European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 09, Issue 02, 2022

Original research article

Adverse events following COVID vaccination among undergraduate students in a medical college, South India: A cross sectional study

[1]Dr. Nandini RC, [2]Dr. Tejashwini K, [3]Dr. Shanthi M, [4]Dr. Dilip Kumar, [5]Nishitha Gowda

[1,2,3] Assistant Professor, Department of Community Medicine, Dr BR. Ambedkar Medical Collage, Bengaluru, Karnataka, India
[4]Assistant Professor, Department of Pediatrics, Dr BR. Ambedkar Medical Collage, Bengaluru, Karnataka, India
[5]Undergraduate Student MBBS, Dr BR. Ambedkar Medical Collage, Bengaluru, Karnataka, India

Corresponding Author:
Dr. Dilip Kumar

Abstract

Background: COVID Vaccination has given a ray of hope in fighting against coronavirus disease 2019 (COVID-19).Since the experiences are relatively new to all, it is important to monitor safety of vaccines in a real-world setting. With this background, this study was conducted.
Objective: To assess the pattern of AEFI among undergraduate students.
Methods: This cross-sectional study was conducted in a Hospital setting with 200 vaccinated medical students being enrolled in the study and Data were analysed using SPSS version 20.00.
Results: Total of 200 medical students, 142(71%) and 74(37%) of study subjects had one or more AEFI following COVID-19 vaccination following 1st and 2nd dose respectively. All the AEFI's (100%) were only minor reactions.
Conclusion: The study reflected that COVID-19 vaccination caused only mild and non-serious AEFI in most of the vaccine recipients. Hence the vaccine given can be considered safe.

Key words: Adverse events following immunization, COVID-19, pandemic, vaccination.

Introduction

The "Severe Acute Respiratory Syndrome Corona virus 2 (SARS-CoV-2)" disease has caused a challenging and threatening pandemic globally (COVID-19). This virus is highly contagious and has caused disruption of the world's health and economy [1]. Adverse events following immunization (AEFIs) are defined as any untoward medical occurrence that follows immunization and that does not necessarily have a causal relationship with the usage of a vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom, or disease [2]. WHO has listed the two Indian made vaccines COVISHIELD by Serum Institute of India on 15 February 2021 and COVAXIN (Bharat

Biotech) vaccines on 3rd November 2021 for emergency use [3]. Initially, in the first phase, the country vaccinated people at the high risk of exposure, such as healthcare and frontline workers, on priority with Covishield TM, and then, Covaxin TM was made available. From March 2021, the second phase of vaccination was started. Vaccines were available first for people aged above 60 and above 45 with comorbidities. This was expanded on April 1, 2021, to cover everyone above 45 years. In the third phase, vaccines were made available for people above 18 years of age. The guideline document released by the Government of India mentioned management plans for AEFI and recording of the same through the COVID Vaccine Intelligence Network (CoWIN) software [4]. The WHO COVID vaccine safety surveillance manual recommends active and various passive systems to monitor AEFIs. This is to ensure vaccine safety and generate data on the overall short-term and long-term. Previous systematic reviews and studies conducted mostly on healthcare workers and published reports on the active surveillance of spontaneous reports by AMCs pointed toward the fact that COVID-19 vaccines are relatively safe. The studies stressed the need for population-based surveillance and a long-term follow-up especially in vaccinated individuals with comorbidities [5, 6, 7, 8, 9]. As there are no much studies done to throw light regarding the topic in our locality, present study was done to assess the proportion and pattern of AEFI among medical college students who received COVID 19 vaccination.

Methodology: A descriptive cross-sectional study was conducted in a Tertiary care centre, Bengaluru after getting clearance from the Institutional Ethical Committee. A total of 200 Undergraduate medical students who had completed their second dose of covid vaccination were enrolled in the study after taking consent and the duration of the study period was for 2 months between September 2021 to November 2021.

A pre-tested semi-structured questionnaire was administered, the questionnaire included personal information on the respondent's demographic characteristics, general information related to the COVID-19 vaccine, the type of vaccine received, the number of doses, AEFIs, and health status in terms of comorbidity, and details on AEFI reporting. Baseline data were assessed using descriptive statistics. All quantitative variables are presented as means and standard deviations, and all qualitative variables are presented as frequencies and percentages. For the comparison of categorical variables, the chi-square test was used. Data were entered into Microsoft Excel and analysed using SPSS version 20.00.

