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Side Effects of Covishield Vaccine among Frontline Healthcare Workers of a Tertiary Health Care Center

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ABSTRACT

Introduction: COVID started in late 2019 and within a short time became a pandemic. With increasing morbidity and mortality and therapeutics not doing wonders, scientists were in the attempt to develop vaccines as a mitigating measure. With continuous efforts and developments, different vaccines were developed and rolled out gradually in different countries. Concerns were notable for occurrence of side effects. Hence this study was done to assess the side effects following Covishield vaccination in Nepal at the initial stage.

Methods: This was a cross-sectional study done via snowball sampling method among healthcare workers at a tertiary hospital after obtaining ethical consent from the institutional review committee (Ref no:10/2078/2079) from July 1st, 2021 to July 15th, 2021. Total of 139 respondents were obtained. The data were entered into SPSS and analysed using descriptive and inferential statistics. P-value ≤ 0.05 was considered statistically significant.

Results: Majority (64.7%) were female healthcare workers. More than half (52.3%) used pre-medication in an attempt to avoid the side effects. Most (90.6%) reported at least one side effect to the first dose and approximately three-quarter (74.3%) reported side effect to the second dose. Common side effects were pain at injection site, muscle pain, headache, fatigue and weakness. Most of the side effects were higher with the first dose as compared to the second dose.

Conclusions: Prevalence of side effects was comparable to other studies. Side effects were common with Covishield vaccination, significantly more with the first dose as compared to the second dose. Female gender, younger age and past covid infection were associated with higher occurrence of side effects; however not found to be statistically significant.

Keywords: *Covid; Covishield; Nepal; Side effects; Vaccine.*

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INTRODUCTION

Coronavirus disease 2019 (COVID-19) started in late 2019 and caused a pandemic around the world including Nepal. [1,2] With increasing cases and mortality, there was dire need of some intervention. Coronavirus vaccine was first administered to 90-year-old on December 8, 2020. [3] Nepal launched the COVID-19 vaccination campaign on 27 January 2021 vaccinating the frontline healthcare workers with Covishield vaccine at the first phase.[4] Second dose of the Covishield was provided to the healthcare workers on the end of April.[5]

Local and systemic side effects have reported in different studies. [6-10] Common side effects included fever, headache, myalgia and dizziness. Local effects mainly included itching and redness. [8-13] Various studies have been published in relation to the occurrence of the side effects internationally. [6-13] Datas related to side effects have been minimal in context of Nepal. [14-19]

Hence this research is an attempt to address the side effects of Covishield vaccine in healthcare workers working at a tertiary health care center in Nepal.

METHODS

A cross-sectional study was conducted among the healthcare workers at a tertiary care hospital in Pokhara, Nepal from July 1st, 2021 to July 15th, 2021 after obtaining ethical approval from the Institutional Review Board of concerned teaching hospital (Ref no:10/2078/2079). Informed consent was taken from all respondents. All healthcare workers that received vaccine and willing to participate were included in the study. Those who didn't give consent were excluded.

As per a study, 90 percent of the vaccinated healthcare workers developed adverse effect related to vaccination.[6] Hence with 95% confidence and a margin of error of 5%, the sample size calculated using Cochran's formula:

$N=z2^* p (1-p)/ e2 = 1.96*1.96* 0.9*0.1/ 0.0025= 138$

z=z-score

p=prevalence of side effects

e=margin of error

Data was collected via online means via google form and also via printed form of the performa. Those healthcare workers included in the inclusion criteria were contacted via different social platforms like messenger, facebook, Whatsapp and viber for filling the form. Snowball sampling technique was be used. The primary respondents of the study were identified as per the familiarity with the researcher and those respondents were further requested to forward the link of the questionnaire to others whom they knew and have got two doses of Covishield vaccination. The semi-structured questionnaire performa containing the sociodemographic details along with multiple options selection questions was prepared based on the extensive literature review and peer review. Open-ended questions of medications taken were included and remaining questions were close-ended.

The form consisted of informed consent at first. If respondent answered no, then no further questions were asked. If respondent answered yes, then it would lead to the other parts of the form. Hence the study questions were followed after obtaining informed consent only. This included demographic characteristics, history of comorbidity, history of past covid infection, use of premeditations prior vaccination and work area involved. This was followed by multiple choice options related questions of the local

side effects and the systemic side effects that occurred following vaccination. Total of 160 responses were collected.

After obtaining the responses, the data were entered into Microsoft Excel and checked for duplications and incomplete responses. After omitting duplications and incomplete responses, 139 responses were finally analysed in SPSS 21. The demographic characteristics were expressed in terms of percentages. For comparison of side effects between different categorical variables like gender, history of covid infection, dosage of Covishield vaccine, chi-square test was used. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Majority of the respondents were below 40 years of age. Approximately ten percent of the respondents used medicines in an attempt to avoid the side effects. Use of medications for symptom relief was seen in nearly half of the individuals after receiving the first dose of Covishield vaccine. The medications commonly used were paracetamol and ibuprofen. Twenty-four respondents (17.3%) had an episode of covid infection prior to the vaccination. Majority of the respondents developed side effects following the first dose whereas a quarter of those receiving the second dose didn't develop side effect. (Table 1)

Table 1: Basic characteristics of the participants (n=139)

Characteristics		Frequency	Percentage
Gender	Female	90	64.7
Age	Below 40 years	115	82.7
Work area involved	Doctor	78	56.1
Known comorbidity	Yes	10	7.2
Use of medications for relief from side effect	First dose	73	52.5

Pain at the injection site was the most common local side effect reported. Most of the local side effects except itching were more common after the first dose received. (Table 2)

