

STUDY ON ADVERSE EFFECTS OF COVISHIELD VACCINE AMONG HOSPITAL EMPLOYEES OF NEPAL MEDICAL COLLEGE AND TEACHING HOSPITAL

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ABSTRACT

Nepal government provided COVISHIELD vaccine first to the hospital employees and other front liners in January 2021. The objective of our study was to observe the adverse effects of the COVISHIELD among hospital employees of Nepal Medical College and Teaching Hospital (NMCTH). This was a descriptive cross-sectional study conducted from March to August 2021. The study was commenced after obtaining ethical clearance from the Institutional Review Committee of NMCTH. Self-reported socio-demographic details and symptomatic adverse effects reported after the first and second dose of COVISHIELD were noted. The data were entered in SPSS 16 and analysed. Out of 436 participants, 360 (82.6%) and 243 (55.7%) had reported adverse effects after the first and second dose of the COVISHIELD respectively. The adverse effects reported following COVISHIELD were common and predictable.

KEYWORDS

Adverse effect, COVISHIELD, vaccine

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INTRODUCTION

Any health problem occurring subsequent to vaccination either associated with the vaccine or concomitant event following vaccination is considered an adverse event of immunization.¹ The occurrence of adverse effects can be categorized as very common (>10%), common (1-10%), uncommon (0.1-1%), rare, and very rare.²

The immune response generated by the COVISHIELD helps to protect against SARS-COV-2.³ Emergency use approval (EUA) for COVISHIELD was approved in spite of still being in the phase III trial.⁴ Nepal government provided COVISHIELD vaccine first to the hospital employees (clinician, academician, administrative, maintenance, and security personnel) and other front liners (Police personnel) in January 2021. We, therefore, studied the adverse effect of the vaccine among the hospital employees of a tertiary care center in Kathmandu, Nepal.

MATERIALS AND METHODS

It was a descriptive cross-sectional study conducted among the hospital employees (clinician, academician, administrative, maintenance, and security personnel) of Nepal Medical College and Teaching Hospital (NMCTH). The study was commenced from March to August 2021 for six months. Ethical approval was obtained from the institutional review committee of NMCTH (Ref no: 042-077/078). Written informed consent was taken from each employee. Employees who had been vaccinated with COVISHIELD and were willing to participate voluntarily were included in the study. The employee who had not been vaccinated with COVISHIELD and who did not want to participate were excluded.

The data were collected from 436 hospital employees and the sampling method used was convenience sampling. Data were collected by the researchers themselves from each participant (after the first and second dose respectively) by approaching individually through the preformed self-constructed questionnaire. Self-reported socio-demographic details and symptomatic adverse effects of COVISHIELD after the first and second dose were noted by the investigators. The questionnaire also included consumption of paracetamol to avoid or decrease the adverse effects following vaccination. Data were entered in SPSS 16 and analyzed using chi-square test.

RESULTS

Data were collected from 436 hospital employees who were vaccinated with COVISHIELD. Out of 436 hospital employees, 259 (59.4%) were females and 177 (40.6%) were males. The age ranged from 20 to 72 years with a mean age of 35.64±9.8.

Table 1: Table showing no adverse effect of COVISHIELD based on gender.

	Gender		p value
	Male (n=177)	Female (n=259)	
No adverse effect after first dose	45 (25.4%)	31 (12%)	<0.001*
No adverse effect after second dose	90 (50.8%)	103 (39.8%)	<0.001*

Chi-square test, p value <0.05 statistically significant*

We observed that males were at less risk for developing adverse effects of COVISHIELD. (Table 1). Similarly, we observed that 360 (82.6%) and 243 (55.7%) reported adverse effects after the first and second dose of COVISHIELD, respectively.

We observed injection site tenderness, myalgia, and fatigue were reported more commonly than other adverse effects. We also observed that the adverse effects seen following the second dose of COVISHIELD were comparatively lesser than the first dose (Fig. 1).

The uncommon adverse effects observed were anorexia, diarrhea, skin discoloration at the injection site, nausea, and vomiting. We observed that paracetamol was consumed to resolve the adverse effect. The number of participants consuming paracetamol was comparatively lower during the second dose (Table 2).

Table 2: Table showing consumption of Paracetamol following COVISHIELD.

Paracetamol consumed	1 st dose n (%)	2 nd dose n (%)	p value
prior to vaccination	44 (10.1)	20 (4.6)	0.01*
after vaccination	215 (49.3)	104 (23.9)	<0.001*
due to adverse effects	164 (37.6)	45 (10.3)	<0.001*