Results

Table 1: Demography and vaccination details

Variable	Outcome	Percentage	frequency
Gender	Male	44	88
	Female	66	132
Age (yrs)	19-22	57.5	115
	23-26	41	82
	27-30	1.5	03
Comorbidities	Asthma	07	14
	Allergy	01	02
	Cardiac disease	01	02
Type of vaccine	Covishield	100	200
Vaccination facility	Govt facility(free)	83	166
	Private facility(paid)	17	34
Interval between two doses	<90 days	16	32
	≥90days	84	168
Post vaccination covid infection	yes	1	2
	no	99	198

ISSN 2515-8260 Volume 09, Issue 02, 2022

Demographic profile: The demographic profile of vaccine recipients shows that 57.5% belonged to age group of 19 to 22 years, 41% belonged to age group 23 to 26 years and 1.5% belonged to 27 to 30 years with mean 21.4±1.045. Majority of our study subjects were females 66%.

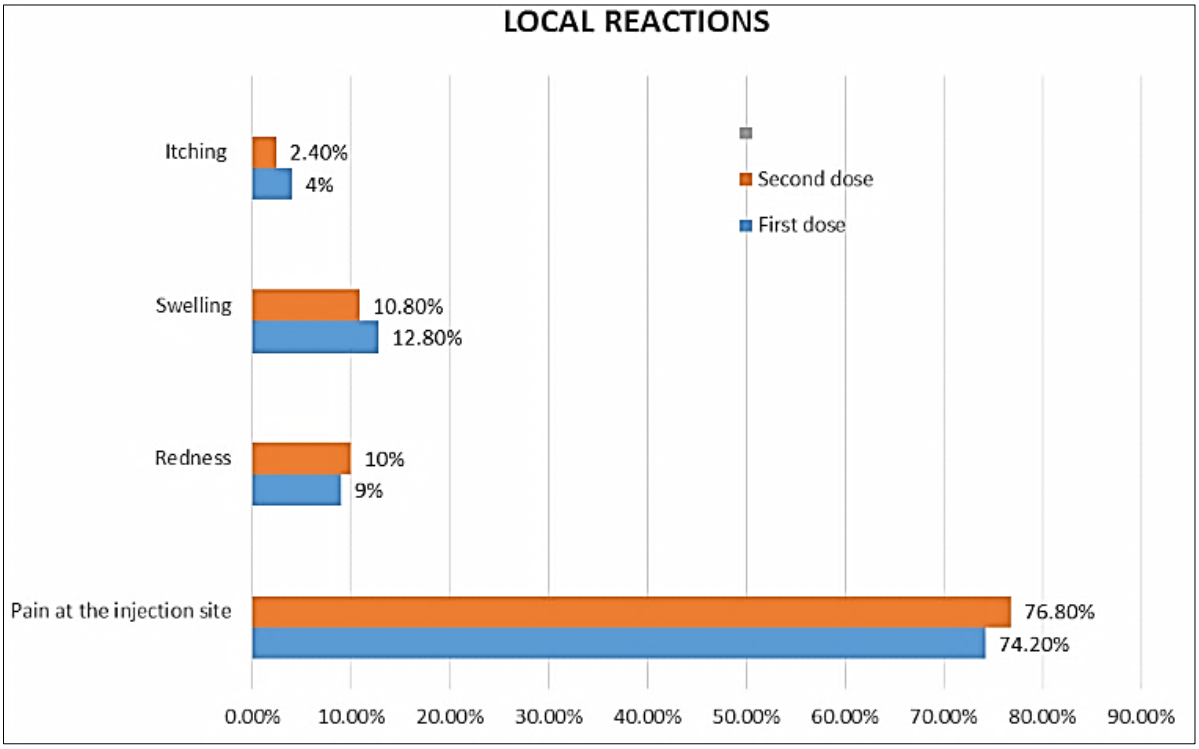
Type of vaccine: All the study participants (100%) had received Covishield TM

Vaccination Facility: Majority of the study participants 166(83%) got their vaccination from government facility and 34(17%) got their vaccination from private facility.

