International Journal of Scientific Research in Dental and Medical Sciences

www.ijsrdms.com

Study of Clinical Profile of COVID-19 Patients with Respect to COVID-19 Vaccination Status: An Analytical Study from a Tertiary Care Center in India

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ARTICLE INFO

Article history:
Received 17 March 2022
Received in revised form 02 May 2022
Accepted 26 May 2022
Available online 30 May 2022

Keywords:
COVID-19
Hospitalization
Intensive Care Units
Vaccination

ABSTRACT

Background and aim: India is witnessing the third wave of COVID-19 in the background of the vaccination program in 2021. Many studies are being done worldwide to evaluate the short-term and long-term impact of vaccines. This study was done to determine the impact of vaccines on the clinical status of the patients that came to our tertiary care center.

Material and methods: An observational study was done at LN Medical College and JK Hospital Bhopal. Data were tabulated in MS Excel spreadsheets. Fisher Exact test was used as a statistical tool to calculate the p-value to assess the association's significance level.

Results: Out of 61 patients, male patients were more than female. The younger age group was more likely to require home isolation. Vaccinated patients were significantly found to have less probability of needing hospitalization (p=0.0192), less duration of stay in hospital (p=0.0081), and less chances of needing Intensive Care Units (ICU) support (p=0.0254). We also evaluated the impact of vaccines in patients with co-morbidities and without co-morbidities.

Conclusions: Vaccination against COVID-19 has proved to help mitigate the damage caused so far by COVID-19. However, the real-life effectiveness of vaccines in different individuals with different co-morbidities and other influencing factors should be studied in depth so vaccine programs can progress before the virus evolves.

1. Introduction

Since it arrived in the human ecosystem, many countries have encountered multiple epidemic waves of COVID-19. As of March 2022, severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), the agent causing COVID-19, accounted for more than 476 million infections and more than 6 million deaths worldwide.[1] In India, more than 43 million confirmed cases and more than half a million deaths have been reported.[2] Continuous mutations result in the emergence of many variants of SARS-CoV-2, many of which differ in antigenicity, pathogenicity, and transmissibility. These mutations directly or indirectly affect the resistance that develops in an individual following natural infection or artificial immunity as provided by vaccines.[3] Vaccines against SARS-CoV-2 have been an area of intense research in the past two years. Many vaccines, like BNT162b2 (Pfizer-BioNTech), mRNA 1273 (Moderna), Oxford-AstraZeneca vaccine (Covishield), and Covaxin); have shown good efficacy so far in preventing new COVID-19 infections, limiting hospitalization as well as in preventing mortality.[4] The government of India started the largest vaccination program in the whole of the susceptible population of India on 16 January 2021 onwards.[5] To date, 182,87,68,476 doses of vaccine against COVID-19 have been given, of which about 72.16% of Indian citizens have received at least 1 dose of vaccine and 60.69% have received double doses.[6] However, many studies suggested that the immunity of COVID-19 vaccines may wane off with time, with an average time of 20 weeks, after which protection from severe illness decreases. The immune response decreases more in older adults and those with co-morbidities than in young people.[7] Anticipating a possibility of a third wave, many countries started a booster dose of the vaccine.[8] Ours is a tertiary care centre in the capital city of Madhya Pradesh, India, and we established a separate COVID-19 clinic and admission facilities for the patients who got infected in the third wave of COVID-19. [9] We did this study to find the impact of COVID-19 vaccination so far on the occurrence of new cases as well as its impact on the clinical manifestations. The results of this study can open new research areas in the evolution of vaccines and a better understanding of the disease with respect to vaccines.[10]

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http://doi.org/10.30485/IJSRDMS.2022.339254.1289

2. Material and methods

Ethics approval

The tertiary care hospital approved the study in the south-Central part of the Saurashtra Peninsula ethics research committee at the authors' affiliated institution. All participants obtained consent after being notified of the study objectives and the confidentiality of the responses in the introduction section of the electronic questionnaire.

Study design

Cross-sectional analytical study.

