



## POST VACCINATION COVID POSITIVE INPATIENTS IN A TERTIARY CARE HOSPITAL – AN ANALYSIS

<b>Dr Keerthana.S</b>	M.D Pharmacology, 3rd Year Postgraduate(2019-2022), Department Of Pharmacology, Govt. Stanley Medical College, Chennai, Tamilnadu.
<b>Dr.M. Kulandaiammal*</b>	M.D. Pharmacology, Professor and HOD, Department Of Pharmacology, Govt. Stanley Medical College, Chennai, Tamilnadu. *Corresponding Author
<b>Dr. Jamila A</b>	M.D., Vice Principal, Stanley Medical College, Chennai, Tamilnadu.
<b>Dr. Dharani Sudha G</b>	M.D. Pharmacology, Assistant Professor, Department Of Pharmacology, Govt. Stanley Medical College, Chennai, Tamilnadu.

### ABSTRACT

**AIM:** This study aims to observe and analyse the data of post vaccination Covid positive inpatients.

**METHODOLOGY:** In a retrospective cohort, data of post vaccination COVID positive cases who were admitted and discharged during April 2021 to May 2021 were collected from data operating centre and medical records department such as patient's demographics, dates of swab positivity, admission, vaccination, discharge/transfer out, clinical profile, treatment given.

**RESULTS:** 196 patients (84 females, 112 males; median age 57 years) were included in this study. 102 patients received one dose and 94 patients received both doses. 12% patients had breakthrough infection ( $\geq 14$  days after complete vaccination). Median interval between date of vaccination and swab positivity was 11 days and median duration of hospital stay was 4 days irrespective of the comorbid status. 113 patients had oral drugs alone, 49 patients needed Dexamethasone, 34 patients received Remdesivir and methylprednisolone. Subgroup analysis showed significant difference in D Dimer, CRP values and duration of hospital stay between patients who were vaccinated with one dose and both doses of vaccine. 89% of patients had been discharged and 11% of patients had been transferred out.

**CONCLUSION:** COVID-19 vaccines does not guarantee protection from the risk of infection, but instead help in curing the disease faster and reducing its severity.

**KEYWORDS :** COVID-19, post vaccination, COVID inpatients, Remdesivir, breakthrough

### INTRODUCTION

**Vaccine is a product** that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease(1). COVID-19 vaccines are a critical tool for controlling the ongoing global pandemic Nationwide Covid vaccination campaign was started in India on 16<sup>th</sup> January, 2020 with Covishield, a viral vector vaccine and Covaxin, inactivated viral vaccine.

Despite the high level of vaccine efficacy, a small percentage of fully vaccinated persons will develop symptomatic or asymptomatic infections with SARS-CoV-2, the virus that causes COVID-19(2). Experts have said that the vaccine doesn't guarantee protection from the risk of infection of Covid-19, but instead help in curing the disease faster and reducing its severity(3).

A post vaccination infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person after COVID-19 vaccination. As of April 20,2021, press news says "The proportion of people testing positive is 0.04 per cent after first dose of covaxin and 0.04 per cent after the second dose of covaxin and in persons taking covishield, the proportion of people testing positive is 0.02 per cent after the first dose, and 0.03 per cent after the second dose", based on data collected from frontline healthcare workers(4).

A vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person  $\geq 14$  days after receipt of all recommended doses of an FDA-authorized COVID-19 vaccine(2). The Indian Council of Medical Research (ICMR) puts the rate of reinfections in the country at 4.5% and that of breakthrough infections at two to four infections per 10,000(5). Data from the first week of April to May 27, 2021 shows a 0.1% mortality in those who are fully vaccinated(6).

Post vaccination Covid infections are matter of concern but adequate data regarding these infections among public are yet to be available.

This study aims to observe and analyse the data of post vaccination Covid positive inpatients.

### METHODS:

The study was started after getting Institutional Ethics Committee approval. It is a single centre, retrospective observational study of two months duration (April 2021 to May 2021). All data of post vaccination

COVID positive patients were collected from the Data Operating Centre, and Medical Records Department of our medical College after obtaining permission from the concerned authorities.

