ORIGINAL ARTICLE

Adverse Events Following COVID-19 Vaccination among the Beneficiaries of Sikkim Manipal University: A Cross Sectional Study

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Abstract | Introduction | Methodology | Results | Conclusion | References | Citation | Tables / Figures

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Abstract

Background: Covid-19, an infection caused by SARS- CoV2 has claimed millions of lives since late 2019 with no curative measures. In India, 4 vaccines have been approved for use i.e. Serum Institute's Covishield, Bharat Biotech's Covaxin, GRIEM's Sputnik V and Moderna's Covid-19 vaccine. **Aims:** This study aims to find the adverse events following Covishield vaccination among the beneficiaries of Sikkim Manipal University, Sikkim. **Material &Methods:** A cross sectional study was conducted among the beneficiaries of Sikkim Manipal University to find out the adverse events following the first dose of vaccination. The data was collected using a self-administered questionnaire when the beneficiaries came for their second dose of vaccination. Microsoft Excel and SPSS version 27 was used for statistical analysis. **Results:** Out of 716 study participants majority i.e. 79.5% of the study participants developed adverse events following their first dose with maximum (73.8%) complaining of pain at the site of infection followed by fever (65.2%). **Conclusions:** Vaccines may prevent diseases, but it also brings about adverse effects, be it minor or major. Hence, many studies are required to study their full-fledged side effects and the means to overcome them.

Keywords

Covid-19 Vaccine, Covishield, Adverse Events, AEFI, Side Effects

Introduction

COVID-19, (1) an infection caused by SARS-CoV-2 (Severe Acute Respiratory Corona Virus-2) spreads through discharges or droplets from the nose and mouth. Symptoms vary from asymptomatic cases to deaths.

It has affected millions worldwide (117 million and still counting) and lead to massive loss to the human race (2.59 million deaths) (2). The International Monetary Fund estimated that the global economy fell by 4.4% (3) and mental health was seriously affected. (4)(5)

A new path emerged with the possibility of a vaccine. Countries came forward like China with its Can Sino vaccine (6), Russia with Sputnik V(7),USA along with Germany with Pfizer-BioNTech vaccine(8). Likewise Bahrain and the UAE with BBIBP-CorV(9) and USA with the Moderna vaccine.(10)

In India, the vaccines that have been approved for use against Covid-19 infection are: Covishield, Covaxin, Sputnik V and Moderna vaccines. 13 vaccines are in trials currently like Novavax, Covovax, ZycoV-D, Becov2 series vaccines, HGCO19, etc.(11,12)

The largest vaccination drive began in India from late January 2021 in a phased manner.(13) Till date nearly 83 million people have been fully vaccinated and 321 million have received at least one dose of the vaccine.(14)

There is a growing need of studies in Covid-19 vaccines, not just to study its efficacy but also to know about the associated adverse events.

Aims & Objectives

To find the numerous adverse events following Covishield vaccination among the beneficiaries.

Material & Methods

Study Type: Cross sectional type of descriptive epidemiological study.

Study population: Beneficiaries of Sikkim Manipal University who received their 2nd dose of Covishield Vaccine during the study period.

Study Area: Sikkim Manipal University, Gangtok, East Sikkim.

Study Duration: Six months (March-August 2021).

Sample size calculation: Total enumeration of SMU beneficiaries who received their 2nd dose of Covishield vaccine during the study period.

Inclusion Criteria: Beneficiaries who gave their consent for the study.

Exclusion criteria: Beneficiaries who received their 2nd dose of the vaccine before March 2021.

Study Tool: Pre-designed semi structured questionnaire.

Data Collection Procedure: Beneficiaries who came for their second dose of the Covishield vaccine at the Central Referral Hospital vaccination site were informed about the study. A self-administered questionnaire was provided after getting their consent. The questionnaire was filled during the observation period.

Ethical approval: Approved by the Institute Ethics Committee, Sikkim Manipal University.

Consent: Written informed consent taken.

Data Analysis- Software: The collected data was entered in Microsoft Excel spread sheet and summarized and analyzed through descriptive and inferential statistics using SPSS software version 27. The descriptive statistics were displayed using tables and figures by frequencies and percentages; Chi square test was used for the inferential statistics.

Flow Diagram: (Figure 1)

Results

Out of the total 716 study participants, only 8.8% (n=63) of the study participants were currently suffering from co-morbidities which included mostly hypertension (27%), thyroid disorders (17.5%) and diabetes mellitus(17.4%).

55 study participants (7.7%) reported being infected by COVID-19 in the past whilst majority (92.3%) did not have any history of C0VID-19 infection. Among those who were infected, most were either asymptomatic or only mildly symptomatic.

79.5% (n=569) of the study participants developed adverse events following their first dose of Covishield vaccination with maximum (73.8%) complaining of pain at the site of infection. Other minor side effects recorded were nausea, vomiting, vision complaints, rashes over the body, breathlessness, palpitations, lump formation at site of injection, lack of appetite and bowel disturbances. (Figure 2) & (Figure 3)

Using Chi Square test by SPSS version 27, it was observed that there was no association between the personal habits of the study participants (smoking, drinking and consuming other substances) or past Covid-19 infections and the development of adverse events following vaccination.