Co-morbidities: Only 9% (18) of the study participants had comorbidities. Around 1% (2) of them were found to have allergy, 1% (2) cardiac disease and 7% (14) had Bronchial asthma.

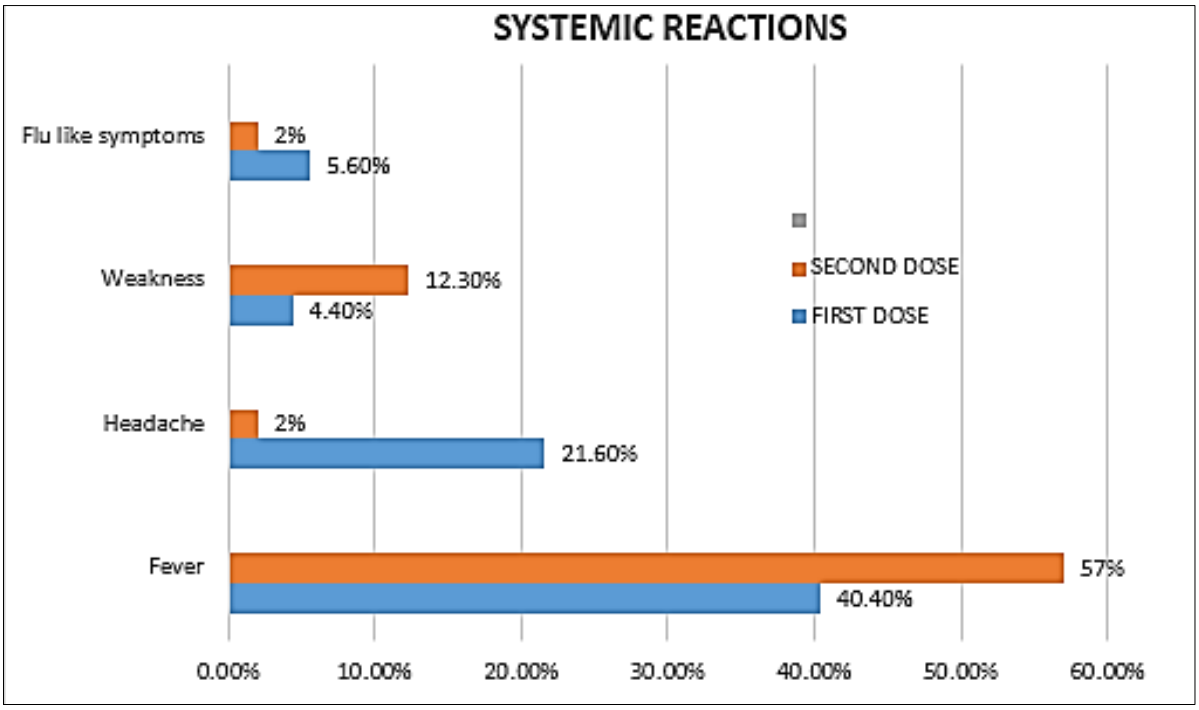
Post-vaccination COVID infection: 2 Study participants were diagnosed with COVID infection after second dose of vaccination (mean duration 14±6 days). None were hospitalized and recovered with home care.

Adverse events following immunisation



Graph I: Local reactions following 1st and 2nd dose of COVID vaccination

ISSN 2515-8260 Volume 09, Issue 02, 2022



Graph II: Systemic reactions following 1st and 2nd dose of COVID vaccination

Adverse events following immunization after the first dose
Number of students who had AEFI was 142 (71%) with 1st dose. The most common side effects were.

Local reactions: Pain at the site of injection 127(74.2%), swelling 22(12.8%), redness 16(9%) and itching 6(4%). (Graph I). Many developed local reactions between 6-12 hours after injection.

Systemic reactions: Fever among 101(40.4%), Body pain - 65(26%) and headache 54(21.6%). No serious adverse events were reported (Graph 2). The mean duration of developing systemic reactions was 24-48hrs and none of them reported to any clinic / Hospital nor reported AEFI on website portal, most of them -112(78.8%) took paracetamol for fever and body pain.