Table 2: Frequency of local side effects (n=139)

Characteristics	First dose	Second dose	P-value
	Frequency (percentage)		
Local effects	105 (75.51)	86 (61.82)	.02
No side effects	34 (24.52)	53 (38.21)	
Pain	101 (72.63)	84 (60.43)	.04
Swelling	11 (0.08)	8 (0.06)	.64
Redness	8 (0.06)	5 (0.03)	.57

Systemic side effects were also more common after the first dose of Covishield vaccine seen in 121/139 and 77/139 cases with the first and second dose respectively. All the systemic side effects were significantly reported higher with the first dose of vaccine in comparison with the second dose. Muscle pain was most common reported symptom followed by headache, fatigue and weakness. (Table 3)

Table 3: Frequency of systemic side effects (n=139)

Characteristics	First dose	Second dose	P-value
	Frequency (percentage)		
Fever	50 (35.97%)	3 (2.1%)	.000
Muscle pain	80 (57.55%)	45 (32.37%)	.000
Weakness	59 (42.45%)	23 (16.55%)	.000
Headache	65 (46.76%)	33 (23.74%)	.000
Fatigue	66 (47.48%)	23 (16.54%)	.000

On comparison of side effects both local and systemic of different Covishield doses with different sociodemographic variables, no factors were found to be significantly associated except for systemic side effects after first dose in those aged below 40 years. (Table 4 and 5)

Table 4: Sociodemographic variables with first dose of vaccine (n=139)

Demographic variables/ Side effects	Local	p-value	Systemic	p-Value
Below 40	90/115	0.12	106/115	0.001
40 years and above	15/22		15/24	
Comorbidity	8/10	1	8/10	0.5
History of covid infection	20/24	0.4	22/24	0.7
Premedication use	11/13	0.7	13/13	0.14

Table 5: Sociodemographic variables with second dose of vaccine (n=139)

Demographic variables/ Side effects	Local	p-value	Systemic	p-Value
Below 40	73/115	0.5	67/115	0.2
40 years and above	13/24		10/24	
Known comorbidity	8/10	0.32	6/10	1
History of covid infection	17/24	0.3	12/24	0.65
Premedication use	6/8	0.7	5/8	0.67

DISCUSSION

Among the respondents, females were the majority one which is also similar to other studies done among healthcare workers in different countries. [6, 8, 12-14, 20] Females are found to be more responding than males.

Common side effects being reported were pain at injection site, muscle pain, fatigue, headache and weakness. This was similar to side effects reported to same or other vaccines in other studies. [7-13, 21, 22] However the occurrence of side effects was less in healthcare workers in Turkey who received CoronaVac vaccine and also lower in those receiving Sputnik vaccine. [7,20] Similar to the Pfizer-BioNTech vaccination of healthcare workers at Malta's state hospital, local side effects were common with the first dose as compared to the second dose. However the systemic side effects were common with the first dose of Covishield vaccine unlike Pfizer vaccine.[8] Similar to the

side effects reported by healthcare workers in Iran who received first and second dose of Sputnik vaccine and Egyptian population receiving first and second dose of AstraZeneca vaccine, the frequency of side effects like injection site pain, fever, headache, body pain, fatigue were more among those receiving the first dose as compared to second dose and was statistically significant ($p<0.05$).[7,9] This is also in congruence with the study done among Jordanian healthcare workers who reported more occurrence of systemic side effects with first dose of AstraZeneca vaccine as compared to the second dose.[6]

Similar to the study done in Patan of Nepal, among those receiving first dose of Covishield in the rollout vaccine campaign, more than half (52.5%) used some medications for symptom relief for the side effect. [14] Those with prior history of covid had higher frequency of side effects both local and systemic, however was statistically insignificant and this was similar to the study done in Iran for the Covishield group and also in Nepal. [14, 22] This finding is in contrast to the study done in a university tertiary hospital in France. Possible reason may be due to the difference in the type of vaccine used and difference in the study population.[21] Similar to other studies, there was no significant difference in occurrence of side effects between males and females. [14, 22] Nonetheless, female healthcare workers in Iran receiving Sputnik vaccine reported statistically significant higher occurrence of side effects as compare to the male groups. [7] Possible reason may be due to the difference in the study population, timing of the study and the difference in the type of vaccine. On analysis it was found that those aged below 40 years reported more side effects than the group aged above 40 years. However, it was statistically significant only for the systemic effects following the first dose. These findings were similar to other studies which showed higher prevalence of side effects in those below 40 years of age. [7, 8, 12, 13, 22] However German healthcare workers of older age group reported more systemic side effects as compared to younger age group among the viral-vector based COVID-19 vaccine. [11] Presence of comorbidities didn't affect the occurrence of side effects and was similar to the finding among Turkish healthcare workers.[20]

The limitations of this study are it is a single-center study with moderate sampling size. The respondents were asked about the side effects that occurred during the time of vaccination so recall bias can occur. The side effects though given options were self-reported by the respondents hence direct face-to-face questionnaire wasn't done. This could cause the respondent to report only the symptoms which the patient thought important and worrisome. Also, the sampling method was snowball sampling method hence may not be actual representation of the targeted population. Hence the findings may not be generalizable to the general population.

CONCLUSIONS

The prevalence of side effects both local and systemic was similar to other studies. Commonest side effects were pain at injection site, malaise, headache and muscle pain. The side effects were more pronounced with the first dose of Covishield vaccine in comparison to the second dose. Past COVID infection, presence of comorbidities, age, use of pre-medication for side effect relief and gender didn't have a significant difference in the occurrence of side effects.

CONFLICT OF INTEREST

None

SOURCES OF FUNDING

None

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