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Post-Vaccination Side Effects after First Dose of VeroCell vaccine among Vaccinated Individuals in a Tertiary Care Center in Nepal: A Descriptive Cross-Sectional Study

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Abstract: ***Introduction: During this challenging period of rapidly spreading corona virus infection, vaccines have brought a new hope as they are the most effective way to beat this pandemic. Along with its positive impact, misconceptions regarding the side effects are spreading among the public leading to vaccine hesitancy. Post vaccination side effect study can help in decreasing vaccine hesitancy and encourage public to get vaccinated. Therefore, this study focuses on exploring the side effects experienced by Nepalese individuals after the first dose of Vero Cell vaccine. Methods: This was a descriptive cross - sectional study conducted among 516 Nepalese residents to assess the post Vero Cell vaccination side effects. Data collection was done via phone interview after initial consent taken at vaccination site. Data was analyzed using Microsoft Excel and Software Statistical Package for Social Sciences (SPSS) version 26.0 and frequency and percentage were calculated. Results: Out of 516participants, nearly half of them 248 (48.1 %) experienced some post vaccination side effects, in which majority170 (32.94 %) had pain at injection site, few of them experienced fatigue 48 (9.30%), headache 38 (7.36 %) and minority of them 12 (2.32 %) showed some rare side effects too. Conclusions: The study showed majority of participant's experienced common side - effects like pain at injection site, headache and fatigue with few showing rare side effects post vaccination.***

Keywords: Nepalese, post-vaccination, side-effects, Vero Cell

1. Introduction

WHO declared 2019-nCoV epidemic as a Public Health Emergency of International Concern on 30January, 2020. [1]With the rapid global spread of corona virus, vaccines have brought a new hope as they are the most effective way to beat this pandemic.

Along with the positive impact brought by the vaccination, misconceptions regarding the side effects are spreading among the public leading to vaccine hesitancy and it can negatively impact government's vaccination campaign. The misconceptions could be clarified by providing evidence regarding the side effects of these vaccines. However, very few studies are published to explore these side effects in Nepal.

Therefore, in this study, we are trying to look at the vaccine side effects in the context of the Nepalese population receiving the first dose of Vero Cell (Sinovac - CoronaVac and Sinopharm/BIBP). Through the documentation of side effects, this study could decrease the vaccine hesitancy and encourage the public to participate in the vaccination program.

2. Methods

This study was a descriptive cross - sectional study conducted among the 516 Nepalese population who got vaccinated with the first dose of Sinopharm Beijing: BIBP - CorV and Sinovac: CoronaVac vaccine as per the Nepalese government's vaccination policy. The survey was conducted in the government allocated vaccination center at Nepal Armed Police Force (APF) Hospital, Balambu, Kathmandu, Nepal from 22 April to 15 July 2021. Ethical approval for the study was taken from Nepal Health Research council (NHRC) (Reference no 2899).

The sample size was calculated by using the Cochran's formula.
Sample size n = (Z2×pq) /e2
where,
n = required sample size,
Z = confidence level at 95% (Standard value of 1.96),

e = margin of error, confidence level at 5% (standard value of 0.05),
p = estimated proportion of the population which has the attribute in questions (50%=0.5), q = (1 - P) and keeping non response rate at 20%.
now, n = ([1.96]2×0.5 (1 - 0.5)) / [0.05]2 =384.16≈385

Keeping the non-response rate at 20%, the required sample size will be:
N= n/1 - non response rate
= 385/1 - 0.2 = 481.25
= 482

The sample size of 482 was taken as per the calculation from Cochran's formula with a margin of error 5% and a confidence interval of 95%.

A new questionnaire with possible post - vaccination side effects was prepared in both English and Nepali languages and pretesting was done prior to data collection. The questionnaire consisted two sections.1) Demographic information and 2) Questions regarding the vaccination side effects The pilot survey was carried out for establishing the validity of the questionnaire.

