DOI: 10.7860/JCDR/2022/53414.16016

Original Article

Pharmacology Section

Severity of COVID-19 in Vaccinated and Non Vaccinated COVID-19 Positive Cases: A Cross-sectional Study

PADMA SRAVANI SAGI[1], A VENKATA KALYAN KUMAR[2], SAHILA BHANU[3], C KEERTHI[4], D NEERAJA[5], R SRINIVAS RAO[6], T DURGA[7], BR SHYAM PRASAD[8]

ABSTRACT

Introduction: Coronavirus Disease-2019 (COVID-19) vaccine was reported to be used in China, after the outbreak of Coronavirus. COVID-19 vaccine requires validation of efficacy and adverse reactions as target vaccine population include high risk over the age of 60, medical frontline workers and people working in essential industries. After Spanish flu, COVID-19 pandemic is most devasting situation in the world.

Aim: To evaluate the effectiveness of COVID-19 vaccine in COVID-19 positive vaccinated cases compared to non vaccinated cases.

Materials and Methods: This cross-sectional study was conducted in Government Super Specialty Hospital Andhra Pradesh, India, from July to September 2021. COVID-19 positivity was confirmed by Reverse Transcription Polymerase Chain Reaction (RT-PCR) test in vaccinated and non vaccinated patients, admitted in a Government Super Specialty Hospital. Severity of the disease was studied in 1423 non vaccinated and 601 vaccinated cases of all age group above 18 years. Patients were categorised based on symptoms and oxygen saturation (SpO_2) in to Mild-SpO_2 >94%, Moderate-SpO_2 <94%, Severe- SpO_2 <90%. Patients were subdivided into three groups based on age 18-44 years, 45-64 years and ≥65 years age. Data was collected and tabulated using Microsoft excel and Statistical Package for the Social Sciences (SPSS) version 15.0. The statistics of percentage was used.

Results: A total of 2024 COVID-19 positive cases were studied, out of which, 1423 were non vaccinated and 601 were vaccinated. Among non vaccinated group of 1423 cases, 712 cases had mild symptoms, 510 patients were of moderate symptoms, 201 patients were of severe symptoms. In 601 vaccinated cases, mild cases were 352, moderate cases were 185 with SpO_2 <94%-90%, 64 cases are severe with SpO_2 <90%. In this study the vaccinated patients had less severe disease with mild symptoms, in the cases of present study from COVID-19 compared to non vaccinated cases.

Conclusion: Vaccine effectiveness was noted after two doses. Vaccinated people had less severe symptoms and disease compared to non vaccinated people. Finding would support the effort to maximise vaccine with two doses among vulnerable population.

Keywords: Coronavirus disease-2019, Polymerase chain reaction test, Vaccination

INTRODUCTION

Coronavirus caused Severe Acute Respiratory Syndrome (SARS) across the world which was labelled as Coronavirus Disease-2 (SARS-CoV-2). It was reported pandemic in December 2019. The first case was reported in Wuhan, China and later spread worldwide [1]. Various control measures such as wearing masks, social distancing, maintaining personal hygiene helped in limiting the spread of disease. World Health Organisation (WHO) has been constantly updating the information regarding the Coronavirus Disease-2019 (COVID-19) in its website [2].

Numerous drugs were used and investigated for therapeutic efficacy against Coronavirus, including available drugs and newer drugs, for use in treatment and prophylaxis. WHO declared COVID-19 pandemic and monitored various notable efforts for evaluating efficacy of various drugs. Some studies showed men and women had a similar incidence and some showed higher risk for men with COVID-19 infection [3]. Vulnerability and outcomes are more common among men compared to women [3]. Vaccines were thought to be needed to reduce the morbidity and mortality associated with COVID-19 and multiple organisations have been involved in rapid development of vaccine. Various methods were used to observe and communicate the case safety reports in COVID-19 treatment by WHO programs for international drug monitoring for drugs used to treat COVID-19 by VigiBase [4].