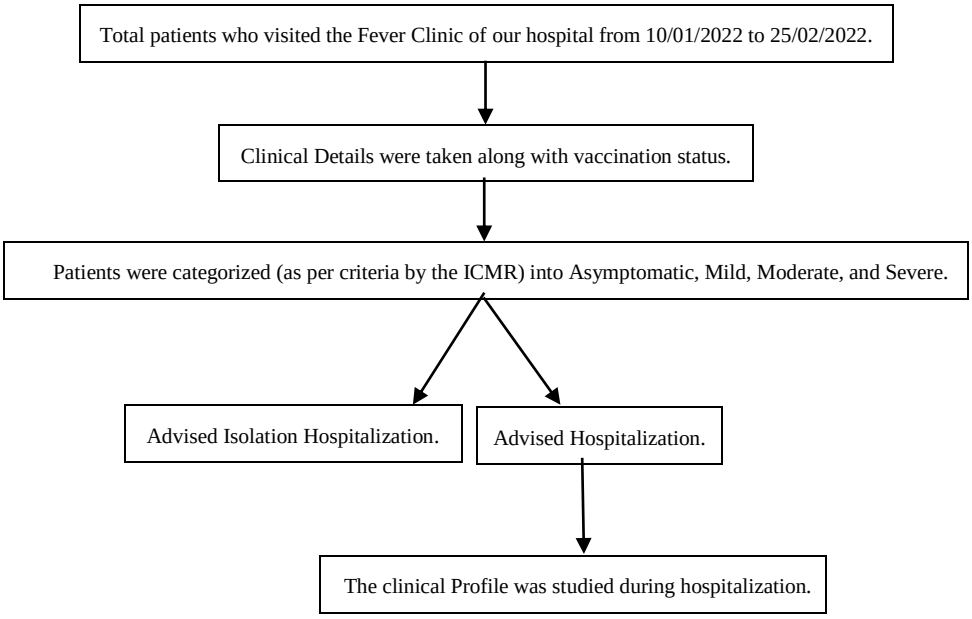

Fig. 1. Study algorithm.

Study setting

LN Medical College and JK Hospital, Bhopal.

Study population

All COVID-19 RTPCR Test positive patients were approaching JK Hospital Medicine Department OPD.

Study duration

Approx. 01 month (Period for which the hospital received patients during the third wave of COVID-19).

Study parameters

*Age and gender
*Vaccination status
*Presence of co-morbidities
*Total number of Co-morbidities.
*Hospital Stay
*Total number of symptoms
*Disease severity
*Need for ICU / Ventilator support
*Clinical outcome

Inclusion criteria

All RTPCR-positive COVID-19 patients approaching JK Hospital Fever clinic with awareness about their vaccine status were included in the study.

Exclusion criteria

Patients unaware of their COVID-19 vaccination status and whose medical records were incomplete were excluded from the study. Patients who did not consent to participate in the study were also excluded.

Statistical software

MS Excel spreadsheets. Fisher Exact and Chi-Square tests are used as a statistical tool to calculate the p-value and assess the association's significance level.

3. Results

As per the methodology steps, 61 patients were included in the study. Out of 61, 33 (54%) were males, and 28 (46%) were females (Table 1). Out of 33 male patients, 10 were advised home isolation (30%), and 23 were hospitalized (69.7%), while out of 28 female patients, 9 (32%) were advised home isolation. The percentage population of males and females had no difference with respect to home isolation and hospitalization (p=0.8875).

Table 1. Total patients who were advised home isolation/hospitalization.

	Male	Female	Total
Advised Home Isolation	10	09	19
Advised Hospitalization	23	19	42

