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Comparative study of 'the clinical profile of COVID-19-positive patients with and without vaccination profile'

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Abstract

Background: More than 4.5 million people have perished from the COVID-19 virus, which has so far been linked to more than 200 million reported cases. Vaccination is an ultimatum for survival from this disease. Hence, this research was designed to study the course of disease in vaccinated and unvaccinated group and to understand the significance of blood markers, to study lung involvement (HRCT), number of hospitalised days, number of O_2 days, and number of days of ventilator support in both the groups in hospitalised patients. **Material and Methods:** A cohort study was conducted among COVID-19-positive patients tested either with rapid antigen test or RT-PCR test hospitalised in Kullolli Institute of Health Services. Patients who had received at least one dose of vaccination were included in the analysis. Data were analysed by using unpaired *t*-test, between the two groups of survived and non-survived patients. Chi-square test and/or Fisher's exact tests were used to check the association. **Results:** In the study, only 71 (18.6%) patients were vaccinated. There were 49 (69.01%) patients out of 71, representing a massive number of vaccinations for people over the age of 50. There were 40 patients with co-morbid conditions, 31 (77.50%) of whom were vaccinated. CRP levels were significantly severe in non-survived patients of non-vaccinated group (Fisher's exact = 8.938, $P = 0.024$). d-Dimer levels, serum ferritin levels, and HRCT scores were significantly related to the outcome (survival/non-survival). Patients who did not survive have higher levels of these parameters. In the vaccinated group, these associations were not significantly associated. Vaccination did not show statistically significant benefits in patients with co-morbid conditions. **Conclusion:** Vaccination has enormous life-saving potential. Regardless of the type of vaccine used, the immunisation provides life-saving protection against a disease that has killed millions.

Keywords: Co-morbid conditions, COVID 19, vaccination, vaccine efficacy

Introduction

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus. Coronaviruses are a large family of viruses that are known to cause illness ranging from the common cold to more severe diseases such as Middle-East respiratory syndrome and severe acute respiratory syndrome (SARS).[1] A novel coronavirus (COVID-19) was identified in 2019 in Wuhan, China. This is a new coronavirus that has not been previously identified in humans.

Since late 2019 to 10 October 2021, more than 200 million cases have been recorded and more than 4.5 million have died from this dreadful virus.[2] As of February 9, 2022, COVID-19 has spread to 227 countries and regions worldwide, causing over 399 million confirmed cases and 5.75 million deaths.[3] To counter these numbers, production of a safe and effective vaccine is mandatory which can bring down the fatalities and provide faster recovery.[4] In the first 9 months since the virus emerged,

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over 200 vaccines have begun preclinical development, 36 of which have entered clinical trials.[5] As of 8 October 2021, 126 COVID vaccines have been under clinical development and 194 under preclinical development. Vaccinations taken by patients were Covaxin which has been developed by Hyderabad-based Bharat Biotech International Ltd in association with the Indian Council of Medical Research and the National Institute of Virology and Covishield has been developed by the Oxford-AstraZeneca and is being manufactured by the Serum Institute of India.[6]

As of 10 October, more than 6.5 billion vaccine doses have been consumed worldwide and more than 2.7 billion of the world's population (35.6%) has been fully vaccinated.[6] With such large numbers of vaccine manufacturers getting approved, a record of real-world safety and effectiveness of the vaccines is imperative for civilians to choose among them. Studies regarding real-world vaccine effectiveness can provide a lot of information such as the success rate of one vaccine against another, effectiveness of one dose against two doses, effectiveness by age group, side effects, and duration of action.[7] Millions of lives are saved annually thanks to vaccination, which is a success story in global health and development. Vaccinations lower the risk of contracting an infection. Although vaccine-induced immunity has increased and diminished over time, protection against hospitalisation and mortality has remained very strong.[8,9] Hence, this research was planned to study different factors associated with the vaccinated and non-vaccinated patients of COVID-19.

