on 17 March 2020.<sup>5</sup> To combat this spread, the government of Nepal imposed lockdown, closed all the educational organizations, and encouraged quarantine and social distancing.<sup>6,7</sup> Till 11 January 2023, the total number of COVID-19 cases is 669,357,326 and in Nepal it has reached 1,001,031.<sup>8,9</sup>

The causative agent for COVID-19 is SARS-COV-2, a single-stranded RNA virus with an envelope containing proteins.<sup>10,11</sup> The common clinical features of this disease are fever, cough, malaise, difficulty in breathing, etc.<sup>12,13</sup> The massive spread of this disease caused thousands of casualties and vaccines came as a ray of hope in this dark phase. The Vaccination program against COVID-19 was initiated in Nepal in January

2021 after nearly one year of the discovery of the first case.<sup>14</sup> More than 80% of the population in Nepal has been vaccinated most commonly with Covishield (AstraZeneca, from India) and Vero Cell (Sinopharm, China).<sup>15,16</sup> Both of the vaccines are administered in two doses of 0.5 ml each, Covishield within an interval of 12-16 weeks, and Verocell within 14-28 days.<sup>17,18</sup> It is recommended to get booster doses of those vaccines after two months of the last dose.<sup>19</sup>

Among those who are vaccinated, many are experiencing side effects. Some studies have been done regarding Covishield and Vero cell Vaccines and a study in India has reported more side effects from COVID-19 booster shots than regular doses.<sup>20</sup> However, there are no studies to our knowledge assessing the adverse effects of the booster dose of Covishield and Vero Cell vaccine among the people of Nepal. Hence, this study aims to assess the adverse effect of booster dose of these vaccines and the vaccine having more side effects of booster shots among staff and medical students of Nepalgunj Medical College.

## **METHODOLOGY:**

### **Study Design and the Participants:**

This is a descriptive observational study conducted among the Staff and medical students of Nepalgunj medical college (NGMC), Banke, Nepal. It has a cross-sectional design. The study was carried out in June, 2022.

### **Questionnaire:**

It is made after an extensive review of literature<sup>21, 22</sup>. The people getting vaccinated with the booster doses were given the questionnaire at the vaccination site. The questionnaire had the objectives of our study explained, a consent form, questions related to the name of the vaccine they received and their socio demographic profile, and a side effect schedule. The participants who got vaccinated on 5<sup>th</sup> and 6<sup>th</sup> June 2022 were given the questionnaire and asked to fill the details, record the side effect after the vaccination if any in the schedule, and to return us after one week. The questionnaires were collected by contacting the study participants.

### **Inclusion Criteria:**

The participants should be either Staff or Medical students pursuing their bachelor in medicine and bachelor of surgery (MBBS) from Nepalgunj Medical College who were administered the booster dose of either Covishield or Vero cell were included in the study

### **Exclusion Criteria:**

The paramedical students and those who failed to provide consent were excluded from the study.

### **Sample Size:**

A total of 210 Staff and medical students got vaccinated with the booster doses on 5<sup>th</sup> and 6<sup>th</sup> June 2022 among which 4 decided not to participate and were not included in the study

The sample size of our study was 206.

### **Outcome and Explanatory Variables:**

The Participants response through the tick mark for adverse effect they experienced for the booster dose they received was the outcome variable. The age, sex, religion, ethnicity was the independent variable of the study.

