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ASSESSING THE IMPACT OF THE COVID-19 VACCINE ON DISEASE SEVERITY AND DEATH OUTCOME: AN AUDIT STUDY

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ABSTRACT **Introduction:** The prime focus of SARS-CoV-2 vaccines was on preventing symptomatic, often severe illness. Initially, most COVID-19 vaccines were two-dose vaccines. However, immunity from the vaccines has been found to wane over time, requiring people to get a booster dose to sustain immunity against COVID-19. **Objective:** The current study aimed to evaluate the extent of the benefit of the two doses of vaccination over non-vaccinated patients admitted to the ICU. **Materials and Methods:** A retrospective single-center study was conducted between December 2021 and February 2022 at a tertiary care hospital in India of 239 patients with severe COVID-19 infection divided into vaccinated (N=71) and non-vaccinated (N=168) groups. Patient demographic and clinical presentations were retrieved from the electronic medical records. Chi-square test or Fisher's Exact test analyzed categorical data presented as numbers and percentages. Continuous data were checked for normality using a Shapiro-Wilk test and are presented as mean and standard deviation. An independent t-test or Mann-Whitney U test was used to check the group's differences. A two-tailed P-value of <0.05 is considered statistically significant. All statistical analyses were performed using STATA 17.0. **Results:** 239 COVID-19 patients were included in the audit, out of which 71 (29.7 percent) were vaccinated while 168 (70.3 percent) were not. Predominantly male gender was noted in both groups, with a mean age of 65. The two groups were similar in comorbidities except in CKD. Surprisingly, very few CKD patients were vaccinated. Non-vaccinated patients had more severe disease (CTSI 11.2 vs. 7.5, p=0.004) and P/F <100 (18.5 percent vs. 8.5 percent,p=0.051) as compared to vaccinated patients. In the non-vaccinated group, more patients required mechanical ventilation (48.2 percent vs. 23.9 percent, p=0.000), developed septic shock (20.8 percent vs. 11.3 percent, p=0.079), suffered GI- bleeding (11.9 percent vs. 2.8 percent, p=0.026), and succumbed to death as compared to vaccinated group. (36.3 percent vs.19.7 percent, p=0.012). **Conclusion:** From the present study, results indicate that using vaccines decreased the severity of COVID-19 infection, reduced the requirement for mechanical ventilation and complications, and increased the probability of survival. Thus, COVID-19 vaccines are widely credited for reducing the severity and death caused by COVID-19.

KEYWORDS : Covid 19 vaccine, Audit,Severity Assessment, Survival Probability

INTRODUCTION

1. BACKGROUND

COVID-19 is an viral infection caused by the SARS-CoV-2 virus. Its source was traced to Wuhan, China, in December 2019, and the World Health Organization (WHO) subsequently labeled it a pandemic in March 2020 (1).

This virus can spread from person-to-person, causing flu-like symptoms and, in severe cases, mortality. Individuals having pre-existing complications such as high blood pressure, diabetes, stroke, heart or kidney issues, elderly individuals, and those with compromised immune systems are at greater disposition to severe outcomes in the event of COVID-19-like infections (2).

More than 650 million cases have been recorded, leading to a toll of over 6 million deaths. India stands second in COVID-19 cases globally, registering alone around 45 million infections and approximately half a million deaths (3). Besides social distancing and face masks, COVID-19 vaccines are the most effective means to prevent the propogation of the infection. Consequently, the remarkable commitment led to the exceptional development and manufacturing of SARS-CoV-2 vaccines, which attained rapid endorsements for emergency utilization and official authorizations, establishing an unprecedented pace of achievement. As of March

2022, the global count of vaccine administrations reached 10 billion, with at least one vaccine dose given to 63.1 percent of the global population (4).

On January 16, 2021, India commenced the distribution of COVID-19 vaccinations. In the beginning, it granted authorization for the usage of the Oxford–AstraZeneca vaccine (produced under the Serum Institute of India's license as Covishield) and Covaxin (created domestically by Bharat Biotech) (5). According to litertaure, majority of critical COVID-19 cases occur in non-vaccinated individuals. Although completely vaccinated individuals can still contract with the SARS-CoV-2 virus but the likelihood of them experiencing severe complications and needing hospitalization is significantly lower compared to those who haven't been vaccinated (6-7). Research endeavours support the fact that fully vaccinated people have a robust defense against severe illnesses and demonstrate a more resilient immune response to the virus when compared to individuals who haven't received immunization (8).

