



## EFFECT OF COVID-19 VACCINATION ON OUTCOME OF PATIENTS WITH COVID-19 INFECTION-A RETROSPECTIVE OBSERVATIONAL STUDY.

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**ABSTRACT** **Background:** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have distressed tens of millions of people in a worldwide pandemic. Safe and effective vaccinations are needed crucially.

**Aim:** To evaluate the efficacy of COVID-19 vaccination based on outcome of hospitalised COVID19 infected patients.

**Material And Method:** In this single hospital based retrospective observational study, we enrolled 225 patients admitted under Department of Respiratory Medicine and General Medicine at Pacific Institute of Medical Sciences, Udaipur, Rajasthan between period of April 2021 to June 2021. Demographic data, co-morbidities, hospital stay and vaccination statuses were all collected. Outcome in terms of hospital stay and mortality were compared among non-vaccinated, partially vaccinated and fully vaccinated patients.

**Result:** Among 225 covid-19 infected cases, 159 patients (70.7%) had not taken vaccine at the time of admission, out of which 38 (23.8%) did not survive while rest 121 survived. Among 58 partially vaccinated patients, 24.1% did not survived and out of 8 fully vaccinated patients, 62.5% patients recovered and 37.5% died. Among 159 non-vaccinated patients, 18.2% patients required more than 10 days of hospital stay while out of 58 partially vaccinated patients, 24.1% patients required more than 10 days hospital stay. However, among 8 fully vaccinated patients, none of required more than 10 days stay.

**Conclusion:** A chi-square test of independence showed that there is no statistically significant association between vaccination and mortality ( $p = 0.682$ ), and hospital stay ( $p=0.687$ ) but highly significant association between vaccination with Age and Comorbidity ( $p = 0.000$ ). However, safe vaccination should remain an absolute priority.

**KEYWORDS :** covid-19 vaccine, hospital stay, outcome

### INTRODUCTION

Coronavirus disease 2019 (COVID-19) is caused by a novel coronavirus, known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a newly recognised illness that has spread fast throughout Wuhan to other provinces in China and around the world<sup>1,2</sup>. As of 12 September 2021 the total number of patients in world were 225,213,508 and in India total number of cases were 3,32,36,921 including 4,42,655 deaths<sup>3</sup>. Multiple organs are involved in COVID-19 illness but lung injury is one of the most clinical manifestations<sup>4</sup>. There is a wide clinical spectrum of SARS-CoV-2 infection, circumscribing asymptomatic infection, mild upper respiratory tract illness and severe viral pneumonia with respiratory failure and even death<sup>5</sup>. Over the time virus mutated and now there are various variants around the world. Some variants named B.1.1.7 (Alpha) formerly called as UK variant, B.1351(Beta) formerly called South Africa variant, P.1(Gamma) formerly called Brazil variant, B.1.617.2(Delta) formerly called India variant<sup>6</sup>.

In India, the frequency of 501.Y.V1 is higher than that of 501Y.V2 and 501Y.V3. In India the recently nominated variant of worry B.1.617 and variant of interest B.1.618 have also been acquiring attention. Another similar variant of worry, B.1.617.2, with various mutations, is highly prevalent in the state of Gujarat in India. Prevalent variant in the state of West Bengal, India with mutation E484K is B.1.618. Another worry about the appearance of new variants is the possible failure of RT-PCR tests for diagnostics. From the earliest stages of the coronavirus disease 2019 (COVID-19) pandemic, the development of safe and effective vaccines against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the viral cause of COVID-19, has been widely considered an essential component of any strategy to control the virus, the disease, and its effects.<sup>(14)</sup> In India vaccination programs started in mid-January 2021, with the BBv152 and ChAdOx1 vaccines. There are some worries that new variants of concern and variants of interest may be able to escape immunity, produced by natural infection or vaccines. There are at least 13 vaccines across four different platforms presently in use globally.<sup>15</sup> Of these seven vaccines

have seen widespread use across countries and it is estimated that there are 150 other types of vaccines in various stages of development or efficacy testing.