### INCLUSION CRITERIA:

Data of all Covid positive cases of either sex becoming positive after vaccination who got admitted and discharged

### EXCLUSION CRITERIA :

Data of non vaccinated Covid positive patients

### ETHICAL CONSIDERATION :

This study was conducted after getting approval from Institutional Ethics Committee, Govt. Stanley medical college, Chennai.

### STUDY PROCEDURE :

Data of 196 postvaccination covid positive inpatients admitted and discharged during the month of April and May 2021 such as their demographic details(age, sex), vaccination data (type of vaccine, number of doses, date of recent vaccination), hospital data ( date of swab positivity for RTPCR, date of admission, symptomatology, comorbid conditions, oxygen saturation at admission, treatment given, date of discharge) and lab investigational data( serum values of D-dimer, Lactate dehydrogenase, C reactive protein and blood counts) were collected for analysis.

### STATISTICAL ANALYSIS :

All data collected were entered in Microsoft excel worksheet (version – 2010). Data like age, sex, symptomatology, comorbid conditions, treatment given are described in number and percentage, other numerical data like time taken for RTPCR positive from vaccination, duration of hospital stay, oxygen saturation at admission, serum values of D- dimer, Lactate dehydrogenase, C reactive protein and blood counts are expressed in terms of mean and 95%CI.

A subgroup analysis using independent T test was performed with laboratory and hospital data involving comparison of patients who had one dose and who had two doses is done.

### RESULTS:

196 medical records of post vaccination Covid positive inpatients during April and May 2021 were taken for observational study. Among 196 patients, 6% belong to age group 18-25 years, 22% belong to age

group 26-40 years, 46% belong to 41-60 years of age and 26% are between 61-80 years of age as illustrated in figure 1. Figure 2 reveals male predominance (57%) and 43% were female.

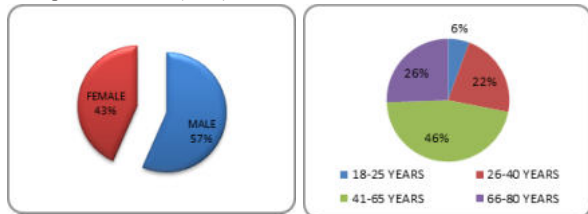


Figure 1 : Sex Distribution

Figure 2 : Age Distribution

52% of patients were vaccinated with one dose of vaccine(34%-Covishield and 18% Covaxin) and 48% of patients had received both doses of vaccines(25% Covishield and 23% Covaxin). The comorbid conditions of the patients are depicted in Figure 3 which shows majority patients had no comorbidities(56%) with next common comorbid presentation being diabetes(12%), hypertension(13%) and both(13%), 4 patients were known case of heart disease and minority of patients had chronic obstructive pulmonary disease(0.5%) and thyroid disease (1%)

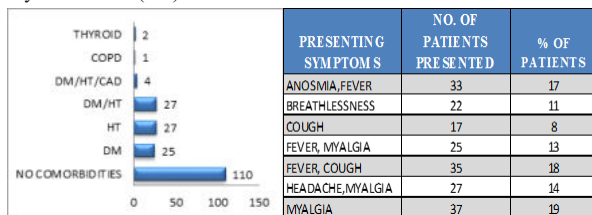


Figure 3 : Comorbidity Status

Table 1: Presenting Symptoms

Table 1 summarizes about the number and percentage of patients presenting with symptoms, most common symptom being myalgia, fever with cough and fever with anosmia Time interval taken for the patient to become swab positive after vaccination against the comorbidities of the patient is given in Table.2 23 patients(12%) had breakthrough infection (defined as patients who got infected ≥14 days of complete vaccination) of which 14 patients had history of diabetes and hypertension and 2 patients are known cases of coronary artery disease.