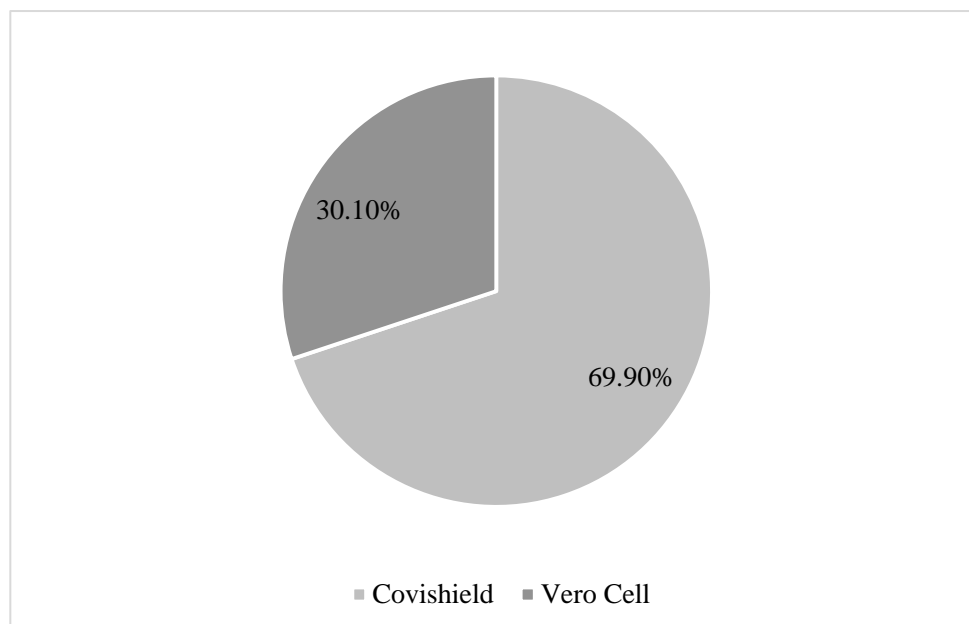
### **Ethical Committee Approval:**

The proposal for ethical review was submitted to institutional review committee of Nepalgunj Medical College, Kohalpur, Nepal on 5<sup>th</sup> January, 2022 and it was approved by the committee on 2<sup>nd</sup> February 2022. The written consent was taken from the participants after explaining the objectives of the study and addressing their all questions.

### **Data Management and Statistical Analysis:**

The data collected were entered and statistically analyzed in the statistical package of social sciences software (SPSS v.20). The testing of hypothesis between two variables was done using P value.

## **RESULTS:**



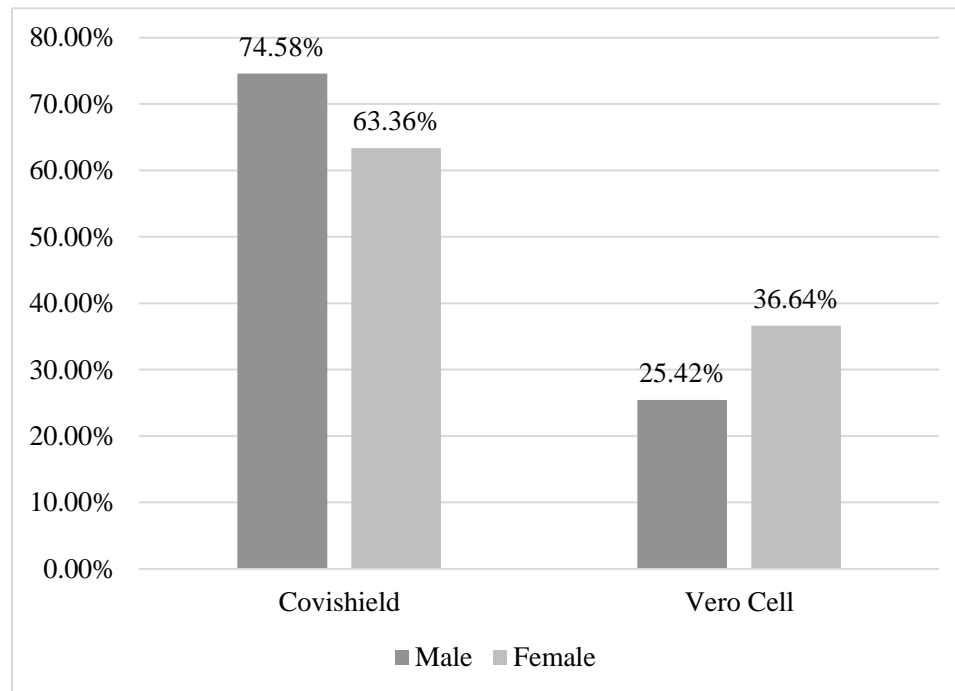
**Figure 01- Pie chart showing distribution of vaccines among participants**

Out of the total participants, the number of people vaccinated with Covishield is 144(69.90%) and Vero cell is 62 (30.1%).