The two most widely used vaccines in India are the COVISHIELD developed by AstraZeneca/Oxford University and being manufactured by the Serum Institute of India (SII) and the COVAXIN developed indigenously in India by the Indian Council of Medical Research (ICMR) and Bharat Biotech.<sup>13</sup> The recent vaccines also seem to provide protection from critical illness and death, but not necessarily from infection<sup>6</sup>. In India 73,82,07,378 total vaccine doses were given<sup>6</sup>. This study is planned to evaluate impact of COVID-19 vaccination on hospital stay and on outcome in relation to stages of vaccination.

**AIMS AND OBJECTIVE** of this study to evaluate impact of COVID-19 vaccination on hospital stay and on outcome in relation to stages of vaccination.

### MATERIAL AND METHODS

#### Study Design:

This Retrospective observational randomised study included patients from a dedicated COVID hospital from southern part of Rajasthan, India. All adult patients who were hospitalized for COVID-19 disease and those who were either discharged from the hospital or died in hospital by were included in the study. We excluded the patients who either transferred to another care centre or who died and discharged within 48 hours of hospital admission. Patients were considered as case of COVID-19 illness if they were tested positive by RT-PCR method. The present study was approved by institutional ethical committee.

#### Data Collection:

We collected data regarding patient's demographic details, clinical symptoms and signs with personal medical history and covid vaccine status, treatment details including oxygen requirement and requirement of non-invasive and invasive ventilatory support. Further,

we also obtained outcome data of the patients, either discharged or deceased. Data collection was done by accessing hospital record (patient's file and electronic record) and standard data collection form was used to extract the data. Data collection was done by two researchers (NG and KP) which was further cross-checked by third and fourth researchers (KS and PR). Any discrepancies in interpreting the data were determined by the third researcher.

We collected data on the total length of hospital stay, days in intensive care unit, and days of non-invasive / invasive ventilatory support, days on high frequency nasal cannula (HFNC) oxygen or oxygen with mask / nasal prong. Data on use of antiviral drugs (fabiravir or remdesivir) and systemic corticosteroids (dexamethasone, methylprednisolone) was also collected.

**Sample Size:**

After approval from Institutional ethical committee, a total of 225 confirmed cases of COVID-19 positive patients admitted to the hospital.

**Statistical Analysis -**

The data was analysed using statistical package for social sciences (SPSS version 21.0). Quantitative data was presented as mean and standard deviation and qualitative data were presented as frequency and percentage. Univariate analysis was carried out to find out any association between various parameters and mortality among COVID patients. Parameters which have statistically significant association ( $p < 0.05$ ) on univariate analysis were subjected to multivariate analysis to determine independent risk factors for mortality.

**Inclusion Criteria**

- COVID-19 confirmed positive patients
- Patients with mild, moderate or severe pneumonitis
- Single dose, double dose or non-vaccinated COVID-19 patients

**Exclusion Criteria**

- Referral patients from outside
- Hospital stays less than 2 days

**Patient Data Recording**

- Demographic data
- Co-morbidities
- Hospital stay and Vaccination status

**RESULTS -**

A total of patients were admitted in our hospital till June 2021. Among 225 covid-19 infected cases, 159 patients (70.7%) had not taken vaccine at the time of admission, out of which 38 (23.8%) did not survive while rest 121 survived. Among 58 partially vaccinated patients, 24.1% did not survive and out of 8 fully vaccinated patients, 62.5% patients recovered and 37.5% died. Among 159 non-vaccinated patients, 18.2% patients required more than 10 days of hospital stay while out of 58 partially vaccinated patients, 24.1% patients required more than 10 days hospital stay. However, among 8 fully vaccinated patients, none of required more than 10 days stay.