Total	33	28	61

Table 2 shows a comprehensive representation of all the parameters included in the study. Out of 33 males, 5 (15%) were asymptomatic, 20 (60.6%) had mild clinical symptoms, 6 (18%) had moderate severity, and 2 (6%) were severely ill/critical. While out of 28 females, 4 (14%) were asymptomatic, 21 (75%) had mild disease, 1 (3.5%) was moderate, and 2 (7%) were severely ill. In both male and female patients, majority of the patients (male 93% vs 7%; female 92.5% vs 7%) were non severely ill (p=0.729). 29 of 33 males recovered (87.8%) and 4 died (12%) while 25 of 28 females recovered (89%) and 3 died (10.7%) (p=0.8231). The mean age groups of male and female patients in non-severely ill patients were <50 years, while in severely ill, it was >50 years. Similar mean age groups were found for those who recovered and died in both males and females. With respect to the presence or absence of co-morbidity, 17 of 33 male (51.5%) patients and 8 of 28 females (28.5%) had a co-existing illness. Out of these 17 male patients, 15 were non-severely ill (88%) (p=0.2462) while 7 were non-severely ill amongst 8 (87.5%) female patients (p=0.9203). These showed no difference in the severity of illness whether co-morbidity was present. Almost 77% of male and female patients with co-existing illnesses had good outcomes, while 23% died. Patients were assessed based on a mean number of symptoms, of which it was found that the mean number of symptoms was 2 in the severely ill category of female patients while it was <2 in non-severely ill patients. No such difference was found in male patients. Concerning the mean number of co-morbidities, it was found that non-severely ill male patients had an average of 1 mean co-morbidity while 2 co-morbidities were in the severely ill group. No such difference was found in female patients. The mean number of symptoms did not alter the clinical outcome regarding recovery and death. While a mean number of co-morbidities were <1 for both males and females in clinically recovered patients in comparison to 2 (in males) and 1 (in females) mean several co-morbidities in deaths. Vaccination status was studied for all patients, and it was found that out of 33 male patients, 23 (69.7%) were vaccinated, and of those 23, 21 (91%) were non- severely ill; (p=0.8625). Amongst female patients, out of 28 patients, 21 (75%) were vaccinated, and out of those 21, 20 (95%) were non-severely ill; (p=1.0). With regards to clinical outcomes, it was found that out of 23 vaccinated males, 21 survived (91%), while out of 10 unvaccinated males, only 8 survived (80%); (p=0.7401). Likewise, out of 21 vaccinated females, 20 survived (95%), while out of 7 unvaccinated patients, only 5 (71%) survived; (p= 0.2999). Mean hospitalization days were assessed and found that, in non-severely ill male patients, the mean number of hospitalization days was 5.7 days compared to 6 days for severely ill patients. Likewise, in females, the mean number of days of hospitalization was 6.6 for non-severely ill patients and 7.5 days for severely ill patients. However, the mean number of hospitalization days did not significantly alter the clinical outcome in both groups.

Table 2. Clinical category-wise distribution of various parameters taken in the study.

Parameters	Asymptomatic	Mild	Moderate	Severe / Critical	Clinical Outcome	
					Recovered	Death
Male	5	20	6	2	29	4
Female	4	21	1	2	25	3
Mean age in years (Male)	42.6	44.4	70.5	70	50	7
Mean age in years (Female)	32.7	36.5	95	78.5	39	84
Mean age in years (total Patients)	38.2	40.3	74	45	45	76.5
Co-morbidities (+) (Male)	2	8	6	2	14	4
Co-morbidities (+) (Female)	0	7	1	1	7	2
Mean number of symptoms (Male)	0	2.35	2.5	1.5	1.9	1.75
Mean number of symptoms (Female)	0	2.5	1	2	2	1.6
Mean number of co-morbidities (Male)	0.4	0.45	2.16	2	0.94	2
Mean number of co-morbidities (Female)	0	0.6	2	0.5	0.68	1
Vaccination status (Male)						
Single	0	1	0	2	1	0
Double	4	13	2	0	19	2
Triple	0	1	0	0	1	0

Unvaccinated	1	5	4	0	8	2
Vaccination status (Female)						
Single	0	0	0	0	0	0
Double	3	17	0	1	20	1
Triple	0	0	0	0	0	0
Unvaccinated	1	4	1	1	5	2
Mean days of hospitalization (Male)	4.2	4.3	8.6	6	7.8	5.5
Mean days of Hospitalization (Female)	4.2	4.8	10	7.5	7.3	8.3
Total						

Table 3 shows the distribution of male and female patients with respect to age categorization. It was found that age-group distribution was not significantly different in both groups. (p=0.0762).

