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## Original Research Article

## A study to compare the disease severity between vaccinated and unvaccinated COVID 19 patients in Tumkur city

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## ABSTRACT

**Introduction:** WHO declared coronavirus 2(SARS-CoV-2) as a pandemic on March 11, 2020.

COVID-19 vaccines have been rapidly developed and distributed to help fight the pandemic. By January 2021, use of the Covishield vaccine and Covaxin vaccine use was approved. India began its vaccination program on 16 January 2021.

The objective of the study is to assess the severity of COVID 19 infection among those vaccinated and unvaccinated as this will help us to assess the efficacy of the vaccines.

**Methodology:** By Convenient sampling technique the data of all those patients who were admitted in tertiary care centers in Tumkur district during second wave (April-July 2021) of COVID 19 infection were assessed from their medical records. The severity of the COVID 19 infection was assessed by evaluating the CT scores, lymphocyte/ neutrophil ratio, platelet distribution width, medical treatment provided and outcome which was later compared to vaccine status of the patients.**Results:** Out of 220 patients in the study, 188(85.5%) were not vaccinated, 183(83.2%) had a positive RT PCR report, with most having CT of moderate changes (45.9%). Only 42(19.1%) patients underwent intubation and 28(12.7%) patients died. Using Chi Square test it was seen that those who were not vaccinated had moderate to severe CT scores (P = 0.026).**Conclusion:** Those who were not vaccinated had a higher chance of developing moderate to severe CT changes, though the death rate was less. Vaccine is found to be efficacious in fighting against COVID-19.This is an Open Access (OA) journal, and articles are distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License](https://creativecommons.org/licenses/by-nc-sa/4.0/), which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.For reprints contact: [reprint@ipinnovative.com](mailto:reprint@ipinnovative.com)

## 1. Introduction

It was the scenario the public health community had feared for decades. A dangerous virus emerged and was spreading rapidly around the world.

Coronavirus disease 2019 (COVID-19) is a contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first known case was identified in Wuhan, China in December 2019. The disease has since spread worldwide, leading to an ongoing pandemic.<sup>1</sup>

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The first cases of COVID-19 in India were reported on 30 January 2020 in Kerala. Lockdowns were announced from 25 March 2020.<sup>2</sup>

Since the publication of the whole genome sequence of the SARS-CoV-2 virus on 11 Jan 2020, the race for development of vaccines that began against COVID 19 has progressed with unprecedented pace and magnitude. As of July 2021, one hundred and eight vaccines were in clinical development and 184 were in pre-clinical development. Covaxin and Covishield were granted emergency use authorization (EUA) in India on 03 Jan 2021. The four vaccines, which were given EUA in India are Covaxin, Covishield, Sputnik V and Moderna.<sup>3</sup>

A second wave beginning in March 2021 was much more devastating than the first, with shortages of vaccines, hospital beds, oxygen cylinders and other medical supplies in parts of the country.<sup>4</sup> By late April, India led the world in new and active cases. On 30 April 2021, it became the first country to report over 400,000 new cases in a 24-hour period.<sup>5</sup>

India began its vaccination program on 16 January 2021 with first recipients being the health workers dealing with Covid patients.<sup>6</sup> COVID-19 vaccines have been rapidly developed and distributed to help fight the pandemic. From May 1 onwards vaccination has been open to all individuals (>18 y of age) in India.<sup>7</sup>

Different types of vaccines work in different ways to offer protection. But with all types of vaccines, the body is left with a supply of memory T-lymphocytes as well as B-lymphocytes that will remember how to fight that virus in the future. It typically takes a few weeks after vaccination for the body to produce T-lymphocytes and B-lymphocytes.<sup>8</sup>

Hyderabad-based Bharat Biotech India Ltd (BBIL) along with Indian Council of Medical Research (ICMR) publicized that Covaxin had an overall efficacy of 77.8% against symptomatic COVID. This is higher than the overall 70.4% efficacy reported of the AstraZeneca (Covishield). The two-dose vaccine was also 93.4% effective against severe disease and 63% protective against asymptomatic COVID.<sup>9</sup>

With this Background this study was designed to assess the severity of COVID 19 infection among those vaccinated and unvaccinated population.

## 2. Materials and Methods

A cross sectional study designed to assess the severity of Covid-19 disease between vaccinated and not vaccinated population.

By Convenient sampling technique the data of all those patients who were admitted in tertiary care centers in Tumkur district during the second wave (April 2021- July 2021) of COVID 19 infection were assessed from their medical records.

All the data collected from the data base managed in the respective tertiary care centers were assessed for the severity of the COVID 19 infection by evaluating their CT scores, lymphocyte/ neutrophil ratio, platelet distribution width, CRP, D Dimer, medical treatment provided and outcome and was compared to the vaccine status.

Institutional Ethical clearance was taken from Sri Siddhartha Medical College, Institutional Ethics Committee. Ref No. SSMC/MED/IEC-48/JULY-2021. Date of Approval 6 August 2021. Permission from Tertiary care centers were also taken to collect the data.

