

Original Research Article

Prevalence and pattern of adverse events following immunization to Covishield vaccine in a tertiary care hospital: a cross-sectional analytical study

Suji V. Sumedhan¹, Sangeetha Gopinath^{1*}, Karthika Gopan²

¹Department of Pharmacology, ²Department of Paediatrics, SUT Academy of Medical Sciences, Thiruvananthapuram, Kerala, India

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*Correspondence:

Dr. Suji V. Sumedhan,
E-mail: suji182@gmail.com

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ABSTRACT

Background: The COVID-19 pandemic has emerged as the most important public health issue in the past two years. Multiple preventive and treatment modalities are being tried to contain this pandemic. Several countries have documented vaccines as a vital tool to combat this pandemic across the globe. Hence, we tried to evaluate the adverse events following immunisation at the study site following Covishield vaccination among front-line health workers in our tertiary care hospital.

Methods: A cross-sectional descriptive study was planned in the vaccination site of our institute, where all details of the frontline workers who were vaccinated for the Covishield vaccine were included, and they were followed up to study the prevalence and pattern of AEFIs. The participants were observed for 30 minutes after the jab and were reviewed/called upon on the third day following immunization to gather information. The data was collected using a semi-structured questionnaire

Results: Our study included around 159 frontline workers and medical students who received their vaccination during the study period. The mean age distribution was 24.3 ± 7.6 years, with female predominance. We observed an AEFI prevalence of 33.3% among the study participants at the end of 30 minutes, while after 30 mins and during the next 3 days of follow-up by our staff, we observed that the prevalence increased to 80%. We observed that the commonest AEFI observed at 30 minutes and during the 3 days follow up was tenderness/pain, fever, body ache and light-headedness. Only 4% of the patients required hospitalisation following AEFI.

Conclusions: Around 1/3rd of our study participants reported AEFI following vaccination during the first 30 minutes of observation which is much higher than the national average.

Keywords: Vaccination, Covishield, COVID-19, Front line workers, AEFI

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a contagious viral infection brought on by coronavirus 2 that causes severe acute respiratory syndrome (SARS-CoV-2). These RNA viruses undergo genetic evolution throughout time, giving rise to mutant variations that could differ from their ancestor strains in certain ways. In the past two years, the COVID-19 virus, which predominantly affects the lungs,

has become a fatal sickness that has wiped out millions of people worldwide. Although it primarily affects the respiratory system, it can also have an impact on other organs.¹ People who have contracted COVID-19 have described a wide range of symptoms, from minor discomfort to serious disease. Symptoms of COVID-19 include fever, sore throat, fatigue, anosmia, dysgeusia, and gastrointestinal symptoms.²

The usual treatment modalities for viral infections were proven to be ineffective against COVID-19 and the main modality of treatment remained supportive and oxygen therapy (with or without ventilatory support). Development of new drugs takes time and has to run through several requirements before it hits the market. Efforts to reuse existing regimes used for similar viral infections for COVID-19 proved promising.³ The creation of coronavirus vaccines has received attention. A vaccination is a biological preparation prepared from a microorganism's toxins or surface proteins that have been weakened or killed. A vaccine's development cycle generally includes the following stages: exploratory, pre-clinical, clinical, regulatory review and approval, manufacturing, and quality control.⁴ By January 2021, there were more than 350 COVID-19 medicines under investigation (the majority of which had been repurposed), more than 75 percent of which had begun human clinical trials, and more than 150 of which had been repurposed. About 25% of vaccines are now through various stages of human testing. On December 31, 2020, the Pfizer/BioNTech comirnaty vaccine was added to the WHO emergency use listing (EUL).⁵ On January 3, 2021, India granted emergency use authorization for two COVID-19 vaccinations. These were Covaxin and Covishield, two vaccines produced by Serum Institute of India, private limited for AstraZeneca and Bharat Biotech Limited, Hyderabad, India respectively. Clinical trials for the vaccinations were in phase III.⁶