In October 2020, India's Ministry of Health and Family Welfare announced that government should use 400-500 million COVID-19 vaccine doses to cover 200-250 million people at the end of July 2021. India began vaccinating the population on January 16, 2021 [5]. Two main vaccine manufacturers, Serum Institute of India prepared COVISHIELD (recombinant replication chimpanzee adenovirus vector encoding the SARS-CoV-2 spike-s glycoprotein, produced in genetically modified human embryonic kidney 293 cells) and Bharath Biotech prepared COVAXIN (whole virion inactivated vaccine) [5]. Serum Institute of India manufactured 65 million doses per month. Bharath Biotech manufactured 20 million doses per month. Vaccination program in India had three phases. First phase which began on January 16, 2021, focused on health care professionals and frontline workers. Second phase started on March 1st 2021, consist of two parts, during first part people over the age of 60 and those above 45 years with specific co-morbidities were vaccinated [6].

On April 1st 2021, Government decided to expand the availability of vaccine to everyone over age of 45. Third phase began on May 2021, with anyone above the age of 18 eligible to get vaccinated [7]. Various studies, have been published on the effectiveness of vaccine across different countries in COVID-19 infection [8-10]. This study provides the estimate of effectiveness of both the doses of the vaccines against SARS-CoV-2 infection and to evaluate protection against SARS-CoV-2 following widespread introduction of vaccines. In the present study, authors analysed, the severity of the COVID-19 infection in vaccinated people compared to non vaccinated people.

MATERIALS AND METHODS

This cross-sectional study was conducted at the Government Super Specialty Hospital Andhra Pradesh, India, from July 5th to September 5th 2021. Ethical Committee clearance was obtained from Institutional Ethical Committee (reference no 12A/2021).

Inclusion criteria: The cases admitted in the age group of 18-64 year, both vaccinated and non vaccinated with RT-PCR positive cases were included in this study. Vaccine effectiveness was calculated in cases who had received two doses of vaccine and 14 days has passed after the second dose.

Exclusion criteria: Cases admitted with age less than 18 years, cases with one dose of vaccination, cases with vaccination within seven days of admission, pregnant women and lactating mothers were excluded in this study.

Total number of patients studied was 2024 members. Study population consisted of cases aged 18 years and older as these were the cases admitted in the hospital. The cases studied were stratified by age group for convenience to study the risk age group as 18-44 years, 45-64 years and above 65 years.

Study Procedure

Testing for SARS-CoV-2: Gold standard testing for SARS-CoV-2 was done by test Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR). All the patients were screened by computed tomography chest to assess the severity of disease. Other blood investigations of complete blood picture, plasma glucose, serum creatinine, liver and kidney function tests were done to screen for co-morbidities. The values of the parameters and status of co-morbidities were not studied.

A total of 2024 admitted patients in Government Super Specialty Hospital, were verbally asked regarding the vaccination status. The institutional criteria were used to categorise severity of COVID-19 based on the SpO_2 (i.e., oxygen saturation) into mild (>94%), moderate (<94%), severe (<90%). Vaccine effectiveness was assessed against three SARS-CoV-2 outcomes comprising of asymptomatic infection, symptomatic COVID-19 cases and severe or critical hospitalised patients. Asymptomatic infection was defined as person with RT-PCR positive but no fever and respiratory symptoms and not hospitalised and not died from COVID-19 with saturation above 94%. Symptomatic were positive cases with above symptoms with mild and moderate severity and severe were of cases who were positive, with symptoms and saturation below 90%. Individuals were described non vaccinated if they did not receive any dose of COVID-19 vaccine, and as fully vaccinated if they passed seven days after COVID-19 vaccination. Severity of disease was analysed between non vaccinated and fully vaccinated individuals aged 18 years and above with SARS-CoV-2 infection.

STATISTICAL ANALYSIS

Data was collected and tabulated using Microsoft excel. Strata version 15 binominal regression model was used to derive incident rate ratios with 95% confidence interval for each outcome. The statistics of percentage was used.

