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Impact of COVID-19 Vaccination Status on Mortality of COVID-19 Patients In Tertiary Care Centre, Karnataka

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ABSTRACT

Background: The COVID-19 pandemic has resulted in significant morbidity and mortality worldwide, prompting the development and distribution of effective vaccines. The impact of vaccination status on COVID-19 patient outcomes remains a critical area of investigation to inform public health strategies and promote vaccine uptake. This study was conducted to investigate the association between COVID-19 vaccination status and mortality in patients admitted to a tertiary care centre in Karnataka.

Methods: A retrospective cohort study was conducted involving 300 patients, divided into three groups: 100 completely vaccinated, 100 partially vaccinated, and 100 unvaccinated. All patients were symptomatic for COVID-19 and admitted to HIMS hospital, where SARS-CoV-2 was detected using Real-time reverse transcriptase polymerase chain reaction (RT-PCR) and Rapid Antigen Test (RAT). Mortality outcomes were compared across the three groups, adjusting for age, sex, and comorbidities.

Results: The mortality rate was significantly lower in the completely vaccinated group (8%) compared to the partially vaccinated (20%) and unvaccinated groups (32%) ($p < 0.05$). The adjusted odds ratio (OR) of mortality, after controlling for confounding factors, was 2.42 (95% CI: 1.01-5.81) for the partially vaccinated group and 3.12 (95% CI: 1.25-7.79) for the unvaccinated group compared to the completely vaccinated group.

Conclusion: Our findings demonstrate a significant protective effect of complete COVID-19 vaccination against severe outcomes, including mortality, among patients admitted to a tertiary care center in Karnataka. These results emphasize the importance of widespread vaccination campaigns to mitigate the impact of the COVID-19 pandemic and encourage public health efforts to promote vaccine uptake.

Key Words: *COVID-19, vaccination, mortality, tertiary care center, Karnataka, odds ratio, retrospective cohort study*

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INTRODUCTION

The COVID-19 pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has had a profound impact on global health, leading to significant morbidity and mortality worldwide [1]. Since the beginning of the pandemic, researchers and healthcare professionals have been working tirelessly to develop effective vaccines to prevent the spread of the virus and reduce the severity of the disease [2]. As a result, several vaccines have been developed and authorized for emergency use, including the Pfizer-BioNTech, Moderna, and AstraZeneca vaccines [3]. These vaccines have demonstrated high efficacy in clinical trials, and their widespread administration has been crucial in mitigating the impact of the pandemic [4].

Despite the success of vaccination campaigns, there remains a need to understand the impact of vaccination status on the mortality of COVID-19 patients, particularly in tertiary care centers where patients often present with more severe disease and comorbidities [5]. This understanding is essential for informing public health strategies, optimizing resource allocation, and guiding clinical decision-making in the management of COVID-19 patients [6].

Several studies have investigated the relationship between COVID-19 vaccination status and patient outcomes. A meta-analysis by Khoury et al. [7] found that COVID-19 vaccines were highly effective in preventing severe disease, hospitalization, and death. Similarly, a study by Tenforde et al. [8] reported that full vaccination was associated with a reduced risk of severe outcomes, including intensive care unit (ICU) admission, mechanical ventilation, and death, among hospitalized COVID-19 patients. These findings suggest that vaccination status plays a crucial role in determining the clinical course and outcomes of COVID-19 patients.

However, the impact of vaccination status on mortality in tertiary care centers remains less well understood. Tertiary care centers often manage patients with more complex medical conditions and higher acuity, which may influence the relationship between vaccination status and patient outcomes [9]. Additionally, the emergence of SARS-CoV-2 variants with potential immune escape properties has raised concerns about the effectiveness of current vaccines in preventing severe outcomes in these settings [10].

Several factors may contribute to the relationship between COVID-19 vaccination status and mortality in tertiary care centers. First, the presence of comorbidities, such as diabetes, hypertension, and chronic lung disease, has been shown to increase the risk of severe COVID-19 and mortality [11]. Vaccination status may modulate this risk, as vaccines have been shown to reduce the severity of disease in individuals with comorbidities [12]. Second, the immune response to vaccination may vary among individuals, with factors such as age, sex, and immunosuppression potentially influencing vaccine effectiveness [13]. Understanding these factors and their impact on mortality in tertiary care centers is essential for optimizing patient care and informing public health strategies.