In a comprehensive analysis of 51 studies conducted in 14 different countries regarding vaccine efficacy, Zheng et al. found that the effectiveness of the vaccines against infection, hospitalization, admission to the intensive care unit (ICU), and mortality stood at 89.1 percent, 97.2 percent, 97.4 percent, and 99 percent, respectively (9).

As per the U.S. Centers for Disease Control and Prevention (CDC), adults aged 65 and above who are fully vaccinated have a 94 percent lower risk of COVID-19-related hospitalization than individuals who have not yet received their vaccinations. In comparison, those who have received only partial vaccination have a 64 percent reduced likelihood of being hospitalized (10). As stated in a report, vaccinations play a role in decreasing the occurrence of long-term COVID-19 by preventing initial infection. They also modify and shorten the duration of illness in cases of breakthrough infections, thereby diminishing the potential for long-term COVID-19 in fully vaccinated individuals. However, specialists are actively researching the influence of COVID-19 vaccines on long COVID-19 and have not yet arrived at a definitive conclusion (11).

Vaccination could decrease the seriousness and complexities linked to COVID-19 infection among patients admitted to the hospital. This research sought to identify the traits, clinical features, and results of COVID-19 infection in patients who had received vaccinations and those who had not.

2. MATERIALS AND METHODS

In this retrospective single-center audit conducted at a tertiary care hospital in India between December 2021 and March 2022, we investigated the influence of COVID-19 vaccination on the clinical outcomes of 239 patients diagnosed with severe COVID-19 infection, stratified into vaccinated (N=71) and non-vaccinated (N=168) groups. No institutional approval was sought given the audit nature of study. Patient data encompassed key socioeconomic and demographic factors such as age, sex, and comorbidities including obesity, hypertension, diabetes mellitus, and ischemic heart disease. Additionally, a comprehensive set of clinical parameters was collected, including the APACHE score, CT Severity Index, CORAD score, P/F ratio, time of symptom onset, length of ICU and hospital stay, and duration of mechanical ventilation. Clinical variables included repeated P/F ratio measurements, oxygen therapy modalities, blood glucose levels, need for vasopressors, and clinical outcomes such as survival status and ICU readmission.

2. Statistical tests

The data from the electronic medical record was compiled and imported into MS Excel. All further statistical analyses were performed using STATA 17.0. Numbers and percentages were used to present categorical data. The Chi-square or Fisher's Exact tests were employed to analyze any association between selected covariates. Continuous data were checked for normality using the Shapiro-Wilk test and are presented as mean and standard deviation. An independent t-test or Mann-Whitney U test was used to check the difference between the two groups. A two-tailed P-value of <0.05 was considered statistically significant.

3. RESULTS

3.1 Results: Descriptive statistics

Table 1 shows the distribution of the two groups based on socio-demographic covariates like age, sex, obesity, and other comorbidities. A total of 239 patients were included in the study, out of which 168 (70.29 percent) were not vaccinated, while 71 (29.71 percent) were fully vaccinated. The mean age of the patients in the non-vaccinated group was approximately 64 years, while it was around 69 years in the vaccinated group. There was a significant statistical difference between the two groups regarding age (p-value= 0.037). In the non-vaccinated group, there was around 64.29 percent of males; in the vaccinated group, there were around 76.96 percent of males. In the non-vaccinated group, 24.40 percent of the patients were obese, while it was 28.17 percent in the vaccinated group. There was no statistical difference between the two groups regarding sex and obesity (p-value>0.05).

Approximately 60 percent of the patients in both groups had hypertension (58.33 percent vs. 61.97 percent). Majority of the patients in both groups had diabetes mellitus. It was 52.38 percent in the non-vaccinated group and around 57.75 percent in the vaccinated group. One in every five people had IHD in both groups. It was slightly lower in the non-vaccinated group compared to the vaccinated group (18.45 percent vs. 23.94 percent).

3.2 Severity score and LOS

Table 2 shows the difference between the two groups based on severity scores like APACHE, CORAD, and CTSI, the LOS in ICU and hospital. After checking for the normality of the numerical data using the Shapiro-Wilk test, the Mann- Whitney U test was used to compare the difference between the two groups. The mean APACHE score in the non-vaccinated group was 10.72± 5.09 and 9.82± 3.91 in the vaccinated group. Similar results were seen for the CORAD scores as well. Even though the scores were lower for the vaccinated group than the non-vaccinated group, a significant statistical difference was not achieved (p-value> 0.05). The mean CORAD score in the non-vaccinated group was 4.17± 1.64 and 3.55± 2.01 in the vaccinated group. Also, the mean CTSI score was 11.18±8.67 in the non-vaccinated group and 7.51± 8.68 in the vaccinated group. A significant statistical difference was seen in the CTSI scores in the two groups (p-value= 0.004).