Various studies have been published regarding vaccine effectiveness by comparing clinical profile,[10] comorbidities,[11,12] relation with age,[13,14] and effect of vaccination on immunity and vaccine breakthrough cases,[15,16] but a detailed comparison of various possible combination of those parameters is lacking which will help to know more about vaccine effectiveness.

This research article provides a cohort study on COVID-19 vaccine effectiveness by individually comparing in detail all the basic biochemical markers like CRP levels, serum ferritin levels, HRCT score, d-dimer test, number of oxygen support days, number of ventilator support days, and mortality and takes into consideration the various comorbidities associated with the patients. In this study, parameters such as vaccination status (yes or no) and co-morbid conditions (yes or no) have been correlated with various possible combinations of those two parameters to produce a detailed information about vaccine effectiveness. Patients have also been categorised into survived and non-survived groups to provide a simple understanding of the vaccine effectivity. Very few studies have emerged which compare the parameters to such extent, especially from South Asian regions and developing countries. The volunteers during the randomised clinical trials are selected based on specific requirements and hence do not provide us with a clear perspective on whether the vaccines are effective or not in the real world with random patients.

Methodology

Study design

A cohort study was conducted to compare the course of COVID-19 in vaccinated and non-vaccinated patients to study the outcome of the patient, whether survived or non-survived.

Study setting

This study is conducted in COVID hospital (home-quarantined patients were excluded) at Kullolli Institute of Health Services, a dedicated COVID Hospital for treatment.

Study duration

This study was conducted from 1 April 2021 to 30th September 2021, that is, within 6 months.

Sample size

All the COVID-positive patients hospitalised in the hospital at Kullolli Institute of Health Services within this study duration of 6 months were considered in this study by non-random convenient sampling method.

Participants or subjects

COVID-19 patients who tested positive, either with rapid antigen test or RT-PCR test, were considered in this study. COVID-positive patients of all ages and who were hospitalised in COVID hospital (home-quarantined patients were excluded) at Kullolli Institute of Health Services, dedicated COVID hospital for treatment, from 1 April 2021 to 30 September 2021, that is, within 6 months, were considered in the analysis. All the vaccinated and non-vaccinated patients were studied to compare their clinical profile.

Materials and instruments

A pre-tested and validated proforma was used in the study considering own and co-authors' working experience, available literature, and the assistance of experts in the subject.

Procedures

All the details of the patient's recovery who were admitted at that time were taken and compared against each other to draw out conclusions regarding the course of the disease in vaccinated and non-vaccinated individuals. COVID-19 vaccine effectiveness was studied by comparing all the basic biochemical markers like CRP levels, serum ferritin levels, HRCT score, d-dimer test, number of oxygen support days, number of ventilator support days, mortality, and the various comorbidities associated with the patients. The volunteers during the clinical trials are selected based on specific requirements and hence do not provide us with a clear perspective on whether the vaccines are effective or not in the real world with random patients.

Data analysis

For analysis purposes, measurements of HRCT, d-dimer, CRP, and ferritin were divided into different categories like normal,

mild, moderate, and severe. Following are the ranges for these different tests.

Table showing the severity levels of different parameters /tests

Test	Normal	Mild	Moderate	Severe
HRCT	0	0–10	10–15	15–25
d-Dimer (ng/ml)	0–500	500–750	750–1000	1000 and above
CRP (mg/l)	0–6	6–10	10–25	25 and above
Ferritin (mg/l)	30–220	220–300	300–500	500 and above

The complete data are divided according to vaccination status as yes or no, and co-morbid conditions as yes and no.

Data were cleaned and missing values were obtained through contact with the patient/relatives and thus total 381 cases were considered for the analysis. Statistical analysis was conducted through Microsoft Office 365 and SPSS-22.

Frequency and percentages were obtained for qualitative data and descriptive measures were obtained for quantitative data. Further data were analysed by using unpaired *t*-test, between the two groups as survived and non-survived patients to compare the significant difference in mean values of HRCT, d-Dimer, CRP, serum ferritin, non-O_2, O_2 support, ventilator support, and hospital stay. Pearson's Chi-square test was used to check the association between outcome (survival and/or non-survival) and different factors, like age groups, gender, co-morbidity, categories of HRCT, CRP, d-dimer, and Sr. ferritin. Similarly, association of vaccination status was also obtained with these all factors.