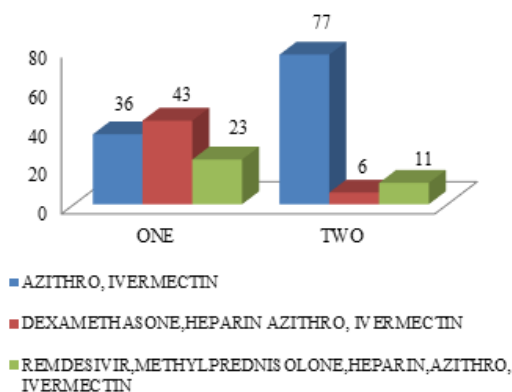


Figure 4: Treatment Given

Figure 4 explains that out of 102 patients who received one dose of vaccine, 23 patients were in a clinical condition to receive intravenous remdesivir and methylprednisolone among whom 61% were aged above 45 years. Among 94 patients who received both doses of vaccine only 11 patients were in a clinical condition to receive remdesivir and methylprednisolone among whom 82% were aged above 45 years. Independent T test was performed for the numerical variables like lab investigations and hospital parameters between patients who received one and those who received both doses of vaccination is depicted in table 3, showing significant difference in the D dimer values, C- reactive protein values (inflammatory markers) and duration of hospital stay, there was no ICU stay in any patients.

There is no significant difference seen in variables like lactate dehydrogenase, oxygen saturation, cell counts and swab positivity after vaccination between two doses of vaccine.

89% of patients were discharged while 11% of patients were transferred to care centres.

Table 2: Interval Between complete vaccination (2 doses) and Swab Positivity against comorbidities

	NO	DM/HT	CAD
<7	15	13	0
7 TO 13	18	15	0
≥14	7	14	2

Table 3: Laboratory and hospital variables between patients who received one dose and two doses of vaccination.\* - p value<0.05 significant

VARIABLES	ONE DOSE MEDIAN (95% CI)	TWO DOSES MEDIAN (95% CI)	P VALUE
D DIMER(mg/L)	0.19(0.16-0.21)	0.19(0.16-0.22)	0.003*
Lactate Dehydrogenase(IU/L)	220(204.3-235.6)	210(192.9-227)	0.13
C- Reactive Protein(mg/L)	7.3(5.9-8.7)	3(1.1-4.8)	0.03*
Oxygen Saturation(%)	91(89.9-92)	94(92.9-95)	0.23
Neutrophils	63.3(61-65.5)	75(72.6-77.3)	0.144
Lymphocytes	23.5(21.3-25.6)	19.5(17.4-21.5)	0.08
Total Leucocyte Count	7600 (7258.2-7941.7)	7900 (7649-8150.8)	0.3
Interval between vaccination and swab positivity	13.5(10.3-13.6)	12.2(8.3-11.7)	0.07
Duration of Hospital Stay	7.4(5.05-6.9)	5.8(3.8-6.1)	0.01*

DISCUSSION

In this study, case sheets of 196 postvaccination covid positive patients who were admitted and discharged during april and may 2021 were taken for retrospective analysis of variables regarding vaccination, laboratory parameters, hospital parameters was done.

196 patients(111 males and 85 females with median age of 57 years).102 patients received one dose of vaccine the remaining 94 patients received both doses of vaccine.56% of the population had no comorbidities which explains that understanding the factor that influence transmission, such as human behaviour is essential for creating preventive techniques and to reduce COVID-19-related morbidity and mortality, multifaceted preventive methods such as Covid appropriate behaviour and complete vaccination are required(7).Serious clinical symptoms like breathlessness and cough was most commonly seen in old frail patients which was consistent with postvaccination swab study by Michela Antonelli et al. done at UK(8).

Among 196 patients a total of 34 patients were in a condition to receive remdesivir and methylprednisolone among whom 68% were aged above 45 years reinforcing the fact that severity of covid increases with age which may be explained due to frailty.Results were consistent with study by Dagan et al explaining, the COVID-19 vaccine was highly efficient in reducing severe infection outcomes, such as hospitalisation, severe disease, and death(9).Also a research published in The Lancet substantiates our findings which explains, 1.24 million people in the United Kingdom were followed after receiving vaccines. They discovered that if someone had already received two injections, severity of symptoms of the disease after vaccination were lowered in half, implying that the risk of protracted COVID is reduced in those who have received both doses(10).