Discussion

In this study, all the beneficiaries of Sikkim Manipal University who came for their second dose of the vaccination (N=716) in the period of March and April 2021 were included in the study. Most of the study populations were females and mostly students of varied departments of Sikkim Manipal University belonging to the age group of 18-28 years. Similarly in a study conducted at Norway and Denmark among the recipients of ChAdOx1-S, it was seen that most of the study participants were females and health workers with median age of 44 and 45 years respectively.(15)

In this study, majority of the study participants complained of one or more adverse events following vaccination, out of which pain at the site of injection was the highest in number. It was followed by fever, body ache/myalgia, headache, lethargy and chills. The minor adverse events reported by the participants included giddiness, breathlessness, rigors, vision complaints, bowel disturbances, rashes over the body and lump formation at the site of injection. 2 serious complications of excessive vomiting and palpitations were observed who required a visit to the hospital but soon recovered after medications. Similarly in a report from among the health workers of South Korea also, the adverse events reported were injection site pain, myalgia, fatigue, headache and fever with 1 serious adverse event of vomiting who required hospitalization.(16) However, in the study conducted at Norway and Denmark it was seen that most of the study participants complained of venous thrombo-embolic events, bleeding and coagulation disorders or thrombocytopenia.(15) In lieu of these findings from Norway, Denmark and other places of Europe, ChAdOx1-S was banned for use.(17)

In this study, no significant association was seen between personal habits of smoking, consuming alcohol or consuming other substances like paan, gutka or chewing betel nuts and development of adverse events following vaccination. In a study conducted in Bundelkhand, Uttar Pradesh, India, it was seen that the developments of AEFI was found to be associated with past Covid-19 infections (18) but no significant association between past Covid-19

infections and the development of adverse events was seen in this study.

Conclusion

In this study, majority of the participants (79.7%) reported side effects of varied nature with maximum complaining of pain at the site of injection (58.7%) followed by fever (51.8%), body ache, headache, lethargy and chills. The minor adverse events reported by the participants included giddiness, breathlessness, rigors, vision complaints, bowel disturbances, rashes over the body and lump formation at the site of injection.

These were the findings of just one centre with beneficiaries involving the health-care workers. There may have been varied adverse events, rare or even fatal consequences all over the world. Hence, similar studies are required to study all the Covid-19 vaccines, the spectrum of side effects and the ways to overcome them.

Recommendation

Our study shows majority of the study population reporting adverse following vaccination while Co-Win portal reports less than 1 percentage of AEFIs (till date).(19) Hence, robust reporting and monitoring of adverse events post vaccination is required.

Limitation of the study

The current study is the first of its kind conducted in Sikkim regarding the adverse events following vaccination in the first phase of Covid-19 vaccination covering health care workers and medical students.

This study also has certain weaknesses. The study included only the beneficiaries for one centre i.e. Sikkim Manipal University and its affiliated hospital, Central Referral Hospital and cannot be generalized to other healthcare workers of the State. It also includes only healthcare workers and hence cannot be generalized to other population of the state. Majority of the study participants belonged to younger age groups (18-28 years) and the percentage of people suffering from co-morbidities were also less. Method used was a self-administered questionnaire provided to the participants when the beneficiaries came for their second dose of vaccination.

Relevance of the study

Pandemic of Covid-19 resulted in urgent need of vaccines which were regulated by the Government and accepted by the masses. Therefore, any new information will be only adding to the knowledge which will be beneficial for further research.

Authors Contribution

JLB: Concept, Design, Clinical Studies, Literature search, Data acquisition, Data analysis, Statistical analysis, manuscript preparation, manuscript editing, manuscript review. BU: Concept, Literature search, manuscript preparation, manuscript editing, manuscript review, Guarantor. EJB: Concept, Design, Clinical Studies, Literature search, Data analysis, Statistical analysis, manuscript review. SK: Manuscript editing, manuscript review, Guarantor. FAZ: Manuscript editing, manuscript review, Guarantor

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Tables

TABLE 1 DISTRIBUTION OF THE STUDY PARTICIPANTS ACCORDING TO THEIR SOCIO-DEMOGRAPHIC PROFILE (N=716)

Parameters		Frequency	Percentage (%)
Age	18-28 years	399	55.7
	29-38 years	178	24.9
	39-48 years	105	14.7
	49-58 years	25	3.5
	Above 59 years	9	1.3
Gender	Male	229	32
	Female	487	68
Educational level	Post graduate degree	144	20.1
	Graduate degree	220	30.7
	Senior Secondary School Certificate	299	41.8
	Secondary school certificate	33	4.5
	Middle school certificate	17	2.4
	Primary school certificate	2	3
	Literate	1	1
Occupation	Doctor	112	15.6
	Nurse	128	17.9
	Administration/clerical/technical	73	10.2
	Other healthcare workers	151	21.1
	Student	252	35.2

