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Original Research Article

Pattern of Adverse Events Following COVID-19 Vaccine among Vaccinated Individuals Aged Above 18 yrs in Kerala

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Abstract

Background: Coronavirus pandemic is an ongoing pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). WHO declared the outbreak as a Public Health Emergency of International Concern in January 2020 & a pandemic in March 2020. In India Oxford University-Astra Zeneca's Covishield vaccine, manufactured by serum institute of India and Bharath Biotech's Covaxin are being used for vaccination programme. In this study, we assess adverse reactions following Covid-19 vaccination & incidence of COVID-19 disease among vaccinated people across Kerala. Since it was newer vaccine and general population was afraid of side effects. The present study aimed to study the adverse effects of COVID-19 vaccination among general population aged above 18 years in Kerala.

Methods: A descriptive cross sectional study was conducted among COVID-19 vaccinated individuals above 18 yrs of age residing in Kerala from July 2021 to December 2021. Pattern of adverse events following COVID-19 vaccination (AEFI) were assessed using a semi structured questionnaire. An online questionnaire using Kobo Toolbox was developed and shared via online platform to record the self-reported adverse events following vaccination. A respondent driven sampling method was used. The data was downloaded in MS Excel and analysed using Microsoft excel.

Results: Study was conducted among 526 people across Kerala, among which both males(45.63%) and females (54.18%). Majority of them received COVISHEID (92.97%) and rest of them received COVAXIN (6.24%) and SPUTNIK (0.57%). Out of which 65.97% received 2 doses and 34.03% received only one dose of vaccine. More than half of them (61.5%) faced side effects during post vaccination period. The symptoms were very mild in which fever (65.74%) and tiredness (76.85%) were the commonest symptoms.

Conclusion: In the present study, majority of the vaccinated people experienced very mild and self limiting adverse effects, those were very mild & self limiting. It is a fact that COVID-19 vaccines doesn't provided 100% efficiency, but our study indicates that it does provides protection against COVID-19 infection to a great extend & breakthrough infections are very less severe and asymptomatic for vaccinated people.

Keywords: COVID-19 vaccination, AEFI, Covishield.

Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the infectious virus that causes the 2019 coronavirus disease (COVID-19). These RNA viruses undergo genetic evolution throughout time, giving rise to mutant variations that could differ from their ancestor strains in certain ways. Although it primarily affects the respiratory system, it can also have an impact on other organs. People who have contracted COVID-19 have described a wide range of symptoms, from minor discomfort to serious disease. After being exposed to the virus, symptoms can start appearing two days to two weeks later and can include fever, shortness of breath, body aches, exhaustion, and gastrointestinal symptoms like nausea, vomiting, and diarrhoea as well as loss of taste and smell [1-3]. According to WHO total confimed cases of COVID-19 is 76.6 million cases and 6.9 million deaths till 17 th May 2023 [3].

Trial-and-error techniques are frequently ineffective, and conventional drug development procedures are time-consuming. Due to the demands of safety and efficacy, the development of a new medicine often takes one to two decades. The strategy of repurposing the current medications based on similar disease processes appears to be quite promising. Additionally, repurposed medications benefit from reduced time and cost of development due to their prior knowledge on safety data [3,4]. A successful vaccine is urgently required to control this pandemic due of its high mortality and quick spread. As a result, the government, business, and academic worlds are collaborating closely to create and test a wide range of vaccines at a previously unheard-of rate [5]. On December 31, 2020, the Pfizer/BioNTech comirnaty vaccine was added to the WHO emergency use listing (EUL).[5] On January 3, 2021, India granted emergency use authorization for two COVID-19 vaccines. These were Covaxin and Covishield, two vaccines produced by Serum Institute of India, private limited for AstraZeneca and Bharat Biotech Limited, Hyderabad, India respectively. On January 16, 2021, free vaccination against COVID-19 began in India. The government is asking all of its inhabitants to get immunised as part of what is anticipated to be the greatest vaccine campaign in history. Four of the eight COVID-19 vaccines undergoing various phases of clinical testing in India right now were created there [6,7].

