

A Cross-Sectional Study to Determine Post-Vaccination Symptoms after Covishield Vaccine among Health Care Workers

Vishwanath Prasad

Tutor, Department of Community Medicine, Anugrah, Narayan Magadh Medical College, Gaya, Bihar, India

Received: 10-01-2023 / Revised: 16-02-2024 / Accepted: 18-03-2024

Corresponding Author: Dr. Vishwanath Prasad

Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to determine post-vaccination symptoms after the first dose of Covishield vaccine among health care workers at a tertiary care centre in Bihar Region.

Methods: A cross-sectional study was conducted among the health care workers hospital in Anugrah, Narayan Magadh Medical College, Gaya, Bihar, India, who received their first dose of the Covishield vaccine from February 2020 to February 2023. A pre-tested questionnaire was used. Of the 1425 health care workers who received the Covishield vaccine at the study center, 1000 health care workers completed the questionnaire.

Results: In the study, it was noted that most of the frontline workers were less than 50 years of age and male predominance. Most of the patients had not allergy and 760 workers continued their work after the vaccination. The most common symptoms were pain at the site of injection (80%), myalgia (68%), tiredness (64%), a feverish feeling (55%), fever (48%), headache (15%), nausea (14%), giddiness (13%) and redness at the site of injection (5%). Rare symptoms reported included anaphylaxis, peri-orbital edema and breathlessness.

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

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

COVID-19 pandemic has escalated to devastating proportions with 50 crore confirmed cases globally as of April 2022 based on WHO dashboards and death toll hitting 62 lakhs worldwide. [1] All governmental organizations have adopted preventive strategies comprising of lock down measures, social distancing, appropriate sanitization, and face masking to curb the spread of the virus.

The advent of vaccine development and its subsequent administration among the population have been believed to be the major and effective prophylactic measure amidst the escalating subsequent waves of COVID-19 infections. India is touted to be one of the countries with the largest vaccine roll-out targets presently administering vaccines according to the recommendations of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). [2-5] Initially Covishield and Covaxin manufactured by Serum Institute of India and Bharat Biotech Ltd respectively were administered in the country. India has administered 187 crores of total COVID-19 vaccination doses with first and second doses

vaccination coverage to almost 100 and 85 crores respectively till April 2022. [4,6]

The health system, economy, and lifestyle were affected globally by coronavirus disease with more than 168 million infections and three-million mortalities as reported to WHO till last week of May 2021. [7] The burden of the disease was expected to decrease with development of herd immunity through acquiring natural immunity via infections or vaccines. The death toll will be overwhelming if we expect natural herd immunity. [8,9] The development of vaccines have opened possibility of herd immunity. [10] The Oxford-AstraZeneca's COVID-19 vaccine AZD 1222 was developed in Serum Institute of India as COVISHIELD vaccine, [11] which was vectored with adenovirus. [11,12] The average efficacy of the vaccine was 70.4%, [13] and was safe. [14]

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. [15] The number of new cases peaked in early January 2021 when there were just under five million cases reported in 1 week. [16] Safe and effective vaccines are needed for both individual protection and the development of herd immunity. [17] COVID-19 is associated with a high mortality rate in vulnerable populations¹⁸ 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. [19]

Although the protective efficacy and side effects of the new vaccines are frequently discussed, little is known about their post-vaccination effects outside of clinical trial conditions. 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.

The aim of the present study was to determine post-vaccination symptoms after the first dose of Covishield vaccine among health care workers at a tertiary care centre in Bihar Region.

Materials and Methods

A cross-sectional study was conducted among the health care workers hospital in Anugrah, Narayan Magadh Medical College, Gaya, Bihar, India, who received their first dose of the Covishield vaccine from February 2020 to February 2023. A pre-tested questionnaire was used. Of the 1425 health care workers who received the Covishield vaccine at the study center, 1000 health care workers completed the questionnaire.

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. 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. 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.