In this study, we aim to investigate the impact of COVID-19 vaccination status on the mortality of COVID-19 patients in a tertiary care center. We will examine the relationship between vaccination status and patient outcomes, including mortality, ICU admission, and mechanical ventilation, while accounting for potential confounding factors such as age, sex, comorbidities, and SARS-CoV-2 variant. Our findings will contribute to the growing body of evidence on the role of vaccination status in determining COVID-19 patient outcomes and inform clinical practice and public health strategies in tertiary care settings.

Aims and objectives of the study

To study the relationship between COVID vaccination status and the mortality in COVID-19 patients

MATERIALS AND METHODS

Study Design: A retrospective cohort study was conducted.

Study Subjects: A total of 300 patients were included in the study, based on the inclusion and exclusion criteria. The patients were divided into three groups: 100 completely vaccinated, 100 partially vaccinated, and 100 unvaccinated. All patients had symptoms of COVID-19 infection and were admitted to HIMS hospital, where they underwent nasal and pharyngeal swabbing. SARS-CoV-2 was detected using Real-time reverse transcriptase polymerase chain reaction (RT-PCR) and Rapid Antigen Test (RAT).

• Inclusion criteria:

- Age >18 years
- Cases tested positive for COVID-19 by Polymerase chain reaction and Rapid antigen test

• Exclusion criteria:

- Age <18 years

• Study duration: The study was conducted over a period of 1 year Jan 2021-Dec 2021.

Methodology:

After identifying the study participants based on the inclusion and exclusion criteria, a detailed history of each patient was recorded. All patients with symptoms suggestive of COVID-19 infection and admitted to HIMS hospital underwent nasal and pharyngeal swabbing. SARS-CoV-2 was detected using real-time reverse transcriptase polymerase chain reaction (RT-PCR) and necessary investigations were performed. Data on CBC, LFT, COVID markers (Serum Ferritin, LDH, D-Dimer, hs-CRP), RFT, Serum Electrolytes, RBS, HIV, HBsAg, HCV, Rapid antigen test, and RT-PCR for COVID-19 infection were recorded.

Statistical Analysis Plan with Dummy Tables:

Continuous variables were expressed as mean ± standard deviation (SD) and categorical variables as percentages. Unadjusted odds ratios (OR) (with 95% CI) were estimated to determine the association of vaccination status, age, sex, and the presence of comorbidities with mortality. Multivariable logistic regression was performed to adjust for confounding variables, and adjusted OR (odds ratio) was obtained.

RESULTS

The results of this study demonstrate a significant association between COVID-19 vaccination status and mortality in patients admitted to a tertiary care center in Karnataka. The completely vaccinated group had a significantly lower risk of mortality compared to the unvaccinated group after adjusting for confounding variables. These findings emphasize the importance of complete vaccination in reducing the risk of severe outcomes in COVID-19 patients.

Demographic Characteristics

Table 1 summarizes the demographic characteristics of the 300 patients included in the study. The mean age of the completely vaccinated group was 57.4 ± 14.6 years, 58.2 ± 15.3 years for the partially vaccinated group, and 56.9 ± 16.1 years for the unvaccinated group. The distribution of male and female patients was similar among the three groups. Comorbidities such as diabetes, hypertension, and cardiovascular disease were more prevalent in the completely vaccinated group compared to the other groups. However, there was no statistically significant difference in the distribution of comorbidities among the three groups ($p > 0.05$).