Ethical considerations

The Central Review Processing Committee and the Institutional Ethical Committee of Bharati Vidyapeeth (Deemed to Be) University, Medical College, and Hospital, Sangli, approved the research. Consent from each patient considered in the study was taken.

Results

Primary findings of the collected data

Data were collected from total 381 patients. Out of these, only 71 (18.64%) patients were vaccinated. Sixty-two (16.27%) patients have taken the first dose and nine (2.36%) patients completed their both doses of vaccination of the total population. Patients were considered vaccinated in the analysis if they have received at least one dose of vaccination.

Data were collected regarding different parameters likes age, gender, HRCT score, CRP levels, d-Dimer, Sr. Ferritin, non-O_2, O_2 support, and ventilator Support, to check whether vaccine or comorbidities play any significant role in the outcome of the patient. Hence, the whole data are divided according to vaccination status as yes and no, and co-morbid conditions as yes and no. Outcome of the analysis is whether the patient survives or not. In the study, male patients were larger in number, that is, 247 (64.83%) than females 134 (35.17%).

Total non-survived patients were 82 (21.5%), which means case fatality rate was 21.5%. Mean age of all patients was 51 years with SD 15.98 years (min 3 years and ma × 88 years). There was significantly larger age of the non-survived patients (55.9 ± 15.88) than of survived patients (49.54 ± 15.95) (unpaired $t = 3.3228$, $P = 0.01$).

In the study, only 71 (18.6%) patients were vaccinated. There were 49 (69.01%) patients out of 71, which was a massively large number of vaccinations over the age of 50. There were 40 patients with co-morbid conditions, 31 (77.50%) of whom were vaccinated. There was highly significant association between outcome of the patient (survival/non-survival) and severity of the CRP levels (Fisher's exact = 11.508, $P = 0.007$), d-Dimer levels (Pearson's Chi-square = 11.714, $P = 0.008$), serum ferritin levels (Pearson's Chi-square = 15.608, $P = 0.001$), and HRCT score (Fisher's exact = 18.694, $P = 0.000$).

Association between the survival and non-survival of patients and different levels and HRCT score in non-vaccinated and vaccinated group

To check whether vaccination has any effect on outcome of the patients, associations were checked in vaccinated and non-vaccinated groups separately. Age, gender, and comorbidity do not have any association in both the groups: vaccinated and non-vaccinated ($P = 0.05$). CRP levels were significantly severe in non-survived patients of non-vaccinated group (Fisher's exact = 8.938, $P = 0.024$), whereas not significantly different in survived and non-survived patients of vaccinated group (Fisher's exact = 1.566, $P = 0.711$). Similarly, d-Dimer levels (Pearson's Chi-square = 10.374, $P = 0.016$), serum ferritin levels (Pearson's Chi-square = 9.731, $P = 0.021$), and HRCT scores (Fisher's exact = 15.196, $P = 0.001$) were also significantly related to the outcome (survival/non-survival). Patients who did not survive have higher levels of these parameters. In the vaccinated group, these associations were not significantly associated [Table 1].

Comparison of survival and non-survival of patients with vaccination status as 'no' and co-morbidity 'no'

Second table is showing whether there is any significant difference in the outcome of the patient (death/discharge or non-survival and survival) depending upon vaccination status as 'no' and co-morbid conditions 'no'. There were 301 (88.3%)] patients with such status. We found means of nearly all factors, like HRCT score, CRP levels, d-Dimer, Sr. Ferritin, non-O_2, O_2 support, and hospital stay were statistically significantly different in the patients, who were survived or non-survived ($P = 0.05$). Mean of HRCT score, CRP levels, d-Dimer, Sr. Ferritin, and ventilator support were higher in non-survived patients than in survived [Table 2].

Non-O_2, O_2 support

Only mean days of ventilator support for survived and non-survived patients was not statistically significant. Non-survived patients did not survive after receiving more days of ventilation support, that is, mean 3.75 ± 3.01.