**Table1: Demographic Profile of the participants**

Variable	Mean± SD	Name of vaccine		P-value
		covishield	Verocell	
Age	27.68 ±7.96			
Sex	Male	88 (61.1 %)	30(48.4%)	0.090
	Female	56 (38.9%)	32(51.6%)	
Education	Faculty	12(8.3%)	0	0.001
	Post graduate	6 (4.2%)	0	
	undergraduate	90 (62.5%)	60 (96.8%)	
	Certificate level	26 (18.1%)	2 (3.2%)	
	Lower secondary level	10 (6.9%)	0	
Marital status	Married	48 (33.3%)	4 (6.5%)	0.001
	Unmarried	96 (66.7%)	58 (93.5%)	

The mean age of the participants was 27.68 (SD=7.96).25.24 % (52) of them were married. 72.82% of the subjects were undergraduates out of which 60% were vaccinated with the booster shot of Covishield and the remaining received Verocell. All the faculty members, students pursuing Post graduation, and lower secondary level received Covishield.



**Figure 02- Chart Showing Gender Distribution of Individual Vaccines**

The above figure shows that 74.58 % of males were vaccinated with Covishield and 25.42 % of male received Vero cell vaccine where as 63.36% of female got vaccinated with Covishield and 36.64% female received Vero cell vaccine.

**Table02: Adverse Effects at Local Site of Injection with Booster Dose of COVID-19 Vaccine.**

Adverse effects		Name of vaccine		P-value
		Covishield	Verocell	
Pain at local site	Yes	114 (79.2 %)	54(87.1%)	0.178
	No	30 (20.8%)	32(12.9%)	
Redness at local site	Yes	36 (25%)	8 (12.9%)	0.052
	No	108 (75%)	54 (87.1%)	

Swelling at local site	Yes	8 (5.6%)	4 (6.5%)	0.756
	No	136 (94.4%)	58 (93.5%)	
Itching at local site	Yes	2 (1.4%)	2 (3.2%)	0.585
	No	142 (98.6%)	60(96.8%)	
Change in skin color	Yes	2 (1.4%)	2 (3.2%)	0.585
	No	142 (98.6%)	60(96.8%)	

At the local site of injection, pain and redness were more common. 79.2% of people vaccinated with Covishield and 87.1% of people with Verocell vaccination developed local site pain. Redness was present in 25% of Covishield-vaccinated people and 12.9% of Verocell-vaccinated people

**Table 3. Adverse Effects with Booster Dose of COVID-19 Vaccine.**

Adverse effects		Name of vaccine		P-value
		Covishield	Verocell	
Body ache	Yes	62 (43.1%)	34 (54.8%)	0.120
	No	82 (56.9%)	28 (45.2%)	
Headache	Yes	50 (34.7%)	20 (32.3%)	0.732
	No	94 (65.3%)	42 (67.7%)	
Fever	Yes	44 (30.6%)	20 (32.3%)	0.809
	No	100 (69.4%)	42 (67.7%)	
Muscle pain	Yes	38 (26.4%)	12 (19.4%)	0.280
	No	106 (73.6)	50 (80.6%)	
Fatigue	Yes	28 (19.4%)	10 (16.1%)	0.574
	No	116 (80.6%)	52 (83.9%)	
Joint pain	Yes	4(2.8%)	14 (22.6%)	0.001
	No	140 (97.2%)	48 (77.4%)	
Cough	Yes	0	4 (6.5%)	0.008
	No	144(100%)	58 (93.5%)	
Sneezing	Yes	4(2.8%)	0	0.236
	No	140 (97.2%)	62(100%)	
Runny nose	Yes	0	0	
	No	144(100%)	62(100%)	
Diarrhea	Yes	0	0	
	No	144(100%)	62(100%)	
Nausea	Yes	0	0	
	No	144(100%)	62(100%)	
Vomiting	Yes	0	0	
	No	144(100%)	62(100%)	
Throat pain	Yes	0	0	
	No	144(100%)	62(100%)	
Difficulty in breathing	Yes	0	0	
	No	144(100%)	62(100%)	
Tingling sensation	Yes	0	0	
	No	144(100%)	62(100%)	
Dizziness	Yes	2 (1.4%)	0	0.448
	No	142(98.6%)	62(100%)	
Fainting	Yes	0	0	
	No	144(100%)	62(100%)	
pruritis	Yes	0	0	
	No	144(100%)	62(100%)	
Skin rashes	Yes	0	0	
	No	144(100%)	62(100%)	