In the initial days, these vaccines were provided to the healthcare providers and general public in a phased manner. Due to their higher risk of exposure, frontline and healthcare personnel initially received first priority for immunization. The second immunization phase began in March 2021. People with comorbidities who are older than 60 and over 45 were the first to receive vaccines. On April 1, 2021, this was extended to include all people above the age of 45. Vaccines were made accessible to anyone above the age of 18 in the third phase. The immunization program began at hospital immunization clinics and was thereafter followed by immunization drives held at outreach locations. The National expert group on vaccine administration for COVID-19 was established by the Indian government to monitor all facets of the COVID-19 vaccine's introduction in India.⁷ Any unfavorable medical occurrence that follows immunization but does not necessarily have a causal connection to the use of a vaccine is referred to as an adverse event following immunization (AEFI).⁸ Any undesirable or unanticipated symptom, abnormal laboratory finding, or disease may be an adverse event. The management plan and surveillance mechanisms to tap the AEFI following COVID-19 vaccines were monitored by the Government of India using the COVID Vaccine Intelligence Network (CoWIN) software.⁹ According to the operational standards, each beneficiary must be watched at the immunization centre for AEFIs or AEs of Special Interest for a minimum of 30 minutes. The beneficiaries are allowed to contact the vaccination centre whenever they experience any AEs after 30 minutes have

passed. The purpose of this study was to evaluate the adverse event following immunisation at the study site following Covishield vaccination among front-line health workers in our tertiary care hospital.

METHODS

Study design and location

Current study was a cross-sectional analytical study conducted among front-line health workers who were getting their vaccination from the vaccination centre arranged by our tertiary care hospital at SUT Academy of Medical Sciences, during the months of March to May 2021. We recruited all patients consecutively until the sample size was reached.

Study participants

The data collection was done over 3 months from the vaccination site attached to the tertiary care hospital. Based on inclusion and exclusion criteria, the subjects were chosen. Front-line health workers who had had two doses of Covishield immunization and those who were open to participating were included in the inclusion criteria. Subjects who are unvaccinated, have only received the first dose of Covishield or another COVID-19 vaccine, or who are unwilling to participate were excluded from the study. Each participant's general socio demographic information was gathered. The study population was verbally informed of the objectives of the study, and the criteria for choosing participants before including them in the study. The reported AEFI were handled following Government of Indian regulations.¹⁰

Sample size

With reference to a study done by Patil et al in 2021 in India, to estimate the proportion of individuals reporting AEFI after getting vaccinated with Covidheild vaccine, to be 9.8%, with 5% absolute precision, 95% CI, the required sample size was calculated to be 132, adding an additional non-response rate of 20%, the required sample size was calculated to be 158 using online software OpenEpi version 3.02.¹¹

Procedure

Following vaccination, each front-line health worker at the vaccination site was watched for 30 minutes. To inform the beneficiaries of potential AEFIs, posters detailing the potential AEFIs were placed in the vaccination and observation area. The vaccine team also advised the recipients to let them know if they experience any adverse reactions. After receiving informed consent from each beneficiary, information such as demographic details (age, gender, and contact information) of the beneficiary, the date and time of vaccination, vaccine details (name, batch number, and dose number), details of pre-existing medical conditions, past covid infection, and response to

immunization and details of AEFI (hours of occurrence, duration of persistence and outcome of adverse effects) were collected in the appropriately designed semi-structured questionnaire. The reported events were evaluated for causality using a new algorithm created by the WHO's safety and vigilance division.⁸ The degree, seriousness, type of medical intervention for the adverse effects, and outcome of the incident were all used to characterize reported events. Data was entered into Microsoft Excel and analyzed using SPSS 20. The mean and standard deviation were used to convey numerical variables, and frequency and proportions were used to summarize categorical data.

RESULTS

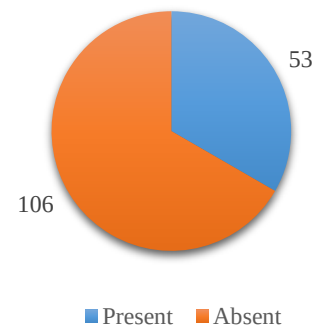
In current study around 159 participants were recruited who were front-line health workers including students who got vaccinated in our vaccination centre during the study period. Everyone agreed to participate in the study. The demographic characteristics of the study participants is shown in (Table 1). We found that the majority (66%) of the study participants belonged to the age group between <30 years, with a mean age distribution of 24.3 ± 7.6 years.

Table 1: Demographic characteristics of the study participants (n=159).

Characteristics	N (%)
Age group (years)	
<30	105 (66.0)
31-60	44 (27.7)
>61	10 (6.3)
Gender	
Male	49 (30.8)
Female	110 (69.2)
Occupation	
Non-teaching staff	9 (5.6)
Students	103 (64.7)
Lab technicians/nurses	11 (6.9)
Doctors	36 (22.6)
Past COVID infection	
Yes	11 (6.9)
No	148 (93.1)

Around 70% were females by gender, and 65% were medical students. Around 7% reported previous COVID-19 infection in the past. We observed an AEFI prevalence of 33.3% among the study participants at the end of 30 minutes, while after 30 mins and during the next 3 days of follow-up, we observed that the prevalence increased to 80%. The distribution of various AEFI among the study participants as shown in (Figure 2), we observed that the commonest AEFI observed was tenderness/pain, fever, and light-headedness at the end of 30 mins of observation. Whereas during the 3 days follow-up time, we observed that almost 64% of the study participants experienced tenderness/pain, followed by malaise (62%), and fever (56%).