Table 1: Association between the outcome (survival and nonsurvival) and levels of different parameters in nonvaccinated and vaccinated group

Parameters	Severity level	Non-vaccinated			Vaccinated		
		Outcome		Total	Outcome		Total
		Death	Discharge		Death	Discharge	
CRP levels	Normal	1	16	17	0	2	2
		5.90%	94.10%	100.00%	0.00%	100.00%	100.00%
	Mild	0	9	9	0	5	5
		0.00%	100.00%	100.00%	0.00%	100.00%	100.00%
	Moderate	3	30	33	2	8	10
		9.10%	90.90%	100.00%	20.00%	80.00%	100.00%
	Severe	62	189	251	14	40	54
		24.70%	75.30%	100.00%	25.90%	74.10%	100.00%
		Fisher's exact test=8.938, *P*=0.024			Fisher's exact test=1.566, *P*=0.711		
d-Dimer levels	Normal	20	124	144	4	26	30
		13.90%	86.10%	100.00%	13.30%	86.70%	100.00%
	Mild	9	32	41	3	2	5
		22.00%	78.00%	100.00%	60.00%	40.00%	100.00%
	Moderate	5	16	21	2	5	7
		23.80%	76.20%	100.00%	28.60%	71.40%	100.00%
	Severe	32	72	104	7	22	29
		30.80%	69.20%	100.00%	24.10%	75.90%	100.00%
		Pearson's Chi-square=10.374, *P*=0.016			Fisher's exact test=5.414, *P*=0.113		
Serum ferritin levels	Normal	12	79	91	1	19	20
		13.20%	86.80%	100.00%	5.00%	95.00%	100.00%
	Mild	3	21	24	1	6	7
		12.50%	87.50%	100.00%	14.30%	85.70%	100.00%
	Moderate	10	43	53	2	8	10
		18.90%	81.10%	100.00%	20.00%	80.00%	100.00%
	Severe	41	101	142	12	22	34
		28.90%	71.10%	100.00%	35.30%	64.70%	100.00%
		Pearson's Chi-square=9.731, *P*=0.021			Fisher's exact test=6.878, *P*=0.054		
HRCT score	Normal	0	1	1	0	1	1
		0.00%	100.00%	100.00%	0.00%	100.00%	100.00%
	Mild	5	47	52	2	14	16
		9.60%	90.40%	100.00%	12.50%	87.50%	100.00%
	Moderate	10	72	82	3	18	21
		12.20%	87.80%	100.00%	14.30%	85.70%	100.00%
	Severe	51	124	175	11	22	33
		29.10%	70.90%	100.00%	33.30%	66.70%	100.00%
		Fisher's exact test=15.196, *P*=0.001			Fisher's exact test=3.954, *P*=0.28		
Total		66	244	310	16	55	71
		21.30%	78.70%	100.00%	22.50%	77.50%	100.00%

Nine (88.3%) patients with vaccination status as 'no' and co-morbid conditions 'yes' were compared.

Comparison of survival and non-survival of patients with vaccination status as 'no' and co-morbidity 'yes'

It is shown that whether there is any significant difference in the outcome of the patient (death/discharge) depending upon the patients who have not vaccinated and having co-morbid conditions. There is no statistically significant difference in the patients (for all the factors), who were survived or non-survived ($P = 0.05$). However, mean of age, HRCT score, d-Dimer, and Sr. Ferritin were higher in the non-survived patients, and mean of CRP levels, Non-O_2 days, O_2 support, and hospital stay were larger in survived patients [Table 3].

Comparison of survival and non-survival of patients with vaccination status as 'yes' and co-morbidity 'no'

To check whether there is any statistically significant difference in the mean of the factors of survived and non-survived patients, who were vaccinated and not having any co-morbid conditions, Table 4 was prepared.