In the initial days, these vaccines were provided to the healthcare providers and general public in a phased manner. Initially to the health care workers and front line workers. The third phase of the COVID-19 immunisation effort for those over the age of 18 was launched by the Indian government on May 1, 2021 [7,8]. Our study focuses on this area since vaccine adverse effects are a major factor in the general public's acceptance of immunisations. People were concerned about the safety and side effects of the COVID-19 vaccination because it was a novel vaccine that had only recently been created. Like any other vaccine, COVID-19 can have moderate short-term side effects like mild fever, soreness, redness at the injection site, body pain, etc., but all these side effects subside within a few hours to days after the vaccination. There was an information gap about the COVID-19 vaccine's safety. This study was carried out to inform individuals about the side effects of COVID vaccinations. This study was conducted to evaluate the pattern of adverse events following various COVID-19 vaccination among individuals aged above 18yrs residing in Kerala

Materials and Method

A descriptive cross sectional study was conducted among COVID-19-vaccinated individuals above 18 yrs of age residing in Kerala, from July 2021 to December 2021. The sample size was calculated to be 544, using the formula, for a cross sectional study with an anticipated population proportion of adverse

effect sleepiness 15% [9], confidence level of 95% at 5% significance level and an allowable error of 20%. Non-probability sampling technique based on convenience was used to select the participants. Respondent driven sampling method was used. The variables such as age, sex, socio-demographic details, and occupation were assessed by a semi structured questionnaire. This questionnaire, which included the consent form, was shared via an online platform using Kobo tool Box for humanitarian response to the undergraduate medical students and then to their family members and friends after obtaining Institutional Ethical Committee clearance. Apart from those who were not willing to participate 526 individuals in total gave their permission and took part in the study. The collected data was downloaded in MS Excel sheet and analyzed by MS Excel.

The semi structured questionnaire collected information on age, gender, socio-demographic details, self-reported adverse events following vaccination, dose of vaccination, type of vaccine, duration and onset of AEFI, and need for hospitalization. The qualitative variables expressed as proportions and quantitative variables are expressed as mean and standard deviation.

Results

In the present study around 526 study participants were responded to the online questionnaire. The socio-demographic details of study participants were shown (Table no:1).

Table 1: Demographic characteristics of the study participants

Characteristics	Number (N=526)	Percentage (100%)
Age group (years)		
< 30	344	65.4%
31-60	144	27.4%
>61	38	7.2%
Gender		
Male	241	45.8%
Female	285	54.2%
Place of residence		
Urban	288	54.8%
Rural	238	45.2%
Educational status		
<12th std	93	18%
Degree and above	433	82%
Economic status based on colour of ration card		
White		
Blue	279	53%
Pink	197	38%
Yellow	42	7%
	8	2%

In the present study, most of the study participants (65.4%) were below 30yrs of age group with mean age of 33.18 (15.4) years. Around 45.8 % were males and 54.2% were females. There were of equal representation from urban and rural areas. Majority (83%) had educational status degree and above. Only 392 study participants (74.52%) responded to question of their occupational status. Among these 104 (26.53%) are unemployed, 104 (26.53%) are students, 147 (37.5%) are

skilled workers and 37 (9.43%) are unskilled workers. Skilled workers mainly consists of Doctors, Teachers, Nurses, Engineers, Pharmacist etc. Unskilled group mainly consists of Businessmen, Agricultural Workers, Social Workers, Politicians etc. Unemployed group mainly consists of homemakers & retired employees.

The study participants of the present study received three types of vaccine, Covishield, Covaxin and Sputnik. The details shown in (Fig No.1). Majority (93%) received Covishield followed by other vaccines based on the availability. About 179 (34%) received only one dose and 347 (66%) received two doses of vaccine.

