

Original research

Comparison of the clinical profile and outcomes of Covid-19 infection in vaccinated and unvaccinated people

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Abstract

Objective: Vaccinating people can be an effective way of controlling the ongoing COVID-19 pandemic because vaccines have shown high efficacy in preventing serious illness and hospitalization. However, the long-term effectiveness of the vaccines is still unknown. Vaccines are not fully effective as evidenced by the reports of fully vaccinated people who developed COVID-19 infection.

The aim of the study was to compare the clinical profile and outcomes of the COVID 19 infection among vaccinated and unvaccinated patients.

Methods: The observational study was conducted from March to May 2023 at tertiary care center, Kakinada, India.

Results: In this study out of 56 COVID-19 infected patients, frequency of COPVID-19 according to age distribution was higher in 41 to 50 years of age population. There was no significant sex preponderance. Out of 56, most common presenting symptoms were breathlessness 37 (66%). Out of 56, 51 (91%) patients were vaccinated (Covisheild, Serum Institute India PVT LTD, India), remaining were not vaccinated. Out of 56, 35 (62%) patients had comorbidities. Out of 56, 44(79%) patients presented with bilateral multiple opacities on chest X- Ray. Out of 56, 36 patients` saturation was maintained on room air which constitutes (64%). Out of 56, 36(64%) patients presented with mild disease severity. Out of 56, 10 patients succumbed to death of whom 7 (70%) patients were vaccinated , 3 (30%) patients were unvaccinated ($p>0.05$).

Conclusion: Although the vaccination does not restrict/avoid infections, it appears to protect the vaccinated people from severe forms of COVID 19 infections.

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Observational study conducted from march to may 2023 in 56 covid-19 infected patients out of which 51 were vaccinated and 5 were unvaccinated

Most common presentation was breathlessness and mild form of disease was seen in 36 patients who maintained saturation on room air

Mortality in vaccinated was 13% whereas in unvaccinated it was 60%

Key words: COVID-19, vaccination status, outcomes, disease severity, mortality

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Introduction

Since the start of the pandemic, COVID-19 infection has resulted in 9.4 million deaths worldwide resulting in one of the major global health crises of the 21st century (1).

Covid-19 has contributed to enormous adverse impact globally (2). Vaccinating people can be an effective way of controlling the ongoing COVID-19 pandemic because vaccines have shown high efficacy in preventing serious illness and hospitalization (3, 4). Vaccinations against coronavirus disease 2019 (COVID-19) have undoubtedly conferred widespread protection against infection worldwide and are strongly associated with prevention of serious illness, with a hospitalization rate 10.5 times higher in unvaccinated compared with fully vaccinated persons (3,4).

However, the long-term effectiveness of the vaccines is still unknown. India has started its largest free vaccination drive in January 2021 (5). Initially vaccination was performed in health care workers. This study aimed to determine clinical profile and outcomes in vaccinated and unvaccinated patients with COVID-19.

Methods

An observational study was done to compare the clinical profile and outcomes of the Covid 19 infection among vaccinated and unvaccinated patients admitted in COVID ward from March 2023 to May 2023 in tertiary care center, Kakinada, India. Patients with symptoms like breathlessness, cough, chest pain and fever, patients with recent travel history, patients with COVID real time polymerase chain reaction (RTPCR) positive test, patients older 12 years were included in the study.

Ethics approval of local Ethic Committee was obtained and patient consent was taken.

Patients age, symptoms, vaccination status, radiological profile, course of the disease were taken into consideration.

Vaccination was made using Covisheild™ vaccine (Serum Institute India PVT LTD, India), 2 doses 12-16 weeks apart.

X-ray was taken for all patients, saturation was recorded with pulse oximeter and ABG was sent for hypoxic patients. Based on AIIMS/ICMR joint monitoring group patients were classified as having mild, moderate and severe forms of disease.

Based on clinical, radiological and grading patient were kept on oxygen, non-invasive ventilation and mechanical ventilation.

Statistical analysis was done using Chi-square test.

