

A Field Survey after COVID-19 Immunization Programme at Ghaziabad, India: Highlighting Adverse Events

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ABSTRACT

Background: COVID-19 has been named as the third most pathogenic human coronavirus disease to date. The SARS-CoV-2 epidemic is still continued, and the new strain is expected to co-habit with us for a significant duration. The only way of protection from SARS-CoV-2 depends upon public health interventions such as active testing, along with immediate tracking of cases and limited social gatherings until clinically approved vaccines become widely available. Further, personal prophylactic measures such as social interspacing and proper use of quality masks can prevent the spread of this contagious virus.

Objective: The current protocol aims to collect data on adverse events after COVID vaccination, and such studies in the future can help prevent and treat COVID-19.

Method: The protocol was conducted in selected centers of Uttar Pradesh, India. It was done over a time period of 3 months. A valid protocol includes two shots of the immunization procedure for all enrolled participants. Immediate (within 6 hrs), sudden (within 24 hours) and delayed adverse events occurred after 24 hours of vaccine administration were noted.

Conclusion: In India, vaccine pharmacovigilance is still in its developmental stages. Irrespective of whether the adverse event (AE) after immunization (AEFI), a steady stream of full information on vaccine-related AE is required. As there are few Indian research on adverse vaccination effects, therefore, the need for vaccine pharmacovigilance on a broad scale in India has emerged in recent times.

Keywords: Adverse event following immunization (AEFI), Coronavirus (COVID-19), Immunization, Vaccine.

Journal of Applied Pharmaceutical Sciences and Research, (2021); DOI: 10.31069/japsr.v4i2.3

INTRODUCTION

Immunization has drastically decreased instances of sickness and fatalities from many infectious diseases, making it perhaps the best public health achievement of all time. Routine immunization of toddlers, teenagers, and adults provides protection from a wide variety of infectious pathogens.^[1] A “vaccine adverse event,” also known as an “adverse event following immunization” (AEFI), is an adverse health hazard or health event that occurs following or during vaccine administration. A vaccine may cause AE, or it may be purely coincidental and unrelated to vaccination.^[2] The current protocol deals with the experimental studies (field trial), where the investigator is not acting upon study participants but instead observing natural relationships between exposure and outcomes.^[3,4] It involves an intervention that tests the association between exposure and outcome.

Coronavirus has a spherical or pleomorphic shape, enveloped single-stranded RNA, and a club-shaped glycoprotein covering. Coronaviruses are classified into four subtypes: alpha, beta, gamma, and delta, which further have many serotypes. Some infect humans and others affect animals such as cats, mice, pigs, birds, and dogs.^[5] Generally, coronavirus spread via airborne zoonotic droplets. The virus replicates in the ciliated epithelium, resulting in cellular damage and infection. As per a study published in 2019, Angiotensin-converting enzyme 2 (ACE2), a membrane

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How to cite this article: Majhi S, Verma M, Chauhan I, Rajkumari, Sharma M. A Field Survey after COVID-19 Immunization Programme at Ghaziabad, India: Highlighting Adverse Events. *Journal of Applied Pharmaceutical Sciences and Research*. 2021; 4(2):10-14

Source of support: Nil

Conflict of interest: None

exopeptidase in the receptor, is used by the corona virus for entry in to human cells.^[6]

Because health system resources have been diverted to the pandemic response, supply lines have been interrupted. The travel obstacles and fear of acquiring the virus have prevented health care usage, with major disruptions to health services globally.^[7,8] Immunization services which are the prime preventive health services, have faced setbacks in both rich and lower-income countries.^[9-11]

The timeline of COVID-19 from the outbreak of the pandemic till the approval and usage of the vaccine is depicted in Figure 1.

In lieu of time, a variety of potential vaccines for COVID-19 are in the market as well as under development, as shown in Figure 2.

