

Original Research Article

COVID-19 vaccination status and its effect on outcome and disease severity

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ABSTRACT

Background: The cardinal method for preventing future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death is COVID-19 vaccination, despite the possibility that the epidemiology of COVID-19 may change as new variants appear. There is little research on the vaccination status of adult COVID-19 patients and the role of vaccines in mitigating the severity and clinical presentation of COVID-19 patients among local population in Kerala. Objectives were to assess vaccination status and clinical profile of adult COVID-19 patients in Arpookara, Panchayath in Kerala and its association with disease severity and outcome among same.

Methods: A cross sectional study was conducted in Arpookara Panchayath in central Kerala, among adult COVID-19 patients during the months of September and October 2021. The required 380 samples were selected by simple random sampling and data was collected by interviewing the subjects using semi structured questionnaire.

Results: It was found that 46.1% of the study population were unvaccinated, whereas 30.8% of the population were partially vaccinated and 23.1% were fully vaccinated at the time of COVID-19 infection. A significantly higher proportion of unvaccinated population required hospital admissions, oxygen support and ICU stay when compared to those who took at least one dose of vaccine.

Conclusions: Increasing the vaccination coverage of at least single dose of vaccine can reduce rate of hospital admission, ICU stay, oxygen requirement and can improve the outcome of disease. Steps to increase vaccine coverage should be implemented for better outcome of COVID-19 disease as well as to reduce the admission load on the hospitals.

Keywords: Vaccination status, COVID-19 vaccination, Vaccination coverage, Clinical presentation

INTRODUCTION

WHO declared COVID-19 a public health emergency of international concern on 30 January 2020, and later a pandemic on 11 March 2020. Vaccination against COVID-19 is one of the critical tools to fight the ongoing pandemic. Globally, it began on 31st December 2020, when WHO issued an emergency use listing (EUL) for the Pfizer vaccine. In India, the central drugs standard control organization (CDSCO), a regulatory body, has provided emergency use authorization to Covishield

(AstraZeneca's/ serum institute of India) and Covaxin (Bharat biotech limited) on 3rd January 2021 and the first phase of vaccination started in January 2021 included health care professionals and frontline workers.¹ ChAdOx1 (Covishield) and BBV152 (Covaxin) were given free of cost in various government vaccination centres throughout India. The second phase of vaccination which was started in March 2021 enabled individuals above 60 and individuals between 45 and 59 with comorbidities. As of October 9, 2021, more than 946 million doses of vaccine have been administered and aims

to vaccinate the entire eligible population of India in the near future.²

In an interim analysis of four randomized controlled trials, the efficacy of two doses of the ChAdOx1 nCoV-19 vaccine for preventing symptomatic COVID-19 was 70.4%.³ The BBV152 was found to have an overall efficacy of 77.8% against symptomatic COVID-19. The efficacy of ChAdOx1 nCoV-19 against the delta variant was found to be 67.0%, while that of BBV152 was 65.2%.⁴

According to a multicentre case control study in the US, Vaccination with an mRNA COVID-19 vaccine has significantly reduce COVID-19 hospitalization as well as the disease progression to death or mechanical ventilation.⁵

However not much studies have been undertaken in Kerala so far on the vaccination status among COVID-19 patients and the effectiveness of the vaccines. Hence the study had been conducted to assess the vaccination status and its role in mitigating the symptoms, severity and determining the outcomes of COVID-19 patients.

METHODS

This cross-sectional study was conducted in Arpoorkara panchayat, a rural area in central Kerala during the months of September and October 2021. The study samples were selected by simple random sampling from the list of COVID-19 patients of Arpoorkara Panchayat who were laboratory-confirmed cases of COVID-19 based on semiquantitative real-time reverse transcriptase-polymerase chain reaction (RT-PCR) or rapid antigen test (RAT), each of them was interviewed and data was collected with a semi structured questionnaire.

Data related to demographic details, vaccination status, clinical manifestations, and disease outcomes were collected. Ethical approval was obtained from the institutional review board (IRB), govt. medical college, Kottayam. IRB No: 92/2021.

Inclusion criteria

Laboratory-confirmed cases of COVID-19 based on semiquantitative real-time reverse transcriptase-polymerase chain reaction (RT-PCR) or rapid antigen test (RAT).

Exclusion criteria

People who were unable to contact even after 3 attempts to contact them at their place of residence.

Sample size estimation

Sample Size was calculated using the formula:

$$N = Z\alpha^2 p q / d^2$$

Where $Z\alpha = 1.96$, $p = 21.1\%$ as per the data obtained from district control cell of COVID-19.

The sample size calculated was 380. The inclusion criteria were those individuals who are 18 years or above, without any cognitive impairment and became COVID-19 positive during the months of June, July and August 2021. The exclusion criteria used was people who were unable to contact even after 3 attempts to contact them at their place of residence.

Operational definitions

Fully vaccinated: Individuals are considered as fully vaccinated if it has been over 2 weeks since their second dose.

Partially vaccinated: Individuals are considered as partly vaccinated If it has been over 2 weeks since their first dose.