Individual consent from patient's/guardians were taken through telephonic conversation.

### 2.1. Statistical analysis

Data collected was entered and analyzed using SPSS version 22.0. Statistical analysis was done using descriptive statistics like proportion and inferential statistics like Chi-square test. P-value less than 0.05 was taken as statistically significant.

## 3. Results

### 3.1. Socio-demographic characteristics

Out of 220 patients in the study, majority of them belongs to age group 36-55 years 102(46.4%) and least were those aged above 75. Most of the patients were males 142(64.5%).

### 3.2. Vaccination status

Only 32(14.5%) patients were vaccinated with either single or both doses when compared to the 188(85.5%) patients not vaccinated.

### 3.3. Disease profile

66(30%) had RBS more than 200mg/dl and 172(78.2%) had a normal BP. Only 67(30.50%) and 49(22.3%) were diagnosed to have diabetes and hypertension respectively. (Figure 1) 27(12.3%) had other comorbidities. The most common symptom seen was a respiratory symptom along with fever/myalgia 136(61.8%), 37 (16.8%) patients had respiratory symptoms alone and only 1(0.5%) patient was asymptomatic

### 3.4. Covid severity

Most of them (83.2%) had a positive RT PCR report, with most having CT of moderate and severe changes respectively 101(45.9%) and 66(30%). Of the 220 patients only 42(19.1%) patients underwent intubation and 28(12.7%) patients died. (Table 1).

124(56.4%) patients had a neutrophil to lymphocyte ratio of <5.94 and 73(33.2%) of platelet distribution width were <17% and 109(49.5%) had normal eosinophil count, 83 (37.7%) had CRP less than 40mg/L and 81 (36.8%) had D Dimer less than 384ng/ml. (Figure 2)

### 3.5. Study of association between vaccination status and severity of covid

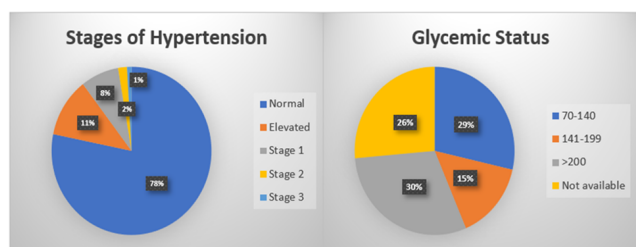
When we studied the association between vaccination status and RT PCR, CT Score, neutrophil Lymphocyte ratio, Platelet distribution width, Eosinophil, D dimer and CRP by applying Chi Square test, we got statistically significant result with CT Score (P = 0.026) (Table 2).

**Table 1:** Distribution of subjects based on COVID 19 severity

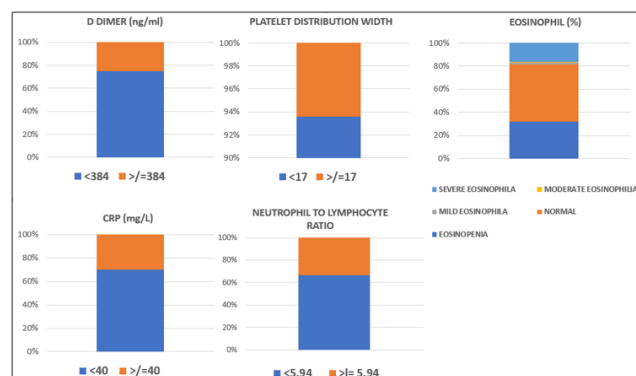
<b>RT PCR Status/Score</b>	<b>Frequency</b>	<b>Percentage</b>
Positive	183	83.20%
Negative	22	10.00%
Not done	15	6.80%
<b>CT Score</b>		
No changes	7	3.20%
Mild changes	36	16.40%
Moderate changes	101	45.90%
Severe changes	66	30.00%
Not done	10	4.50%
<b>Treatment Outcome</b>		
<b>Outcome</b>	<b>Frequency</b>	<b>Percentage</b>
Discharged	192	87.30%
Death	28	12.70%
<b>Intubation Status</b>		
<b>Intubated</b>	<b>Frequency</b>	<b>Percentage</b>
Yes	42	19.10%
No	178	80.90%
<b>Total</b>	<b>220</b>	<b>100%</b>

**Table 2:** Distribution of subjects based on association between covid vaccine status with other covid severity factors