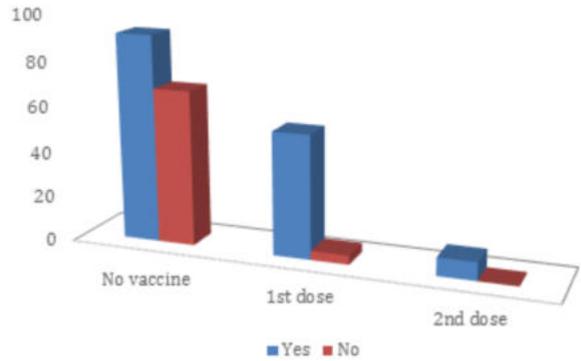
The comparison of demographic characteristics, hospital stay and vaccination status (1<sup>st</sup> dose, 2<sup>nd</sup> dose, non vaccinated) and comorbidities are mention in below table. The mean age of the study population was 52 years (SD, 14.4) and majority of them were males (61%) and female (39%). here Age factor is highly significant with vaccination status  $p$  value=0.000

Comorbidities were present in 153(68%) of the patients of which hypertension, diabetes mellitus, chronic lung disease, chronic kidney and liver disease and hypothyroidism are mention in table among them 91(57.23%) not vaccinated, 54(93.10%) with 1<sup>st</sup> dose 8(100%) with 2<sup>nd</sup> dose vaccinated. it shows that comorbidities association with vaccination status are highly significant  $p$  value= 0.000

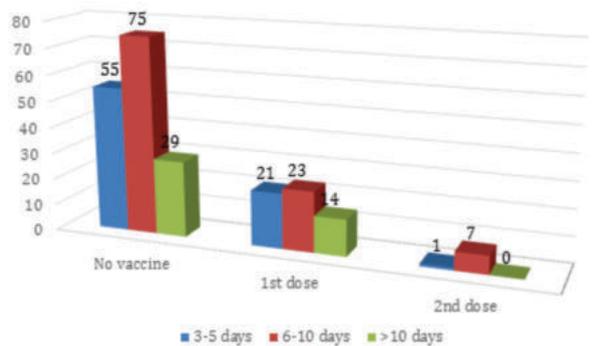
In our study Mortality is 55(24.4%) patients among them 38 patients were not vaccinated, 14(24.1%) patients 1<sup>st</sup> dose and 3(37.5%) patients had 2<sup>nd</sup> dose vaccinated, this result highly insignificant with  $p$  value = 0.682 so unfortunately mortality of covid is independent from covid vaccine

Our most indicative factor hospital stay with vaccination status are highly insignificant because more than 10 day staying 43(19.1%) patients among them 29(18.2%) non vaccinated, 14(24.1%) 1<sup>st</sup> dose

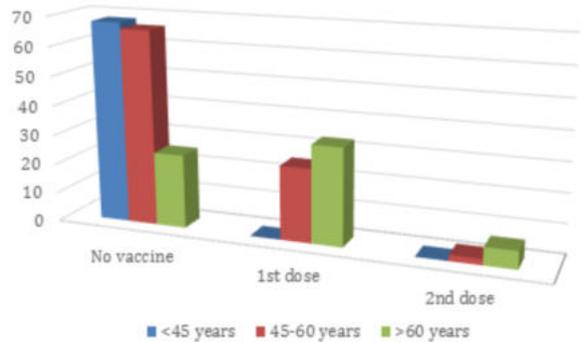
and 0(0%) had 2<sup>nd</sup> dose vaccinated where 77(34.2%) patients were stayed in hospital among them 55(34.6%) non vaccinated. 21(36.2%) 1<sup>st</sup> dose and 1(12.5%) had 2<sup>nd</sup> dose of vaccine. Moderate stay in hospital 6 to 10 days 105(46.7%) patients among them 75(47.2%) non vaccinated 23(39.7%) 1<sup>st</sup> dose and 7(87.5%) 2<sup>nd</sup> dose vaccinated, so here  $p$  value = 0.687 indicated there is no effect of vaccine on hospital stay of patient.