Prevalence of AEFI at 30 minutes of observation



Prevalence of AEFI after 30 minutes of observation

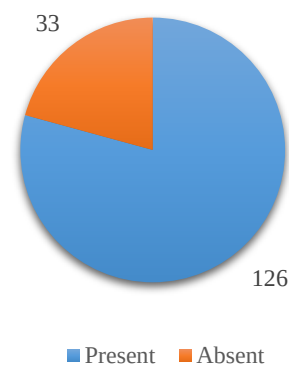


Figure 1: Prevalence of AEFI among study participants (n=159).

One participant reported that the vaccine triggered an episode of migraine. Another participant complained that the vaccine cause pre-ponement of menstruation by 6 days. The outcomes of patients who presented with AEFI (Table 2), we observed that only 3.7% of the participants required hospitalisation, and none of them had any serious AEFI.

Table 2: Outcomes of AEFI among study participants (n=159).

Parameters	N (%)
Hospitalisation required	
Yes	6 (3.7)
No	153 (96.3)
Leave following vaccination	
Yes	73 (48.9)
No	86 (51.1)
Pain relieved on NSAIDs (n=101)	
Yes	34 (32.6)
No	67 (66.3)

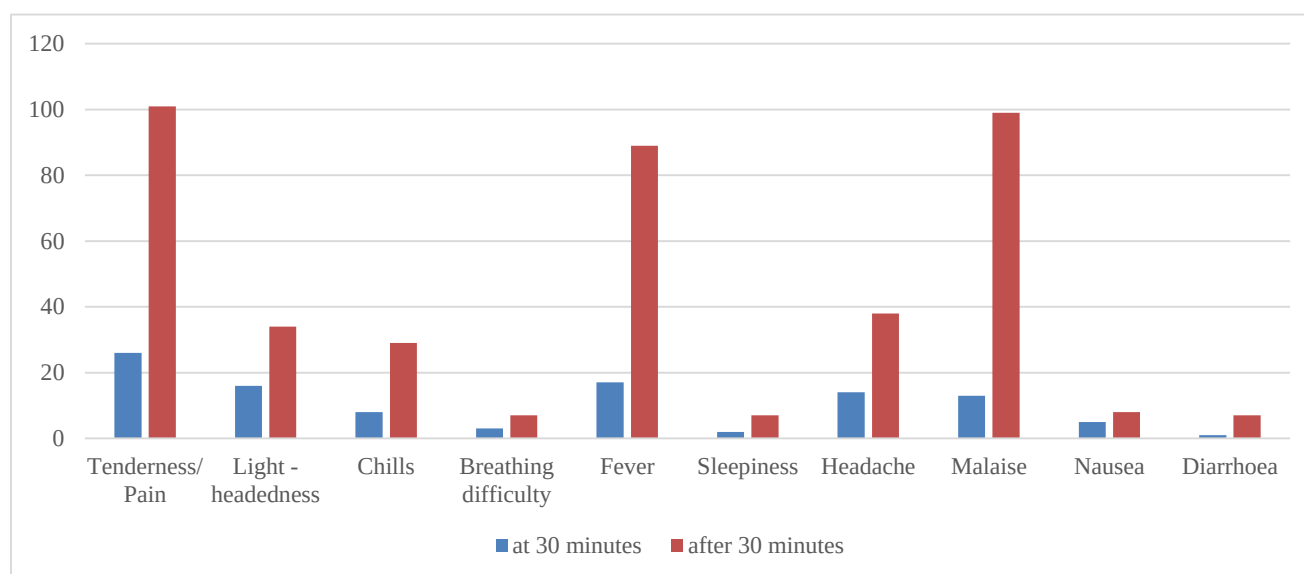


Figure 2: Type of AEFI amongst study participants (n=159).

Those who were hospitalised were mainly admitted for fever, vomiting, light headedness and diarrhoea. We observed that almost half of the study participants took leave following AEFI, whereas among the individuals who experienced pain, only 1/3rd of them had relief with NSAIDs.