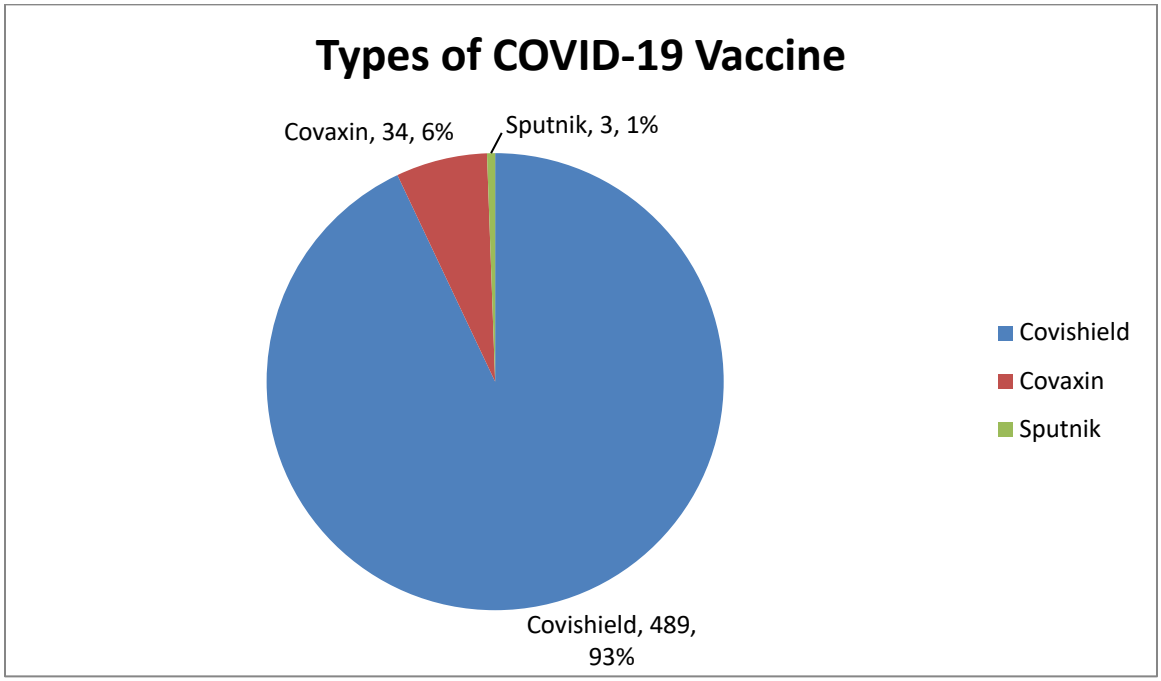

Figure 1: Distribution based on the type of vaccine received.

Among the total study participants, 324 (61.5%) were self-reported AEFI following vaccination whereas 202 (38.5%) were having no adverse events. The self reported symptoms were shown (Table No. 2). Most of the study participants experienced more than one symptoms. Most common is tiredness (76.8%), fever (65.7%) and headache (47.8%) followed by other symptoms.

Table 2: Distribution of various AEFI experienced by study participants

Self reported AEFI	Number	Percentage
Fever	213	65.7%
Tiredness	249	76.8%
Weakness of hands and legs	105	32.4%
Headache	155	47.8%
Joint pain	54	16.6%
Nausea	13	4.01%
Loss Of Taste	10	3.08%
Injection site redness and swelling	9	2.77%
Diarrhoea	8	2.46%
sleepiness	5	1.5%
Vomiting	5	1.5%
Seizures	1	0.30%

Among the 324 study participants reported adverse events developed after 8 hours following vaccination (111 or 36.44%). Immediate symptoms were shown by only 13 (4.04%) (within 4 hours) whereas 80 (24.92%) developed symptoms only lately (more than 8 hours). Among people who developed symptoms,116 (36.13%) symptoms lasted for 12-24 hours. For 79 (24.61%) it lasts for 24-48 hours & for 76(23.67%) symptoms lasts for 6-12 hours. Least duration of symptoms (6 hours) were shown by 34 (10.59%) & longest duration by 16 (4.98%). Thus for 95.02%, the symptoms subsided by within 48 hours. Only a small percentage were having sustained symptoms. Among this, only 3 people (1.19%) needed hospitalisation whereas 314 (99.05%) were not having severe adverse events following vaccination.

