

A Hospital-Based Study to Determine Post-Vaccination Symptoms after the First Dose of Covishield Vaccine among Health Care WorkersJay Jyoti¹, Kumar Vikas², Dinesh Kumar³, Amita sinha⁴¹Tutor, Department of Community Medicine, Nalanda Medical College and Hospital, Patna, Bihar, India²Tutor, Department of Community Medicine, Nalanda Medical College and Hospital, Patna, Bihar, India³Tutor, Department of Microbiology, Patna Medical College and Hospital, Patna, Bihar, India⁴Associate Professor, Department of Community Medicine, Nalanda Medical College and Hospital, Patna, Bihar, India

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Conflict of interest: Nil

Abstract**Aim:** The aim of the present study was to determine post-vaccination symptoms after the first dose of the Covishield vaccine among healthcare workers at a tertiary care centre.**Material & methods:** A descriptive cross-sectional study in Department of Community Medicine, Nalanda Medical College and Hospital, Patna, Bihar, India from Jan 2022 to December 2022. Data on adverse effects following vaccination with the first dose of Covishield vaccine were collected from healthcare workers through online surveys and interviews. Baseline characteristics were described with frequency, percentages, and mean. Associations between categorical variables were assessed using the Chi-square test.**Results:** In the present study, majority of the participants were male (95%) and 95% had no allergy from the vaccine. 92% had COVID-19 infection and 60% workers were in clinical department. The majority of the respondents reported post-vaccination symptoms. The most common symptoms were pain at the site of injection, myalgia, tiredness, fever, headache, nausea, giddiness, diarrhea, and redness at the site of injection. Rare symptoms reported included anaphylaxis, peri-orbital edema, breathlessness, vomiting, and passage of red-coloured urine.**Conclusion:** The symptoms reported in the study were those already known to be the general side effects associated with vaccines. The information obtained from this study will aid in health promotion activities related to COVID-19 vaccination.**Keywords:** Covishield vaccine, health care workers, SARS-CoV-2.

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Introduction

COVID-19, a novel viral disease caused by SARS CoV-2 originated in Wuhan, China, during the investigation of a cluster of cases leading to unknown pneumonia in December 2019 [1,2] and it spread globally to become a pandemic. [3] SARS-CoV-2 rapidly spread worldwide and still poses a major challenge and threat to public health and healthcare systems. [4] With the increasing cases and mortality all over the world, there was dire need of some intervention to halt the effect. Healthcare workers (HCW), including doctors, nurses and other paramedical staff, are the leading frontline personnel of a medical health care system. Due to the prolonged period of exposure, HCW are the most vulnerable cohort at a high risk of COVID-19 infections compared to the general population. [5] Infected HCW may pose risk to patients, family members and to the community as

well. Therefore, the safety of HCW is essential to safeguard continuous patient care. WHO reports have documented that until 2020, at least 90,000 healthcare workers had been infected by COVID-19. [6]

Safe and effective vaccines are needed for both individual protection and the development of herd immunity. [7] COVID-19 is associated with a high mortality rate in vulnerable populations, [8] and therapeutic options are limited. Widespread vaccination with highly effective vaccines against COVID-19 is an important tool in the efforts to control this pandemic. [9] With different therapies introduced but none as major success, the introduction of vaccines became a major boom in the fight for covid. Different vaccines have been made to control COVID-19. The ones currently

approved by WHO include Pfizer, AstraZeneca, Covishield, Janssen, Moderna, Sinovac, Sinopharm, Covaxin and various other vaccines are ongoing assessment. They include inactivated, live-attenuated, viral-vectored, replicating and nonreplicating, protein and peptide-based, and nucleic acid approaches. [10] As part of initiation of global vaccination program, a coronavirus vaccine was first administered to 90-year-old Margaret Keenan in the UK on December 8, 2020. [11]

India introduced a mass COVID-19 vaccination programme (Covishield and Covaxin) with two candidate vaccines from 16 January 2021 after the Emergency Use Approval. [12] Both Covishield® (AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin® (made by Bharat Biotech Limited) were approved for emergency use authorization by the Central Drugs Standard Control Organization in India. The Covishield® vaccine is a viral vector-based technology, whereas Covaxin® is a whole-virion inactivated coronavirus vaccine. [13] Covishield vaccine showed reports of local and systemic reactions, such as injection-site pain, a feverish feeling, muscle aches, and headaches. [14] The reactions were less common in older adults (those aged more than 56 years) than in younger adults. In India, the priority groups vaccinated were health care workers, those aged more than 60 years, and those between 45 and 59 years of age with co-morbid conditions. [15] The Ministry of Health and Family Welfare recommended the strengthening of surveillance systems capable of investigating adverse events of special interest and adverse events following immunization. [16] To address the issue of vaccine hesitancy among the general population and manage their post-vaccination symptoms, it is necessary to identify the symptoms immediately following COVID-19 vaccination.

Hence, we conducted a study to identify the post-vaccination symptoms after the first dose of the Covishield vaccine.

Material & Methods

A cross-sectional study was conducted among the health care workers in Department of Community Medicine, Nalanda Medical College and Hospital, Patna, Bihar, India from Jan 2022 to December 2022, who received their first dose of the Covishield vaccine between the duration of 1 year. The hospital is a government-designated centre for COVID-19 vaccination. The questionnaire was in English. Approval for the study was obtained from the Institutional Ethics Committee and informed consent was taken from the participants before they were given the questionnaire. In the initial phase of the vaccination drive in India, health care workers were among those on the priority list. A pre-tested questionnaire was used. It was developed by the authors after reviewing previously conducted studies and WHO-reported side effects of vaccination. The questionnaire was checked and validated for content. Expert opinions were taken into consideration and used in modifying the questionnaire into an easier, simpler, and shorter version that could be filled out within 5 min. The questionnaire included the following sections: baseline demographic information, the category of the health care worker, the time of vaccination, symptoms after vaccination, duration of symptoms, information about health care utilization, and pre-existing morbidities. One week after the administration of the first dose of vaccine to all those willing to be vaccinated, questionnaires (Google forms) were sent through email and WhatsApp groups to the beneficiaries.