Adverse events following immunization after the second dose
Number of students who had AEFI reduced to 74 (37%) with 2nd dose.
The most common side effects were:

Local reactions: Pain at the site of injection 63(76.8%) redness 8(10%), swelling 9(10.8%) and itching 2(2.4%). (Graph II). The mean duration of developing local reactions was between 6-12 hours after injection

Systemic reactions: Fever among 28(57%), Body pain-13(26.7%) and weakness 6(12.3%). No serious adverse events were reported. (Graph 2). The mean duration of developing systemic reactions was 24-48hrs and none of them reported to any clinic /Hospital nor reported AEFI on website portal. Around 42(56.7%) took paracetamol for fever and body pain.

ISSN 2515-8260 Volume 09, Issue 02, 2022

Table 2: Association of AEFI with gender

Association of AEFI		AEFI following the first dose			AEFI following the second dose		
		Yes	no	p-value	Yes	no	p-value
Gender	Male	41	27	0.016*	19	49	0.056
	Female	101	31	(X^2=5.73)	55	77	($X^{2=}$3.6)

*significant p value

Table 3: Association of AEFI with Dose of vaccine

Association of AEFI	AEFI present	AEFI absent	Chi square	p value
1st dose	142	58	46.53	<0.0001*
2nd dose	74	126		

*significant p value

Association of AEFI with gender and dosage of vaccine: The number of females who experienced AEFI was found to be higher when compared to males with the first dose. The difference was statistically significant. There was no statistically significant difference in the number of participants experiencing AEFI following second dose. There was a significant association noted with the dose of vaccine and AEFI. (Table II &III).

Discussion

In the current study the majority of adverse events reported after the ChAdOx1 nCoV -19 vaccine (Covishield) were non-serious. Overall 71% recipients developed non-serious AEFI rate after the first dose of vaccination. Similar finding was reported at similar frequencies in comparison to the Phase 2/3 trial of the ChAdOx1 nCoV19 (COVISHIELD) vaccine where 88% of recipients (18 to 55 years) reported adverse events [10]. In another study conducted 33.7% of recipients reported adverse events after the first dose of vaccine [11, 12]. Variation in the rate might be because of younger age group involved in the current study whereas the other study included subjects between 18-99 years. All our study participants were medical students who were able to recognize the AEFI and report it. Hence, we could trace for adverse events from more subjects.

We reported fewer adverse events after the second dose. Overall 34% recipients reported adverse events after the second dose. Findings are in line with the observations of phase 1 and phase 2/3 trials where the incidence of adverse events were fewer after booster doses [10]. Similarly a decline of adverse events was noted in a study done by in Andhra Pradesh among health care works receiving COVISHILED vaccine [13]. In our study, very common side effects were- pain at the injection site, redness and fever along with Body pain. According to Serum Institute of India tenderness, pain, warmth, redness, itching, swelling, or bruises where the injection is given, feeling unwell, fatigue, chills, or feeling feverish, headache, nausea, and joint pain or muscle ache are included in “very common” side effects affecting more than 1 in 10 people. However, higher incidence of local adverse events were observed in our study. And none of our subjects reported their adverse effects either in hospital nor the portal (COWIN). In few studies its reported that majority of the subjects did not have any idea about adverse event reporting and many sought self-treatment [14].

Strengths and limitations

To the best of our knowledge, this study was conducted and all the vaccine recipients were enquired about the adverse events on uniform AEFI reporting forms. We studied adverse events from all the subjects with each dose of COVISHIELD. All the recipients received two

doses of vaccines and we collected data for the occurrence of adverse events for both doses. The completeness of reporting was ensured by the investigator to ensure accurate and complete reporting of the adverse events. Since all the subjects were medical students they could easily identify and report AEFI. Hence, we could report all the possible adverse events with more precision. The authenticity and accuracy of reporting the adverse events were better as the study was conducted exclusively in health care workers who could assess or understand and precisely report the adverse events.