There was a statistically significant difference between the two groups regarding the time to onset of symptoms (p-value= 0.005). The mean time to onset of symptoms in the non-vaccinated group was 6.76± 4.83, while the meantime was 4.96±4.04 in the vaccinated group. The duration of MVT was 5.23± 9.22 in the non-vaccinated group compared to 2.70± 7.14 in the vaccinated group (p-value= 0.001). The LOS in ICU for the non-vaccinated group was 11.39± 11.22 compared to 9.28± 8.97 in the vaccinated group (p-value> 0.05). Also, the LOS in the hospital was 18.01± 15.38 in the non-vaccinated group. In comparison, the LOS in the hospital for the vaccinated group was 14.75± 9.62. There was a significant difference in the LOS in hospitals between the two groups (p-value= 0.044).

3.3 Outcome

Table 3 shows the difference in the two groups' P/F ratio at the admission and other outcomes. A P/F ratio of more than 100 was observed in 81.55 percent of the patients in the non-vaccinated group compared to 91.55 in the non-vaccinated group. Almost 20.83 percent of the patients in the non-vaccinated group developed septic shock, which was around 11.27 percent in the vaccinated group. Hyperglycemia was seen in 23.81 percent of the patients in the non-vaccinated group compared to 25.35 percent in the vaccinated group. There was no significant association between the vaccination status and P/F ratio at admission, development of septic shock, and hyperglycemia (p-value> 0.05). However, GI bleeding was seen to be associated with vaccination status (p-value= 0.027). 11.90 percent of the patients in the non-vaccinated group had GI bleeding compared to 2.82 percent in the vaccinated group. Also, oxygen therapy was required in 31.55 percent of the patients in the non-vaccinated group compared to 14.08 percent in the vaccinated group (p-value= 0.005). The mortality in the non-vaccinated group was 36.31 percent compared to 19.72 percent in the vaccinated group. Also, there was a significant association between the patient's vaccination status and mortality (p-value=0.012).

Tables

Table 1. Distribution Of The Two Groups Based On Socio-Demographic Covariates

Variables	Not-vaccinated		Vaccinated		Total		p-value
	N	percent	N	percent	N	percent	
Mean Age and SD.	64.04	15.33	68.87	11.99	65.48	14.57	0.037

Gender							0.075
Male	108	64.29	54	76.06	162	67.78	
Female	60	35.71	17	23.94	77	32.22	
Obesity							0.542
No	127	75.6	51	71.83	178	74.48	
Yes	41	24.4	20	28.17	61	25.52	
HTN							0.601
No	70	41.67	27	38.03	97	40.59	
Yes	98	58.33	44	61.97	142	59.41	
DM							0.447
No	80	47.62	30	42.25	110	46.03	
Yes	88	52.38	41	57.75	129	53.97	
IHD							0.333
No	137	81.55	54	76.06	191	79.92	
Yes	31	18.45	17	23.94	48	20.08	
Total	168	100	88	100	256	100	

Table 2. Difference Between The Two Groups Based On Severity Scores

Variables	Not-vaccinated		Vaccinated		Mann Whitney U test
	Mean	SD	Mean	SD	p-value
APACHE score	10.72	5.09	9.82	3.91	0.348
CORAD score	4.17	1.64	3.55	2.01	0.090
CTSI score	11.18	8.67	7.51	8.68	0.004
Time of symptom onset	6.76	4.83	4.96	4.04	0.005
Duration of MVT	5.23	9.22	2.70	7.14	0.001
LOS (ICU)	11.39	11.22	9.28	8.97	0.189
LOS (Hospital)	18.01	15.38	14.75	9.62	0.044

Table 3. Difference In The Two Groups' P/f Ratio At The Admission And Other Outcomes.