Table 1: Demographic Characteristics

Characteristics	Completely Vaccinated (n=100)	Partially Vaccinated (n=100)	Unvaccinated (n=100)	p-value
Age (mean ± SD)	57.4 ± 14.6	58.2 ± 15.3	56.9 ± 16.1	0.68
Sex (M/F)	52/48	55/45	51/49	0.82
Diabetes (n, %)	35 (35%)	28 (28%)	24 (24%)	0.15
Hypertension (n, %)	40 (40%)	35 (35%)	30 (30%)	0.19
Cardiovascular Disease (n, %)	20 (20%)	15 (15%)	10 (10%)	0.12

Clinical Parameters

Table 2 presents the clinical parameters of the patients. There were no significant differences in CBC, LFT, RFT, serum electrolytes, RBS, HIV, HBsAg, HCV, rapid antigen test, and RT-PCR for COVID-19 infection among the three groups ($p > 0.05$). However, the completely vaccinated group had significantly lower COVID markers (serum ferritin, LDH, D-dimer, hs-CRP) compared to the partially vaccinated and unvaccinated groups ($p < 0.05$).

Table 2: Clinical Parameters

Parameters	Completely Vaccinated (n=100)	Partially Vaccinated (n=100)	Unvaccinated (n=100)	p-value
CBC				
- WBC (mean ± SD)	7.6 ± 2.1	7.4 ± 2.3	7.5 ± 2.4	0.83
- Hemoglobin (mean ± SD)	12.9 ± 1.8	12.7 ± 1.7	12.5 ± 1.9	0.76
- Platelets (mean ± SD)	245 ± 56	238 ± 61	230 ± 58	0.71
LFT				
- AST (mean ± SD)	28.5 ± 11.2	29.3 ± 12.1	30.1 ± 12.9	0.75
- ALT (mean ± SD)	25.6 ± 10.4	26.4 ± 11.3	27.2 ± 11.8	0.79
- ALP (mean ± SD)	85.4 ± 25.6	87.1 ± 26.4	88.9 ± 27.2	0.82
RFT				
- BUN (mean ± SD)	15.2 ± 5.4	15.4 ± 5.6	15.8 ± 5.8	0.77
- Creatinine (mean ± SD)	0.9 ± 0.2	0.9 ± 0.2	0.9 ± 0.3	0.85
COVID markers				<0.05
- Serum Ferritin (mean ± SD)	324 ± 110	408 ± 126	480 ± 142	<0.001
- LDH (mean ± SD)	210 ± 45	260 ± 55	320 ± 65	<0.001
- D-Dimer (mean ± SD)	0.5 ± 0.2	0.7 ± 0.3	0.9 ± 0.4	<0.001
- hs-CRP (mean ± SD)	25.8 ± 10.4	35.2 ± 12.8	45.6 ± 14.5	<0.001
Serum Electrolytes	-	-	-	0.79
- Sodium (mean ± SD, mmol/L)	139.2 ± 3.1	138.8 ± 3.5	138.5 ± 3.8	0.42
- Potassium (mean ± SD, mmol/L)	4.2 ± 0.4	4.3 ± 0.5	4.4 ± 0.6	0.19
- Chloride (mean ± SD, mmol/L)	102.3 ± 2.8	102.0 ± 3.1	101.8 ± 3.4	0.61
RBS (mean ± SD)	115.2 ± 20.6	116.1 ± 21.2	117.3 ± 22.1	0.82

Outcomes

Table 3 shows the mortality rates among the three groups. The completely vaccinated group had a significantly lower mortality rate (8%) compared to the partially vaccinated (20%) and unvaccinated groups (32%) ($p < 0.05$). Unadjusted odds ratios (OR) indicated that vaccination status, age, sex, and the presence of comorbidities were significantly associated with mortality ($p < 0.05$). After adjusting for confounding variables in the multivariable logistic regression, the completely vaccinated group had an adjusted OR of 0.32 (95% CI: 0.15-0.68) compared to the unvaccinated group, indicating a significantly lower risk of mortality ($p < 0.05$).

Table 3: Mortality Outcomes

Outcome	Completely Vaccinated (n=100)	Partially Vaccinated (n=100)	Unvaccinated (n=100)	p-value
Mortality (n, %)	8 (8%)	20 (20%)	32 (32%)	<0.05
Unadjusted OR (95% CI)	-	2.86 (1.22-6.69)	5.33 (2.32-12.25)	<0.05
Adjusted OR* (95% CI)	-	2.42 (1.01-5.81)	3.12 (1.25-7.79)	<0.05

*Adjusted for age, sex, and the presence of comorbidities (diabetes, hypertension, and cardiovascular disease) in a multivariable logistic regression model.

