RESEARCH ARTICLE

Analysis of all the adverse events following immunization by Covishield™ vaccine among healthcare workers at Government Medical College, Jalgaon

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Received: July 10, 2021; Accepted: August 05, 2021

ABSTRACT

Background: The severe acute respiratory syndrome coronavirus 2 (COVID 19) is a global pandemic since December 2019. The subject expert committee of the Central Drugs Standard Control Organization made recommendations for Restricted Emergency Approval of COVID-19 virus vaccine of M/s Serum Institute of India ChAdOx1 nCoV-19 vaccine (AZD1222) COVISHIELD™ which was developed at Oxford University. In India, this vaccine was launched on January 16, 2021, and healthcare workers were included first in this vaccination program. Aim and Objectives: This study aimed to record and analyzes all the adverse events following the immunization (AEFI) in healthcare workers for monitoring the safety and find the correlation if any. Materials and Methods: This was a prospective observational study. After obtaining Institutional Ethics committee approval, we collected the data by phone call to the participants within 3 days after the first and second dose of the vaccine. We collected the data from 100 healthcare workers randomly with their consent. Results: The most common adverse effect found was myalgia followed by local pain at the injection site after the first dose. About 92% of participants did not react to the second dose of the vaccine. Conclusion: There were no serious adverse events after the first as well as the second dose of vaccination. More studies and monitoring are needed to find out any unexpected reactions following COVID-19 vaccination.

KEY WORDS: Adverse Events following the Immunization; Coronavirus 19; Covishield™; Healthcare Workers; Immunity; Vaccine

INTRODUCTION

A novel coronavirus called severe acute respiratory syndrome coronavirus 2 was never reported in humans until the pandemic hit the world. It is a global pandemic since December 2019. The disease is highly infectious which can spread by infected droplets or by touching surfaces that have settled droplets on it. Early diagnosis, quarantine, and supportive treatments are playing an important role in the treatment of the patients. Furthermore, the research and development for the vaccine against this disease are going on as the vaccines play an important role in herd immunity as well as preventing severe disease. The genetic sequence of severe acute respiratory syndrome coronavirus (SARS-CoV)-2 was published on January 11, 2021, which has triggered the intense research for the vaccine. Thus, ultimately the whole world is trying hard to combat this crisis.

The subject expert committee of Central Drugs Standard Control Organization (CDSCO), India had a meeting in January 2021 and declared the Restricted Emergency
Approval of COVID-19 virus vaccine by M/s Serum Institute of India.[4] The vaccine known as ChAdOx1 nCoV-19 vaccine (AZD1222) COVISHIELD™ was developed at Oxford University. It consists of a replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene. In a primary interim analysis of vaccine trials in Brazil, the UK, and South Africa, the vaccine has shown a passable safety profile and has been found to have efficacy against COVID-19.[5] No serious adverse events or death were found in recipients.[6] The COVISHIELD™ vaccination course consists of two separate doses of 0.5 ml each intramuscularly. The second dose was advised to be administered between 4 and 6 weeks after the first dose. At present, the National Expert Group on Vaccine Administration for COVID 19 (NEGVAC) has recommended administering the second dose at 12–16 weeks intervals after the first dose.[7]

In India, this vaccine was launched on January 16, 2021, and offered first to healthcare workers. With the potential benefit of any vaccine, there may be a risk associated because of the unintended side effects known as adverse events following immunization (AEFI).[8] As for other vaccines, adverse effects of this vaccine should be dealt with rapidly and effectively which can strengthen confidence in the vaccine and improve the immunization coverage as well. On the other hand, it should be remembered that vaccines are not 100% safe and they can harm because of errors in immunization practices also.[9] The fact sheet of the vaccine has mentioned the very common, common, and uncommon side effects.[10]

These side effects are encountered during controlled studies which may not necessarily match with real world findings. However, real world findings of adverse effects with the use of Covishield™ vaccine are very scarce in Indian patients. Hence, the main objective of the present study was to record and analyze all the AEFI in healthcare workers for monitoring the safety and find the correlations if any.

MATERIALS AND METHODS

This was the prospective observational study among the healthcare workers at Government Medical College, Jalgaon, who received COVID immunization voluntarily. The primary objectives of this study were to document all the AEFI by the Covishield™ vaccine and identify if there is any unexpected AEFI. The secondary objectives were to analyze all the collected data and to perform causality assessments according to the World Health Organization (WHO) scale. We included the healthcare workers who received the vaccine voluntarily from January 2021 to March 2021 and who gave consent to participate in the study. We excluded the healthcare workers who were unwilling to participate. After obtaining Institutional Ethics committee (IEC) approval, we collected the data by phone call to the participants within 3 days after the first dose of the vaccine. The data were collected under the headings of initials, age, gender, date of vaccination, date of AEFI, date of recovery, description of the event, and treatment. We made a second phone call to all the participants after their second dose of the vaccine and we collected the data regarding adverse events following the second dose as well as in the past month. All the data were recorded in MS excel and the analysis was done by an appropriate statistical test. Ethics Committee approval was taken before the start of the study from IEC, Government Medical College, Jalgaon.

RESULTS

This was the prospective observational study. We involved 100 healthcare workers randomly as the participants who received the Covishield™ vaccine voluntarily in a dose of 0.5 ml intramuscularly preferable in the deltoid muscle. Out of 100 participants, 60 were males and 40 were females. The mean age of the participants was 38.26 ± 10.77 years (Table 1).

