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COVID-19 Vaccine Effectiveness in Preventing Severe Infections and Mortality among Patients in Kerala, India.

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COVID-19 Vaccine Effectiveness in Preventing Severe Infections and Mortality among Patients in Kerala, India.

Abstract

ABSTRACT

Background:

India has a top status among world countries, related to the COVID-19 mortality that had crossed the 3-lakh level. The second wave of COVID19 had ravaged the world countries, created havoc of the highest order, leaving many hapless, thanks to the low availability of oxygen, ICU facilities, vaccines and counselling prospects.

There is a lack of information about how COVID-19 vaccines have affected mortality in specific geographic areas.

Method:

A Retrospective record-based design. Patients were matched for age, sex, ethnicity, co-morbidities and grouped into fully immunized, partially immunized and non-immunized.

The primary outcome was in-hospital deaths and secondary outcome was severe covid infections. (Severe covid infections are defined as Category C in WHO and ICMR classification)

Results:

Vaccines administered in standard dosage confer considerable benefit by reducing severe illness, hospitalization and death. This is clearly visible by the lower proportions of those with hypoxia, high levels of markers, those requiring ICU support and death in vaccinated individuals. The type of vaccine administered did not have any influence on the severity and outcome of illness.

Conclusion:

The second wave that peaked in May 2021 would have been less disastrous had more people been vaccinated. Without a reimagined vaccination strategy, reaching the desired full vaccination status was a difficult endeavor.

The signs are unmistakable that a combined approach involving swift vaccination and scientific measures to curb transmission holds great promise. A zero covid world looks less imminent. But humans can make the microbe less lethal.

Keywords

Covid-19, Pneumonia, Vaccine effectiveness, Treatment

Cover Page Footnote

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COVID-19 Vaccine Effectiveness in Preventing Severe Infections and Mortality among Patients in Kerala, India.

Introduction

There was finally light at the end of the tunnel in December 2020 when the world saw the emergence of covid vaccines. Based on the interim results on safety and efficacy, Indian health authorities gave emergency use approvals to the vaccines even before large scale trials were completed.

More than a year had passed when the Government of India announced a nation-wide lockdown to control the virus and flatten the curve. A year later, India continued to bear the brunt of the microorganism's impact. Crores of people found it difficult to make ends meet and were made to flee their temporary abodes in the towns and trek thousands of miles on their way back home, creating one of the most heartrending episodes of Independent India. At the one-year mark, India retained its position as the third country globally in terms of both Covid cases and fatalities, ranking behind only the United States and Brazil.

Two COVID-19 vaccines, Covaxin (whole-virion SARS-CoV-2 vaccine strain NIV-2020-770) and Covishield (recombinant replication-deficient chimpanzee adenovirus vector encoding the spike protein ChAdOx1 nCoV- 19) were given emergency use authorization by the Indian Government to be used on a large scale.

Practical research into vaccine efficacy is needed to better understand the level of protection provided by vaccines and to advance vaccination. This will help us make better use of our resources and develop strategies to adhere to strict infection prevention protocols in the underserved subgroup with inadequate vaccine effectiveness. In India, pioneering reports on Covid infections are mostly limited to healthcare professionals in individual facilities and do not compare inflammatory responses or course of disease during hospitalization. This study aims to compare the differences in clinical and biochemical parameters and the hospitalization outcomes in fully vaccinated

versus unvaccinated and partially vaccinated individuals with SARS-CoV-2 infection.

Methods

Study setting- patients admitted to the COVID-19 treatment facility at the Government Medical College, Pariyaram, Kannur during the period from June 2021 to August 2021.(Pariyaram is a small town on National Highway NH 66 between Taliparamba and Payyanur in Kerala state of India. As of 2011 census, Pariyaram town had total population of 20,405 where 9,582 males and 10,823 females with an area spreads over 32.68 km^2). Only patients aged >18 years (who were eligible to get a COVID-19 vaccine as per vaccination policy of the Government of India) with COVID positive result (RAT/RT-PCR) were included in the study. Those COVID positive patients with a primary diagnosis other than Covid pneumonia (e.g.- Acute Coronary Syndrome) were excluded from the study. At the time of admission to the facility, patients were enquired about their vaccination status, name of the vaccine and the date of first and second dose along with other demographic parameters and symptomatology. We classified the patients into three groups based on the duration of symptoms from the date of vaccination–

Unvaccinated: Those who had not received any vaccine or became symptomatic in less than two weeks of receiving the first dose.

Partially vaccinated: Got symptomatic two or more weeks after the first dose but not received the second dose or received the second dose less than two weeks before getting symptomatic.