Conclusion

The short-term adverse events of both the doses were observed to be non serious. The rate of reactions reduced greatly with second dose of COVID vaccine. The AEFI reports were mostly non serious and resolved completely with or without treatment. Symptoms were mild in severity and short-lived. Our study showed that the vaccine was safe and well-tolerated. And also it was observed that the adverse event reporting was poor. It is, therefore, important to take up more awareness campaigns regarding reporting of AEFIs through the COVID Vaccine Intelligence Network (CoWIN) portal.

References

1. Meo S, Al-Khlaiwi T, Usmani A, Meo A, Klonoff D, Hoang T. Biological and epidemiological trends in the prevalence and mortality due to outbreaks of novel coronavirus COVID-19. Journal of King Saud University – Science. 2020;32(4):2495-2499. DOI:10.1016/j.jksus.2020.04.004.
2. AEFI-Surveillance-and-Response-Operational-Guidelines ministry of health and family welfare, 2015. Availablefrom:http://www.nhm.gov.in/New_Updates_2018/NHM_Components/Immunization/Guildelines_for_immunization/AEFI_Surveillance_and_Response_Operational_Guidelines_2015.pdf
3. COVID19vaccinesWHOEULissued:https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued.
4. Ministry of Health and Family Welfare: COVID-19 vaccines operational guidelines, 2021. Accessed: Feb 22 2022: https://main.mohfw.gov.in/newshighlights-3)
5. Konda VC, Gokul T, Poojitha M, Rao KU. Adverse events following immunization to COVID-19 vaccines in a tertiary care hospital - a descriptive study. Biomed Pharmacol J. 2021;14:10. https://dx.doi.org/10.13005/bpj/2312
6. Kaur R, Dutta S, Bhardwaj P, Charan J, Dhingra S, Mitra P, *et al*. Adverse Events Reported From COVID-19 Vaccine Trials: A Systematic Review. Indian Journal of Clinical Biochemistry. 2021;36(4):427-439. https://dx.doi.org/10.1007%2Fs12291-021-00968-z
7. Basavaraja C, Sebastian J, Ravi M, John S. 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. https://doi.org/10.1177/25151355211055833
8. Mohammed R, Garout R, Wahid S, Ayub F, Firas ZinAlddin L, Sultan I. A Survey on the Side Effects of Pfizer/BioNTech COVID-19 Vaccine Among Vaccinated Adults in Saudi Arabia. Cureus, 2021. DOI:10.7759/cureus.19222.
9. Jahan N, Rahman F, Saha P, Ether S, Roknuzzaman A, Sarker R, *et al*. Side Effects Following Administration of the First Dose of Oxford-AstraZeneca's Covishield Vaccine in Bangladesh: A Cross-Sectional Study. Infectious Disease Reports. 2021;13(4):888-901. https://doi.org/ 10.3390/idr13040080

10. Voysey M, Pollard A. ChAdOx1 nCoV-19 vaccine: asymptomatic efficacy estimates – Authors' reply. The Lancet. 2021;397(10291):2248. DOI: 10.1016/S0140-6736(21)00976-4.
11. Zhu F, Guan X, Li Y, Huang J, Jiang T, Hou L, *et al*. Immunogenicity and safety of a recombinant adenovirus type-5-vectored COVID-19 vaccine in healthy adults aged 18 years or older: a randomised, double-blind, placebo-controlled, phase 2 trial. The Lancet. 2020;396(10249):479-488. DOI: 10.1016/S0140-6736(20)31605-6.
12. Ramasamy, Maheshi N, *et al*. 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. Lancet (London, England). 2020;396(10267):1979-1993. DOI: 10.1016/S0140-6736(20)32466-1
13. Kamal D, Thakur V, Nath N, Malhotra T, Gupta A, Batlish R. Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study. Medical Journal Armed Forces India. 2021;77:S283-S288. DOI: 10.1016/j.mjafi.2021.06.014.
14. Rajpurohit P, Suva M, Rajpurohit H, Singh Y, Boda P. A Retrospective observational survey of adverse events following immunization comparing tolerability of covishield and covaxin vaccines in the real world. Journal of Pharmacovigilance and Drug Research. 2021;2(3):21-26. https://doi.org/10.53411/jpadr.2021.2.3.5.