Results

In this study out of 56 COVID-19 infected patients, frequency COVID-19 according to age distribution was higher in 41 to 50 years of age, which constitutes 23% of sample size (Table 1). There was no significant sex preponderance. Of 56, 51 (91%) patients were vaccinated with Covisheild vaccine. remaining 5 (9%) were not vaccinated (Fig. 1). In out of 56 patients, the most common presenting symptoms were breathlessness 37 (66%) followed by fever 35(63 %), and cough 30(54 %). Out of 56, 44 (79 %) patients presented with bilateral multiple opacities on chest X-ray, 12 (21%) patients do not have significant abnormalities on their X rays (Fig. 2). Out of 56, 35 (62%) patients have co-morbidities, 21 (38%) patients do not have comorbidities. Mild disease was detected in 61%, moderate in 9% and severe in 30% of patients (Fig. 1).

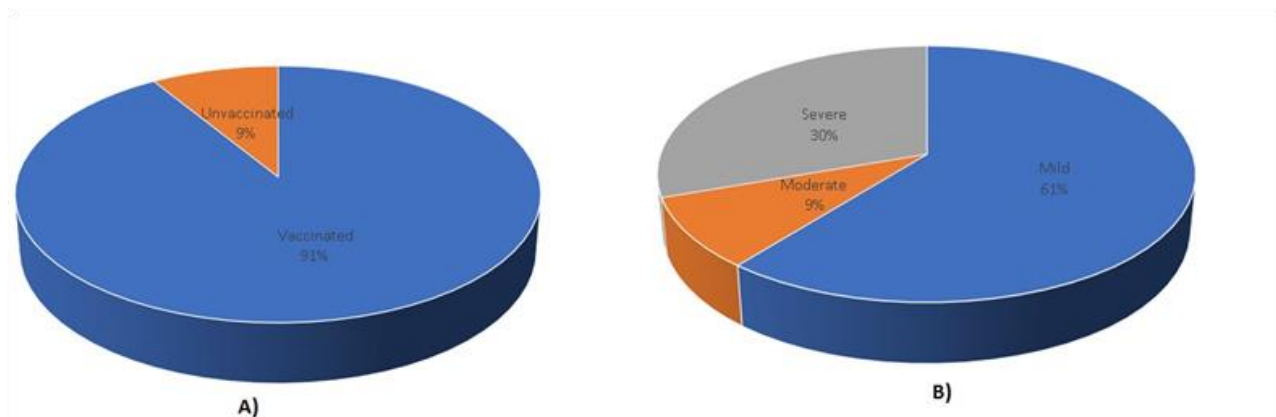


Figure 1. Distribution of patients by vaccination status and severity of COVID-19 disease

Table 1. Clinical characteristics		
Variables	Number of patients (n=56)	Percentage (%)
Demographic characteristics		
Sex		
Male	30	54
Female	26	46
Age, years		
<20	5	9
21-30	8	14
31-40	7	13
41-50	13	23
51-60	9	16
61-70	9	16
71-80	5	9
Vaccination status		
Vaccinated	51	91
Unvaccinated	5	9
Symptoms		
Breathlessness	37	66
Cough	30	54
Fever	35	63
Nausea & Vomiting	3	5
Abdominal pain	2	4
Body pain	2	4
Headache	3	5
Chest pain	8	14
Comorbidities		
Comorbidities	35	62
No Comorbidities	21	38
Disease severity		
Mild	34	61
Moderate	5	9
Severe	17	30

Analysis of association of clinical signs and disease severity demonstrated that patients with severe disease had higher comorbidities ($p=0.028$), lower

oxygen saturation ($p=0.017$) and multiple opacities on chest X-Ray ($p=0.005$). Patients with and without vaccination did not differ by demographics, symptoms