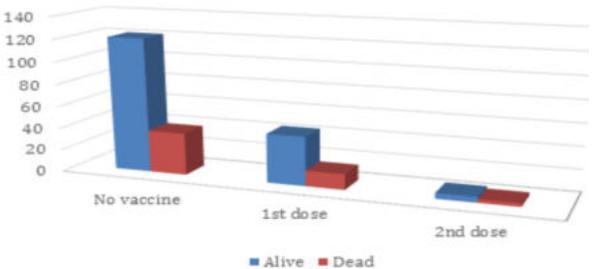
**Graph 1** Shows In Our Study Vaccination Status Vs Comorbidities



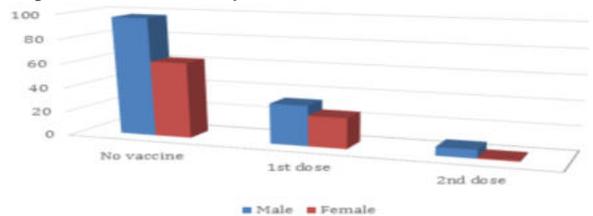
**Graph 2** Shows In Our Study Vaccination Status Vs Hospital Stay



**Graph 3** Shows In Our Study Vaccination Status Vs Age



**Graph 4** Shows In Our Study Vaccination Status Vs Outcome



**Graph 5** Shows In Our Study Vaccination Status Vs Gender

	NO VACCINATION	1 <sup>ST</sup> Dose	2 <sup>ND</sup> Dose	TOTAL	P VALUE
Age					
<45 years	68 (42.8%)	0 (0%)	0 (0%)	68 (30.2%)	
45-60 years	66 (41.5%)	25 (43.1%)	2 (25%)	93 (41.3%)	
>60 years	25 (15.7%)	33 (56.9%)	6 (75%)	64 (28.4%)	
Total	159	58	8	225	0.000
Gender					
Male	97 (61%)	33 (56.9%)	7 (87.5%)	137 (60.9%)	
Female	62 (39%)	25 (43.1%)	1 (12.5%)	88 (39.1%)	
Total	159	58	8	225	0.251
CO-Morbidities					
Yes	91 (57.23%)	54 (93.10%)	8 (100%)	153 (68%)	
No	68 (42.77%)	4 (6.90%)	0 (0%)	72 (32%)	
Total	159	58	8	225	0.000
Hospital stay					
3-5 days	55 (34.6%)	21 (36.2%)	1 (12.5%)	77 (34.2%)	
6-10 days	75 (47.2%)	23 (39.7%)	7 (87.5%)	105 (46.7%)	
>10 days	29 (18.2%)	14 (24.1%)	0 (0%)	43 (19.1%)	
Total	159	58	8	225	0.687
Mortality					
Alive	121 (76.1%)	44 (75.9%)	5 (62.5%)	170 (75.6%)	
Dead	38 (23.9%)	14 (24.1%)	3 (37.5%)	55 (24.4%)	
Total	159	58	8	225	0.682

## DISCUSSION-

This Retrospective study was conducted in a dedicated COVID treatment facility in Udaipur, Rajasthan Western India to determine the predictors of mortality in COVID 19.

Our study has several limitations like retrospective in nature, having low sample size and single centre study. The data in this study permit a preliminary assessment of the clinical course and outcomes of hospitalized patients with SARS-CoV-2 pneumonia.

Here >45 years of age group more vaccinated with many comorbidities still low mortality rate and less hospital stay in vaccinated patients as compared to partially and no vaccinated patients.

Still result of our study comparing hospital stay, outcome mortality (live or dead), comorbidity between vaccination statuses of covid19. The severity of infection and duration of hospital stay was also less in double dose or fully vaccinated patients as compared to non-vaccinated and single dose vaccinated-patients.

Advanced genomic studies are justify for evaluating infections mostly in cases of vaccine breakthrough are due to variant strains of the corona virus. Hospital stay, outcome course both short and long term are also of special interest in vaccine-breakthrough infections due to variants.<sup>13</sup> A point-prevalence survey<sup>13</sup> of almost 100 000 people conducted in England in June–July 2021 during the height of that country's spring Delta variant surge found that fully vaccinated people (n = 55962) were two-thirds less likely to harbour SARS-CoV-2 compared with unvaccinated people (n = 15 135), with absolute rates of 0.40% vs 1.21%, respectively.

Likewise, in a randomized trial<sup>12</sup> of the mRNA-1273 vaccine (Moderna) vs placebo, vaccinated participants (n = 14 287) were two-thirds less likely to be asymptomatic carriers than unvaccinated participants (n = 14164), with absolute rates of 1.5% vs 3.5%, respectively (estimated vaccine effectiveness against asymptomatic infection, 63.0% [95% CI, 56.6%–68.5%]).