TABLE 2 DISTRIBUTION OF STUDY POPULATION BASED ON THEIR PERSONAL HABITS (N=716)

Parameter		Frequency	Percentage (%)
Smoking	Smoker	91	12.7
	Non smoker	625	87.3
	Smoked within 48 hrs of vaccination (n=91)	48	52.74
Alcohol consumption	Alcoholic	214	29.9
	Non alcoholic	502	70.1
	Consumed alcohol within 48 hrs of vaccination (n=214)	15	7
Consumption of other substances (gutka, paan, betel nut, etc.)	Yes	52	7.3
	No	664	92.7
	Consumed within 48 hrs of vaccination (n=52)	23	44.2
Skipping meal before vaccination	Yes	82	11.5
	No	634	88.5

TABLE 3 DISTRIBUTION OF STUDY PARTICIPANTS BASED ON ONSET, DURATION AND MODE OF RECOVERY OF ADVERSE EVENTS FOLLOWING VACCINATION. (N=569)

Parameter		Frequency	Percentage (%)
Onset of adverse events	≤ 6 hours	168	29.52
	6-12 Hours	285	50
	>12 hours	116	20.38

Duration of adverse events	≤ 24 hours	317	55.71
	> 24 hours	252	44.29
Mode of recovery from adverse events	Self-recovery	256	45
	By self medication	311	54.7
	Hospital visit	2	0.3

TABLE 4 ASSOCIATION BETWEEN PAST COVID-19 INFECTION AND THE DEVELOPMENT OF ADVERSE EVENTS FOLLOWING VACCINATION

Covid-19 infection	Adverse events		*χ2/ df/ p-value*
	Yes	No	
Yes	45	9	0.465/1/0.495
No	526	136	

Figures

FIGURE 1 FLOW DIAGRAM

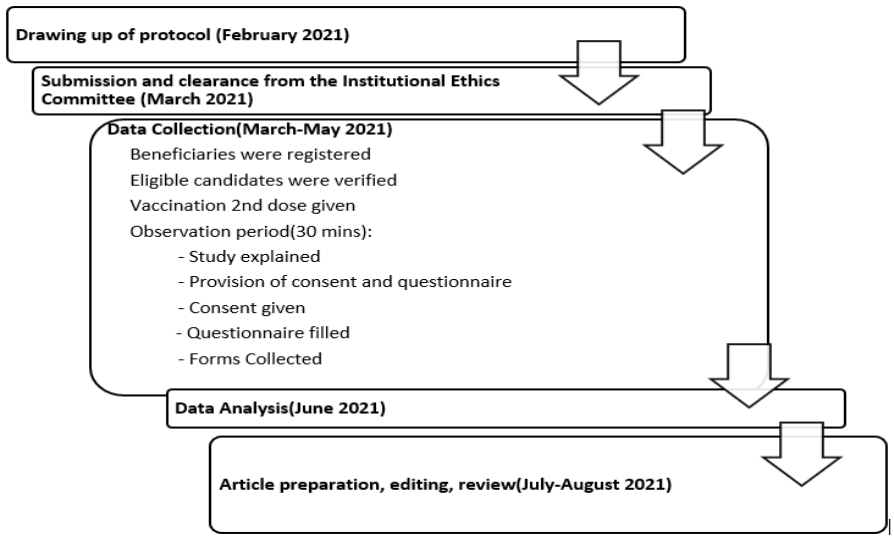

FIGURE 2 DISTRIBUTION OF STUDY PARTICIPANTS BASED ON PRESENCE OF ADVERSE EVENTS FOLLOWING VACCINATION (N=716)

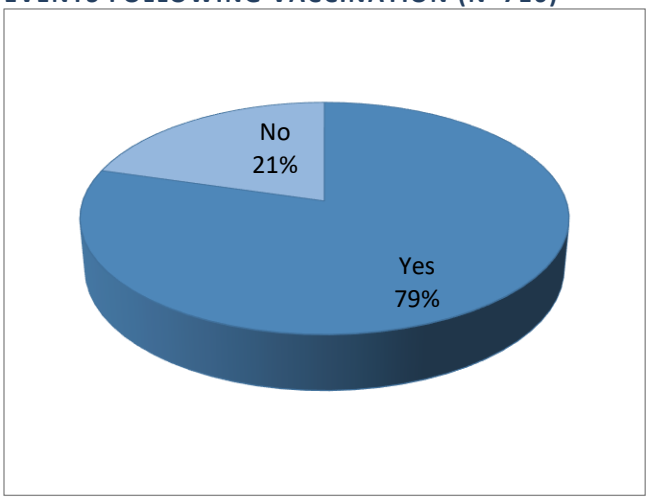

FIGURE 3 DISTRIBUTION OF STUDY PARTICIPANTS BASED ON TYPE OF ADVERSE EVENT EXPERIENCED FOLLOWING VACCINATION (N=569)*