The inclusion criteria for the study was "All the individuals 18 years and above participating in the vaccination program" The participation was voluntary and written informed consent was taken from the interested participants. The data collection was done in two phases. In the first phase, collection of demographic information and contact numbers of the participants was done in the vaccination site. During that time the participants were explained about the purpose of surveys, ways of recording of the symptoms and the follow ups via phone interview after one week. They were also given the survey questionnaires and requested to maintain the record of the post vaccination side effects up to seven days. In the second phase, participants were interviewed via phone call for the various post - vaccination side effects after seven days.

Data analysis was carried out by entering the data on Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS 26.0). Frequency and percentage were calculated and further represented in tables and figures.

3. Results

The study included 516 participants out of which more than half were male 282 (54.7%) and others were female 234 (45.3%). Among the total participants, 246 (47%) of them were of age group 18 - 36 years followed by 208 (40.31%) were of age group 36 - 54 years and 54 (10.46%) of participants were of 54 - 72 years. Whereas, only 8 (1.6%) of the respondents were of age group 72 years and above which is presented in Table 1.

Table 1: Demographic Information of the respondents

Characteristics	Number (%)
Gender	
Male	282 (54.7%)
Female	234 (45.3%)
Age	
18 - 36	246 (47.67%)
36 - 54	208 (40.31%)
54 - 72	54 (10.46%)
Above 72	8 (1.6%)

While taking the medical history of each participant, more than two third had no any chronic illnesses 397 (76.9%) while remaining of them had some chronic illnesses 119 (23.1%). Majority of the participants 492 (95.3%) had no history of any allergies but few of them 24 (4.7%) were found have history of allergy. Similarly, large number of participants 471 (91.3%) had no prior COVID - 19 infection whereas some of them 45 (8.7%) were infected with COVID - 19 previously. Among the total infected participants, 41 (91.11%) were symptomatic while only 4 (8.89%) were asymptomatic which is shown in Table 2.

Table 2: Medical Information of the respondents

Characteristics	Number (%)
History of chronic illness	
Yes	119 (23.1%)
No	397 (76.9%)
History of allergy	
Yes	24 (4.7%)
No	492 (95.3%)
Prior COVID infection	
Yes	45 (8.7%)
No	471 (91.3%)
Symptoms during past COVID infection	
Yes	41 (91.11%)
No	4 (8.89%)

Out of the total vaccinated participants, more than half of them 268 (51.9%) showed no side effects whereas nearly half of them 248 (48.1%) showed at least one side effect post vaccination. Among the participants who showed certain side effects, majority of them showed common symptoms in which most of them 170 (32.94%) experienced pain at injection site. Similarly, some of them showed uncommon symptoms like severe flu symptoms and dizziness; each of which were present in 14 (2.71%). Also, few of them showed rare side effects like constipation in 3 (0.58%) and tingling and numbness sensation in 2 (0.38%). Other common, uncommon and rare side effects were also present which are mentioned in Table 3.

Table 3: Post Vaccination side - effects

Post Vaccination side - effects	Number (%)
Yes	248 (48.1%)
No	268 (51.9%)
Common Symptoms	
Pain at injection site	170 (32.94%)
Fatigue and weakness	48 (9.30%)
Headache	38 (7.36%)
Feverish feeling	24 (4.65%)
Nausea	10 (1.93%)
Joint and muscle pain	9 (1.74%)
Uncommon Symptoms	
Lump at injection site	2 (0.38%)
Dizziness	14 (2.71%)
Severe flu symptoms	14 (2.71%)
Chest Pain	4 (0.77%)
Skin Rash	6 (1.16%)
Rare Symptoms	
Loss of Smell	1 (0.19%)

Tingling and numbness	2 (0.38%)
Abdominal Discomfort	3 (0.58%)
Constipation	3 (0.58%)
Tinnitus	1 (0.19%)
Shortness of breath	1 (0.19%)
Facial swelling	1 (0.19%)

Time of appearance of side effects after vaccination varied individually. Nearly half of the participants experienced symptoms within 12 - hour post vaccination and very few of them experienced some side effects after 3 days which is shown in figure 1. While assessing the duration of symptoms experienced by the participants, it was found that most of them 101 (40.72%) had their symptoms subsided within a day while few experienced it for more than a week.