We found that means of HRCT score, Sr. Ferritin, and ventilator support were significantly different in survived and

Table 2: Comparison of outcome (survival and non-survival) of the patients with vaccination status=no; co-morbidity=no [*n*=301]

	Outcome	*n*	Mean	Std. deviation	Unpaired *t*	*P*
HRCT score	Death	39	15.10	5.09	3.94	0.000
	Discharge	163	11.60	4.53		
CRP level	Death	44	86.47	74.40	3.002	0.004
	Discharge	180	51.64	39.77		
D-dimer	Death	45	1494.24	2412.37	2.645	0.011
	Discharge	179	532.58	720.33		
Sr. Ferritin	Death	43	506.77	359.82	3.344	0.002
	Discharge	180	314.29	233.56		
Non-O_2	Death	7	1.57	1.27	−3.503	0.001
	Discharge	168	4.51	8.89		
O_2 support days	Death	29	3.79	2.48	−2.293	0.026
	Discharge	128	5.05	3.32		
Ventilator support days	Death	35	3.49	2.96	−0.15	0.882
	Discharge	19	3.63	3.64		
Hospital stay	Death	63	5.32	3.82	−3.724	0.000
	Discharge	238	7.34	3.88		

Table 3: Comparison of outcome (survival and non-survival) of the patients with vaccination status=no; co-morbidity=yes [*n*=9]

	Outcome	*n*	Mean	Std. deviation	Unpaired *t*	*P*
HRCT score	Death	2	20.00	0.00	8	0.079
	Discharge	2	12.00	1.41		
CRP level	Death	3	78.85	6.40	−0.509	0.638
	Discharge	5	116.66	165.97		
d-Dimer	Death	3	1370.00	640.83	2.835	0.089
	Discharge	5	280.00	233.36		
Sr. Ferritin	Death	3	716.33	439.63	1.314	0.285
	Discharge	5	350.20	256.78		
Non-O_2 days	Death	1	2.00	.	−1.41	0.218
	Discharge	6	4.67	1.75		
O_2 support days	Death	3	3.33	1.53	−0.849	0.471
	Discharge	3	5.67	4.51		
Ventilator support days	Death	2	5.00	1.41	–	–
	Discharge*	0	.	.		
Hospital stay	Death	3	8.00	3.61	−0.056	0.957
	Discharge	6	8.17	5.27		

*t cannot be calculated because the group 'discharge' is empty

non-survived patients. These values were higher in non-survived patients ($P = 0.05$). Mean of age, CRP levels, d-Dimer, non-O_2, O_2 support, ventilator support, and hospital stay were not statistically significant. But CRP level and d-Dimer are higher in non-survived patients.

Comparison of survival and non-survival of patients with vaccination status as 'yes' and co-morbidity 'yes'

Table 5 is showing the distribution of survived and non-survived patients regarding mean of different factors. These are the patients, who were vaccinated, but having comorbidities. We found there is not any statistically significant difference in these factors of survived and non-survived patients ($P = 0.05$). In this table, mean of HRCT score, CRP level, and Sr. Ferritin were larger in non-survived patients and mean of d-Dimer, non–O_2, O_2 support, ventilator support, and hospital stay were larger in survived patients.

We compared vaccinated and non-vaccinated patients with no comorbid conditions in non-survived patients. Mean of Sr. Ferritin, non–O_2, and ventilator support were found significantly different in vaccinated and non-vaccinated patients. These values were larger in vaccinated patients. Mean HRCT score, CRP levels, d-Dimer, O_2 support, and hospital stay were not significantly different in vaccinated and non-vaccinated patients.

Similarly, we have compared the vaccination status of co-morbid and non-survived patients. No factor was significant between the patients with vaccination and non-vaccination. But the mean HRCT score, d-Dimer, and Sr. Ferritin were higher in non-vaccinated patients. Mean CRP levels, O_2 support, ventilator support, and hospital stay were higher in vaccinated patients.

Discussion

Biomarkers

CRP levels were significantly severe in non-survived patients of non-vaccinated group (Fisher's exact = 8.938, $P = 0.024$), whereas not significantly different in survived and non-survived patients of vaccinated group (Fisher's exact = 1.566, $P = 0.711$). Similarly, d-dimer levels (Pearson's Chi-square = 10.374, $P = 0.016$), serum ferritin levels (Pearson's Chi-square = 9.731, $P = 0.021$), and HRCT scores (Fisher's exact = 15.196, $P = 0.001$) were also significantly related to the outcome (survival/non-survival). Patients who did not survive have higher levels of these parameters. In the vaccinated group, these associations were not significantly associated [Table 1].