Statistical analysis used

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	Symptomatic		Total	P Value
	N	%		
Age (years)				
<50	900	95.74	940	0.172
>50	55	91.66	60	
Gender				
Female	718	95.73	750	0.525
Male	237	94.8	250	
Allergy				
Absent	1055	95.0%	950	0.71
Present	55	5.0%	50	
Continue your work on the day of vaccination				
No	225	93.75	240	0.452
Yes	720	94.73	760	
COVID-19 infection				
No	4	10	250	0.376
Yes	36	90	750	
Place of work				
Clinical	605	96.03	630	0.488
Laboratory	19	95	20	
Others	330	94.28	350	

In the study, it was noted that most of the frontline workers were less than 50 years of age and male predominance. Most of the patients had not allergy and 760 workers continued their work after the vaccination.

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

Side effects	Male	Female
Fever	335	145
Myalgia/Muscle pain/Body pain	400	280
Pain at site of infection	450	350
Redness in site of infection	35	15
Periorbital edema	12	7
Anaphylaxis	4	3
Breathlessness	5	2
Feverish feeling	300	250
Headache	85	65
Tiredness	350	290
Nausea	95	45
Giddiness	88	42

The most common symptoms were pain at the site of injection (80%), myalgia (68%), tiredness (64%), a feverish feeling (55%), fever (48%), headache (15%), nausea (14%), giddiness (13%) and redness at the site of injection (5%). Rare symptoms reported included anaphylaxis, peri-orbital edema and breathlessness.

Discussion

Worldwide, more than 120 vaccine candidates are in various preclinical and phase 1–3 clinical trials. They include inactivated, live-attenuated, viral-vectored, replicating and non-replicating, protein and peptide-based, and nucleic acid approaches. [20] 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. [21]

A single-blind, randomized, controlled, clinical trial conducted in 20 centers in the UK among those who received the Covishield vaccine showed reports of local and systemic reactions, such as injection-site pain, a feverish feeling, muscle aches, and headaches. [22] 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. [23] 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. [24]

In the study, it was noted that most of the frontline workers were less than 50 years of age and male predominance. Most of the patients had not allergy and 760 workers continued their work after the vaccination. The most common symptoms were pain at the site of injection (80%), myalgia (68%), tiredness (64%), a feverish feeling (55%), fever (48%), headache (15%), nausea (14%), giddiness (13%) and redness at the site of injection (5%). Rare symptoms reported included anaphylaxis, peri-orbital edema and breathlessness. 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. [25] The use of paracetamol for minor symptoms following vaccination is considered acceptable. [26] 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.²¹ 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 (79.8%). [27] Although symptomatic status had no association with various other variables considered in our study, Poland GA et al [21] 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.

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.