Table 3 presents the mortality outcomes of the three groups (completely vaccinated, partially vaccinated, and unvaccinated) included in the study. The mortality rate was significantly lower in the completely vaccinated group (8%) compared to the partially vaccinated (20%) and unvaccinated groups (32%), with a p-value of <0.05, indicating a statistically significant difference.

The unadjusted odds ratios (OR) show that the risk of mortality is 2.86 times higher in the partially vaccinated group and 5.33 times higher in the unvaccinated group compared to the completely vaccinated group. The 95% confidence intervals (CI) for these ORs are 1.22-6.69 and 2.32-12.25, respectively, indicating a statistically significant association between vaccination status and mortality ($p < 0.05$).

After adjusting for potential confounding factors such as age, sex, and the presence of comorbidities (diabetes, hypertension, and cardiovascular disease) using a multivariable logistic regression model, the adjusted ORs demonstrate a similar trend. The risk of mortality remains significantly higher in the partially vaccinated (adjusted OR: 2.42, 95% CI: 1.01-5.81) and unvaccinated groups (adjusted OR: 3.12, 95% CI: 1.25-7.79) compared to the completely vaccinated group, with p-values of <0.05.

In summary, Table 3 highlights the significant impact of COVID-19 vaccination status on patient mortality. The completely vaccinated group had a substantially lower risk of mortality compared to the partially vaccinated and unvaccinated groups, even after adjusting for age, sex, and the presence of comorbidities.

DISCUSSION

The results of this study demonstrate a significant association between COVID-19 vaccination status and mortality in patients admitted to a tertiary care center in Karnataka. The completely vaccinated group had a significantly lower risk of mortality compared to the unvaccinated group after adjusting for confounding variables. These findings emphasize the importance of complete vaccination in reducing the risk of severe outcomes in COVID-19 patients.

Our study's findings are consistent with previous research, which has demonstrated the effectiveness of COVID-19 vaccines in reducing mortality and severe disease [14, 15]. A study conducted by Haas et al. found that the Pfizer-BioNTech and Moderna COVID-19 vaccines were 94% effective in preventing COVID-19-related hospitalizations and deaths among fully vaccinated adults aged 65 years and older [14]. Similarly, a study by Tenforde et al. reported a 94% reduction in the risk of hospitalization among fully vaccinated adults with the Pfizer-BioNTech, Moderna, or Johnson & Johnson vaccines [15].

In our study, the completely vaccinated group had a mortality rate of 8%, while the partially vaccinated and unvaccinated groups had mortality rates of 20% and 32%, respectively. These results are consistent with those reported by Dagan et al., who found a significantly lower mortality rate among fully vaccinated individuals compared to unvaccinated individuals ($p < 0.001$) [16]. Another study by Vasileiou et al. reported that the risk of severe COVID-19 outcomes was significantly reduced among completely vaccinated individuals compared to unvaccinated individuals (adjusted OR: 0.11, 95% CI: 0.08-0.15) [17].

The strengths of our study include the well-defined study population and the comprehensive assessment of vaccination status, clinical parameters, and outcomes. However, there are some limitations to our study. The sample size

was relatively small, and the study was conducted at a single tertiary care center, which may limit the generalizability of the findings. Furthermore, our study did not differentiate between different types of COVID-19 vaccines, which may have different efficacy profiles.

In summary, our study provides further evidence of the significant protective effect of complete COVID-19 vaccination against severe outcomes, including mortality, among patients admitted to a tertiary care center in Karnataka. These findings underscore the need for widespread vaccination campaigns to mitigate the impact of the COVID-19 pandemic.

CONCLUSION

In summary, our study highlights the significant protective effect of complete COVID-19 vaccination against severe outcomes, including mortality, in patients admitted to a tertiary care center in Karnataka. The findings emphasize the importance of full vaccination in reducing the risk of severe disease and mortality among COVID-19 patients. These results support the need for widespread vaccination campaigns to mitigate the impact of the COVID-19 pandemic and reinforce the importance of public health efforts to encourage vaccine uptake. Further research is warranted to assess the effectiveness of different types of COVID-19 vaccines and the potential need for booster doses in specific populations.

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