Fully vaccinated: Those participants who became symptomatic two or more weeks after the receipt of the second dose of the vaccine.

Patients who were admitted to our institute with symptoms of COVID-19 and had RT-PCR/RAT+ve were classified into mild, moderate and severe COVID-19 according to the NIH recommendations.[14] Clinical symptoms, baseline laboratory parameters, treatments offered and complications during hospital stay were collected from the case files and electronic hospital records. The outcomes of the patients considered for analysis were – development of

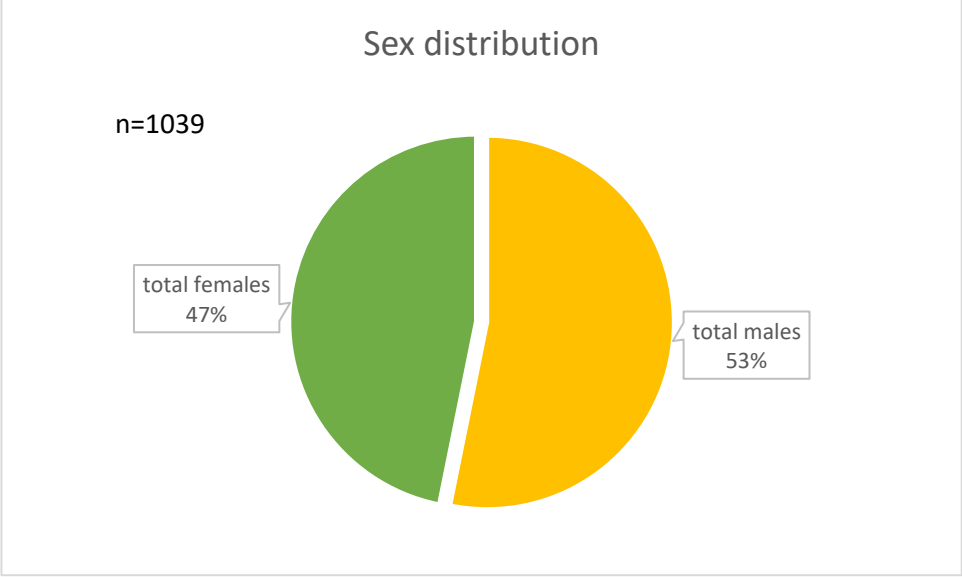
severe illness(NIH recommendation) needing oxygen therapy, deterioration in clinical condition during hospital stay and death.

Results

A total of 1085 covid positive patients were studied during the 3-month period from June 2021 to August 2021. From this total, 46 patients were excluded from the study (lost to follow-up, inadequate data collected, comorbidities that could bias the results).

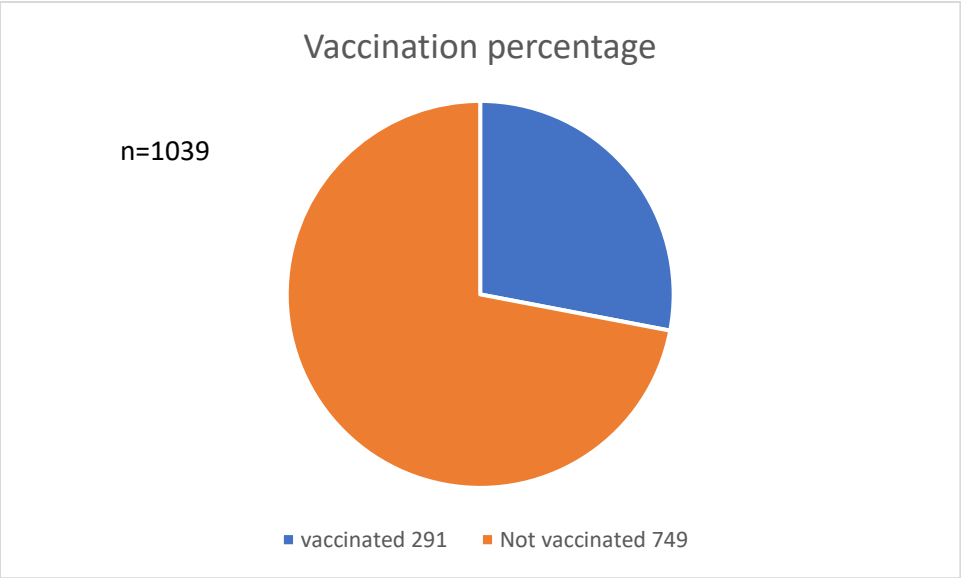
Apart from the above 46 patients, the total number of patients included in the study was 1039 during a 3-month period. In this study cohort of 1039 patients, 553 of them were males and 486 were females.