Among the people vaccinated with Verocell, 54.8% developed body ache, 32.3% experienced headache, 19.4% developed muscle pain, 32.3% had a fever, and 22.6% experienced joint pain. Similarly, 43.1% developed a bodyache, 34.7% had a headache, 30.6% had a fever, 26.4% developed muscle pain and 2.8% developed joint pain with Covishield.

## **DISCUSSION:**

More than two-thirds of the subjects were vaccinated with the booster dose of Covishield as shown in figure 01. This is probably because Nepal had started its vaccination program with the Covishield vaccine and healthcare workers were the priority of distribution of the vaccine. In this study, an attempt has been made for a comparative study of the side effects of the booster dose of the Covishield and Vero Cell vaccine.

Bodyache, fever, headache, muscle pain, fatigue, and joint pain were the common side effects of both boosters as illustrated in Table 03. Covishield and Vero cell both produced pain and redness in the majority of subject at the local site of injection as depicted by Table 02. Similar findings were present in the study done in 2021 on healthcare professionals after the administration of the second dose of the Covishield vaccine.<sup>22</sup>The study regarding the adverse effect of Verocell done at Gazi university hospital also reported headache, fatigue, and local reaction as the common adverse effects post-vaccination.<sup>23</sup>All these studies indicate similar side effects in the first two doses and the booster shot of both vaccines. The center for disease control and prevention also advocated the similarity of the side effect of the booster shot of the COVID-19 vaccine with its other two doses, the most commonly reported side effects being Fever, headache, fatigue, and the pain at injection site.<sup>24</sup>A prospective study regarding the effectiveness and the side effects of the booster shots also interpreted the adverse effects after boosters to be similar the effects after second dose.<sup>25</sup>

At the local site, the commonest side effect was pain in the case of both boosters. It was present in more than three-fourths of the vaccinated individuals. 80% of those vaccinated with Moderna boosters and 60% of participants with Pfizer boosters had also reported pain at injection site after vaccination.<sup>26</sup>During the safety analysis of Verocell vaccine by the manufacturer company, the pain at the local site was seen in only 33.3% with the first dose and 30% with the second dose which is very less than our finding regarding the booster dose.<sup>18</sup>The occurrence of pain was more among the subjects vaccinated with Vero cell boosters than Covishield booster. Very few people developed other local reactions than pain at the site of injection. A study carried out among 91 staff of Nepalgunj Medical

College found the pain at injection site with the first dose of Covishield in 69.23% of the participants which is less compared to its booster dose.<sup>27</sup>

The commonest general adverse reaction was Bodache with the boosters of both vaccines.

It occurred in 43.1% of individuals with Covishield boosters and 54.8% of individuals with Verocell boosters. Both the body ache and Fever were more common with Verocell boosters but the headache was slightly greater in number in subjects vaccinated with Covishield boosters. The side effects of booster shots of Covishield and Verocell were similar to that of the Moderna and Pfizer boosters.<sup>26</sup>Interestingly Cough, nausea, vomiting, runny nose, diarrhea, difficulty in breathing, etc were reported in none of the participants. All the side effects were mild to moderate. No severe side effects requiring immediate hospitalization or treatment were found in any of the participants. No deaths due to vaccines were recorded.

## **Limitations:**

The study should be considered in light of the following limitations. It had not assessed the adverse effects of the previous two doses of the Covishield and Verocell vaccines. It only studied the side effects that appeared within one week of the administration of the boosters. The participants were all youths only. No participation of children and elderly was there and hence the findings cannot be generalized to all the people of Nepal.

## **CONCLUSION:**

The adverse effects of Covishield and Vero cell boosters were similar to the other two doses of the vaccines but the pain at the injection site was present in a higher number of participants vaccinated with boosters. No severe side effects requiring hospitalization were reported. Pain at the injection site, bodyache, and fever were more in people vaccinated with Verocell boosters than in Covishield boosters.

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