RESULTS

Out of 2024 COVID positive cases, 1423 (70.31%) were non vaccinated. A total of 601 (29.69%) were vaccinated. Among 1423, in non vaccinated group, 18-64 years aged were 702 (49.33%), 45-64 years aged were 432 (30.36%) and ≥65 years aged were 289 (20.31%). Among 601 vaccinated cases, 18-64 years were 123 (20.47%), 45-64 years old was 178 (29.61%) and aged ≥65 years were 300 (49.92%) cases. The age wise distribution among vaccinated and non vaccinated cases is depicted in the [Table/Fig-1].

COVID-19 status	Non vaccinated	Vaccinated
SARS-CoV-2 infection		
18-64 years	702 (49.33%)	123 (20.47%)
45-64 years	432 (30.36%)	178 (29.61%)
≥65 years	289 (20.31%)	300 (49.92%)
Total	1423 (70.31% of total cases)	601 (29.69% of total cases)
Mild COVID-19		
18-64 years	477 (66.99%)	113 (32.1%)
45-64 years	207 (29.07%)	130 (36.93%)
≥65 years	28 (3.94%)	109 (30.97%)
Total	712 (50.04% of total non vaccinated cases)	352 (58.57% of total vaccinated cases)
Moderate COVID-19		
18-64 years	184 (36.08%)	9 (4.86%)
45-64 years	153 (30%)	37 (20%)
≥65 years	173 (33.92%)	139 (75.14%)
Total	510 (35.84% of total non vaccinated cases)	185 (30.78% of total vaccinated cases)
Severe COVID-19		
18-64 years	41 (20.4%)	1 (1.56%)
45-64 years	72 (35.82%)	11 (17.19%)
≥65 years	88 (43.78%)	52 (81.25%)
Total	201 (14.2% of total non vaccinated cases)	64 (10.65% of total vaccinated cases)

[Table/Fig-1]: Age wise distribution of cases studied among the groups.

Among 1423 non vaccinated cases, 712 were mild cases. Among these 477 (66.99%) were of age 18-64 years old, 207 (29.07%) of age 45-64 years old, ≥65 years old were 28 (3.94%) of cases.

In vaccinated COVID positive moderate, the total cases were 185, in that aged 18-64 years old were 9 (4.86%) cases, 45-64 years old were 37 (20%), and ≥65 years old were 139 cases (75.14%).

Severe cases of non vaccinated group with oxygen levels of <90 were as follows: in age group of 18-64 years old were 41 (20.4%), 45-64 years old were 72 with (35.82%) and ≥65 years old were 88 (43.78%). In Vaccinated COVID-19 positive severe group total cases were 64. Out of which, 18-64 years old were 1 (1.56%) 45-64 years old were 11 (17.19%) and ≥65 years old were 52 (81.25%) [Table/Fig-1].

DISCUSSION

The COVID-19 is caused by SARS-CoV-2 [11]. Among confirmed positive cases of COVID-19, people developing mild to moderate respiratory illness recovered better compared to severe illness. Some become seriously ill and developed various complications like Mucormycosis [12]. Older people and people with underlying co-morbid diseases like cardiovascular diseases, diabetes, chronic respiratory disease, or immunocompromised patients developed serious illness [13,14]. This observational prospective study was followed for a period of two months, to know the severity of infection in vaccinated and non vaccinated cases of COVID-19 admitted in our hospital.

The present study showed that severity of the disease in vaccinated people is less compared to the non vaccinated COVID-19 positive cases. This study study was supported by previous preliminary studies of Jackson LA et al., [15]. This study shows that severity of the disease is less in fully vaccinated compared to non vaccinated people. A two doses regimen of both vaccines was found to be safe and 90% efficacy against the COVID-19. Some studies showed that low levels of neutralising antibodies were observed after one dose compared to two full doses and also varied between type of vaccine [16,17].