Figure 1: Sex distribution



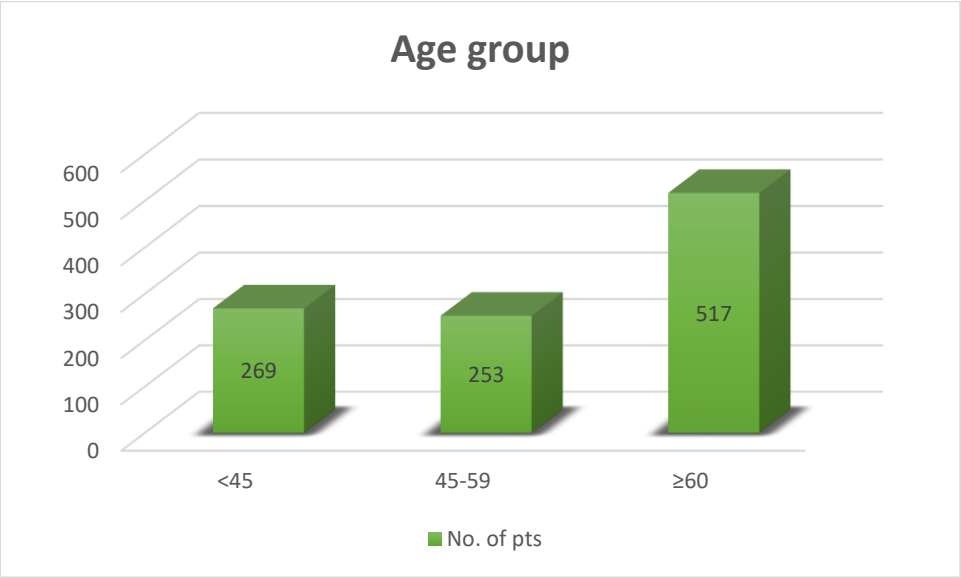
Among the 1039 patients, 748 patients (72%) were not vaccinated and the rest 291 patients (28%) were vaccinated either with a single dose or both doses.

Figure 2: Vaccination percentage



50% of patients (517) belonged to the above 60 age group. Patients in the <45 yr (26%) and 45-60 yr category (24%) were distributed almost equally.

Figure 3: Age distribution



The 1039 patients were categorized into 3 groups based on the vaccination status. 'Fully vaccinated', 'partially vaccinated' and 'not vaccinated'.

Baseline socio-demographic characteristics and comorbidity profile of fully immunized, partially immunized, and unimmunized, participants are reported in Table 2.

Table 1: Socio-demographic, Risk Factors and Comorbidities Among Fully, Partially and Not Immunized Groups

	Fully immunized(n=115)	Partially immunized(n=176)	Not-immunized(n=748)
Demographic and Behavioral characteristics			
Age- n			
<45	48	20	201
45-60	15	58	180
>60	52	97	368

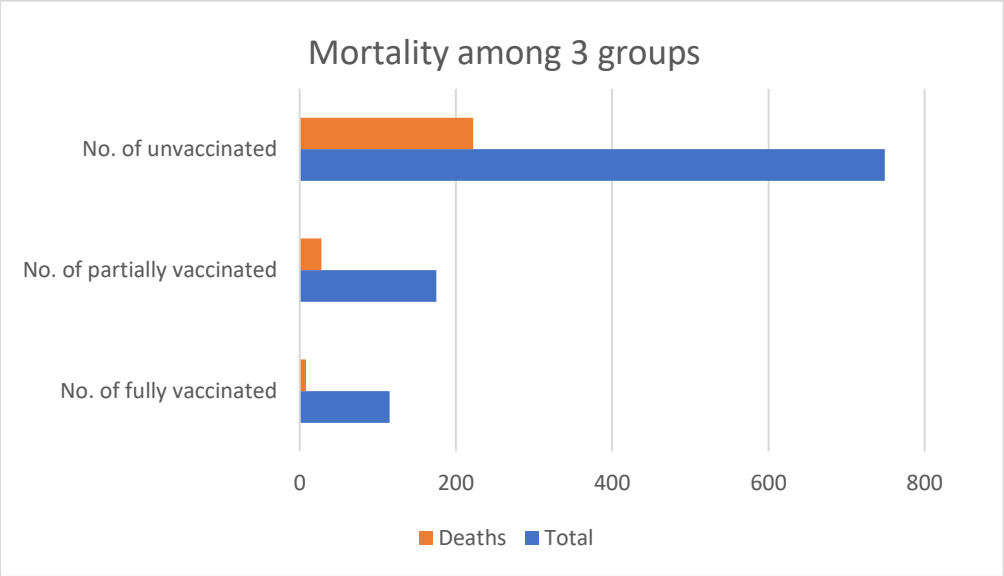
M:F ratio	51:62	100:72	402:316
Smoking	16	24	110
Comorbidities and Coexisting conditions			
Diabetes mellitus(n=323)	28	57	238
Chronic kidney disease(n=71)	10	10	51
COPD(n=60)	9	9	42
CVA(n=37)	2	9	26
CLD/Alcoholism	1	6	9
Ischemic heart disease(n=135)	20	27	88
Malignancy	1	2	8
HIV/AIDS	0	0	2
Pregnancy	0	0	6