Table 3. Age and sex distribution of study population.

	Male	Female	Total
Age group 10-30 Years	6	13	19
Age group 31-50 Years	12	4	16
Age group 51-70 Years	9	7	16
Age group 71 years and above	6	4	10
Total	33	28	61

Table 4 shows the distribution of the vaccination status of the patients with respect to various age groups of the male and female patient population. Of 61 patients, 17 were unvaccinated (27.8%). Out of 17 unvaccinated, 1 was advised of home isolation. Sixteen were hospitalized. Out of 19 patients who have advised home isolation, 18 were vaccinated (94%); the p-value was 0.0192. It was found that the vaccination status did not differ significantly amongst the different age groups of patients in both males and females. (p=0.4336).

Table 4. Vaccination status of patients with respect to age and sex.

Vaccination status	Age group					
	10 – 30		31 – 50		71 and Above	
	Male	Female	Male	Female	Male	Female
Single	0	0	1	0	0	0
Double	5	10	8	3	3	2
Triple	0	0	1	0	0	0
Unvaccinated	1	3	2	1	3	2
Total	6	13	12	4	6	4

Table 5 shows data on severely ill and non-severely ill patients with respect to vaccination status. It was found that out of a total of 61 patients, 57 (93.4%) patients (male and female combined) were non- severely ill, and out of those 57, 41 were vaccinated (71.9%), and 16 were unvaccinated (28%). Total 4 patients (6.5%) were severely ill; out of which 3 (75%) were vaccinated and 1 (25%) was unvaccinated; (p=0.6547).

Table 5. Clinical severity with respect to vaccination.

	Asymptomatic	Mild	Moderate	Severe/ Critical	Hospitalization			ICU Support	Ventilator or Support	Clinical Outcome	
					<5 Days of Home Isolated	5 – 10 Days	>10 Days			Recovered	Death
Single	0	1	0	0	1	0	0	0	0	1	0
Double	7	30	2	3	17	25	0	5	4	39	3
Triple	0	1	0	0	1	0	0	0	0	1	0
Unvaccinated	2	9	5	1	1	15	1	7	2	13	4
Total	9	41	7	4	20	40	1	12	6	54	7