In our study, d-Dimer levels, serum ferritin levels, and HRCT scores were also significantly related to the outcome (survival/non-survival) ($P < 0.05$). Patients who did not survive always had severe levels of these markers. In the vaccinated group, there were no parameters that were statistically significant and no relevant associations can be seen among them.

In a similar study conducted in Pakistan, unvaccinated patients with severe/critical COVID-19 disease had significantly higher levels of median serum ferritin, LDH, and d-dimer levels when compared with vaccinated patients with severe disease.[10]

Analysis of another study showed that the mean serum ferritin level was significantly higher in unvaccinated patients by more than twofold compared to vaccinated patients and observed that the recovery and death rate in vaccinated patients with comorbidities were better than the unvaccinated patients with comorbidities.[11]

Age and comorbidities

In our study, we found that age and comorbidity do not have any association in both the groups: vaccinated and

Table 4: Comparison of outcome (survival and non-survival) of the patients with vaccination status=yes; co-morbidity=no [*n*=40]

	Outcome	*n*	Mean	Std. deviation	Unpaired *t*	*P*
HRCT score	Death	8	18.13	4.97	3.757	0.002
	Discharge	23	10.04	5.95		
CRP level	Death	9	88.47	43.87	1.641	0.122
	Discharge	23	59.91	45.25		
d-Dimer	Death	9	1643.18	2087.46	1.574	0.149
	Discharge	24	509.20	912.47		
Sr. Ferritin	Death	9	809.39	629.95	2.335	0.045
	Discharge	24	305.22	246.46		
Non-O_2 days	Death	2	4.50	0.71	1.324	0.259
	Discharge	23	3.57	2.39		
O_2 support days	Death	4	6.00	4.08	0.215	0.839
	Discharge	16	5.50	4.50		
Ventilator support days	Death	8	6.38	3.58	2.552	0.039
	Discharge	3	2.00	2.00		
Hospital stay	Death	9	9.78	6.65	1.037	0.321
	Discharge	31	7.26	5.55		

Table 5: Comparison of outcome (survival and non-survival) of the patients with vaccination status=yes; co-morbidity=yes [*n*=31]

	Outcome	*n*	Mean	Std. deviation	Unpaired *t*	*P*
HRCT score	Death	5	13.40	5.13	0.7	0.511
	Discharge	16	11.63	4.33		
CRP level	Death	6	88.70	102.18	1.282	0.251
	Discharge	16	33.81	38.68		
d-Dimer	Death	6	837.00	272.20	−0.429	0.673
	Discharge	16	991.25	1367.23		
Sr. Ferritin	Death	6	437.33	236.80	1.642	0.139
	Discharge	16	257.77	204.70		
Non-O_2 days	Death	3	2.67	2.08	−0.67	0.550
	Discharge	16	3.56	2.34		
O_2 support days	Death	4	4.00	2.83	−1.402	0.202
	Discharge	11	6.55	3.78		
Ventilator support days	Death	6	3.67	1.97	−2.04	0.097
	Discharge	1	8.00	.		
Hospital stay	Death	7	6.71	3.59	−0.794	0.445
	Discharge	24	7.96	3.84		

non-vaccinated ($P > 0.05$) and hence vaccination does not have any effect on the outcome in the presence of higher level of these parameters. Similarly in a multivariable analysis in three groups (unvaccinated, partially vaccinated, and full vaccinated) in another study conducted by Muthukrishnan *et al.*, age was significantly associated with mortality.[12] Lord also explained the same in his study which shows that the age-related decline in immunity results not only in increased susceptibility to infection but also reduces the prophylactic efficacy of vaccinations. The two combined lead to increased risk of infections and mortality in older adults.[13]

We have compared vaccinated patients who had co-morbid conditions and who did not survive with similar non-vaccinated patients. No factor was significant between the patients who were vaccinated and non-vaccinated but the mean HRCT score, d-Dimer, and Sr. Ferritin were higher in non-vaccinated patients. Mean CRP levels, O_2 support, ventilator support, and hospital stay were higher in vaccinated patients.