The present study is supported by Pollack FP and Lipsitch M, Kahn R, about the vaccine effectiveness. estimated from this observational study with 95% efficacy against symptomatic SARS-CoV-2 infection in pivotal Randomized Controlled Trial (RCT) [18,19]. We observed, marked decline in incidence or admission of severe cases of SARS-CoV-2 infection in vaccinated population after vaccination coverage. Nationwide lockdown is a complex and difficult process that may cause decline or delay in incident cases of SARS-CoV-2 for each group compared with achieving high vaccine coverage by the government for sustainable path towards regain of normal health and activity.

Two dose of vaccine effectiveness estimated from observational study with 95% efficacy against symptomatic SARS-CoV-2 infections shown in the RCT [19].

Limitation(s)

Due to absence of randomisation, there will be unmeasured difference between vaccinated and non vaccinated persons e.g., (level of adherence to non pharmacological interventions, co-morbidities) might have confounded the vaccine effectiveness estimates. The study did not take into consideration the history of co-morbidities and its relation to severity of illness. The values of the parameters, duration of hospital stay, outcome and status of co-morbidities were not studied due to limitations of the authors. The present study was also having some limitations regarding, the number of vaccinated and non vaccinated persons in community which might have confounded our vaccine effectiveness estimates.

CONCLUSION(S)

Vaccinated cases had milder symptoms and lesser severity compared to non vaccinated cases. Corroborating the effectiveness observed, marked decline in incident cases and severity of disease of SARS-CoV-2 infection after vaccination coverage. Achieving high vaccine coverage by the government seems to be better solution for sustainable path towards regain of normal activity. Further studies are needed for monitoring of immunity at population levels, and identify the ways to disrupt viral transmission.