Breakthrough infection (defined as detection of SARS CoV2 antigen in respiratory specimen collected ≥14 days after the person has completed all recommended doses of US-FDA authorized Covid 19 vaccine(2) was seen in 23 patients among whom serious symptoms of breathlessness and cough were seen only in 9 patients and notably these patients were aged greater than 65 years.These results are consistent with the scientific conversation with the WHO Director Department of Immunization,Vaccine and Biologicals that people with weakened immune systems, especially those in older age groups, are more likely to have breakthrough disease than others and cases of breakthrough disease is likely due to people discontinuing various interventions that help to prevent the virus from spreading(11). Vaccine breakthrough infections, on the other hand, affect a small

percentage of all vaccinated people and account for a minor proportion of all COVID-19 cases(12–14). Amidst the reports of breakthrough infection across the world, SARS-CoV-2 mutants (e.g., Delta and Alpha variants) are recognized as important causes of increasing Breakthrough Infection(15). Average duration after which the patients acquired breakthrough was 23 days after which there is possibility that people who have been vaccinated change their behaviour (for example, mobility) and follow public health preventive advice (for example, physical separation and face masks), enhancing viral transmission(16) or maybe due to the Variant of Concern(VOC'S) which has high transmission, immune evasion, an increase in virulence causing decrease in the efficacy of public health and social measures(17). A genomic study by Gupta et al. revealed that the Delta variant was shown to be the most common cause of infection among breakthrough cases, indicating that it had a high rate of community transmission during this time period, followed by the Alpha and Kappa variants(18). Table 2 shows irrespective of comorbidities the patient presents with postvaccination covid infection. Patients with no comorbidities(n=110) had postvaccination infection which may be due to their relaxation from behavioural measures in prevention of Covid.

According to Table 3 which shows a subgroup analysis between patients who got vaccinated once and those who completed their vaccination, there is significant difference between patient who received one dose and two doses of vaccine in variables like D-Dimer, C-reactive Protein and Duration of Hospital stay. According to a metaanalysis of severity of COVID compared with D-Dimer and CRP values, CRP of  $\geq 10\text{mg/L}$  and D-Dimer  $\geq 0.5\text{ mg/L}$  had increased likelihood ratios towards severe Covid 19 disease(19). Thus elevated D-dimer and CRP postvaccination even with one dose of vaccine is not more than that of severe Covid which proves the effectiveness of complete vaccination in reducing the morbidity. A study by Antonelli et al. published in Lancet explains COVID-19 was less severe in participants after their first or second vaccine doses (both in terms of the number of symptoms in the first week of illness and the necessity for hospitalisation) than in unvaccinated participants(8) this finding correlates with our reduced hospital stay (requiring no ICU care) in patients who have received both doses of vaccine hence the importance of complete vaccination is pressurised by the above available data.

Though not statistically significant median oxygen saturation of patients who received both doses was 94% which is greater than those who received one dose of vaccine(91%). These findings are consistent with an observational study conducted in Vietnam which explains that among 62 postvaccination covid positive patients only one patient needed oxygen supplementation consistent with the vaccine's ability to protect against serious disease(20).

Strength of this study is in most of the literatures available postvaccination covid trend was observed only in health care workers who were in constant high amount of exposure to covid patients, this study highlights the disease profile of postvaccination covid positivity among public.

#### LIMITATIONS:

- It was a single-center study, the sample size was relatively low. Hence, similar studies with large sample size is needed to prove the generalisability of the results.
- There was no comparative study population of unvaccinated people and asymptomatic patients.
- Due to operational and logistical constraints, infected individuals were not evaluated for tomography, genome sequencing and antibody titers.
- This study only looked at the short-term clinical outcomes of symptomatic postvaccination covid positive patients; consequently, further long-term impacts of the infection must be assessed and reported on these cohorts.

#### CONCLUSION:

In summary, vaccination reduces the clinical severity of the disease in terms of very few symptomatology, need of intravenous medications, decreased duration of hospital stay, no need of intensive care unit admissions. The importance of complete vaccination should be educated to the public as it reduces the possibility of getting infected and even if infected the possibility of severe infection is less postvaccination. Even after complete vaccination Covid Appropriate Behaviour such as wearing masks, using hand sanitizers or handwash and social distancing should be followed which should be reinforced

among the public thus reducing the transmissibility of mutant variants responsible for the emergence of breakthrough infections.

**FUNDING:** No funding sources

**CONFLICT OF INTEREST:** None declared

#### CONTRIBUTION OF AUTHORS:

Dr. Keerthana.S collected the data, performed the analysis and wrote the paper. Dr. Kulandaialmmal M was the guide and corresponding author of the study, designed the analysis, gave fruitful discussions, suggestions in the manuscript, Dr. Jamila. A and Dr. Dharani Sudha G gave suggestions in the manuscript.

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