Hospitalization days/home isolation were calculated and analyzed with respect to vaccination status. Out of 61 patients, 20 (33%) required only either home isolation or hospitalization for < 5 days. Out of these 20 patients, 19 (95%) were vaccinated. Forty patients (65%) required hospitalization for 5-10 days; out of which 25 were vaccinated (62.5%), and 15 were unvaccinated (37.5%). Only 1 patient was admitted for >10 days and was unvaccinated. It was statistically significant (p= 0.0081). Out of 61 patients, 12 patients required ICU support (19.6%) of which 5 (41.6%) were vaccinated and 7 (58%) were unvaccinated; (p=0.0254). Out of 61 patients, 6 (9.8%) patients required ventilator support, of which 4 (66.6%) were vaccinated and 2 (33.3%) were unvaccinated; (p=0.8625). Table 6 shows the clinical severity of vaccinated and unvaccinated patients in the presence or absence of co-morbid illnesses. Out of 61 patients, 25 patients (41%) had some or the other co-morbid illnesses, out of which 22 (88%) were non-severely ill, and 3 (12%) were severely ill. Of these 22, 13 were vaccinated (59%), and 9 were unvaccinated (41%). Amongst 3 severely ill patients, 2 were vaccinated, and 1 was unvaccinated; (p=0.7083). Thirty-six patients had no underlying co-morbid illness, of which 35 were non-severely ill. Of these 35 patients, 28 (80%) were vaccinated and 7 (20%) were unvaccinated; (p=0.4348). Regarding hospitalization days, it was found that out of 25 patients with co-morbid illnesses, 22 patients (88%) had to stay for >5 days in the hospital. Of these 22, 12 (54%) were vaccinated and 10 (45%) unvaccinated; (p=0.380). Among 36 patients without co-morbid illness, 19 (52.7%) were hospitalized for >5 days, out of which 13 (68%) were vaccinated, and 6 (31.5%) were unvaccinated; (p=0.127). Twelve patients required ICU support. Of these 12 patients, underlying co-morbid illness was present in 10 (83%) patients. Of these 10 patients, 4 were vaccinated (40%), while 6 were unvaccinated (60%). It was statistically significant (p<0.0295). Thirty-six patients had no co-morbidity, out of which 2 required ICU support (1 was vaccinated, 1 was unvaccinated) while 34 did not (28 vaccinated, 6 unvaccinated); (p=0.1871). Similarly, of 49 patients who did not require ICU support, 15 had an underlying co-morbid illness (31%), while 34 (69%) had none. Of these 15 patients, 11 were vaccinated (73%) while 4 (26%) were not. Of 34 patients without any underlying co-morbid illness, 28 were vaccinated (82%), and 6 (17%) were not. Out of 25 patients who had an underlying co-morbid illness, 5 required a ventilator (3 vaccinated, 2 unvaccinated), and 20 did not require a ventilator (12 vaccinated, 8 unvaccinated); (p=0.610). Out of 36 patients without underlying co-morbidity, only 1 required ventilator support (1 vaccinated), and 35 did not (28 vaccinated, 7 unvaccinated); (p=0.434). 6 patients out of 61 (9.8%) required ventilator support, out of which 5 (83%) had an underlying co-morbid condition. Of those 5, 3 (60%) were vaccinated. Fifty-five patients did not require ventilator support. Of those 55, 20 had an underlying co-morbid condition (36%), and 35 (63%) did not. Of those 20, 12 (60%) were vaccinated, and 8 (40%) were unvaccinated. Out of 25 patients with underlying co-morbidity, 19 patients recovered (13 vaccinated, 6 unvaccinated), while 6 patients died (2 vaccinated, 4 unvaccinated); (p=0.292). Out of 36 patients who did not have a co-morbid illness, 35 recovered (28 vaccinated, 7 unvaccinated), and 1 died (1 vaccinated); (p=0.434). Of 61, 54 patients were clinically recovered (88.5%), and 7 died (11.4%). Of those 54, 19 patients (35%) had an underlying co-morbid illness. Of those 19, 13 were vaccinated (68%), and 6 were unvaccinated (31.5%). Thirty-five patients (65%) had no co-morbidity. Of those, 28 were vaccinated (80%), and 7 were unvaccinated (20%). Out of 7 patients who died, 6 had co-morbidity (85%). Of those 6, only 2 were vaccinated (33%), and 4 were unvaccinated (66.6%). Out of 61 patients, 44 were vaccinated, of which 41 recovered (93%), and 3 died (7%). Seventeen were unvaccinated, 13 recovered (76%), and 4 died (24%).

Table 6. Clinical severity with respect to vaccination and co-morbidities.

	Asymptomatic		Mild		Moderate		Severe/Critical		Hospitalization Days						ICU Support				Ventilator or Support				Clinical Outcome			
									<5 Days of Home Isolated		5 – 10 Days		>10 Days		Req.		NR		Req.		NR		Recovered		Death	
Co-morbidities	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
Single	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0

Double	2	5	9	21	2	0	2	1	3	14	12	13	0	0	4	1	11	26	3	1	12	26	13	26	2	1
Triple	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0
Unvaccinated	0	2	4	5	5	0	1	0	0	1	9	6	1	0	6	1	4	6	2	0	8	7	6	7	4	0
Total	2	7	13	28	7	0	3	1	3	17	21	19	1	0	10	2	15	34	5	1	20	35	19	35	6	1

Table 7 shows the clinical parameters with respect to time since the last vaccination. Among a total of 44 vaccinated patients, as more and more time passed since vaccination, the number of cases (both non-severe and severe) increased. The hospitalization days were also assessed. Of 18 patients who required either home isolation or <5 days of hospitalization, 18 were vaccinated within 9 months. While of 25 patients who were admitted for >5 days, almost 19 patients (76%) had their last dose of vaccination for more than 6 months. Several patients who required ICU support (0%, 20%, 80% at 3, 6, 9 months, respectively) and ventilator support (0%, 25%, 75% at 3, 6, 9 months, respectively) also increased as the time since last dose vaccine passed. No such trend could be observed with respect to the final clinical outcome.

