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Research Article

Observational Study on Prevalence of Adverse Effects of COVID Vaccination among General Population in South India

Muhas C[1], Anuradha VP[2]*, Sreelakshmi KB[2], Aysha Samrin[2], Shida Ahmed NP[2], Muhammed Anfas P[2]

[1] *Department of Pharmacy Practice, Moulana College of Pharmacy, Perintalmanna, Malappuram Kerala, India, 679321*

[2] *Department of Pharmacy Practice, KTN College of Pharmacy, Chalavara, Ottappalam, Palakkad, Kerala, India, 679505*

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*Address for Correspondence:

Mrs. Anuradha VP, Assistant Professor, Department of Pharmacy Practice, KTN College of Pharmacy, Chalavara, Ottappalam, Palakkad, Kerala, India, 679505

Abstract

Introduction: COVID-19 is a viral disease due to the Severe Acute Respiratory Syndrome Coronavirus 2. The patients show flu-like symptoms with a dry cough, sore throat, high fever, and breathing problems. This was conducted to assess the adverse effects after taking Covid 19 vaccines in general population of Kerala state.

Methodology: About 353 participants were enrolled in the study according to inclusion and exclusion criteria for a period of November 2021 to April 2022. Data collection was done with structured questionnaire in google form. The data were analysed and reported using tables, pie diagram, bar diagrams and different charts forms.

Results: Majority of patients enrolled in the study were vaccinated with 2 dosed of Covid vaccines. From 351 participants vaccinated with Covid 19 vaccine 249 experienced an AEFI. The most reported AEFI was fever, body pain and injection site reactions. From the results it was found that females had experienced more AEFI than males. Most of the participants from our study were vaccinated with Covishield and all participants taken Sputnik vaccine had experienced some adverse effects.

Conclusion: The present study reveal that majority of people vaccinated by Covid 19 vaccines had experienced any kind of AEFIs. Majority of patients enrolled in the study were vaccinated with 2 dosed of Covid vaccines. The most reported AEFI was fever, body pain and injection site reactions. From the results it was found that females had experienced more AEFI than males.

Keywords: Adverse effects, Covid 19, Covishield, Covaxin, Immunization, Vaccination

INTRODUCTION

COVID-19 is a viral disease due to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus. The patients show flu-like symptoms with a dry cough, sore throat, high fever, and breathing problems. About 53.3 Cr people have been infected with more than 6.2 million deaths globally. [1] There is no treatment for this disease best option is to prevention and management. It was analysed that a combination of antiviral drugs with hydroxyl-chloroquine and azithromycin are given for management in the patients, depending on the patient's conditions and symptoms. Vaccines are most accepted prevention method for COVID -19 worldwide. Till now about 11 billion people get vaccinated by COVID 19 vaccines. [2]

Vaccines available in India for COVID 19 include; Oxford–AstraZeneca vaccine (manufactured under license by Serum Institute of India under the trade name Covishield), Covaxin (a vaccine developed locally by Bharat Biotech), Sputnik V (manufactured under license by Dr. Reddy's Laboratories, and CorbeVax COVID-19 Vaccine (BioE COVID-19, BECOV2D) is a protein subunit vaccine developed by Biological Limited.[3, 4]

Even though vaccines are considered safe there may be several adverse event followed by vaccination which need to be identified. Several reports of the impact of COVID-19 vaccines on human health have been published, and each vaccine has a different safety and efficacy profile. These reports were variable depending on the type of vaccine investigated and population characteristics. This variation is possible due to the different ethnic groups and genetic make-up. The reported adverse drug reactions (ADRs) of the vaccines included pain at the injection site, body weakness, myalgia, shivering, headache, tachycardia, and symptoms or signs of upper respiratory inflammation. [5,6,7]

Adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. Effective spontaneous reporting of adverse events following immunization (AEFI) is the first step to making sure that vaccine products are safe and are being safely administered. Yet almost half the world's population lives in countries without an effective system for monitoring the safety of vaccines.[8,9] This study mainly aims to find the occurrence of adverse effects after covid vaccination among general population in the state of Kerala, South India.

MATERIALS AND METHODS

Study Design: This was an observational study.

Study Duration: November 2021 to April 2022 (6 months).