Unvaccinated: They are individuals who have not taken even a single dose of vaccine or they are individuals who took the first vaccine but got COVID-19 positive within 2 weeks after the shot

Severe COVID-19 infection: A COVID-19 infection that caused the patient to get admitted and required oxygen support or ICU admission.

Data management and analysis

Data was properly coded and entered in Microsoft excel and was analyzed using IBM SPSS software version 20. The proportion of vaccination status among COVID-19 positive patients was expressed as percentage. Association between various categorical variables were assessed using chi-square test, with level of significance at 0.05. Risk for unvaccinated was assessed by logistic regression, adjusting age and comorbidities.

RESULTS

A total of 386 individuals with age ranging from 18 to 92 years and a mean age of 44.63 (± 15.95) years were included in the study. Of the total responders, 49.2% (190) were female and 50.8% (196) were male.

We observed that 46.1% (178) of the study population were unvaccinated, whereas 30.8% (119) of the population were partially vaccinated as well as 23.1% (89) were fully vaccinated at the time of the diagnosing COVID-19.

Among the vaccinated group 75.6% (182) had taken ChAdOx1 (nCoV-19 vaccine (recombinant) (Covishield) while 10.6% (26) had taken BBV152 (Covaxin).

Table 1: Distribution of study sample based on socio demographic data.

Variables	Unvaccinated, N (%)	Partially vaccinated, N (%)	Fully vaccinated, N (%)	Total
Gender				
Male	86 (43.8)	72 (36.7)	38 (19.3)	196
Female	92 (48.4)	47 (24.7)	51 (26.8)	190
Total	178	119	89	386
Age (years)				
Above 50	43 (38)	45 (39.8)	45 (39.8)	113
Below 50	135 (53.3)	74 (29.2)	44 (17.3)	253
Total	178	119	89	386
Socio-economical status				
BPL*	103 (54.4)	54 (28.5)	32 (16.9)	189
APL*	75 (38)	65 (32.9)	57 (28.9)	197
Total	178	119	89	386

*APL: Above poverty level, *BPL: Below poverty level.

Severity assessment

As per our study, 88.3% (341) of the study sample was symptomatic. Most of them experienced fever as the chief complaint. Other complaints include cough, sore throat, difficulty in breathing, loss of smell and taste, myalgia, headache, tiredness and rhinitis.

The admission rate was found to be 12.4% (43). They were admitted in various facilities like covid first line treatment centres (CFLTC), private hospitals, secondary or tertiary care centres at government sector. However, 87.6% (343) of patients were in home isolation or domiciliary care centres (DCC).

As per our study, the 4.1% (16) of the study population required oxygen support during their course of the illness.

Among the study population 2.1% (8) of patients required ICU admission. Out of 8 people admitted in ICU, six of them died. Proportion of mortality in patients with

coronavirus disease in ICU was 75%.

In study, 57.8% (223) of study population fully recovered after illness and 40.7% (157) suffer from post COVID-19 complications, which includes shortness of breath, myalgia, loss of smell, loss of taste/ rashes on skin.

Association between vaccination status and severity of the disease

As per our study, 90.4% (161) of unvaccinated and 86.5% (180) of the vaccinated population was found to be symptomatic. However, the symptomatic presentation was not significantly associated with the vaccination status.

The risk for hospital admission, ICU stay, and Oxygen requirement were significantly less among those who had taken at least one dose of vaccine compared with the unvaccinated people. The model was adjusted for age and comorbidities.

Table 2: The association between vaccination status and severity of the disease.

Vaccination status	Admission rate, N (%)	aOR [CI]	Oxygen requirement, N (%)	aOR [CI]	ICU admission, N (%)	aOR [CI]	Total
Unvaccinated	31 (17.4)	0.341 [0.176-0.663]	14 (7.8)	0.074 [0.016-0.343]	7 (3.9)	0.070 [0.008-0.596]	178
Partially or fully vaccinated	17 (8.1)		2 (0.96)		1 (0.48)		208

Table 3: The association between vaccination status and outcome of disease.

Vaccination status	Death, N (%)	Fully recovered, N (%)	Post COVID-19 complication present, N (%)	Total, N (%)	P value
Unvaccinated	6 (3.4)	99 (55.6)	73 (41.0)	178 (100)	0.026
Fully or partially vaccinated	0 (0)	124 (59.6)	84 (40.3)	208 (100)	
Total	6 (1.55)	223 (57.7)	157 (40.67)	386 (100)	

It was noted that 3.4% (6) of unvaccinated individuals died, and 41% (73) had some kind of post COVID-19 illnesses. While in the vaccinated category there were no deaths and 40.3% (84) suffered from post COVID-19 illnesses. The difference was found to be statistically significant ($p=0.026$).

