

Study on breakthrough infection and effectiveness of COVID-19 vaccination among COVID-19 patients visited ayush triage center attached to McGann district teaching hospital, Sims-Shvaimoga, Karnataka, India: A longitudinal and retrospective study



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ABSTRACT

Background: Novel coronavirus (COVID-19) first came to China in December 2019 and had become a public health emergency. There was a sudden rise of COVID-19 cases and its deaths.

Aims and Objectives: This study intends to study the estimation of breakthrough infection among COVID-19 patients and to estimate the vaccination effectiveness among COVID-19 patients concerning the severity of the disease. **Materials and Methods:** This study was conducted in Mc Gann teaching hospital. The patients who were attending the Ayush Triage were included in the study. The sample size of 200 was estimated and the study was conducted for July 5–August 4, 2021, (1 month). A retrospective study design was planned and ethical board clearance was taken before starting the study. Patients were interviewed by telephone. The basic information such as contact number was collected by secondary data available in the triage center. Later details about Vaccination status and outcome of the disease were collected through telephonic interviews. **Results:** Among 200 COVID-19 patients, 28.5% of the patients had taken vaccination. The breakthrough (COVID-19 patients who had taken both doses) infection rate was 10.5% among the people who had been diagnosed with the COVID-19 infection. Most breakthrough infections were mild. The majority of the 163 (81.50%) did not know the source of infection. The majority of the patients 143 (71.50%) were not vaccinated. After the COVID-19 infection, only around 12 (6%) patients were not recovered completely, that is, they had a history of death or hospitalization, and the remaining 188 (94%) patients were completely recovered. **Conclusion:** Overall, one in every tenth individual after complete vaccination against COVID-19 infection had contracted the infection. Most of the breakthrough infections were mild and many of the subjects did not know the source of the infection.

Key words: COVID-19; Communicable disease; Breakthrough infection; Vaccine; Immunization

INTRODUCTION

As we are on the verge of a coronavirus disease 2019 (COVID-19) fourth wave, it is very essential to have

information on COVID-19 in our hands. Since December 2019, when groups of patients with viral pneumonia were confirmed to be infected with a novel coronavirus, named SARS-CoV-2, COVID-19 has become a public health

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emergency of international interest.¹ The novel COVID-19 has become a global health emergency. The cumulative number of new confirmed cases and deaths is still increasing. So far, on July 2022, there have been 4.3 crores confirmed cases including deaths. Moreover, more than 99 crore doses of vaccination done in India.^{2,3} Breakthrough infections were operationally defined as the occurrence of COVID-19 infection ≥ 14 days after administration of two doses of either COVID-19 vaccine.^{4,5}

Source: According to the study on breakthrough among healthcare workers (HCWs) in Delhi:

1. Total of 325 HCWs were enrolled
2. Two seventy-nine (85.8%) HCWs were fully vaccinated
3. while 46 (14.2%) were partially vaccinated
4. A total of 37 (11.3%) breakthrough infections were observed in the HCWs
5. Most breakthrough infection cases (94.4%) were mild and did not require supplemental oxygen therapy⁶
6. We do not have many studies on the general public.

Aims and objectives

The objectives of the study are as follows:

1. To estimate the breakthrough infection among COVID-19 patients
2. To estimate the vaccination effectiveness and sources of infection among COVID-19 patients about the severity of disease.

MATERIALS AND METHODS

A retrospective and longitudinal study was done among COVID-19 patients presenting to Ayush Triage of Mc Gann Teaching District Hospital, Shivamogga, Karnataka. All COVID-19 patients presenting to the Ayush Triage of Mc Gann District Hospital are included in the study. People who do not give the consent, have a mental illness, or who do not pick call even after calling them 3 times are excluded from study. Sample size calculated was 200.

According to a Pilot study (Also the same estimation was found in the study published in New English Journal Magazine): The breakthrough infection proportion of vaccinated people found among the general population was $P=2.6\%$. $q=100-P=97.4\%$, $d=2.5$ Sample Size= $4pq/d^2=163$, Rounded off to 200 to reduce nonresponse bias. Duration of the study was 1 month, data of July 5, 2021–August 4, 2021, were taken.

Sampling

All patients who were presenting to the McGann hospital Ayush Triage from July 5, 2021 to August 4, 2021, were included and interviewed through telephone. The basic information such as contact number was collected by

secondary data available in the triage center. Later, details about vaccination status and outcome of the disease were collected through telephonic interviews. All the information regarding the patient was collected after taking informed consent. The permission of the institutional and hospital heads was taken for the study.

Analysis

Data were entered in the excel spreadsheet. Analysis was done with the help of epi-info software. Statistical tests used were: Proportion, percentage, t-test, and Chi-square test. Ethical clearance was obtained from the Institutional Ethical Committee SIMS, Shivamogga

RESULTS

Among 200 COVID patients, 101 (50.50%) were males and the remaining 99 (49.50%) were females. The majority of the patients 58.50% belonged to the urban area, most of the patients (51) were doing other occupations, the majority of them (79%) were Hindus, most of them (65%) were BPL, the majority of them were literates, and 1/4th of them were illiterates (Table 1).

Among 200 COVID-19 patients, most of them (81.50%) did not know the source of infection, followed by family, friends, neighbors, and least was the workplace as the source of infection. Most of the patients (71.50%) were not vaccinated. After the COVID-19 infection, many of the patients recovered completely (94%) and around 6% of patients were not recovered completely, that is, they had a history of death or hospitalization. Around 50% of the hospitalized people died. Among those who had the COVID-19 infection, nearly 40% of the patients had not measured their oxygen level and temperature regularly because of lack of information during home isolation, remaining 60% of the patients measured their oxygen level and temperature regularly (Table 2).