Study Population: This was an observational study conducted in a community of general population in Kerala. The study subjects were general population who receive atleast one dose of vaccine. The studies mainly focus on the adverse events following immunization in vaccinated people of age above 18 years old and persons below 18 years were excluded.

Sample Size: 353 vaccinated people from general population.

Inclusion criteria

- Include all people with minimum of one dose vaccination against Covid 19.
- Persons greater than 18 years old.
- Person who are willing to participate in the study.

Exclusion criteria

- Persons less than 18 years old.
- Non-vaccinated people.
- Those who were not willing to participated in this study

Data Collection: Details will be obtained from the people through structured questionnaire in google form by online method. We developed a form with questionnaires to systematically capture the information about the adverse events occurred after vaccination. Briefly all vaccinated people receive the form and are requested to fill the form with local and systemic adverse events following immunization. From the total details of the study, the prevalence of adverse event of immunization were analyzed and documented. This survey conducted on 353 vaccinated people in Kerala, and collected information on AEFI. All the vaccinated people are requested to fill the developed questionnaire with local and systemic adverse events following immunization.

Ethical Consideration: Ethical clearance was obtained from Human Ethics Committee of Valluvanad Hospital, Ottapalam with HEC No: 108/KTN/VND/2021.

Statistical Analysis: Data obtained was entered into Microsoft Excel Sheet. Qualitative variables will be expressed in percentages. Bar, column and pie charts were used to present percentage distribution of selected variables in the study.

RESULTS

This was an observational study was conducted among general population to assess the adverse effects following Covid vaccination in Kerala. A total of 353 participants were enrolled for the study. Among 353 participants 240 (67.9%) were males and 113 (32%) were females (Figure 1).

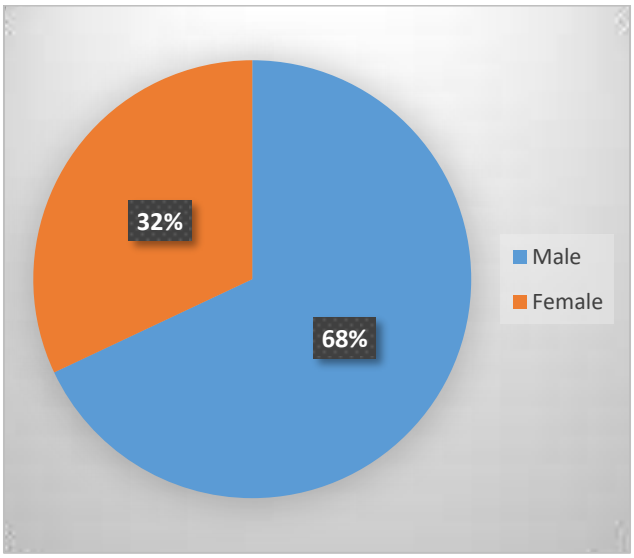

Figure 1: Distribution according to gender

The results from the figure 2 shows among 353 participant's majority (69.12%) were between age group 21 to 30, 13.5% were below 20, 11% 31 to 40, followed by 4.81% between 41 to 50 and remaining 1% between 51 to 60.