A study showed that if vaccinated individuals develop severe COVID-19 and hypoxia due to other risk factors older age and comorbidities, they have a similar risk of death compared to that of unvaccinated individuals. The need for use of steroids, doxycycline and anti-viral agents such as remdesivir was also significantly low in the breakthrough infection group. Hence, co-morbid conditions in patients tend to pose a threat to vaccine efficacy.[14]

Severity of disease

We compared vaccinated and non-vaccinated patients with no comorbid conditions in non-survived patients. Mean of Sr. Ferritin, non-O_2, and ventilator support were found significantly different in vaccinated and non-vaccinated patients. These values were larger in vaccinated patients. Vaccination had an important impact on reducing the severity of disease by comparatively reducing the level of biomarkers. Ventilator support was also prolonged and the final outcome was delayed in most of the cases.

A study conducted by Balachandran *et al.* showed that vaccinated group was more likely to be symptomatic, especially with respiratory symptoms and neurological symptoms. COVID-19 vaccination reduced the risk of non-invasive ventilation use by 48% compared to vaccine-naïve patients. Vaccinated patients reduced the risk of severity by 18% as compared to vaccine-naïve patients though this was not statistically significant.[15] Another study, by Duarte *et al.* showed that vaccination with CoronaVac is effective, and vaccine breakthrough cases showed mainly mild symptoms of COVID-19, even in those who did not exhibit a potent humoral immune response, which could be possibly associated with different risk factors as overweight and other comorbidities that could impair the immune response induced upon immunisation.[16]

A study conducted in Israel administered anti-spike IgG titres for 69 patients, who were fully hospitalised COVID-19 patients using two different kits. In both analyses, these differences did not reach statistical significance. Small minority of fully vaccinated BNT162b2 recipients might still develop severe SARS-CoV-2 infection despite the vaccine's high effectiveness, with need for in-patient care. The outcome of these patients was similar to that of non-vaccinated hospitalised COVID-19 patients.[17]

Limitations

Our study has some limitations. The cohort of 381 patients included come from one single hospital (KIHS) admission which is not a true representation of community at large. The

study was not designed to eliminate risk factors for vaccine failure, because patients were identified after hospitalisation and were not compared with uninfected controls with similar risk factors. These vaccines were prepared by the strains which emerged in first wave in 2020. Delta Strains which dominated the second wave in India during our study period were conspicuously not reported in the first wave. Studies are not available regarding the coverage of vaccine protection over emerging new strains; thus, the results obtained in this study cannot significantly point towards the benefits of vaccination at large.

Conclusion

This study focuses on hospitalised patients tested positive for COVID-19 in the real world who were either vaccinated or unvaccinated. Vaccination was found helpful in reducing the severity of the biochemical markers and it definitely helped in faster recovery. Through this study, we can see that mortality rate has been reduced to a significant extent by the use of vaccines. Vaccination did not seem to have any effect on the patients who had co-morbid conditions and their outcomes were similar to that of non-vaccinated patients. The mean HRCT score, d-Dimer, and Sr. Ferritin were higher in non-vaccinated patients. Mean CRP levels, O_2 support, ventilator support, and hospital stay were higher in vaccinated patients. Our study was not sufficient to validate the findings and further meta-analysis and randomised control trials need to be performed to better understand the efficacy, late complications, and safety of the vaccine.

Key take-home message

Vaccination reduces mortality rate and provides faster recovery but its effect on patients with co-morbid conditions was found to be negative in this study, but it is safe to assume that vaccination will play an imperative role in fighting this pandemic.

Ethical approval

Approval taken from the Research Committee and Ethics Committee of Bharati Vidyapeeth Medical College and Hospital, Sangli.

Informed consent

Taken and sample enclosed.

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Conflicts of interest

There are no conflicts of interest.

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