Table 2: Outcome characteristics Among Fully, Partially and Not Immunized Groups

	Fully immunized(n=115)	Partially immunized(n=176)	Not-immunized(n=748)
Hospital outcomes			
Severe COVID infection(n=599)	42(36 %)	101(58 %)	455(61 %)
In-hospital death (%)	8(7%)	31(18%)	219(29%)

Overall, 258 deaths among Covid-19 hospitalizations were observed in the cohort. 219 (29%) in the unimmunized, 31 (18%) in the partially immunized, and 8 (7%) in the fully immunized group. Severe infections were observed in 455 patients (61%) who were not vaccinated, 101 patients (58%) in partially vaccinated and 42 patients (36%) among fully vaccinated. Despite higher rates of severe infections in each of the three groups, the vaccinated group exhibited a significant decrease in severe infections and in-hospital fatalities.

Figure 4: Mortality among 3 groups



Statistical analysis:

	In-hospital death(Y/N)		Total
Immunization status	N	Y	
Fully Vaccinated	107	8	115
Not Vaccinated	530	219	749
Partially Vaccinated	144	31	175
Total	781	258	1039

Chi-Square Tests	Value	df	
Pearson Chi-Square	32.22994	2	0.000

Since P value < 0.05 We reject the null hypothesis and conclude that immunization status and in hospital death are dependent.

	Severe Covid infection		Total
Immunization status	Not Severe	Severe	
Fully Vaccinated	73	42	115
Not Vaccinated	294	455	749
Partially Vaccinated	74	101	175
Total	441	598	1039

Chi-Square Tests	Value	df	
Pearson Chi-Square	23.95286	2	0.000

Since P value < 0.05 We reject the null hypothesis and conclude that immunization status and severity are dependent.

Chi-square test for testing the independence of Co-morbidities and vaccination status

Co-morbidities	Fully Vaccinated		Not Vaccinated		Partially Vaccinated	
	Frequency	%	Frequency	%	Frequency	%
COPD	9	7.83%	45	6.01%	11	6.29%
HTN	32	27.83%	263	35.11%	74	42.29%
DM	27	23.48%	228	30.44%	57	32.57%
DLP	6	5.22%	27	3.60%	5	2.86%
RA	0	0.00%	5	0.67%	1	0.57%
CAD	20	17.39%	91	12.15%	26	14.86%
CVA	1	0.87%	38	5.07%	9	5.14%
BA	1	0.87%	21	2.80%	5	2.86%
CKD	10	8.70%	48	6.41%	10	5.71%
CLD	0	0.00%	5	0.67%	4	2.29%

Co-morbidities	Pearson Chi-Square Value	Degrees of Freedom	P-Value	Conclusion
COPD	0.562	2	0.755	Independent
HTN	6.524	2	0.038	Dependent
DM	2.947	2	0.229	Independent
DLP	1.118	2	0.572	Independent
RA	0.774	2	0.679	Independent
CAD	2.906	2	0.234	Independent
CVA	4.129	2	0.127	Independent
BA	1.529	2	0.466	Independent
CKD	1.090	2	0.58	Independent
CLD	5.455	2	0.065	Independent

Chi-square test for testing the independence of Co-morbidities and death status

Co-morbidities	Pearson Chi-Square Value	Degrees of Freedom	P-Value	Conclusion
COPD	6.901	1	0.009	Dependent
HTN	28.170	1	0.000	Dependent
DM	27.583	1	0.000	Dependent
DLP	0.028	1	0.868	Independent
RA	2.048	1	0.152	Independent
CAD	14.563	1	0.000	Dependent
CVA	3.021	1	0.082	Independent
BA	0.342	1	0.559	Independent
CKD	12.373	1	0.000	Dependent
CLD	0.033	1	0.856	Independent

Table-3: Treatment patterns and in-hospital complications.