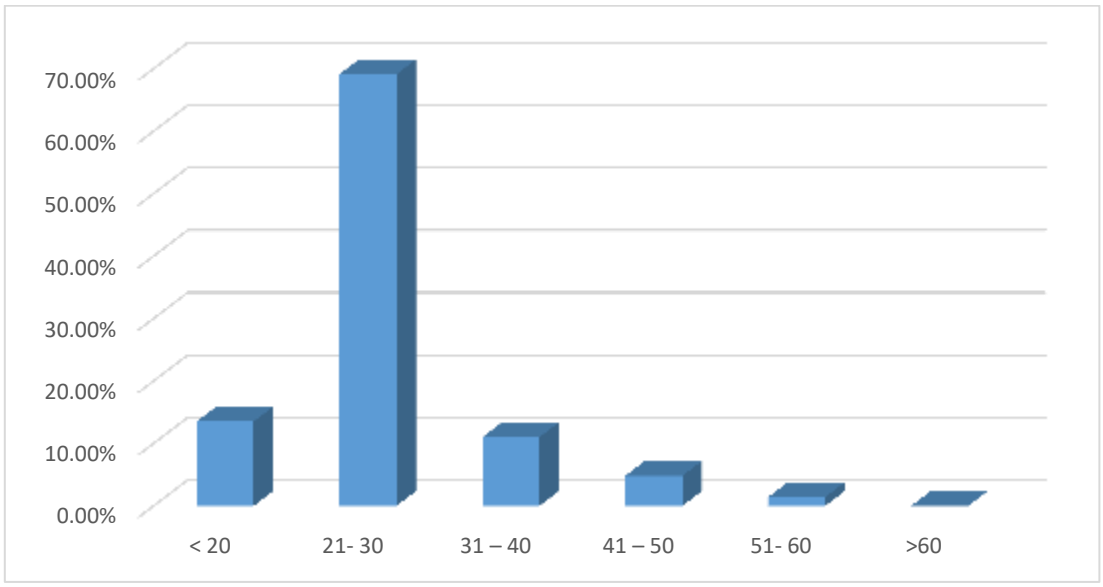

Figure 2: Distribution based on age group

Figure 3 showed that, among 353 participants 16 were having the habit of smoking, 4 persons with alcohol intake and 3 with both alcoholism and smoking.

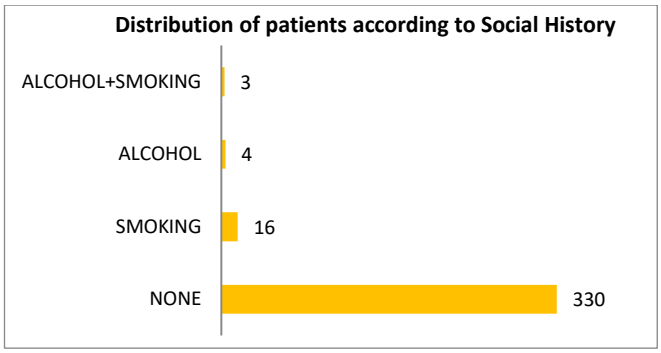

Figure 3: Distribution of patients according to social history

Table 1: Distribution based on comorbidities

Disease Condition	Frequency	Percentage
None	323	91.5%
Hypertension	3	0.8%
Diabetes	6	1.7%
Heart Disease	0	0%
Lung Disease	1	0.3%
Kidney Disease	0	0%
Liver Disease	0	0%
Hyperlipedemia	0	0%
Cancer	1	0.3%
Stroke	1	0.3%
Other	18	5.1%

In the study participants, majority of participants (91.5%) does not having any comorbidities and only 6 persons were with Diabetes, 3 with Hypertension and other disease include lung diseases stroke cancer etc. (Table 1)

Table 2: Distribution of patients according to number of dose

Number of doses	Frequency	Percentage
First Dose	20	5.69%
Second Dose	292	83.19%
Booster Dose	39	11.11%

Table 2 showed that, among 351 vaccinated people 292 have taken second dose, 39 booster dose and 20 had taken first dose of different Covid vaccine. The table 3 exhibited the most of the participants were vaccinated with Covishield (84.61%) followed by Covaxin (07.12%), Pfizer (04.27%), and Sputnik (0.56%).

Table 3: Distribution of patients according to vaccine taken

VACCINE	FREQUENCY	PERCENTAGE
COVISHIELD	297	84.61%
COVAXIN	25	7.12%
PFIZER	15	4.27%
SPUTNIK	2	0.56%
OTHER	12	3.41%

Among 353 participants, 87 persons were Covid positive before vaccination, 84 become Covid positive even after taking 2nd dose of Covid 19 vaccination. 33 after 1st dose and 10 after booster dose (Figure 4).