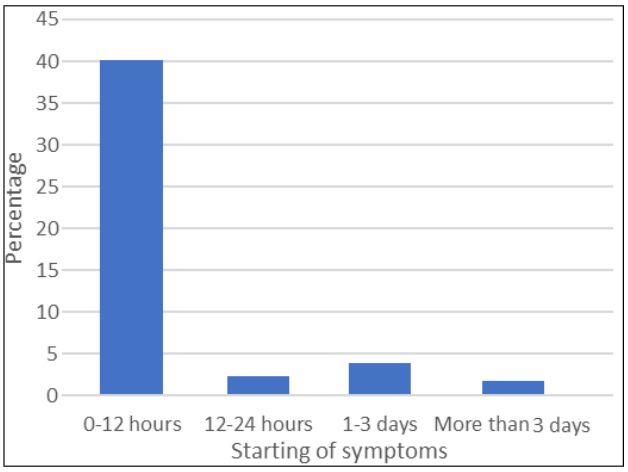

Figure 1: Time of appearance of side effects after vaccination

4. Discussion

The two vaccines, Sinopharm Beijing: BBIBP - CorV, Sinovac: CoronaVac are inactivated vaccines[2]manufactured by Beijing Institute of Biological Products (BIBP) Co. Ltd and Sinovac Life Sciences Co. Ltd respectively. BBIBP - CorV and CoronaVac vaccines are recommended for the emergency use by the World Health Organization (WHO) on May 7, 2021 and June 1, 2021 respectively. [3, 4] This study was conducted to know about the various side effects that can be experienced after the first dose of these two vaccines. Among the 516 participants in the study, nearly half of the participants (48.10%) who received the vaccines experienced at least one side effect. Majority of the side effects experienced were mainly the common side effects (57.92%). Among the common side effects, majority had pain at the injection site (32.94%) followed by fatigue and weakness (9.30%) and headache (7.36%). There was no occurrence of any uncommon adverse reaction like burn at the injection site or adverse systemic reaction like anaphylaxis.

In a study conducted in Patan hospital for the side effects of first dose of Covishield vaccine, side effects were seen in 85.04% which was greater than the finding of this study. [5] The most common side effects were pain at injection site (55%), fever (37.1%), myalgia (30.1%) and lethargy (27.6%). Serious side effects requiring hospital admission was reported in 0.05% and severe minor side effects requiring medication and hospital observation was seen in 0.02%.

In a study conducted in India among participants receiving the Covishield (Astra - Oxford vaccine manufactured by Serum Institute, India) and Covaxin (Bharat Biotech, India), 65.90% of the participants experienced at least one side effect. Tiredness, myalgia and fever were the most common symptoms that were experienced which was similar to our study. [6]

In another similar study in India receiving the first dose of Covishield, systemic effects was seen in nearly half (44.02%) of the participants. Myalgia and fatigue (25.74%), followed by fever (22.01%) and headache (17.16%) were the most common symptoms. [7]

In the study conducted in Jordan, 54.3% of the respondents vaccinated with Sinopharm/BIBP experienced post vaccination side effects out of which majority had minor symptoms (41.3%). [8] The most common side effects seen in this study were fatigue/ tiredness and pain and swelling at injection site. All these findings were comparable to our study. Similarto our study, phase 3 trials conducted in Turkey with CoronaVac vaccine, side effects experienced were only minor with no serious side effects. [9]

5. Conclusion

Our study done among the Nepalese population vaccinated with the first dose of Sinopharm and CoronaVac vaccines showed post vaccination side effects in 48.10 % of participants, out of which majority were common side effects. There were no reported cases of anaphylaxis, hospital admissions or death among the participants. These findings conclude that these vaccines are safe with only minor common side effects in majority of vaccine recipient.

6. Acknowledgements

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Conflict of Interest: No

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