References

1. WHO. WHO coronavirus disease [Internet]. WHO; 2021. p. 1.
2. Kumar VM, Pandi-Perumal SR, Trakht I, Thyagarajan SP. Strategy for COVID-19 vaccination in India: the country with the second highest population and number of cases. *npj Vaccines*. 2021 Apr 21;6(1):60.
3. Ministry of Health and Family Welfare. Government of India. COVID-19 vaccines operational guidelines [Internet]; 2020.
4. Harvard.edu. Covid-19 vaccination tracker.
5. Basavaraja CK, Sebastian J, Ravi MD, John SB. Adverse events following COVID-19 vaccination: first 90 days of experience from a tertiary care teaching hospital in South India. *Therapeutic advances in vaccines and immunotherapy*. 2021 Nov;9:25151355211055833.
6. Ministry of Health and Family Welfare. CoWIN dashboard [Internet].
7. World Health Organization. WHO Coronavirus (COVID-19) Dashboard [Internet]. Geneva: World Health Organization; 2021 May.
8. Shrestha S, Devbhandari RP, Shrestha A, Aryal S, Rajbhandari P, Shakya B, Pandey P, Shrestha RK, Gupta M, Regmi A. Adverse events following the first dose of ChAdOx1 nCoV-19 (COVISHIELD) vaccine in the first phase of vaccine roll out in Nepal. *Journal of Patan Academy of Health Sciences*. 2021 Apr 29;8(1):9-17.
9. Randolph HE, Barreiro LB. Herd immunity: Understanding COVID-19. *Immunity*. 2020 ;52(5):737-41.
10. Kiwan A. Understanding the journey of herd immunity. Seattle (USA): PATH; 2021 Feb.
11. Sinha D. Serum Institute applies for Emergency Use of Covishield Corona vaccine; Check price, likely availability. New Delhi: Financial Express; 2020 Dec.
12. The Hindu. Coronavirus | After SII, Bharat Biotech seeks DCGI approval for Covaxin [Internet]. New Delhi: The Hindu; 2020 Dec.
13. Thiagarajan K. Covid-19: India is at centre of global vaccine manufacturing, but opacity threatens public trust.
14. Voysey M, Clemens SA, Madhi SA, Weckx LY, Folegatti PM, Aley PK, Angus B, Baillie VL, Barnabas SL, Borat QE, Bibi S. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *The Lancet*. 2021 Jan 9;397(10269):99-111.
15. Sharma O, Sultan AA, Ding H, Triggle CR. A Review of the Progress and Challenges of Developing a Vaccine for COVID-19. *Frontiers in immunology*. 2020 Oct 14;11:585354.
16. Weekly epidemiological update on COVID-19 - 29 June 2021.
17. Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR, Voysey M, Aley PK, Angus B, Babbage G, Belij-Rammerstorfer S. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. *The Lancet*. 2020 Dec 19;396(10267):1979-93.
18. Rossen LM. Excess deaths associated with COVID-19, by age and race and ethnicity—United States, January 26–October 3, 2020. *MMWR. Morbidity and mortality weekly report*. 2020;69.
19. Covid CD, Team R, Food and Drug Administration. Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine—United States, December 14–23, 2020. *Morbidity and Mortality Weekly Report*. 2021 Jan 1;70(2):46.
20. Zheng H, Jiang S, Wu Q. Factors influencing COVID-19 vaccination intention: The roles of vaccine knowledge, vaccine risk perception, and doctor-patient communication. *Patient Education and Counseling*. 2022 Feb 1;105(2):277-83.
21. Poland GA, Ovsyannikova IG, Crooke SN, Kennedy RB. SARS-CoV-2 vaccine development: current status. *In Mayo Clinic Proceedings* 2020 Oct 1 (Vol. 95, No. 10, pp. 2172-2188). Elsevier.
22. CDC. COVID-19 vaccination: Clinical considerations. Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Atlanta, GA: US Department of Health and Human Services, CDC; 2020
23. Biasio LR, Bonaccorsi G, Lorini C, Pecorelli S. Assessing COVID-19 vaccine literacy: a preliminary online survey. *Human vaccines & immunotherapeutics*. 2021 May 4;17(5):1304-12.
24. Freeman D, Loe BS, Chadwick A, Vaccari C, Waite F, Rosebrock L, Jenner L, Petit A, Lewandowsky S, Vanderslott S, Innocenti S. COVID-19 vaccine hesitancy in the UK: the Oxford coronavirus explanations, attitudes, and narratives survey (Oceans) II. *Psychological medicine*. 2022 Oct;52(14):3127-41.
25. Chen JS, Alfajaro MM, Chow RD, Wei J, Filler RB, Eisenbarth SC, Wilen CB. Non-steroidal anti-inflammatory drugs dampen the cytokine and antibody response to SARS-CoV-2 infection. *J Virol*. 2021 Mar 10;95(7):e00014-21.

26. Sah R, Shrestha S, Mehta R, Sah SK, Rabaan AA, Dhama K, Rodriguez-Morales AJ. AZD1222 (Covishield) vaccination for COVID-19: Experiences, challenges, and solutions in Nepal. *Travel Med Infect Dis*. 2021 Mar-Apr;40:101989.
27. Azimi M, Dehzad WM, Atiq MA, Bahain B, Asady A. Adverse Effects of the COVID-19 Vaccine Reported by Lecturers and Staff of Kabul University of Medical Sciences, Kabul, Afghanistan. *Infect Drug Resist*. 2021 Oct 2;14:4077-4083.