Among 200 COVID-19 patients, 28.5% of the patients had taken vaccination. The breakthrough (COVID-19 patients who had taken both doses) infection rate was 10.5% among the people who had been diagnosed with the COVID-19 infection (Table 3).

Among 200 patients, 28.50% of the people had contracted an infection after taking one dose of the vaccine. The majority of the patients who were vaccinated with the COVID-19 vaccine got recovered well (92.8%). There was not much difference in death/hospitalization found among those who had taken one shot and two shots of the COVID-19 vaccine. Only around 7.10% of the patients who were vaccinated were either died or hospitalized. It was not found a statistically significant association between different COVID-19

Table 1: Sociodemographic details of COVID-19 patients

S. No.	Variables	Sub-variables	Frequency (Percent)
1.	Gender	Male	101 (50.50)
		Female	99 (49.50)
2.	Address	Rural	83 (41.50)
		Urban	117 (58.50)
3.	Occupation	Businessman	12 (6)
		Daily wage workers	20 (10)
		Govt sector officials	6 (3)
		Frontline workers	1 (0.50)
		Healthcare workers	2 (1.00)
		Other	102 (51.00)
		Private salaried	19 (9.50)
		Students	31 (15.50)
4.	Religion	Hindu	158 (79.00)
		Muslim	19 (9.50)
		Christian	12 (6.00)
5.	SES	APL	69 (34.50)
		BPL	131 (65.50)
6.	Education	Illiterate	52 (26.00)
		SSLC/Equivalent and below	55 (27.50)
		Pre-university college level	29 (14.50)
		Graduate	52 (26.00)
		Post-graduate	12 (6.00)

Table 2: COVID-19 infection and their vaccination status and recovery among patients

S. No.	Variables	Subvariables	Frequency (Percent)
1.	Source of infection	Don't know	163 (81.50)
		Family	21 (10.50)
		Friends	5 (2.50)
		Neighbors	5 (2.50)
		Workplace	6 (3.00)
1.	Vaccination status	Yes	57 (28.50)
		No	143 (71.50)
2.	Complete Recovery	Yes	188 (94.00)
		No	12 (6.00)
3.	Measurement of oxygen level and temperature regularly	Yes	80 (60.00)
		No	120 (40.00)
4.	Outcome	Death	7 (3.50)
		Hospitalization	7 (3.50)
		Recovery	186 (93.00)

Table 3: Distribution of COVID-19 breakthrough infections

Vaccination status	Frequency (Percent)
1 st dose	36 (18)
2 nd dose	21 (10.5)
No	143 (71.50)
Total	200 (100)

vaccination doses and the severity of the COVID-19 infection (P=0.977433). That could be because of very less number of people had taken COVID-19 vaccination at the time of the study (Table 4).

Table 4: Effectiveness of vaccination with respect to severity of COVID-19 infection

Shots of COVID-19 vaccine taken	Outcome		
	Death/hospitalization (%)	Recovery (%)	Total (%)
1	2 (5.50)	34 (94.44)	36 (100.00)
2	2 (9.50)	19 (90.48)	21 (100.00)
Total	4 (7.10)	53 (92.98)	57 (100.00)

The Chi-square statistic with Yates correction is 0.0008. The P=0.977433. Not significant at P<0.05

DISCUSSION

In the study done by Tyagi et al., showed that among 123 employees, 113 were vaccinated (91%) were vaccinated, and among them 19 persons (16.9%) of the vaccinated individuals had the breakthrough infection. Expect 1 had hospitalization. Whereas the present study results had found higher results compared to Tyagi et al., concerning infection among overall vaccination, that is, 28.5%, might be because in the present study, vaccinated individuals were less compared to unvaccinated.⁶

Another study done by Dash et al., found that 274 samples of the vaccinated individuals were found to be positive. Around 83.2% of the individuals were found to be symptomatic with 9.9% of those requiring hospitalization. The seropositivity in individuals receiving CoviShield (96.7%) was significantly higher than in Covaxin (77.1%). Around 9.9% of the individuals were hospitalized with no significant difference between Covaxin and CoviShield recipient groups.⁷ Only one individual (CoviShield recipient) died post-infection during the study period. Whereas the present study showed that 28.50% had an infection after vaccination. There was not much significant difference found between recovery rate and death among those who had taken one shot and 2 shots of the COVID-19 vaccine. Nearly 7.10% of the patients who were vaccinated had a severe infection, and the remaining 93% had completely recovered. It might be because the COVID-19 vaccines do not provide 100% protection, post-vaccination breakthrough infection is possible but not severe and rare.^{8,9}

A limitation of this study is that we did not test asymptomatic individuals who might harbor COVID-19 infection and the study restricted to only one hospital/center and interview was done through telephone. Finally, more community-based studies, direct interview type, and studies involving more centers are needed to estimate the breakthrough infections.

CONCLUSION

Overall one in every tenth individual after complete vaccination against COVID-19 infection had contracted the infection. It is still high in people vaccinated with a single dose. Most of the infections were mild. Most of the people did not know the source of infection. It indicates that the disease spreads rapidly in the community and we were on the verge of fourth wave. We strongly recommend that people need to take vaccine including booster dose and follow the COVID-19 etiquette such as using masks, sanitization of hands, and social distancing even after vaccination and in all public places.

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AK- Concept, design of the study, and reviewed the literature; **KN-** Prepared first draft of manuscript, interpreted the results, and reviewed the literature; **PHL-** Concept, coordination, statistical analysis and interpretation, and preparation of manuscript; **RK-** Concept and design of the study, Interpreted the results, statistical analysis, and preparation and review of manuscript; **MM-** Reviewed the literature, data collection, and reviewed the draft; **DR-** Concept and design of the study and data collection; **SKGM-** Helped in statistical analysis, data collection, and reviewed the manuscript.

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