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CLINICAL PROFILE OF INDIVIDUALS GETTING ADMITTED IN MEDICAL INTENSIVE CARE UNIT (MICU) FOR ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) AFTER FIRST PHASE OF COVID-19 VACCINATION.

Clinical Research

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ABSTRACT

Introduction: COVID-19, first identified in Wuhan province of China in December 2019 and was declared a pandemic by World Health Organization in March 2020. Worldwide vaccination drive has begun against this virus. Concerns arose regarding the safety of COVID- 19 vaccine and this hampers the vaccination programme. **Method:** Individuals getting admitted in medical intensive care unit with complaints of adverse events after first phase of COVID-19 vaccination are included in this study. Clinical, epidemiological profiles are studied and analysed. **Result:** Twenty individuals were admitted for AEFI after first phase of COVID-19 vaccination. Most common complaint was fever, followed by nausea, headache and vomiting. All the individuals recovered and were discharged within a mean period of 2.1 days. **Conclusion:** Only mild and short lasting symptoms were observed post COVID-19 vaccination. These findings should mitigate the fear regarding the safety of these vaccines and should increase the acceptance of vaccines by general public.

KEYWORDS

COVID-19, Vaccination, Adverse events following immunization, Anaphylaxis

INTRODUCTION:

COVID-19 is an ongoing pandemic; till date it has infected more than 114 million people, out of which more than 2.53 million have succumbed to this disease, making it one of the deadliest pandemic in history till date [1]. Initially social distancing, mask wearing and hygiene habits were our only means to decrease the transmission of this deadly disease. It is a feat of human technology that COVID-19 vaccines have been developed in such a short time span.Introduction: On January 16, India launched nation-wide vaccination drive against COVID-19. Till the date, 11.4 million people have received vaccination against COVID-19. Vaccine hesitancy has been noticed due to concerns regarding the safety and efficacy of COVID-19 vaccines. In this study, we analysed the clinical profile of the vaccinated individuals who were admitted in ICU for adverse event after receiving first dose of the vaccine.

Method:

As per protocol all the individuals who reported adverse reaction after receiving the first dose of COVID-19 vaccine in Jaipur city, were admitted in MICU of SMS hospital, Jaipur. All such individuals were for included in this study. A detailed history was taken about date of vaccination, time duration after vaccination when symptoms started, symptoms observed, and number of days spent before medical advice was sought, and date of ICU admission. History of any pre-existing medical, surgical illness was noted. Any drug allergy history was taken.

History of COVID-19 infection was asked for. Apart from routine blood investigations, RT-PCR for COVID-19 was done. Radiological investigations were done as per patient's clinical presentation. Any other specific investigation required was also done. Patients were treated symptomatically and specifically. On recovery, patients were discharged from ICU. Total days of ICU stay were noted.

Method: The individuals who were admitted in MICU for AEFI after inoculation of COVID-19 vaccine at different sites across Jaipur city were included in this study. Epidemiological, clinical, biochemical data were collected from electronic medical records and history given by patients.

RESULTS:

During the course of this study a total of 20 patients reported from 1618/01/2021 till 17/02/2021. Out of these twenty patients 60% were males. Mean age of the population was 31.95±8.97 years. Symptoms developed after on an average of 12 hours after vaccination. An average of 1.45 days were passed before the inoculated person sought the medical help for the symptoms. Forty percent of the individuals presented with fever. Nausea, headache and vomiting were reported by 30%, 30% and 25% individuals respectively. Dizziness was complained by 20% of the individuals. Vertigo and shortness of breath were reported by 3 patients each. (Table 1) (Figure 1)

Table 1: List of sign/symptoms with number of patients having them

Sign/symptoms	No. of patients	Percentage (%)
Fever	8	40
Nausea	6	30
Vomiting	5	25
Diarrhoea	2	10
Headache	6	30
Vertigo	3	15
Shortness of breath	3	15
Cough	2	10
Para paresis	1	5
Anxiety	2	10
Dizziness	4	20
Chest pain	1	5
Abdominal pain	1	5

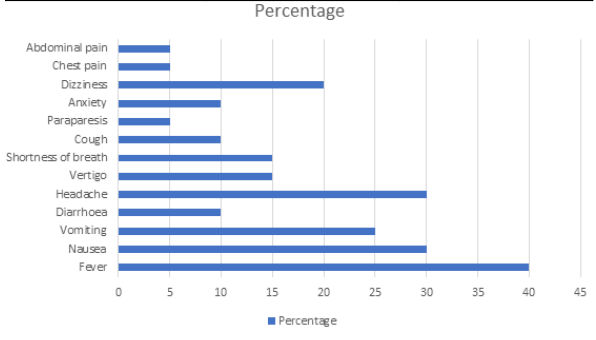

Figure 1: Column chart showing percentage of various symptoms experienced after first dose of COVID-19 vaccination

Every individual was tested for COVID-19 by RT-PCR after admission. None of them were found positive. Number of ICU days stay varied from 1day to 9 days with maximum number of patients (40%) stayed for 2 days (Table 2).