Chi-square test, p value <0.05 statistically significant*

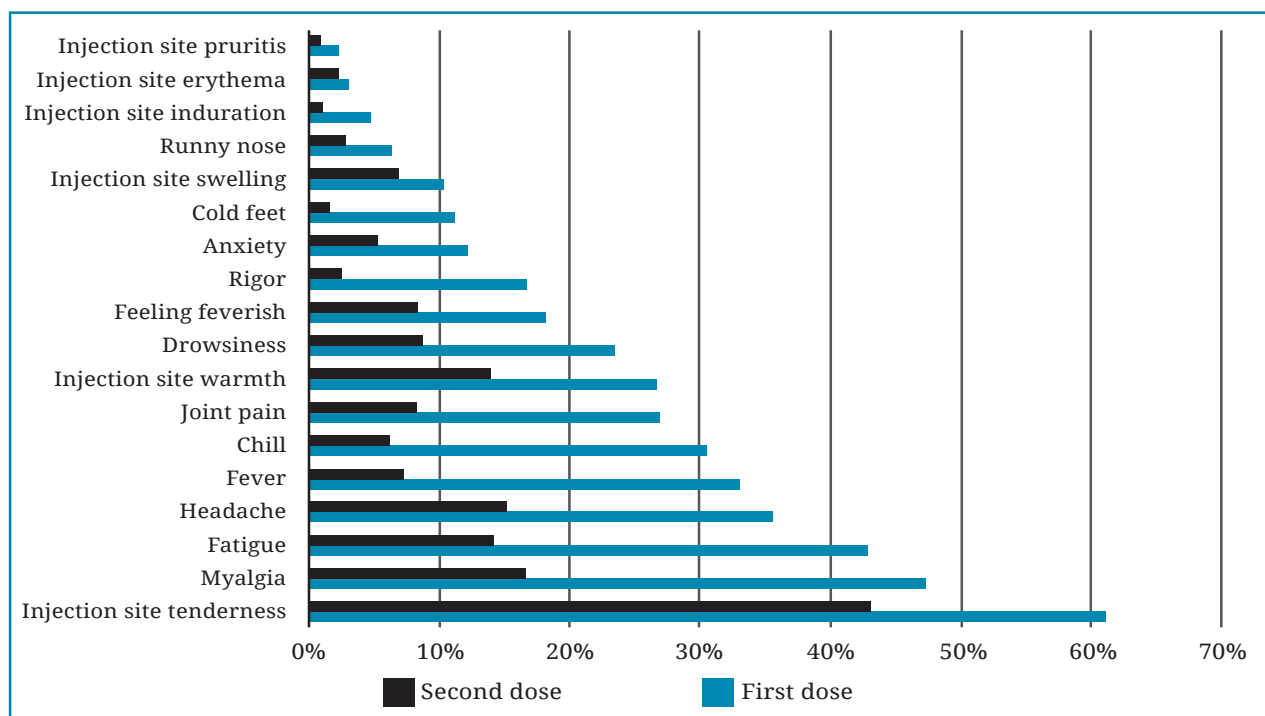


Fig. 1: Various adverse effects among the study participants after the first and second dose of COVISHIELD.

DISCUSSION

The study was aimed to observe the adverse effects of COVISHIELD. We observed the major portion of adverse effects to be injection site tenderness, injection site warmth, myalgia, headache, fatigue, fever, and chills. Monitoring adverse effects should be a continuous process which is guided by a health professional who can elaborate the medical term to the participants in the hospital settings. Due to surge in COVID cases, the time frame for development of COVISHIELD had to be compressed from years to few months which might have led to skipping of few stages of vaccine development. This can be compensated by tracking of adverse effects with a development of mobile-based application.

In the clinical trial fact sheet published by Serum Institute Life Sciences Pvt. Ltd.,⁵ 3.5% were Asian participants. The adverse effect reported in the trial were similar to our study. The trial also reported that the adverse effect after the second dose were milder and reported less frequently⁶ which was similar. The adverse effects resolved on their own or were reduced with the intake of paracetamol.

COVISHIELD was given intramuscularly preferably in the deltoid.⁷ The intramuscular route would lead to a local reaction like injection site tenderness and swelling. Folegatti PM *et al* in their study found that the incidence of local reaction was 4% and the systemic

reaction was 13% which was reduced by the use of prophylactic paracetamol.⁸ In our study, we observed that local reaction was seen in a range of 2.3%-61% in the first dose while in the second dose it was in the range of 0.9-43%. The systemic reaction was seen 6.4%-47% in the first dose and 1.6%-16.7% in the second dose. These results resemble a report published by Serum Institute Life Sciences Pvt. Ltd.⁹

Unsolicited adverse effects reported during the clinical trials were injection site bruise, lymphadenopathy, decreased appetite, dizziness, hyperhidrosis, pruritus, and rash.⁶ These adverse effects were reported less frequently in our study. Syncope was reported in Patan Academy of Health Sciences.¹⁰

Various preclinical and clinical stages following strict regulation have been passed to prevent adverse effect of a new vaccine.¹¹ Despite this, an infrequent adverse effect of neuroinflammatory disorders was reported after vaccination with COVISHIELD. The serum institute of India announced that the neuroencephalopathy had no association with the vaccine.¹² Transverse myelitis developing 14 days after injection, and pyrexia greater than 40°C in recipient are some of the unusual adverse effects. Transverse myelitis was found to be linked with patient with multiple sclerosis. This resulted in delay in COVISHIELD trial.⁷

COVISHIELD presented a ray of hope to end the Coronavirus 2019 (COVID-19) pandemic mostly

for the developing countries due to its low cost and easy storage.^{4,13-15} However, developing countries are also the target for testing their experimental drug because of less regulation and easier access to a large number of patients. When these vaccines are successful in gaining marketing permission, patients in those countries where trials were conducted often cannot afford them adding economic burden of adverse effect.¹⁶

This study has potential limitations. Although most of the questionnaires were filled by the researchers, some questionnaires were self-reported by the hospital employee as they were familiar with the medical terms. The asymptomatic but COVID positive individual might have reported COVID negative history. Co-morbidities were not investigated in this study. Some of the employees were not sure about their blood group. Although the questions

were objective some of the unobserved adverse effects could have been missed. Those employees who had taken the first dose of COVISHIELD but could not receive their second dose were excluded from this study. We observed that most of the adverse effects reported were minor that were resolved with paracetamol. Since this research is carried out in a single tertiary care center, so results from this study cannot be generalized to the general population. Whether these findings are unique to these participants or it coincides with the population will require more researches so that they can be generalized across population, time, and settings. The adverse effects reported following COVISHIELD vaccination were common and normally predictable.

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