Table 7. Clinical severity with respect to time since Double vaccination.

Time Since Last Vaccination (Double)	Asymptomatic	Mild	Moderate	Severe /critical	Hospitalization days			ICU Support	Ventilator support	Clinical Outcome	
					<5 Days of Home Isolated	5 – 10 Days	>10 Days			Recovered	Death
0 – 3 Months	0	1	0	0	1	0	0	0	0	1	0
3 – 6 Months	2	8	1	0	5	6	0	1	1	10	1
6 – 9 Months	4	21	1	3	12	17	0	4	3	27	2
>9 Months	1	2	0	0	0	2	0	0	0	3	0
Total	7	32	2	3	18	25	0	5	4	41	3

Table 8 shows the type of symptoms with respect to vaccination status. Cough was the most common symptom found in both vaccinated and unvaccinated populations. Other prominent symptoms were fever and headache.

Table 8. Clinical Symptoms with respect to vaccination status.

	Vaccinated			Unvaccinated		
	Male	Female	Total	Male	Female	Total
Asymptomatic	4	3	7	1	1	2
Fever	11	8	19	2	1	3
Cough	11	10	21	5	5	10
Throat Pain	5	2	7	2	1	3
SOB	2	3	5	1	0	1
Headache	2	7	9	1	0	1
Body ache	4	4	8	0	2	2
Loss of Smell / Taste	0	0	0	0	0	0
Loss of Appetite	1	2	3	2	0	2

Seizures	0	1	1	0	0	0
Loose Stools	0	0	0	0	0	0
Abdominal Pain	0	0	0	0	0	0
Rash	0	0	0	0	0	0

Table 9 shows the total number of symptoms with respect to vaccination status. Of 61 patients, 44 were vaccinated (72%), and 17 (28%) were unvaccinated. Amongst those vaccinated, 26 patients (59%) had 2 or less than 2 symptoms, and 18 patients (40.9%) had 3 or more symptoms. Amongst unvaccinated, 12 patients (70.5%) had 2 or less than 2 symptoms and 5 patients (41.6%) had 3 or more symptoms; (p=0.590). 3.4 was the average number of symptoms in those who were unvaccinated and died. While 2 was the average number of symptoms in those who were vaccinated and recovered. 1.8 was the average number of symptoms in those who were unvaccinated and recovered. Moreover, 2 was the average number of symptoms in those who died despite being vaccinated.

Table 9. A total number of symptoms with respect to vaccination status.

	Total Number of Symptoms														
	0			**1**			**2**			**3**			**>3**		
	M	**F**	**Total**	**M**	**F**	**Total**	**M**	**F**	**Total**	**M**	**F**	**Total**	**M**	**F**	**Total**
Single	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0
Double	4	3	7	3	3	6	5	7	12	7	5	12	2	3	5
Triple	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
Unvaccinated	1	1	2	3	1	4	4	2	6	1	3	4	1	0	1
Total	5	4	9	6	4	10	10	9	19	9	8	17	3	3	6

Table 10 shows the clinical outcome of patients in a particular category of several co-morbidities with respect to vaccination status. Of total 61 patients, 36 (59%) were without any co-morbid condition, 13 (21%) had 1 co-morbidity, 8 (13%) had 2 co-morbidities and 4 (6.5%) had >2 co-morbidities. Of 36 patients with no co-morbidities, 29 were vaccinated (80%), and 7 (19%) were unvaccinated. Of those 29, 28 recovered (96.5%) and 1 died (3.4%). All of those who were unvaccinated survived; (p=0.434). Of 13 patients with 1 or more co-existing illnesses, 8 were vaccinated (61.5%), and 5 were unvaccinated (38%). All 8 vaccinated patients survived (100%), while out of 5 unvaccinated, 3 recovered (60%) and 2 died (40%); (p=0.248).

Table 10. A total number of co-morbidities with respect to clinical outcome and vaccination status.