In the present study, the information regarding the status of COVID-19 infection were also asked. Among 117 of all the respondents who were infected by COVID- 19 70(59.82%) acquired it before vaccination and 46(39.31%) got breakthrough infection. Out of the 117 people, 73.50% were symptomatic and 26.49% were asymptomatic. Majority of the study population adopted home quarantine (90.70%) whereas 11.63% required steroid therapy 3.49% needed oxygen therapy 1.16% required ventilation therapy. When asked about the opinion of study population on recommending the vaccine to unvaccinated people 98.67% (519) of them voted that they will recommend the vaccine while 1.33%(7)of them voted that they won't recommend it.

Discussion

A descriptive cross-sectional study was conducted to find out the pattern of adverse events following COVID-19 vaccination individuals above 18 yrs in Kerala using an online questionnaire via Kobotool box for humanitarian response. Majority of respondents (65.4%) in this study were below 30 yrs of age. The online questionnaire was initially shared to the medical students of our college, as they were the first respondents. The same was shared via the online platforms so it was available more for younsters. This was similar to various other studies [10,11].

Among 526 people vaccinated, 92.97% received COVISHEILD, 6.24% received COVAXIN and 0.57% received SPUTNIK which is similar to a study conducted in Kerala [10] were majority of them received either covaxin or covisheild (98.3%) because COVAXIN and COVISHEILD were available in most of the centres in Kerala. Among the 526 vaccinated people, 65.97% were fully vaccinated and 34.03 % were only partially vaccinated. The present study shows proportion of self -reported adverse events was found to be 61.5%. This was similar to the study by Krishna *et al* [12], Jayadevan *et al* [10] and Jeskowiak *et al* [11]. However our proportion was observed to be much higher than the proportion reported by Sumedhan SV [13] *et al*, Konda *et al* [11] and Patil *et al* [14]. The difference in proportion may be due to the difference in the population characteristics in different studies.

The most common AEFI reported in the resent study were fever, tiredness, perceived weakness of hands and legs, headache, and joint pain constituting 65.7%, 76.8%, 32.8%, 478% and 54% respectively. This was similar to the most of the studies [9-14]. In the present study it was found that 95.02% of the participants developed AEFI, and the symptoms subsided within 48 hours. Only a small percentage were having sustained symptoms and only a few (1.19%) need hospitalization. This was consistent with many of the studies in the same research area [9-14].

The attitude towards the COVID-19 vaccination in the present study shows that majority (98.7%) recommend the vaccine to others. This was also consistent with the other studies [11,15,16]. Most of AEFI were self limiting. Ongoing surveillance is needed to

find out the long-term effects. Due to COVID-19 safety regulations, it was not possible to conduct direct interviews, hence the present study was limited by the fact that data was collected online. Our study had a poor representation of older people, and the online platforms are more accessible to younger people than to older people.

Conclusion

Even though majority of the vaccinated people experienced adverse effects, those were very mild and self-limiting. Thus hospitalization was only required for a very few people. It'sa fact that COVID vaccines does not provided 100 % efficiency, but studies indicates that it does provides protection against COVID infection to a great extent and breakthrough infections are less severe and mostly asymptomatic for vaccinated people. During the initial period, there were many disputes and rumors about vaccination which created an aversion among common people. But later on, when it became compulsory to take vaccine for many purposes in India, many people started getting vaccinated, and then more people gets to know about the adverse effects and benefits of getting vaccinated. It thus provides confidence for unvaccinated people to get vaccinated. Many threats are still there, emergence of new strains of COVID-19 viruses and the need for long-term surveillance to monitor long term adverse effects

Ethical approval: The study was approved by the Institutional Ethics Committee.

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