REFERENCES

[1] Andersen KG, Rambaut A, Lipkin WI, Holmes EC, Garry RF. The proximal origin of SARS-CoV-2. Nat Med. 2020;26:450-52.
[2] WHO, Last updated on 06 January 2022; https://www.who.int/emergencies/diseases/novel-coronavirus-2019?
[3] Bwire GM. Coronavirus: Why men are more vulnerable to Covid-19 than women? SN Compr Clin Med. 2020;2(7):874-76. Advance online publication. https://doi.org/10.1007/s42399-020-00341-w.
[4] Upsala Monitoring Centre, WHO; https://who-umc.org/COVID-19/.
[5] Kumar VM, Pandi-Perumal SR, 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;6:60. https://doi.org/10.1038/s41541-021-00327-2.
[6] Government of India, Ministry of Health and Family welfare; https://www.mohfw.gov.in/pdf/RevisedVaccinationGuidelines.pdf.
[7] Government of India, Ministry of Health and Family welfare; https://www.mohfw.gov.in/COVID_vaccination/vaccination/index.html.
[8] Tenforde MW, Olson SM, Self WH, Talbot HK, Lindsell CJ, Steingrub JS, et al. HAIVEN Investigators. Effectiveness of Pfizer-BioNTech and moderna vaccines against COVID-19 among hospitalised adults aged ≥65 years- United States. MMWR. Morbidity and Mortality Weekly Report. 2021;70(18):674-79. https://doi.org/10.15585/mmwr.mm7018e1.
[9] Meo SA, Bukhari IA, Akram J, Meo AS, Klonoff DC. COVID-19 vaccines: Comparison of biological, pharmacological characteristics and adverse effects of Pfizer/BioNTech and Moderna Vaccines. European review for medical and pharmacological sciences. 2021;25(3):1663-69. https://doi.org/10.26355/eurrev_202102_24877.
[10] Nanduri S, Pilishvili T, Derado G, Soe MM, Dollard P, Wu H et al. Effectiveness of Pfizer-BioNTech and moderna vaccines in preventing SARS-CoV-2 infection among nursing home residents before and during widespread circulation of the SARS-CoV-2 B.1.617.2 (Delta) variant-national healthcare safety network. MMWR. Morbidity and Mortality Weekly Report. 2021;70(34):1163-66. https://doi.org/10.15585/mmwr.mm7034e3.
[11] Hu B, Guo H, Zhou P, Shi ZL. Characteristics of SARS-CoV-2 and COVID-19. Nat Rev Microbiol. 2021;19:141-54. https://doi.org/10.1038/s41579-020-00459-7.
[12] Singh AK, Singh R, Joshi SR, Misra A. Mucormycosis in COVID-19: A systematic review of cases reported worldwide and in India. Diabetes & Metabolic Syndrome. 2021;15(4):102146. https://doi.org/10.1016/j.dsx.2021.05.019.
[13] Zhou Y, Yang Q, Chi J, Dong B, Lv W, Shen L, Wang Y. Comorbidities and the risk of severe or fatal outcomes associated with coronavirus disease 2019: A systematic review and meta-analysis. International journal of infectious diseases: IJID: Official Publication of the International Society for Infectious Diseases. 2020;99:47056. https://doi.org/10.1016/j.ijid.2020.07.029.
[14] Sanyaolu A, Okorie C, Marinkovic A, Patidar R, Younis K, Desai P, et al. Comorbidity and its Impact on Patients with COVID-19. SN Comprehensive Clinical Medicine. 2020;1-8. Advance online publication. https://doi.org/10.1007/s42399-020-00363-4.
[15] Jackson LA, Anderson EJ, Rouphael NG, Roberts PC, Makhene M, Coler RN, et al. An mRNA vaccine against SARS-CoV-2 - preliminary report. N Engl J Med. 2020;383:1920-31.
[16] Boyarsky BJ, Werbel WA, Avery RK, Tobian AAR, Massie AB, Segev DL, et al. Antibody Response to 2-Dose SARS-CoV-2 mRNA Vaccine Series in Solid Organ Transplant Recipients. JAMA. 2021;325(21):2204-06. Doi:10.1001/jama.2021.7489
[17] Wei J, Stoesser N, Matthews PC, Ayoubkhani D, Studley R, Bell I, et al. Antibody responses to SARS-CoV-2 vaccines in 45,965 adults from the general population of the United Kingdom. Nat Microbiol 2021;6:1140-49. https://doi.org/10.1038/s41564-021-00947-3.
[18] Pollack FP. Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. N Engl J Med. 2020 Doi 10.1056/NEJMoa2034577
[19] Lipsitch M, Kahn R. Interpreting vaccine efficacy trial results for infection and transmission. medRxiv: the preprint server for health sciences. 2021.02.25.21252415. https://doi.org/10.1101/2021.02.25.21252415.

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Pharmacology, Government Medical College, Ananthapur, Andhra Pradesh, India.
2. Assistant Professor, Department of Radiodiagnosis, Narayana Medical College, Nellore, Andhra Pradesh, India.
3. Postgraduate Student, Department of Pharmacology, Government Medical College, Ananthapur, Andhra Pradesh, India.
4. Postgraduate Student, Department of Pharmacology, Government Medical College, Ananthapur, Andhra Pradesh, India.
5. Postgraduate Student, Department of Pharmacology, Government Medical College, Ananthapur, Andhra Pradesh, India.
6. Professor and Head, Department of Pharmacology, Government Medical College, Ananthapur, Andhra Pradesh, India.
7. Professor and Head, Department of Biochemistry, Government Medical College, Ananthapur, Andhra Pradesh, India.
8. Assistant Professor, Department of Biochemistry, Government Medical College, Anantapur, Andhra Pradesh, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
BR Shyam Prasad,
301, Hanuman Classic, 2nd Cross, Aravinda Nagar, Ananthapur, Andhra Pradesh, India.
E-mail: shyamcapt@yahoo.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Nov 24, 2021
- Manual Googling: Jan 11, 2022
- iThenticate Software: Jan 19, 2022 (12%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Nov 23, 2021**
Date of Peer Review: **Dec 28, 2021**
Date of Acceptance: **Jan 17, 2022**
Date of Publishing: **Feb 01, 2022**