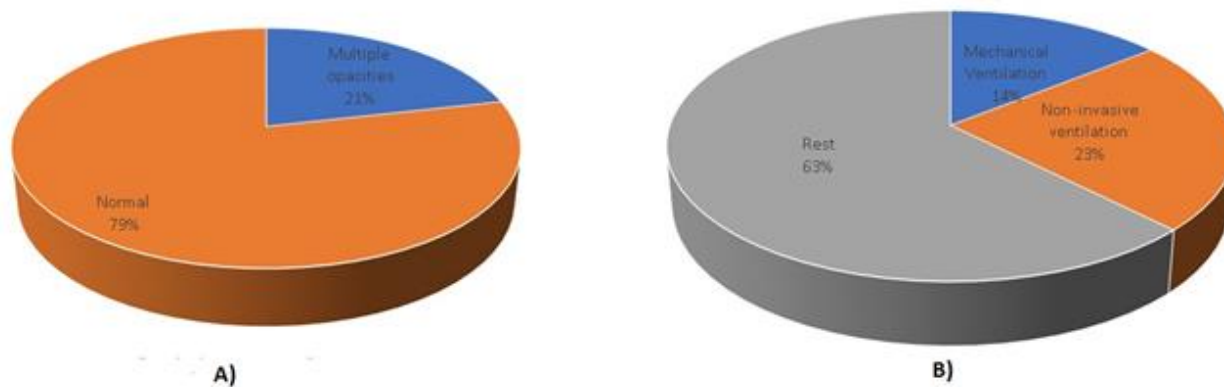


Figure 2. Chest X-Ray findings (multiple opacities) and percentage of patients on noninvasive and mechanical ventilation

Out of 51 vaccinated, mild form of disease was seen in 35 patients who maintained saturation on room air, moderate form of disease was seen in 5 patients who maintained saturation with non-rebreathing mask and non-invasive ventilation and finally severe form of disease was seen in 11 patients who were mechanically ventilated (Table 2). Out of 5 unvaccinated patients, mild form of disease was seen in 1 patient who maintained saturation on room air, moderate form of disease was seen in 1 patient who maintained saturation with non-invasive ventilation and severe form of disease was seen in 3 patients who were mechanically ventilated. Overall severe form of

disease has tendency to be higher in unvaccinated as compared to vaccinated (60% vs 21.6%, p=0.09). Out of 56, 10 patients succumbed to death out of which 7 (70%) patients were vaccinated and having severe form of disease, 3 (30%) patients were unvaccinated who were having severe form of disease. Out of 7 vaccinated patients who were succumbed to death, 1 patient had history of paraquat (herbicide intake results in acute lung failure) intake one week prior to testing COVID-19 positive, 1 patient had severe pancreatitis and 1 patient had poliomyelitis deformity. Mortality rate was 60% in unvaccinated and 13.7% in vaccinated (p=0.85).

Table 2. Outcomes of patients according to vaccination status			
Variables	Vaccinated (n=51)	Unvaccinated (n=5)	p
Disease severity			
mild	35 (68.6)	1 (20)	0.09
moderate	5 (9.8)	1 (20)	
severe	11 (21.6)	3 (60)	
Mortality			
Alive	44 (86.3)	2 (40)	0.85
Death	7 (13.7)	3 (60)	

Discussion

Our study demonstrated that disease severity was associated with comorbidities, low oxygen saturation and multiple opacities on chest X-Ray in hospitalized patients with COVID -19 who received and did not receive COVID-19 vaccine prior to hospitalization. We did not find the association of disease severity with

demographic data, symptoms and hemodynamic data.

Similar we did not find association of demographic and clinical signs with vaccination status.

Analysis of in-hospital outcomes according to vaccination status demonstrated the tendency to higher disease severity in unvaccinated patients

In our study, most common age group was 41-50 years with no gender preponderance. Breathlessness was the most presenting symptom, which was same as in study by Ramachandran et al (6). Overall, 79% of our patients presented with bilateral opacities on chest X-ray which is in accordance with the results of the study conducted by Martinez Chamorro et al (7). In majority of our patients, saturation was maintained with room air. Patients were categorized of having mild, moderate and severe forms of disease based on AIIMS/ ICMR joint monitoring group.