DISCUSSION

Primary vaccination of two doses and booster doses against COVID-19 are recommended for all eligible persons and was available easily and for free. But many had not taken the vaccines. In this analysis of COVID-19 patients, nearly 46.1% (178) individuals were not vaccinated at the time of COVID infection. In an online survey on COVID-19 vaccination hesitancy in India by Chandani et al it is found that about 20.63% were not aware of the vaccine, 27% were not sure if they would get the vaccine, and 10% refused to obtain the vaccine.⁶ So, the high proportion of unvaccinated in our study during the study period in 2021, could be lack of awareness and fear of side-effects. Initially the policy of administration of vaccines was to those belonging to the high-risk category, this could have also affected the vaccine coverage among common population. It was found that the vaccination status among the study group at the time of interview was better as majority of them had been vaccinated even after the infection, 85% of the population reported to have taken at least one dose of the vaccine.

About 88.3% (340) of study population were symptomatic as per our study and the common symptoms were fever, cough, myalgia and throat pain. It was in accordance with study done by Larsen et al in university of Southern California. The order of symptoms occurrence could help the health care providers distinguish COVID-19 from other respiratory diseases thus leading to early diagnosis, isolation and better treatment of the disease.⁷ Vaccination status had no significant role on the symptomatic spectrum of the disease.

The hospital admission of patients in Kerala were based on the five tier COVID-19 care pyramid.⁸ According to our study, the hospital admission rates were significantly higher among the unvaccinated groups with nearly three times risk for them.

In an interim analysis of four randomized controlled trials, the efficacy of two doses of the ChAdOx nCoV-19 vaccine for preventing symptomatic COVID-19 was 70.4%.³ The BBV152 was found to have an overall efficacy of 77.8% against symptomatic COVID-19. The efficacy of ChAdOx nCoV-19 against the delta variant was found to be 67.0%, while that of BBV152 it was 65.2%.⁹

According to a multicentre case control study in the US, Vaccination with an mRNA COVID-19 vaccine has

significantly reduce COVID-19 hospitalization and disease progression to death or mechanical ventilation.⁵

According to Tenforde et al 21-site case-control analysis at USA, the overall vaccine effectiveness is 85% for mRNA vaccines to prevent COVID-19 hospitalizations. The findings also correspond to an estimated vaccine effectiveness of 86% for COVID-19 hospitalizations caused by the Delta variant.⁵ In another study by Bajema et al, COVID-19 mRNA vaccines (Pfizer-BioNTech and Moderna) have been shown to be highly protective against COVID-19-associated hospitalizations.¹⁰ In a multicentre case control study in the US, vaccination with an mRNA COVID-19 vaccine was significantly less likely among patients with COVID-19 hospitalization and disease progression to death or mechanical ventilation was highly unlikely.⁵ Several other studies done on COVID-19 vaccines also shows that vaccinated individuals were either asymptomatic or showed milder disease without requiring hospitalization.¹¹⁻¹⁵

In the current study, there is statistically significant risk of ICU admission among unvaccinated patients. It is in accordance with another study done in Turkey, it is identified that 37.7% of the study population were admitted to hospital ICUs and nearly half of the patients (47.8%) were unvaccinated. In a study at Italy done by Lorenzoni et al among COVID-19 patients admitted at ICU, 18% were vaccinated, 8% were partially vaccinated, and 74% were not vaccinated.¹⁶ Several other studies by Rosenberg et al, Danza et al, Busic et al, Papagoras et al done on COVID-19 vaccines also showed that hospitalization rates were lower for the vaccinated people when compared to the unvaccinated group.^{10,17-24}

In the current study, there was significant reduction in oxygen requirement among those who had taken at least one dose of vaccination. According to a Busic et al on the role of vaccines in providing protection against respiratory deterioration among COVID-19 patients, vaccinated patients experienced significantly less requirement of high flow oxygen therapy (17% vs. 34%; HR: 0.45 [0.26-0.76]; $p=0.005$), and mechanical ventilation (8% vs. 18%; HR: 0.41 [0.20-0.88]; $p=0.027$) in comparison to the matched cohort of unvaccinated patients. Similar findings were obtained in a study on COVID-19 positive patients with systemic rheumatic diseases by Papagoras et al and another study conducted among healthcare workers from a hospital in Tamil Nadu.^{25,26}

According to our study, more than half of the unvaccinated and vaccinated population had recovered without any complications, 41% of unvaccinated population and 40.3% of vaccinated population suffered from some kind of post COVID-19 illnesses, and six unvaccinated individuals died due to COVID-19 while no one in the vaccinated population died of COVID-19. It is found that, there is statistically significant difference in outcome of disease between vaccinated and unvaccinated

patients. It is in line with study done in England by Lopez Bernard et al to study the effectiveness of COVID vaccines, which found vaccination with either one dose of BNT162b2 or ChAdOx1-S was associated with a significant reduction in symptomatic COVID-19 in older adults, and prevented the disease from getting too severe.²⁷ Similar to findings in our study, several other studies also showed that COVID-19 vaccines may effectively reduce the death, severe cases, symptomatic cases, and infections resulting from SARS-CoV-2 across the world.^{28,29}

Limitation

We haven't taken into account vaccinated uninfected controls for comparison and have not included the analysis of different platform vaccines.

CONCLUSION

Increasing the vaccination coverage of at least single dose of vaccine can reduce rate of hospital admission, ICU stay, Oxygen requirement and can improve the outcome of disease. The priority should be in focusing those unvaccinated individuals than increasing the coverage of second dose of vaccination.

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