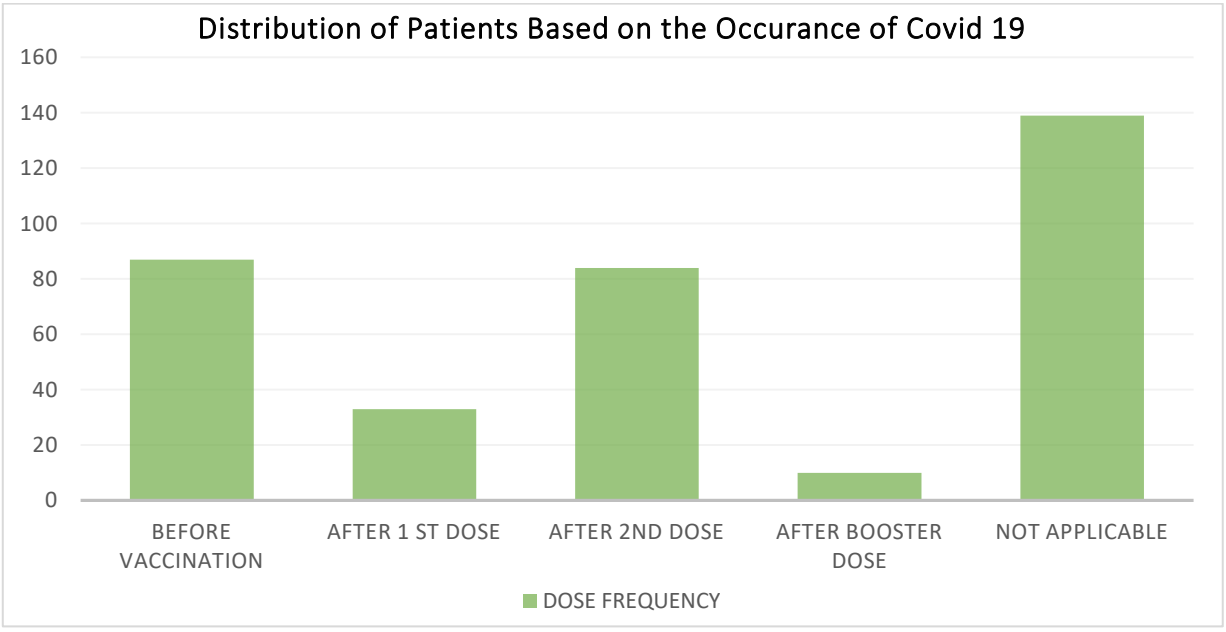

Figure 4: Distribution of participants based on the occurrence of covid 19

Table 4: Distribution of patients according to occurrence of AEFI

AEFI	Frequency	Percentage
Occurred	249	70.94%
Not Occurred	102	29.05%

From 353 participants in our study about 249 participants (70.5%) had experienced AEFI and 104 participants had not experienced any AEFI. (Table 4).

Table 5: Distribution of AEFI in different gender

Gender	Occurrence of AEFI	Percentage
Male	77	30.9%
Female	172	69.07%

Table 5 Showed that, among 249 participants with occurrence of AEFI about 172 (69.07 %) were females and 77 (30.9%) were males. The study revealed that majority (69.87%) of people experienced AEFI were of age group 21-30 followed by less than 20 age group, then 31 -40. (Figure 5)

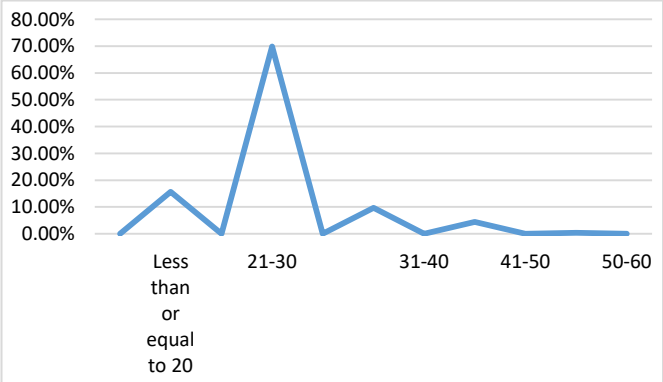

Figure 05: Distribution of AEFI in different age group

Table 06: Distribution of reported AEFI after Covid 19 vaccines

ADRs	Frequency	Percentage
Fever	178	70.6%
Weakness	94	37.3%
Body Pain	134	53.2%
Dizziness	15	6%
Headache	87	34.5%
Pain at Site of Injection	101	40.1%
Nausea	8	3.2%
Vomiting	10	4%
Diarrhoea	4	1.6%
Constipation	0	0%
Allergy	4	1.6%
Itching	0	0%
Rashes	1	0.4%
Increased BP	0	0%
Abdominal Pain	2	0.85%
Menstrual Problems	7	2.8%
Hair Loss	2	0.8%
Breathing Problems	1	0.4%
Joint Stiffness	1	0.4%
No Side Effects	1	0.4%