DISCUSSION

A cross-sectional analytical study was performed to determine the prevalence of AEFI among front-line health workers who got jabbed with Covishield vaccine in the vaccination centre of our institute. We also described the various AEFI experienced by them alongside their clinical outcomes. In our study, we observed that the proportion of AEFI, at the end of 30 minutes of observation was observed to be 33.3%. This proportion was found to be similar to study results published by Krishnan et al from India, who reported a prevalence of 20% following COVISHIELD among medical students.¹² Our proportion was observed to be much higher than the proportion reported by Konda et al and Patil et al from India.^{11,13} However, the probable reasons could be differences in study participant characteristics (the two studies included the general population also) and the older age of study participants in the latter studies. Our study focused on front-line health workers who are prone to increased risk, report adverse effects more promptly and better to the study team, and have better health-seeking behaviour. While during the second follow-up, the proportion of AEFI increased drastically up to 80%. This prevalence was also observed to be comparable to findings reported by Krishnan et al.¹² With respect to the pattern of AEFI, our study findings were observed to be similar to studies done in similar study settings.^{14,15} With more than 52,000 immunisation sites delivering a total of 184 crore doses of the COVID-19 vaccine in India until 2022, the rate of AEFI reported on the COWIN site remained as low as

0.005% of the total doses given.¹⁶ Global statistics show that 73% of all AEFI cases are reported in Europe, followed by America (17%) and Asia (6%).¹⁷ In our study, though we observed an increased prevalence of AEFI following Covishield, we observed that the majority of them were very minor and constitutional, which is expected out of any vaccination taken into consideration. Furthermore, available literature also suggested that the incidence rate of AEFI following Covishield is higher when compared with Covaxin, which can be again explained by the differences in characteristics of the population in which both vaccines were introduced.¹⁸ AEFI data from India, showed a meagre proportion of around 0.61/million doses reported thromboembolic events, which was observed to be much less than 4 cases/million reported by the UK government and 10 events per million doses reported by Germany.¹⁹ In another study from Mumbai, India, Velhal et al estimated that the common AEFI reported included chills, fatigue, fever and myalgia and females, younger individuals and recipients of the first dose of vaccine reported statistically more adverse events compared to men, older individuals (>40 years) and recipients of second dose respectively ($p < 0.05$).²⁰ According to the literature, 306 (93.79%) of the events following CovishieldTM were labelled as vaccine product-related responses, with 94.22% of those events being classed as having a consistent causal link with vaccination. 6.23% of the CovishieldTM related incidents were labelled as "indeterminate" because there was inadequate conclusive evidence that the vaccine was to blame despite the consistent temporal link. Thus, this vaccination could serve as a vital tool for the prevention of COVID-19 without many dreadful side effects.²¹ Intending to contain the ongoing epidemic, all COVID-19 vaccines that are now administered have received authorization for emergency use. Even if their effectiveness and safety are confirmed based on the interim analysis of trial data published based on the follow-up of a few months after the second dosage for several vaccinations, the results on long-term follow-

up are still unknown. Much is unclear about how new vaccines and medications will behave outside of clinical trial settings, as is true for any new vaccine or medication that is put on the market. Concerns about the effectiveness and safety of the vaccinations now in use have also been raised by the discovery of new mutant COVID-19 strains that are more contagious than the ones used to manufacture vaccines. Therefore, ongoing surveillance research on vaccination-related AEFI aids in our understanding of vaccine safety beyond clinical trials in larger populations.²²

Limitations

The current study contains some drawbacks; being a descriptive study of the reported AEFI based on active follow-up with vaccine recipients by calling their registered mobile number, or recording their repeat visit to the centre, there are chances that we might have under or overestimated the AEFIs. Limitations in the availability of data such as weight, height, body mass index, and data on the severity of the reported event are other limitations. The majority of the occurrences that were recorded were only seen in the first 3 days following vaccination. Any AEFI that occurred outside of the scope of staff's follow-up may not have been discovered and reported. While the reported events were based only on the recipient's reaction, some of the reported events may be related to pre-existing chronic medical issues, and their influence on the recorded event could not be entirely ruled out.

CONCLUSION

According to this study, the incidence rate of AEFIs after receiving the COVISHIELD vaccine was higher than the incidence rate nationwide. None of the reported occurrences were severe or dangerous, confirming the safety of the vaccinations used in India and demonstrating that there will be no long-term effects from the events. Studies of this kind emphasise the importance of diligently monitoring and reporting AEFIs, particularly for recently launched vaccinations, to spot potential warnings.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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