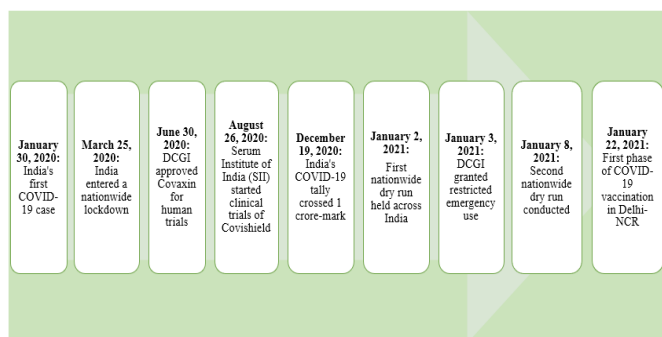


Figure 1: Timeline of COVID-19 pandemic and its vaccination

World Health Organization 2012 defines vaccine pharmacovigilance as “the science and activities relating to the detection, assessment, understanding, and communication of Adverse Event Following Immunization (AEFI) and other vaccination-related issues, and to the prevention of untoward effects of the vaccine or immunization.” Like any other pharmaceutical product, vaccines also possess a certain likelihood of AE, but safety expectations are high, as they are meant to be administered to healthy populations. Because of increase in vaccine coverage, the probability of an AE is proportionally increased. Paradoxically, an effective immunization program decreases the target diseases’ incidence rates and may also raise the AEs.^[12] Classification of vaccine adverse reaction as local, systemic or severe allergic reactions is shown in Figure 3.^[13]

Mild localized responses and fever are typical following immunizations and do not preclude subsequent doses. Anaphylactic responses to vaccinations are uncommon, but they should be investigated using skin testing for the vaccine and its constituents.^[14] Although some responses to a vaccine are absolute contraindications to future dose administration, the majority of such reactions do not prohibit subsequent immunization.^[15]

As defined, the vaccine is a medical product intended to keep the individual safe from disease, can cause side effects, just as any medication can. A possible side effect resulting from vaccination is known as an *adverse event*.^[16]

Researchers analyze evidence to ascertain whether adverse events following vaccination are causally linked to a particular vaccine and if so, they are termed as adverse effects in long-term assessment of vaccines. Hence, the present study was designed to determine the vaccine AEs in the population and the relation of vaccine with the AE.

METHOD

The protocol was carried out from January 2021 to March 2021 at in/out patient setting in Ghaziabad, Uttar Pradesh, for a time duration of 3 months. The protocol of vaccination was explained in detail to the participants by the recruited government healthcare authorities. After the vaccination process, all participants were observed for 30 minutes for any adverse event. A one-to-one direct

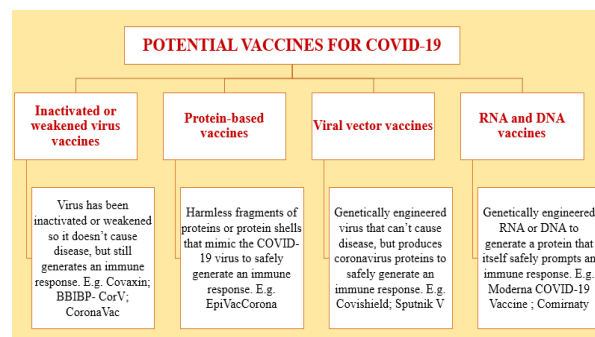


Figure 2: Potential vaccine candidates of COVID-19

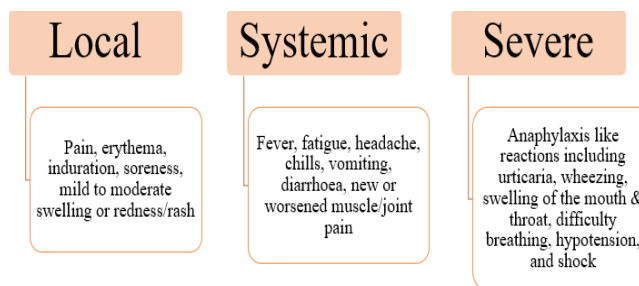


Figure 3: Vaccine adverse events post immunization

interview or telephonic survey of participants was conducted twice. The participants filled a questionnaire including informed consent with or without the help of the author. The initial call was on the day of vaccination and a second call on 28th day after the second vaccination dose was done. Data was collected regarding the participant’s demography and appearance of any reaction followed after administration of the vaccine.^[17]