	Total Number of Co-morbidities							
	0		**1**		**2**		**>2**	
	Recovered	**Death**	**Recovered**	**Death**	**Recovered**	**Death**	**Recovered**	**Death**
Single	1	0	0	0	0	0	0	0
Double	26	1	8	0	3	1	2	1
Triple	1	0	0	0	0	0	0	0
Unvaccinated	7	0	3	2	2	2	1	0
Total	35	1	11	2	5	3	3	1

Table 11 shows that hypertension was the most commonly found co-existing illness, followed by Diabetes Mellitus, Coronary Artery Disease. Some associations with diseases like- Parkinson's disease, Bronchial Asthma, Seizure disorder, Tuberculosis, Hepatitis B, Dyslipidemia, Chronic Kidney disease, and Hypothyroidism were also found.

Table 11. Different co-morbidities in various study groups.

	Recovered		Deaths		Total
Co-morbidity	**Male**	**Female**	**Male**	**Female**	
Diabetes Mellitus	4	2	1	1	8
Hypertension	5	4	2	2	13
Coronary Artery Disease	3	2	2	0	7
Parkinson's Disease	1	0	0	0	1
Seizure Disorder	2	0	0	0	2
Chronic Kidney Disease	2	0	0	0	2
Bronchial Asthma	0	2	0	0	2
Dyslipidemia		1	0	0	1
Benign Prostate Hypertrophy	0	NA	1	NA	1
Cerebrovascular Diasease	1	0	0	0	1
HBsAg Positive	1	0	0	0	1
Tuberculosis	1	1	0	0	2
Lung Carcinoma	0	0	1	0	1
Hypothyroidism	0	0	1	0	1
Total	20	12	8	3	

4. Discussion

This study describes the association of patient-related factors and their vaccination status with various clinical aspects that could play a decisive role in their clinical outcome. Our study's total number of cases and admitted patients had a male predominance. The mean age group was <50 years in the non-severely ill patient group in both males and females. Maslo et al. (2022) also showed that the younger population was mainly affected.[11] Vaccination did make a significant change in hospitalization. Most of the patients who were advised home isolation were vaccinated. It shows that vaccinated people are more likely to get better by staying at home. Even for those who need hospitalization, vaccination significantly reduces the length of stay. Also, the probability of needing ICU care was reduced significantly in those vaccinated. These findings align with Moghadas et al.'s study on the impact of vaccination on COVID-19 outbreaks in the United States.[12] Regarding clinical outcomes, many studies have shown that vaccination decreases the risk of death.[4] In our study, vaccinated people had fewer chances of getting a severe infection. Our data shows the impact of vaccination in the clinical outcome that mortality can be reduced, though it is influenced by several other factors, too, because of which we could not get a statistically significant result. Cough was the predominant symptom in our study. Most of the admitted patients had <10 days of hospitalization. These results of our study are similar to Ojo et al.[13] Mortality increased with age, with a mean age of 71 years for males and 84 years for females. A similar observation was also seen in Julia Hippisley-Cox et al.[14] which found increased death incidences with age, deprivation, and male sex. Muthukrishnan et al. also found that younger age is associated with lower mortality. Age and comorbid conditions like Diabetes Mellitus and Hypertension were strongly associated with death.[15] Though in our study we have only 4 deaths, the percentage of the male is more than females. Also, the associated co-morbidities in our study were Hypertension, Diabetes Mellitus, Coronary artery disease, Parkinson's disease, Seizure disorder, Hypothyroidism, Chronic kidney disease, and Bronchial asthma. Though we could not derive the hazard ratio because of limited data, we believe the presence or absence of any co-morbidity should be addressed as it can provide an opportunity for other fellows to work in and find new associations related to COVID-19. Hypertension, Diabetes mellitus, and coronary artery disease were the 3 most predominant comorbid conditions that were found to be associated in our study. The findings are very similar to the study by Verma et al. in which Diabetes mellitus followed by hypertension, coronary artery disease, and chronic kidney disease were the major associations observed.[16] The direct causal association between age and underlying comorbid illnesses and the clinical Profile of COVID-19 patients is difficult to find. Nevertheless, these mere associations directly or indirectly impact an individual's immune response, response towards immunogenicity offered by vaccination, and responses to drugs used to treat COVID-19. It has been suggested in various studies that neutralizing antibodies wean off as time passes. Three months was the time since the second dose suggested by one of the studies. In our study, the time since the last dose of vaccination was analyzed, and it was found that as the last vaccination passed, the probability of hospitalization increased, the probability of needing ICU care increased, probability of needing ventilator support increased. Though the finding could