Most reported AEFI after taking different Covid vaccination is fever (70.6%), body pain (53.2%), pain at injection site (40.1%), weakness (37.3%), headache (34.5%) and other include dizziness vomiting, diarrhoea, menstrual problems, breathing problem, joint stiffness etc. (Table 6)

Table 07: Distribution of AEFI in Different Covid 19 Vaccines

Type of Vaccine	Freequency	AEFI Occurance	Percentage
Covishield	297	213	77.71%
Covaxine	25	18	72%
Sputnik V	2	2	100%
Pfizer	15	9	60%
Others	12	7	58.33%

From the table 7, more ADR was found to be occurred in participants vaccinated with Sputnik V (100%), followed by Covishield (77.71%), Covaxine (72%), Pfizer (60%) and others (58.33%).

DISCUSSION

This study was conducted to assess the AEFI among general population in Kerala, South India and showed that among 353 participants 240 (67.9%) were males and 113 (32%) were females which was concordance with the study of Nishat Jahan et al and Porus Rajpurohit et al where most of the participants were males[10, 11]. Only a few studies were conducted in this area.

Among the vaccinated participant's, majority had taken doses of Covishield (297), 25 with Covaxin, 15 with Pfizer, 2 with Sputnik and 12 were others. Most taken vaccine was Covishield and Covaxin, and this may be because they were made available free by the government in every PHCs. In this study most of the participants were taken the second dose of vaccine. [12]

Among 353 participants 87 were Covid positive before vaccination, 84 become Covid positive even after taking 2nd dose of Covid 19 vaccination. 33 after 1st dose and 10 after booster dose. Showing vaccination cannot prevent occurrence or reoccurrence of COVID infection but it may decrease worsening of the disease.

From 353 participants in our study about 249 (70.5%) had experienced AEFI and 104 without occurrence of any AEFI. Most reported AEFI after taking different Covid vaccination is fever (70.6%), body pain (53.2%), pain at injection site (40.1%), weakness (37.3%), headache (34.5%) and other include dizziness vomiting, diarrhoea, menstrual problems, breathing problem, joint stiffness etc. this was similar to study of Porus Rajpurohit et al and Amjad Alfaleh et al where fever is most commonly reported AEFI. [14]

The study revealed that majority (69.87%) of people experienced AEFI were of age group 21-30 followed by less than 20 age group, then 31 -40. This may be because most people participate in the study was of same age group. From the above table it clear that more number of participants were from age group 21 to 30 and more percentage of AEFI also from same age group. There is pattern of decrease in occurrence of AEFI as age increases from the above data. From 249 participants with occurrence of AEFI about 69.07 % (172) were females and 30.9% (77) were males the study result

differs from study of Porus Rajpurohit et al and similar to study of Nishat Jahan et al in which most participants experienced AEFI are females. [15]

CONCLUSION

This observational study was conducted to assess the AEFI among general population in state of Kerala, South India. In this study majority of participants were males and majority were vaccinated with Covishield followed by Covaxin. This may be due to the fact that these vaccines were given out of cost in Kerala. Most of them had taken second dose of vaccine followed by booster dose for Covid 19.

Among participants 24.6% were Covid positive before taking any Covid vaccines and 23.6% of participants were Covid positive even after taking 2nd dose of Covid 19 vaccination. In our study about 70.9% had experienced AEFI and most reported AEFI after taking different Covid vaccination is fever (70.6%), followed by body pain (53.2%), pain at injection site (40.1%), weakness (37.3%), headache (34.5%) and minor percentages with dizziness vomiting, diarrhea, menstrual problems, breathing problem, joint stiffness etc.

The present study reveal that majority of people vaccinated by Covid 19 vaccines had experienced any kind of AEFIs. Majority of people participated in our study were of age group 21 to 30 this may because we have conducted study in online platform and majority of users are of this age group.

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Conflict of Interest: None

Funding: None

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