	Vaccination status			
	Unvaccinated	Partially vaccinated	Fully vaccinated	
Status on Admission				
1. Room Air	39%	42%	64%	
2. Oxygen	61%	58%	36%	
Respiratory support				
1. High Flow Nasal Cannula	48	39	26	
2. Non-Invasive Ventilation	40	36	16	
3. Invasive Mechanical Ventilation	36	34	12	
Severe illness	455(61 %)	101(58 %)	42(36 %)	
Discharge	293(39%)	73(42%)	74(64%)	
Death	219(29%)	31(18%)	8(7%)	

Discussion:

While the studies published previously on COVID-19 vaccine effectiveness looked at specific subgroups of population like healthcare workers[9,10], our study had a diverse population group that is more representative of the general population. The study by Hyams et al. examined vaccines administered in the United Kingdom and reported vaccine effectiveness after one dose of the vaccine which specifically looked at preventing hospitalization in patients over 80 years of age, as opposed to the population at large or the vaccine effectiveness at reducing mortality.[1]

An interim analysis of four randomized control trials (RCT) of Covishield vs control has reported an overall efficacy of 70·4% among 11,636 participants.[2] An RCT of Covaxin vs placebo on 25,798 individuals in India reported vaccine efficacy of 93.4% against severe COVID-19 and 63% against asymptomatic COVID-19, with an overall vaccine efficacy of 77.8%.[3]

Due to the nature of the pandemic, vaccine trials had a short duration of follow-up before they were authorized for public use, thereby leading to inadequate information regarding the duration of protection offered and effectiveness against various new variants of concern.[4-6]

Of the 1039 patients in our study cohort, only 11% were completely vaccinated (n=115). This can either be due to: a) lower incidence of symptomatic SARS-CoV-2 infection among the completely vaccinated group, thus obviating the need for hospitalization, as evidenced by reports from India and other countries.[7,8,16,17]

Approximately 18% of the breakthrough infections in our study cohort presented with moderate to severe COVID-19 and required oxygen support as compared to 62.4% in the unvaccinated group. Although this is relatively higher to 9.2% and 6.7% reported in studies by Sharma P et al and Tyagi K et.al among breakthrough infections in Indian health care workers but is comparable to 18.6% reported by Sabnis R et al. [9-11]

Only 4% of Indians were completely vaccinated by the end of June 2021[18.] The reported breakthrough infection rate among the vaccinated Indians was only 0.04% as of April, 2021.[19]

Our results of fully vaccinated individuals having lower odds of requiring oxygen, receiving mechanical ventilation, deteriorating during the hospital stay, developing critical illness and death are in concordance with those reported from India and other countries.[12,13,22] Lesser need for oxygen supplementation and lower risk of death were also evident amongst those who received a single dose of vaccine, thus showing significant protection in this group as well. In our study 6% of the fully vaccinated individuals required mechanical ventilation compared to 20-24% in unvaccinated or partially vaccinated groups. This is comparable to the 4.7% need for mechanical ventilation among fully vaccinated individuals reported by a multicenter cohort study on COVID-19 emergency care/hospitalization encounters in the state of Michigan USA.[22]

These results are also consistent with the reports published earlier stating that vaccination reduces the requirement of mechanical ventilation.[23] Our findings suggest that partial immunization (i.e., receipt of one dose of covid vaccine) is associated with reduced protection against severe disease leading to hospitalization and poor outcomes such as in-hospital mortality. While we document lower effectiveness against mortality, the estimates are imprecise due to the small number of outcome events.

We also noted that the requirement for use of steroid and antiviral agents in fully vaccinated was less compared to the unvaccinated or partially vaccinated group. This may be explained due to less incidence of hypoxia or requirement for oxygen in these individuals. Furthermore, lesser use of steroids may decrease the risk for hyperglycemia and mucormycosis in these individuals.[24]

Conclusion:

In this diverse and well-characterized cohort, we show that the morbidity and mortality of Covid-19 differ markedly between vaccinated and unvaccinated (vaccinated 8% vs unvaccinated 30%). Vaccines remain the central tool for disease control strategies and so ensuring broad and equitable access to vaccines remains imperative for pandemic control moving forward.

Limitations of this study include its observational institution-based design and there may be some residual unmeasured confounding, however, this is unlikely to alter the overall interpretation. Overall, the vaccine effectiveness seen in this study was similar to the vaccine efficacy of clinical trials, which is reassuring.

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