RESEARCH ARTICLE

Evaluation of safety profile of ChAdOx1-nCoV-19 Coronavirus (Covishield) Vaccine among health care professionals in a tertiary care hospital: 6 months follow-up observation

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ABSTRACT

Background: As there were no vaccines available for any strains of coronaviruses, it was inevitable to develop safe and effective vaccines for the prevention of infection. There were limited data on the safety of the vaccine in the real-world environment, so the present study is undertaken to assess the safety of the vaccine. Aim and Objectives: The objective of the study is to evaluate the safety profile of ChAdOx1-nCoV-19 Coronavirus Vaccine (Covishield) among health care professionals. Materials and Methods: This is 6 months follow-up observation of vaccinated individuals, 545 health care workers have taken Covishield Vaccine for a duration of 1 month in a tertiary care hospital in two doses with 28 days apart. Demographic data such as age, gender, and comorbidities were noted. They were given a World Health Organization-based Adverse Event Following Immunization form to fill if they have any of the symptoms. Their phone numbers were collected to check for any adverse reactions every week after the first dose till the next dose and every month for another 6 months. Results: Adverse reactions were reported by 147 out of 297 vaccinated individuals after the first dose, 40 members out of 248 individuals after the second dose 24 h after vaccination. Pain at the site of infection and body ache/myalgia was seen in 27% of individuals. Reactions were mild in most of the individuals which resolved in a day without medication. Conclusions: Although the frequency of adverse reactions was observed in more individuals, they were mostly mild and self-limiting. This may show that vaccine has an acceptable safety profile in our observation among health care professionals.

KEY WORDS: ChAdOx1-nCoV-19 Coronavirus (Covishield) Vaccine; Health Care Professionals; Adverse Reactions

INTRODUCTION

Coronavirus disease 2019 (COVID-19) infection initially emerged in Wuhan city, China, which is caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) causing various manifestations mainly respiratory illness ranging from mild to moderate disease (80%) to severe disease (15%), and even critical illness (5%) with high case fatality rate of around 0.5–2.8. COVID-19 was declared as pandemic in March 2020 and considered as public health emergency of global concern by the World Health Organization (WHO).

COVID-19 is an RNA virus. Specific structural and spike proteins present on the surface of the virus assists in the pathogenesis and development of the complications. The symptoms include high fever with/without chills, generalized weakness, anosmia cough with expectoration, and shortness of breath or difficulty in breathing, myalgia, diarrhea,
fatigue, and hemoptysis. Due to lack of specific treatment and widespread of disease has called it for Fastrack vaccine development.

There were no vaccines available for any of the strains of coronaviruses and it was inevitable to develop safe and effective vaccines for the prevention of infection. Currently, two COVID-19 vaccines that are being extensively used in India which are Covaxin developed from Bharat Biotech and Covishield vaccine from Serum Institute of India.

Among vaccines approved for national immunization program, ChAdOx1 nCoV-19 Coronavirus Vaccine (Recombinant)-Covishield has shown better of 70.4% in a peer-reviewed study.

A chimpanzee adenovirus-ChAdOx1 has been modified to enable it to carry the COVID-19 spike protein into the cells of humans, works by priming the immune system and producing adequate humoral response. Clinical trial reports of 2 COVID-19 vaccines have revealed common adverse effects and acceptable safety data. During vaccine discovery, limited number of selected participants will be included and conducted in a controlled environment for short duration only. Few side effects, particularly rare and very rare onews that are seen in real uncontrolled environment may not be evident. Therefore, it is necessary to closely monitor the safety and effectiveness of approved vaccines in the market.

Vaccines may not work the same for everyone, so it requires re-evaluation and post-marketing surveillance. Hence, the Pharmacovigilance committee of a tertiary care hospital followed up the vaccinated individuals for half a year to check for the safety of Covishield vaccine and severity of adverse effects.

**MATERIALS AND METHODS**

Five hundred and forty-five Health care workers (doctors, undergraduate medical students, nurses, laboratory technicians, and pharmacists) have taken ChAdOx-nCoV-19 Corona Virus vaccine for a duration of one month from January 2021 to February 2021. They were followed up for 6 months by the Pharmacovigilance committee of Sri Siddhartha Medical College, Tumakuru.