- **Inclusion criteria**– Participants \geq 18years age group; of either sex, who came for immunization and developed suspected adverse events after vaccination, were included in the study.
- **Exclusion criteria**– Participants with a severe co-morbid illness or who are not interested in giving consent; were excluded from the study. After completion of the vaccination period, the study participants were subjected to the collection of relevant data and analyzed for different aspects pertinent to adverse events.

DATA COLLECTION

Participants’ demographic details like patient initials, age, sex, occupation, medical history, medication history, allergies, etc. was recorded using a well-structured questionnaire. If there were any AE following vaccination, the event was recorded. Each participant was kept under observation for 30 min to record any immediate reactions. After recording the AE, the data were subjected to analysis.

RESULT AND DISCUSSION

The demographic pattern (Figure 4a, 4b, 4c) of the current study showed participation of 346 (69%) males and

154 (31%) females with an age group of 18 years and above. The study revealed the highest participation was by 18–30 years age group (40%) followed by 31–40 years (28%), 41–50 years (23%), > 60 years (5%), and least by 51–60 years (3%) age group. Maximum participation was of administrative staff (47%), followed by technicians/nurses (32%), others (14%), doctor/faculty (5%), student (2%). All the safety measures of COVID were followed during & after entire vaccination procedure.

Vaccination is the most efficacious long-term preventive and controlled approach for COVID-19 in the upcoming time. SARS-CoV-2 vaccines are being manufactured using a variety of methods, including DNA, mRNA in lipid-based nanoparticles, recombinant vectors, inactivated/live attenuated viruses, and protein components. Currently, more than 150 COVID-19 vaccine candidates have been identified, including 18 approved and 86 under development.^[18] Most of these vaccine proposals undergo phase II testing, while others have entered stage III trials.

In the past 0-6 & 6-12 months, 2 and 6.4% of participants suffered from COVID infection, respectively. Also, 29.6% of participants suffered from comorbidities like diabetes, hypertension, heart-related disease, lung disease, kidney disease, gastrointestinal disease, and others during vaccination, as shown in Figure 5.

The participants showed varied usage of prescription drugs (16.2%), over-the-counter (OTC) drugs (3%), health

supplements (4.2%), herbal remedies (5%), and others (1.2%) shown in Figure 6. Few participants felt stress prior to the vaccination process viz. physical stress (2.4%) and mental stress like fear/anxiety (10.4%). More than 95% participants have not received any vaccine (within 1 month) and have no previous allergies.

The AEs observed by participants were categorized based on hindrance in daily routine activity and normalization time period. In 17.8% participants showed adverse events that does not interfere with activity and resolved in <6 hours. About 14.6% of participants showed AEs that interfere with activity and resolve in 6-12 hours. 40.2% and 21.6% showed AEs that prevented daily routine activity and resolved in 12-24 hours and 24-48 hours, respectively. No case was observed where an emergency room visit or hospitalization is required. The participants variedly showed immediately to delayed adverse events as represented in Figures 7a and 7b.

Also, AEs were resolved with self-medication in 34.4%, with doctor's consultation in 6.4%, whereas no medication was required in 59.2% of participants shown in Figure 8.

Despite the fact that new SARS-CoV-2 research is released every week, our present understanding of this unique coronavirus is only the tip of the iceberg.^[19,20] SARS-animal CoV-2's origin and cross-species infectious pathway are still unknown.