Of the 1958 health care workers who received the Covishield vaccine at the study center, 1000 health care workers completed the questionnaire over 4 weeks.

Statistical Analysis

The data collected were entered into a Microsoft Excel spreadsheet, analyzed using the software SPSS version 25. The baseline characteristics of the study subjects were described in terms of frequency, percentages, and mean. A Chi-square test was used to find the association between categorical variables and a P value of 0.05 was considered statistically significant.

Results

Table 1: Association between post-vaccination symptoms and various other factors

Variables Age (years)	Symptomatic		P Value
<50	940	94%	0.196
>50	60	6%	
Gender			
Female	950	95%	0.469
Male	50	5%	
Allergy			
Absent	950	95%	0.68
Present	50	5%	

Continue your work on the day of vaccination			
No	960	96%	0.558
Yes	40	4%	
COVID-19 infection			
No	80	8%	0.289
Yes	920	92%	
Place of work			
Clinical	600	60%	0.544
Laboratory	300	30%	
Others	100	10%	

In the present study, majority of the participants were male (95%) and 95% had no allergy from the vaccine. 92% had COVID-19 infection and 60% workers were in clinical department.

Table 2: Side effects reported by health care workers after vaccination with Covishield

Side effects	Male	Female
Fever	430	134
Myalgia/Body pain	593	161
Diarrhoea	48	12
Pain at site of infection	702	201
Redness at site of infection	45	15
Periorbital edema	10	0
Anaphylaxis	7	0
Breathlessness	15	1
Headache	148	22
Tiredness	632	149
Vomiting	38	12
Nausea	140	14
Giddiness	120	20
Red colored urine	0	3

The majority of the respondents reported post-vaccination symptoms. The most common symptoms were pain at the site of injection, myalgia, tiredness, fever, headache, nausea, giddiness, diarrhea, and redness at the site of injection. Rare symptoms reported included anaphylaxis, peri-orbital edema, breathlessness, vomiting, and passage of red-colored urine.

Discussion

The novel coronavirus, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), is responsible for the highly infectious disease COVID-19. First identified in Wuhan, China in December 2019, it spread globally to become a pandemic. [17] The number of new cases peaked in early January 2021 when there were just under five million cases reported in 1 week. [14] Safe and effective vaccines are needed for both individual protection and the development of herd immunity. [18] COVID-19 is associated with a high mortality rate in vulnerable populations, [19] and therapeutic options are limited. Widespread vaccination with highly effective vaccines against COVID-19 is an important tool in the efforts to control this pandemic. [20]

In the present study, majority of the participants were male (95%) and 95% had no allergy from the

vaccine. 92% had COVID-19 infection and 60% workers were in clinical department. The majority of the respondents reported post-vaccination symptoms. The most common symptoms were pain at the site of injection, myalgia, tiredness, fever, headache, nausea, giddiness, diarrhea, and redness at the site of injection. Rare symptoms reported included anaphylaxis, peri-orbital edema, breathlessness, vomiting, and passage of red-colored urine. COVID-19 vaccine recipients should be informed about the possible side effects of vaccination before the vaccine is administered. This includes local side effects such as pain, swelling, and redness at the injection site and systemic side effects such as fever, fatigue, headache, a feverish feeling, diarrhea, myalgia, and arthralgia. [21] In the phase 3 trial of the COVID-19 vaccine Pfizer-BioNTech, the incidence of mild headache following vaccination was 42% in the vaccinated and 34% in those who received a saline placebo. [22] The use of paracetamol for minor symptoms following vaccination is considered acceptable. [23] A recent study from Nepal showed post-vaccination effects such as irritability in mood reported 4 h after vaccination, and complaints such as myalgia, nausea, pain at the injection site, and a feverish feeling 6 h after vaccination, which matched our findings. [24] Muscle discomfort

(68.3%) was described as the most common side effect in a study from Kabul, Afghanistan, whereas pain at the injection site was recorded as the most common adverse reaction in our study. [25] Although symptomatic status had no association with various other variables considered in our study, Poland GA et al. found that 80–91% of all vaccine recipients experienced at least one local symptom, and 48–91% experienced at least one systemic symptom after vaccination depending on variables such as age group. [26] The difference in COVID-19 breakthrough infection has been more noticeable in the period after the Delta variant became dominant. [27,28] Overall, 2% of patients had a breakthrough infection during the follow up after completing the course of vaccination. Although the emergence of the Delta variant in India was devastating with high mortality, breakthrough cases tended to be substantially less severe compared with prevaccination COVID-19 cases, regardless of a person's immune status. The data confirmed that SARS-CoV-2 vaccinations are highly successful and the importance of full vaccination for preventing breakthrough infection is emphasized. [29]

Conclusion

The symptoms reported in the study were those already known to be the general side effects associated with vaccines. The information obtained from this study will aid in health promotion activities related to COVID-19 vaccination. Furthering our knowledge about the vaccine side effects will help us educate the public and reduce vaccine hesitancy and misinformation related to vaccines. Therefore, additional independent studies on vaccine safety and post-vaccination symptoms are greatly required to strengthen the public's confidence in accepting this new vaccine. Additionally, further studies are needed to understand the risk factors of specific vaccine side effects, and this requires the continuous monitoring of vaccinated persons for possible side effects.

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