In a study<sup>11</sup> of 7771 household contacts of 4921 index cases in the Netherlands, the rate of transmission from fully vaccinated household members was 13% vs 22% from unvaccinated household members (estimated vaccine effectiveness against transmission, 63% [95% CI, 46%–75%]). Similarly, in an English study<sup>11</sup> of 151 821 contacts of 99567 index patients, the rate of transmission from people fully vaccinated with BNT162b2 (Pfizer-BioNTech) was 23% vs 49% for transmission from unvaccinated people (adjusted odds ratio [aOR], 0.35 [95% CI, 0.26–0.48] for transmission of Delta to unvaccinated contacts; aOR, 0.10 [95% CI, 0.08–0.13] for transmission of Delta to fully vaccinated contacts). The age-adjusted rate of hospitalization among US adults<sup>11</sup> aged 18 years or older was 83.6 per 100 000 for unvaccinated persons compared with 4.5 per 100 000 for fully vaccinated persons.

## CONCLUSION:

In this Retrospective study of covid-19 positive patients treated at single medical institute in Rajasthan, India suggests that duration of hospital stay, need for invasive and non-invasive ventilation and outcome as death were highly insignificant in the vaccinated and non-vaccinated patients. we concluded that there was no effect of covid vaccination on hospital stay and mortality of patients, Still vaccine is definitely prevent death and secondary complications to severe covid19 infection.

## REFERENCES

- Zhao Y, Shang Y, Song W, Li Q, Xie H, Xu Q, et al. Follow-up study of the pulmonary function and related physiological characteristics of COVID-19 survivors three months after recovery. *EClinicalMedicine* [Internet]. 2020 Aug 1 [cited 2020 Oct 8];25. Available from: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(20\)30207-8/abstract](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30207-8/abstract)
- Yang X, Yu Y, Xu J, Shu H, Xia J, Liu H, et al. Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study. *Lancet Respir Med*. 2020 May 1;8(5):475–81.
- COVID Live Update: 225,213,508 Cases and 4,640,672 Deaths from the Coronavirus - Worldometer [Internet]. [cited 2021 Sep 12]. Available from: <https://www.worldometers.info/coronavirus/#countries>
- Zhou F, Yu T, Du R, Fan G, Liu Y, Liu Z, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *The Lancet*. 2020 Mar 28;395(10229):1054–62.
- CDC. Coronavirus Disease 2019 (COVID-19) [Internet]. Centers for Disease Control and Prevention. 2020 [cited 2021 Sep 12]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html>
- SARS-CoV-2 variants of concern are emerging in India | *Nature Medicine* [Internet]. [cited 2021 Aug 6]. Available from: <https://www.nature.com/articles/s41591-021-01397-4>
- #IndiaFightsCorona COVID-19 in India, Vaccination, Dashboard, Corona Virus Tracker | mygov.in [Internet]. [cited 2021 Sep 12]. Available from: <https://www.mygov.in/covid-19>
- Jackson LA, Anderson EJ, RoupaelNG, et al. An mRNA vaccine against SARS-CoV-2 — preliminary report. *N Engl J Med* 2020; 383: 1920-31.
- <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577>
- [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32661-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext)
- Understanding breakthrough infections following mRNA SARS-CoV-2 vaccination [infectious diseases | JAMA | JAMA network. Internet, Available from <https://jamanetwork.com/journals/jama/fullarticle/2786040>; 2021 Nov 7.
- Juthani PV, Gupta A, Borges KA, et al. Hospitalisation among vaccine breakthrough COVID-19 infections. *Lancet Infect Dis*. 2021 Nov 1;21(11):1485–1486.
- <https://doi.org/10.1016/j.cegh.2022.100971> Copyright© 2022 The Author(s). Published by Elsevier B.V. on behalf of INDIACLIN.
- By A. David Paltiel, Jason L. Schwartz, Amy Zheng, and Rochelle P. Walensky Clinical Outcomes Of A COVID-19 Vaccine: Implementation Over Efficacy