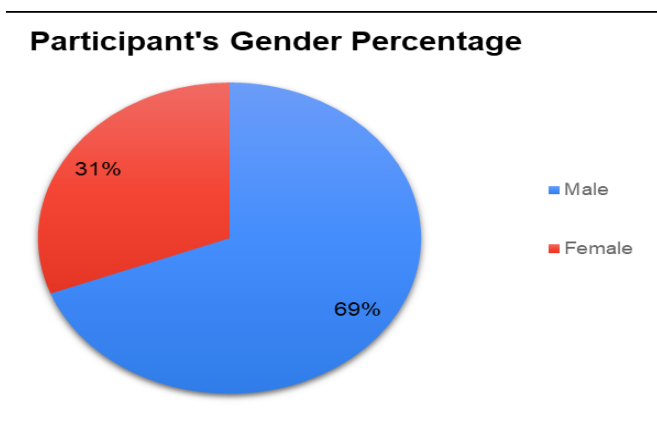


Figure 4a: Demographic pattern of Participants gender

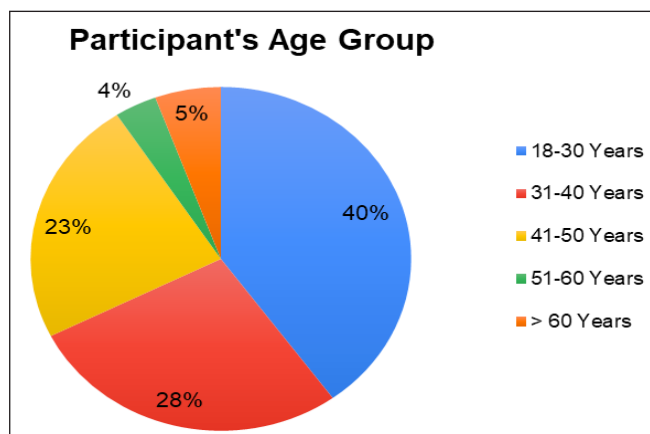


Figure 4b: Demographic pattern of Participants age group

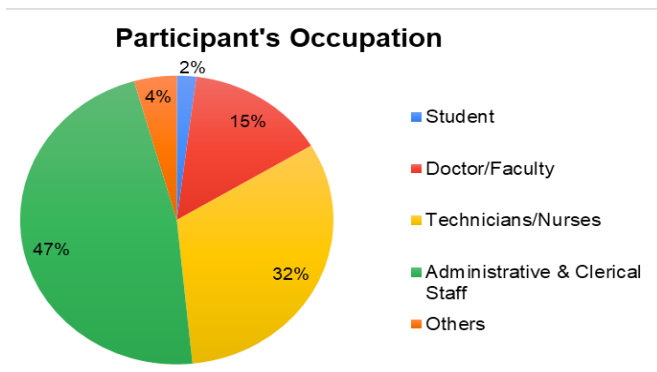


Figure 4c: Demographic pattern of Participants occupation

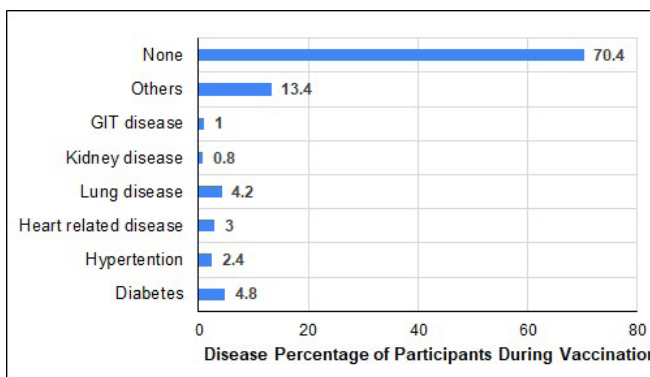


Figure 5: Co-morbid condition of participants during vaccination

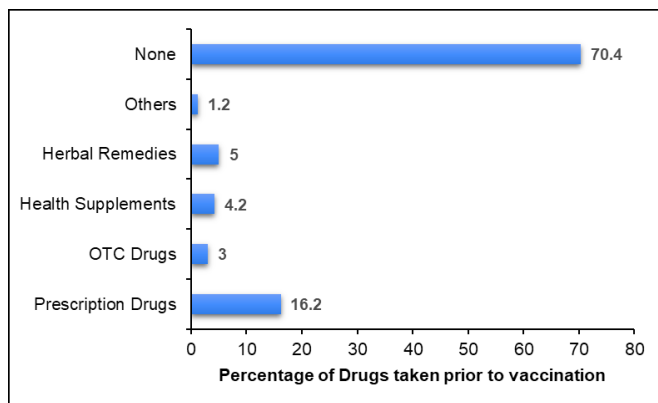


Figure 6: Participants on medication during vaccination

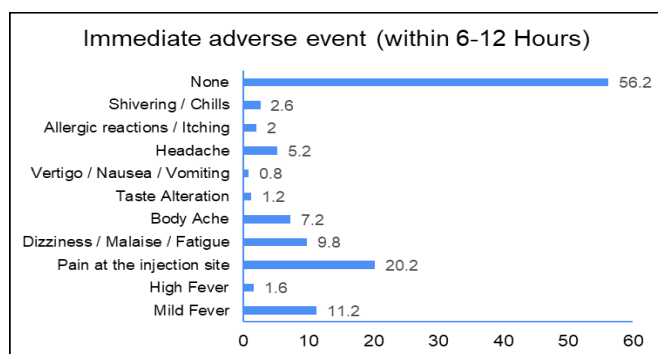


Figure 7a: Immediate adverse events after vaccination

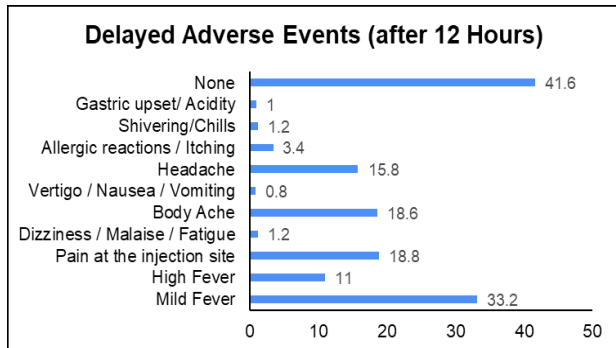


Figure 7b: Delayed adverse events after vaccination

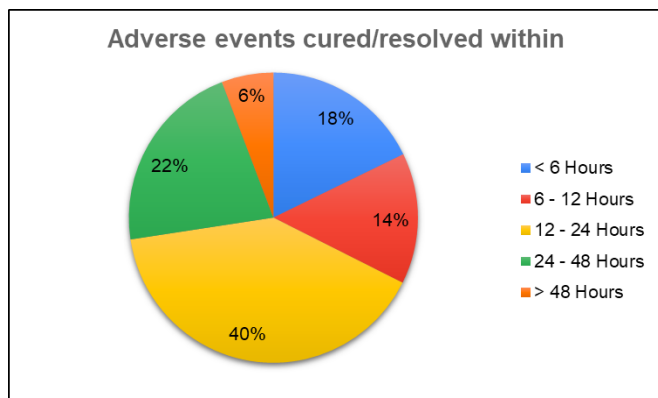


Figure 8: Percentage of adverse events cured in different time slots after vaccination

CONCLUSION

Due to its fast-mutating strain, the molecular underpinnings of SARS-CoV-2 infection pathogenesis and virus-host interactions remain mainly unknown. Intensive research on the virological characteristics of SARS-CoV-2 will pave the way for opportunities for sustainable development of COVID-19 prevention and treatment methods. Furthermore, ongoing genomic surveillance of SARS-CoV-2 in new cases is required worldwide since it is critical to quickly identify any mutation that might lead to phenotypic alterations in the virus. Eventually, COVID-19 poses a challenge to all humans. Combating the pandemic is a continuing task that will need individual efforts and worldwide cooperation between researchers, governments, and the community.

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