not be figured out as statistically significant, we strongly recommend that large-scale studies be done to find the chronology of neutralizing antibodies titer with respect to various clinical parameters. Age is one of the strongest factors influencing one's immune status irrespective of the vaccine.[16] We also tried to assess several symptoms in each patient category with respect to vaccination status and outcome. We found that the number of symptoms was higher in those who died and were unvaccinated than in those who recovered and were vaccinated. This finding, though not statistically significant, is unique as it objectively tries to determine the clinical outcome with several symptoms, and the impact of the vaccine can be assessed indirectly just by looking at the number of symptoms. Studies have been published that support this idea.[17] More studies are needed to ascertain such observation. Socioeconomic status does impact the antibody generation in response to infections. The socioeconomic status of the study population could likely have affected the clinical Profile of our patients. along with many factors like gender, the genetic make-up of an individual, preexisting comorbid conditions, co-existing infections, sleep pattern, body mass index, nutritional status, infections, drugs like antibiotics, probiotics, prebiotics, microbiota existing in an individual, external factors like smoking, alcohol, stress level, physical exercise; socioeconomic background, rural conditions, geographic location of residence, family size, season, vaccine type, product and strain, adjuvants used, a dose of vaccine, site of vaccine, route of vaccine, time of day; are contributing factors to the development of immune responses.[18, 19] The predominant strain of SARS-CoV-2 in the year 2022 in India is said to be Omicron. Few studies have suggested that booster doses are less effective against the spread of the Omicron variant than the Delta variant.[20] An important observation we tried to find was the relation of various clinical outcomes with and without co-morbidities to see whether co-morbidities could make a difference in the vaccine's effectiveness. We found that co-morbidities might impact the disease's severity, prolong the hospital stay, increase the need for ICU/ventilator, and poor clinical outcomes. Though our results are not clinically significant, we recommend that more such studies can bring more information on the subject on a larger scale. Also, it was found that the mean number of comorbid illnesses in severely ill patients was 2, while it was 1 in non-severely ill patients. Nevertheless, given the potential benefits of preventing severe illness, the susceptible population should be given a booster dose. Our study brings out one of the most needed data on new cases of COVID-19 since the start of the universal COVID-19 vaccination program. Many benefits that have been known theoretically are yet to be understood from a public health point of view because when in public, the effect of vaccine can be mitigated by many external and internal factors that have been discussed above. Large-scale studies are needed to evaluate every public health benefit provided by the vaccines deeply.[21]

Limitations

Our study has several limitations. We did not include the type of vaccine given to the patients. We could not do the genetic analysis of each patient, whether it was Omicron or Delta variant or some other variants. The biggest limitation of our study was a smaller sample size. We tried to analyze many parameters and find out many associations in a small sample size that could have impacted the results of our study.

5. Conclusion

Our study supports the idea that vaccination against COVID-19 is an effective measure to combat the pandemic. Vaccination reduces the risk of hospitalization, hospital stay, and the need for ICU care. As viruses tend to mutate, we should also evolve with our vaccines. Studies are required to deeply investigate the role of co-morbidities that can affect the effectiveness of vaccines so that specialized vaccines can be made available to those burdened by many chronic diseases.

Conflict of Interest

The authors declared that there is no conflict of interest.

Acknowledgements

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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How to Cite this Article: Verma I, Kumar A, Antony J, Ansari SA, Kaushal R, Rajput DP. Study of Clinical Profile of COVID-19 Patients with Respect to COVID-19 Vaccination Status: An Analytical Study from a Tertiary Care Center in India. International Journal of Scientific Research in Dental and Medical Sciences. 2022;4(2):57-66. http://doi.org/10.30485/IJSRDMS.2022.339254.1289.