Table 2: List of number of ICU stay days

Days of ICU stay	No of patients
1	1
2	8

3	5
4	3
5	1
6	0
7	0
8	0
9	1

Mean duration of stayMean stay of the patients in ICU was 2.1±1.7 days. 100% of the individuals were discharged from the ICU after recovery.

DISCUSSION:

On January 16, India launched nation-wide vaccination drive against COVID-19 [(2)], in which 30 million health workers were supposed to be first to receive the vaccine [(3)]. Discussion: World Health Organisation (WHO) [(4)] defines Adverse Event Following Immunization as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

Adverse reactions to a vaccine are broadly categorised based on their cause, severity, and frequency.

a. Common minor reactions: This is basically defined as an event that is not serious and does not pose a potential risk to the health of the recipient.
b. Serious and severe vaccine reactions: An event that results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious
c. Cause-specific reactions: Vaccine product-related reaction and vaccine quality defect-related reaction

Widespread vaccination against COVID-19 with highly effective vaccines represents an important tool in efforts to control the pandemic. Risk of adverse events is a major concern against the vaccination drive. In India, in the first phase of COVID-19 vaccination, front line workers were enrolled. None of the patients admitted at our centre ever tested positive for COVID-19 by RT-PCR. No major adverse events reported during the first phase of vaccination. No incidence of anaphylactic reaction was reported. In our study, fever being the most common complaint, was reported by 40% of individuals. Other symptoms included nausea, vomiting, diarrhoea, headache, dizziness, cough, shortness of breath, chest pain, abdominal pain, anxiety. All theseRest other symptoms were also mild and short lasting. Except three, Also all the patients recovered and were discharged within an average day span of 2.1 days.

One of them experienced persistent fever for a week after vaccination. On evaluation supraclavicular, mediastinal and abdominal lymphadenopathies were found. Lymph node biopsy was advised but the patient refused for the biopsy. The patient became afebrile and was discharged on request with advice to remainbe in follow up for lymphadenopathies.

Another patient, presented with complaint of pain and weakness in bilateral lower limb. Neurological examination of the patient was unremarkable. Radiological imaging of brain and nerve conduction study also came out to be normal. The patient improved and was discharged.

Third patient, presented with fever and shortness of breath and a saturation of 94% on room air. This patient had a history of pulmonary tuberculosis one and half year back for which she had taken full course of Anti- tubercular drugs. On evaluation during this admission, she was found to have large pleural effusion at left side. The fluid was drained and sent for laboratory examination, turned out to be lymphocytic. The patient improved symptomatically and was shifted to ward to be enrolled in DOTS programme. Out of the total twenty patients only this patient required supplementary oxygen for two days. Oxygen demand significantly decreased after pleural fluid drainage.

CONCLUSION:

This study shows that the reported symptoms after COVID-19 vaccination were mild and short lasting. No serious adverse event was reported. These finding helps in mitigating the fear regarding the COVID-19 vaccination. This study shows that the COVID-19 vaccine is safe and more and more people should get vaccinated to stop the pandemic.

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CONFLICT OF INTEREST: None declared

Ethical approval: Not required

REFERENCES:

1) COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)". ArcGIS. Johns Hopkins University. Retrieved 3 March 2021.
2) "World's largest vaccination programme begins in India on January 16". The Hindu. 15 January 2021. Retrieved 16 January 2021
3) Kaul, Rhythma (21 October 2020). "30 Million Frontline Workers To Get Covid-19 Vaccine In Phase 1". Hindustan Times. New Delhi. Retrieved 21 October 2020.
4) World Health Organization. Vaccine safety basics learning manual [Internet]. Geneva: World Health Organization; 2013 cited 2017 March 30]. Available from: http://www.who.int/vaccine_safety/initiative/tech_support/Vaccine-safety-E-course-manual.pdf?ua=1