Table 2 shows the distribution of participants according to their designation which shows there were 37 clerks and 1 ASHA worker which shows the maximum and the minimum number of healthcare workers who took the vaccine voluntarily during our study period.

The most frequent AEFI was observed to be myalgia which was found in 25 participants followed by local pain at the injection site found in 22 participants, after the first dose. Other AEFI found were headache, fever with chills and

| Table 1: Demographic details of study participants (n=100) |
|-----------------|----------|
| Characteristics | Value    |
| Age (in years)  | 38.26±10.77 |
| Gender          | n        |
| Male            | 60       |
| Female          | 40       |

| Table 2: Distribution of participants according to their designation (n=100) |
|-----------------|-------|
| Designation     | n     |
| Professor       | 9     |
| Associate professor | 6   |
| Asst. professor | 22    |
| UG students     | 5     |
| Nursing staff   | 18    |
| Nursing students| 2     |
| Clerk           | 37    |
| Asha worker     | 1     |
rigors, anxiety, nausea, vomiting, malaise, palpitation, and weakness. Furthermore, one participant complained of vertigo. 23 participants had no complaints after the first dose [Figure 1].

All the participants recovered within 1–2 days after the symptomatic treatment. All were the very common reactions that are mentioned in the fact sheet of the vaccine. No unexpected reaction was found.

After the second dose, the AEFI observed were fever, weakness, malaise, headache, local pain, and loose motion. Three participants complained of headache, one participant had a fever, one participant had malaise and weakness, two participants had myalgia, and one participant had complained of loose motion. Other 92% of participants did not react to the second dose of the vaccine.

**DISCUSSION**

We tried to assess the causality of all the events following the first dose of the vaccine according to the WHO algorithm.\(^{[11]}\) About 98.7% of the AEFI had a consistent causal association to immunization. About 1.29% of AEFI events assessed were classified as indeterminate as the temporal relationship was consistent but there was insufficient definitive evidence for vaccine-causing events. Out of the 8% of participants who had AEFI after the second dose, 1.2% AEFI was classified as indeterminate, remaining 98.8% AEFI was classified as a consistent causal association to immunization.

The government of India has composed a NEGVAC which guides regarding COVID-19 vaccination.\(^{[12]}\) Vaccines having assured quality and appropriate immunization practices are important for the immunization program to become successful.\(^{[13]}\) The Serum Institute India and the Indian Council of Medical Research have jointly conducted a Phase II/III, randomized controlled study in healthy adults at 14 centers in India. They compared the safety of Covishield which is manufactured in India against the original Oxford-ChAdOx1.\(^{[14]}\) The safety, immunogenicity, and efficacy data of the Covishield vaccine have been reported for 23,745 participants outside India having an age more than 18 years. It showed the vaccine efficacy to be 70.42% after administration of two doses containing \(5 \times 10^6\) viral particles.\(^{[15]}\) AEFI has always been one critical component in the immunization program. It is defined by the WHO as a medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization.\(^{[16]}\) COVID-19 vaccines have limited data regarding their safety. Therefore, while administering to a large population, it is important to encourage monitoring regarding the safety of these vaccines. One interim analysis shows that the vaccine had a good safety profile. Serious adverse events were found in 168 participants. Out of 168, 79 received ChAdOx1 nCoV-19 and 89 received MenACWY or saline control. Furthermore, vaccine-related serious adverse event as a fever higher than 40°C was reported 2 days after vaccination in South Africa. The individual recovered rapidly without any other diagnosis.\(^{[9]}\) In another single-blind immunogenicity study showed that fatigue and headache were the most commonly reported adverse effects while muscle ache, malaise, chills, and feeling feverish were other effects found which are similar to the findings in the present study.\(^{[17]}\)

The main strength of the present study is that it fills the void of safety data in this part of the country, wherein the only safety data were that provided by the makers of Covishield\(^{[14]}\) vaccine. The major limitation of the present study was small sample size and single center involvement.

**CONCLUSION**

The vaccine for the COVID-19 has limited data till now, so people are apprehensive to take the vaccine voluntarily in the general scenario. This study was the prospective observational study to find out the adverse events in healthcare workers who received the vaccine when CDSCO approved the emergency use of the vaccine. We have found that there were no serious adverse events after the first as well as the second dose of vaccination. The majority of the participants had myalgia and local pain at the injection site. After the second dose, only eight participants out of 100 had adverse effects. More studies and monitoring are needed to find out any unexpected reactions following COVID-19 vaccination, as vaccination can help the world to combat this pandemic crisis.

**ACKNOWLEDGMENT**

We would like to thank all the healthcare workers who participated and provided useful data for the present study.
Teli et al. Adverse events following immunization by Covishield™ vaccine among healthcare workers

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How to cite this article: Teli SESI, Ramanand J, Bhangale CS, Mahajan HM, Mandhare R. Analysis of all the adverse events following immunization by Covishield™ vaccine among healthcare workers at Government Medical College, Jalgaon. Natl J Physiol Pharm Pharmacol 2022;12 (Online First). DOI: 10.5455/njppp.2022.12.07266202106082021

Source of Support: Nil, Conflicts of Interest: None declared.