Demographic data of vaccinated individuals such as age, gender, comorbidities were noted. Two doses of vaccine of 0.5 ml intramuscularly to the deltoid region in the upright position with 28 days apart was given. Their phone numbers were collected in order to follow-up for any type of adverse reactions after vaccination. The participants were asked to report symptoms such as fever, headache, myalgia, pain at the injection site, or any other specified symptoms. They were given WHO-based Adverse Event Following Immunisation form to fill if they have any of the symptoms, immediately and after their 30 minutes observation period. After 24 h and after 1 week of vaccination, vaccinated individuals were called up to check for the occurrence of any reactions and duration of symptoms. They were followed up till the next dose of vaccination every week. There were even asked if they get COVID-19 related symptoms post-vaccination. In similar way, $2^{nd}$ dose of vaccine was given after 28 days for all participants and was followed up after 30 min, 24 h and every month for 6 months to check for any other adverse effects and infection.

The symptoms were divided as mild, moderate, and severe according to intensity of discomfort as told by the participants. The number of vaccinated individuals reporting adverse effects during the first and second dose were assessed and adverse effects association with age, comorbidities were estimated.

**Statistical Methods**

Data were entered in excel spreadsheet and analyzed using SPSS software (Version-20). Qualitative variables were expressed as frequencies and percentages and quantitative variables were expressed as mean and standard deviation.

**RESULTS**

After vaccination, participants were observed for 30 min in which no individual complained of any symptoms. Adverse reactions were reported by 147 out of 297 vaccinated individuals after the first dose and by 40 members out of 248 individuals after the second dose in 24 h after vaccination as shown in Figure 1. Pain at the site of infection and body ache/myalgia was seen in 27% of individuals followed by fever in 19%, fatigability in 13%, and giddiness in 7% of individuals in 24 h of vaccination as shown in Figure 2. Severity of symptoms according to participant’s description subjectively shown as mild symptoms in 96 individuals who reported after the first dose and 33 after the second dose, moderate symptoms in 47 after the first dose and 6 after the second dose, severe symptoms was seen in four individuals after the first dose and one after the second dose as shown
in Figure 3. 65 members developed symptoms after the first dose and 18 after the second dose in <25 years age group. Forty-one and nine individuals developed adverse reactions after the first and second dose respectively in the age group of 36–45 years as shown in Table 1. Every week follow-up was done after the first dose till the second dose where no one complained of any symptoms. Every month follow-up after the second dose for 6 months was done which revealed 8% of individuals developed corona-related symptoms after 3 months and rest of the individuals did not complain of any adverse reactions.

DISCUSSION

Follow-up of vaccinated individuals has shown increased adverse reactions after the first dose than after the second dose in first 24 h after vaccination which is similar to Kataria et al. where local and systemic reactions were noticed in both the doses which may be due to immunogenicity.[10]

Pain at the site of injection and body ache/myalgia were the commonly observed symptoms in both the doses. Other systemic symptoms such as fever, headache, giddiness, easy fatigability, and sweating were also reported in early days after vaccination. Participants were >18 years old among which adverse reactions were observed more among younger age and least adverse effects were noted in age group >45 years. This may be due to the presence of more number of health care workers of younger age group in the medical college.

On observation, there was similar frequency of adverse effects among vaccinated individuals with comorbidities such as diabetes or hypertension. Vaccine adverse reactions were classified as mild which usually occurs within hours and resolves in short duration and need no medication was observed more in first dose and less after the second dose. Voysey et al. observed that ChAdOx1 nCoV-19 (Covishield) has an acceptable safety profile and has been found to be efficacious against symptomatic COVID-19 among 11,636 participants from the interim analysis of ongoing clinical trials.[9] Moderate symptoms which were bearable and resolved after taking medications like analgesics and antibiotics were seen in some individuals. Severe reactions which prolonged for >5 days which caused more discomfort to the individual requiring analgesics, antibiotics, and hospitalization seen only in 5 individuals.

Only very few individuals developed COVID-19 related symptoms post-vaccination which shows that vaccine has beneficial effect in producing immune response and preventing infection in majority of individuals.

Limitations

It is a single center observation and evaluated only among vaccinated health care professionals, requires multicentric trials to assess safety among general population.

CONCLUSIONS

Although the frequency of adverse effects of ChAdOx1-vaccine among health care workers was observed in many individuals, but mostly, were mild symptoms which relieved faster. Hence, the vaccine is shown to have a good safety profile in our observation.
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