In our study 91% were vaccinated with Covishield 2 doses in 2021, the gap between 2 doses is 12-16 weeks. In vaccinated group, most of patients had mild and moderate forms of disease that confirms previous studies (8-11) and in-hospital mortality in 91% vaccinated was 13% whereas 9% were unvaccinated in whom mortality was 60%, the latter also confirms in part previously reported data on mortality (12, 13).

Study limitations

Several limitations should be acknowledged as small sample size therefore we could interpret as tendencies for main outcomes in vaccinated and unvaccinated patients. It is worth mentioning this is a single hospital study.

Conclusion

The clinical outcomes of patient with COVID-19 were different among the vaccinated and unvaccinated patients with most of unvaccinated patients suffered from severe form of COVID-19 disease and had higher mortality. Although the vaccination may not protect from the disease it appears to protect the vaccinated people from progressing to severe forms of COVID-19 disease.

Ethics: Informed consent was obtained from patients before all procedures, Study protocol was approved local Ethic Committee.

Peer-review: Internal

Conflict of interest: None to declare

Authorship: S.G., V.S.K., R.G. equally contributed to the study, preparation of manuscript and fulfilled authorship criteria

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References

1. World Health Organization. Weekly Operational Update on COVID-19 January 2022. WHO 2022; 1–10.
2. World Health Organization clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. *Pediatrics* 2020; 16: 9-26.

3. Tenforde MW, Self WH, Adams K, Gaglani M, Ginde AA, McNeal T, et al. Association between mRNA vaccination and COVID-19 hospitalization and disease severity. *JAMA* 2021; 326: 2043-54. doi: 10.1001/jama.2021.19499

4. Havers FP, Pham H, Taylor C.A, Whitaker M, Patel K, Anglin O, et al. COVID-19 associated hospitalizations among vaccinated and unvaccinated adults 18 years or older in 13 US states, January 2021 to April 2022. *JAMA Intern Med* 2022; 182: 1071–81. doi: 10.1001/jamainternmed.2022.4299

5. Kumar VM, Perumal SRP, Trakht I, Thyagarajan SP. Strategy for COVID-19 vaccination in India: The country with the second highest population and number of cases. *NPJ Vaccines* 2021; 60.

6. Ramachandran A. Clinic-radiological profile and outcome of severe COVID 19 patients at a tertiary care in Andhra Pradesh. *IJMSCR* 2021; 4: 663-73.

7. Chamorro EM, Diez Tascon A, Ibanez Sanz L, Ossaba Velez S, Borrueal Nacenta S. Radiological diagnosis of patients with COVID-19. *Radiologia* 2021; 63: 56-73.

8. Mohd A.A., Kamraju m. A study on COVID-19 vaccination drive in India . *BRIS j Educ Res* 2021;1: 76-9.

9. Pramod S, Govindan D, Ramasubramani P, Kar SS, Aggarwal R, and JIPMER vaccine effectiveness study group. Effectiveness of Covishield vaccine in preventing COVID-19-A test-negative case control study. 2022; 40: 3294-7.

10. Tsundue T, Namdon T, Tsewang T, Topgyal S, Dolma T, Lhadon D, et al. First and second doses of vaccine provide high level of protection against SARS-CoV-2 infection in highly transmissible setting: results from a prospective cohort of participants residing in congregate facilities in India. *BMJ Glob Health* 2021; 7: e008271.

11. Notarte KI, Catahay JS, Velasco JV, Pastrana A, Ver AT, Pangilinan FC, et al. Impact of COVID-19 vaccination on the risk of developing long-COVID and on existing long-COVID symptoms: A systematic review. *EclinicalMedicine* 2022; 53: 101624

12. Zheng C, Shao W, Chen X, Zhang B, Wang G, Zhang W. Real world effectiveness of COVID-19 vaccines: a literature review and metaanalysis. *Emerg Microb Infect* 2022; 11: 2383-92.

13. Zontarctor A, Shivaprakash S, Tiwari A, Setia MS, Gianchandani T. Effectiveness of COVID-19 (Covishield TM and Covaxin) vaccines in health care workers in Mumbai, India: a retrospective cohort analysis. *PLoS One* 2022; 17: e0276759.