Variables	Not vaccinated		Vaccinated		Total		p-value
	N	percent	N	percent	N	percent	
PF at admission							0.051
<100	31	18.45	6	8.54	37	15.48	
>100	137	81.55	65	91.55	202	84.52	
Septic shock							0.079
No	133	79.17	63	88.73	196	82.01	
Yes	35	20.83	8	11.27	43	17.99	
Hyperglycemia							0.779
No	128	76.19	53	74.65	181	75.73	
Yes	40	23.81	18	25.35	58	24.27	
GI bleeding							0.023
No	148	88.1	85	96.59	233	91.02	
Yes	20	11.9	3	3.41	23	8.98	
Oxygen Therapy							0.005
No	115	68.45	61	85.92	176	73.64	
Yes	53	31.55	10	14.08	63	26.36	
Outcome							0.012
Dead	61	36.31	14	19.72	75	31.38	
Alive	107	63.69	57	80.28	164	68.62	

4. DISCUSSION

As per a study published in The Lancet in June 2022, COVID-19 immunization in India averted an additional 4.2 million fatalities between December 8, 2020, and December 8, 2021.

The present audit was conducted to assess the impact of COVID-19 vaccination on disease severity and death outcomes among patients admitted to the ICU. The study contrasted patients who had been vaccinated with those who had not, evaluating their demographic features, clinical traits, and results. The findings demonstrated the advantageous impact of vaccination in diminishing the intensity of COVID-19 infection and enhancing survival rates.

In this study, approximately 29.7 percent of the patients were vaccinated, while 70.3 percent were not. The vaccinated and non-vaccinated groups had similar demographic profiles, including age, sex, obesity, hypertension (HTN), diabetes mellitus (DM), and ischemic heart disease (IHD). However, it was observed that very few patients with chronic kidney disease (CKD) were vaccinated, indicating the need for increased vaccination efforts targeting high-risk populations.

The severity of COVID-19 infection was assessed using severity scores such as APACHE, CORAD, and CTSI. The vaccinated group showed a significantly lower CTSI score than the non-vaccinated group, indicating less severe disease presentation. Additionally, the vaccinated patients had a shorter duration of mechanical ventilation (MVT) and a reduced length of stay (LOS) in the hospital, which further supports the effectiveness of vaccination in mitigating disease severity.

Furthermore, the study examined specific outcomes related to COVID-19 complications. The non-vaccinated group had a higher percentage of patients requiring oxygen therapy, and a more significant proportion developed septic shock and GI bleeding than the vaccinated group.

These results indicate that immunization might aid in decreasing the likelihood of severe complications and improving patient outcomes.

The most notable finding was the significant difference in mortality rates between the vaccinated and non-vaccinated groups. Vaccinated patients had a lower mortality rate (19.7 percent) than the non-vaccinated group (36.3 percent). This result aligns with previous studies, demonstrating the effectiveness of COVID-19 vaccines in preventing severe illness and reducing mortality rates.

Several factors contribute to the effectiveness of COVID-19 vaccines in preventing severe outcomes. First, vaccination enhances the body's immune response, leading to a quicker control of viral replication and decreased viral load, which reduces disease severity. Second, vaccinated individuals are more likely to develop a milder infection if breakthrough infections occur due to vaccine-induced immunity.

Emphasizing the significance of vaccination in alleviating burden of the healthcare systems is crucial. By preventing critical cases necessitating intensive care and mechanical support, healthcare resources can be more effectively directed toward attending other medical concerns and urgent situations. Additionally, a diminished demand of ICU admissions can contribute to the availability of ICU beds for patients facing non-COVID-19 critical medical conditions. Although this study provides valuable insights into the impact of COVID-19 vaccination on disease severity and death outcomes, the limitations should be addressed.

This retrospective study is conducted at a single center, which may limit generalizability to other populations and settings. Also, the analysis was carried out during a specific time frame, and the impact of new variants and changes in vaccination strategies might affect the results in varied scenarios.

To gain a comprehensive understanding of COVID-19 vaccine effectiveness, future studies should be channelized on larger multi-center cohorts, examining the effectiveness of vaccines against the emerging variants. Conducting extended monitoring investigations is imperative to understand how long the immunity provided by vaccination lasts and to determine if there's a possible need for additional booster doses.

In a nutshell, this study highlights the implications of COVID-19 vaccination on disease severity and mortality outcomes in ICU patients. Vaccination is essential in managing the pandemic and reducing its devastating effects on individuals and healthcare systems. Public health efforts should prioritize vaccination campaigns, especially for vulnerable and compromised populations, to achieve optimal protection against severe COVID-19 illness and improve public health outcomes.

5. CONCLUSION

The present audit shows that using vaccines decreased the severity of COVID-19 infection, reduced the requirement for mechanical ventilation and complications, and increased the probability of survival. Thus, COVID-19 vaccines are widely credited for limiting adverse patient outcomes associated with COVID-19.

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