	<b>Vaccine Taken</b>	<b>Vaccine Not taken</b>	<b>Total</b>	<b>Chi Square</b>	<b>P value</b>
<b>RT PCR</b>					
Positive	22	161	183		
Negative	6	16	22	4.238	0.12
Not Done/ Not available	3	12	15		
<b>CT Score</b>					
No Changes	0	7	7		
Mild Changes	12	24	36		
Moderate	12	89	101	11.008	<b>0.026</b>
Severe	10	56	66		
Not done/ Not available	1	9	10		
<b>Neutrophil Lymphocyte Ratio</b>					
<5.94	25	99	124		
>5.94	5	58	63	4.683	0.096
Not Done/ Not available	5	28	33		
<b>Platelet Distribution Width</b>					
<17%	7	66	73		
>17%	1	4	5	0.922	0.631
Not Done/ Not available	6	36	42		
<b>Eosinophil</b>					
Eosinopenia	6	64	70		
Normal	22	87	109		
Mild Eosinophilia	1	3	4	4.758	0.313
Moderate Eosinophilia	0	1	1		
Severe Eosinophilia	6	30	36		
<b>D Dimer</b>					
<384ng/ml	14	67	81		
>384ng/ml	4	23	27	4.758	0.313
Not Done/ Not available	17	95	112		
<b>CRP</b>					
<40mg/L	16	67	83		
>40mg/L	5	30	35	1.136	0.567
Not Done/ Not available	14	88	102		



**Fig. 1:** Distribution of subjects based on hypertensive stages and glycemic status



**Fig. 2:** Distribution of subjects based on blood parameters

#### 4. Discussion

India's coronavirus crisis, which was killing thousands of people a day. Now, as India celebrates the delivery of its 1 billionth dose, a feat that until recently seemed improbable, public health experts are sounding a new warning: The turnaround is losing steam. Vaccinations are slowing down. Many people have taken just the first vaccine and not returning for the second dose.

Daily infections have plunged to about 12,000 per day in November 2021, from about 42,000 four months before. Deaths to have fallen by half, to about 400 per day.

But with only one-quarter of its vast population fully vaccinated, India remains deeply vulnerable. The possibility that a dangerous variant will emerge remains a concern. Complacency contributed to the devastation of the second wave.

There was an unfortunate sense of overconfidence that the pandemic had ended with India. Health workers are struggling to persuade millions of people to return for a second dose.<sup>10</sup>

A total of 220 patients were evaluated 188 (85.5%) were not vaccinated and 32 (14.5%) were vaccinated with either single or both doses.

63(28.6%) had a neutrophil to lymphocyte ratio of >5.94 and 5 (2.3%) had a platelet distribution width more than 17%.

It was seen in a study, those with neutrophil to lymphocyte ratio (NLR) of more than 5.94 had higher chance of mortality<sup>11</sup> and those with platelet distribution width of more than 17% was associated with increased mortality.<sup>12</sup>

In a study, there were evidence that the peripheral blood eosinophil counts levels in patients with severe disease group were significantly lower than those with non-severe disease group in COVID-19.<sup>13</sup>

83 (37.7%) had CRP value of less than 40mg/L and 35(15.9%) had CRP of more than 40mg/L.

A study in UK showed that CRP of more than 40mg/L was associated with higher chances of mortality.<sup>14</sup>

14 (67%) had D Dimer value less than 384ng/ml and 4 (23%) of the patients had D Dimer more than 384ng/ml, in a study conducted in New York was seen those with higher D Dimer values were bound to have adverse effects.<sup>15</sup>

When we studied association of vaccine status with other factors, it showed statistically significant results with CT Score ( $P= 0.034$ ), i.e., most of the patients who were not vaccinated had either severe or moderate CT changes.

Some studies show that those who were vaccinated had a low incidence of symptomatic COVID 19 and the fully vaccinated individuals were less likely to develop severe disease.<sup>16,17</sup>

Therefore, complete vaccination of individuals is necessary to fight the pandemic and vaccine hesitancy is one of the main reason to compliance to vaccine as women from some parts of Jammu and Kashmir believe it can cause problems in menstruation, pregnancy and fertility, there were also reports of about 200 residents of a village in Uttar Pradesh jumped into the river to evade vaccination as they believed that COVID-19 vaccine is harmful as people are getting hospitalized and dying after getting the shot. Some rumors prevailing in Indian villages is that the vaccine causes impotence in men.<sup>18</sup> These are some of the reasons of vaccine hesitancy which needs to be looked upon and public needs to be educated of the importance of vaccination.

Finally, from our study we can conclude that the severity of infection was lesser in vaccinated people when compared to the non-vaccinated ones.

#### 5. Conclusion

It can be concluded that the need of complete dose of vaccine is necessary to overcome the pandemic completely, but with vaccine hesitancy of people doubting its effectiveness, mistrust in the health system and the vaccines, concern regarding adverse reactions of the vaccines and preference for natural immunity compared to the vaccines it would be difficult.

## 6. Recommendations

Since new variants of COVID 19 are emerging leading to more Covid waves which is affecting normalcy, it is important that vaccine hesitancy is addressed and reduced.

1. Vaccine hesitancy needs to be addressed and complete dosage of vaccination needs to be encouraged through health education, role plays, as it is the greatest threat to overcome the pandemic.
2. Governments should help secure funds and remove any barriers to equitable distribution. Private sector should also take their responsibility in ensuring complete vaccination.

## 7. Limitations

We collected data from only two hospitals and many records were missing and was only done during short time frame, as a larger number of data collected from various hospitals is required to understand how vaccine affects the severity in COVID-19 infected patients.

## 8. Source of Funding

None.

## 9. Conflict of Interest


The authors declare no conflict of interest.

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