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Original Article

SAFETY MONITORING OF COVID-19 VACCINE: IN A TERTIARY CARE HOSPITAL IN HARYANA

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ABSTRACT

Objective: The present study aimed to ensure the safety and related potential adverse effects following ChAdOx1 nCoV-19 vaccination (AZD1222) in a scenario when numerous vaccines have been approved on an emergency basis by the WHO and other regulatory agencies to prevent the widespread of COVID-19 infection and to decrease the associated mortality and morbidity.

Methods: This study was an open, non-comparative, non-interventional, observational study conducted on healthcare workers of BPS Govt. medical college for women and elderly people who received the first dose of COVID-19 vaccinationChAdOx1 nCoV-19 vaccine (AZD1222) by conducting their interviews and recording the data

Results: Between January and March 2021, a total of 1907 participants were enrolled in this study. Out of 1907 recipients, 70 recipients reports adverse drug events following vaccination. Myalgia (0.629%), headache (1.31%), fever (≥ 37.5 °C, 0.839%) and fever with chills (≥ 37.5 °C, 1.048) were the most common adverse events after the first dose of vaccination of ChAdOx1 nCoV-19 vaccine (AZD1222. Throat irritation (0.209 %) and Generalised itching (0.262) were the least common adverse events.

Conclusion: ChAdOx1 nCoV-19 (Astrazeneca) has an acceptable safety profile as observed in this study. To our knowledge, very few studies are done that review the safety of COVID-19 vaccines. Further safety data from a larger sample size and of longer duration are warranted to establish safety

Keywords: Covid 19 vaccine, Adverse drug reactions, Vaccination, ChAdOx1 nCoV-19 vaccine

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INTRODUCTION

The year 2020 will be remembered in modern history as the most challenging year in terms to combat SARS CoV-2, a viral infection causing intense respiratory illness. This pandemic burdened health professionals globally and led to unprecedented paralysis of healthcare systems and a global economic crisis [1]. COVID-19 infection originated in Wuhan, China in December 2019 and crippled human health globally in no time [2]. The COVID-19 pandemic, which started in late 2019 and continues as of mid-2021, has caused enormous global damage to health and lives. The urgent public health need has led to the development of vaccines against COVID-19 in a record-breaking time. From the initial stage of this pandemic, scientists were focused on either repurposing the existing drugs or developing vaccines against COVID-19 [3]. By Jan 2021, emergency approval was granted to nine vaccines by regulatory authorities in different parts of the globe [4]. The COVID-19 vaccines have been widely rolled out for the masses by many countries following approval for emergency use by the World Health Organization and regulatory agencies in many countries. In addition, several COVID-19 vaccine candidates are undergoing clinical trials. However, myths, fears, rumors, and misconceptions persist, particularly concerning adverse events. However, there is no comprehensive safety data reported from the vaccine trials, which is critical information to inform the policies to improve the uptake of COVID-19 vaccines and mitigate the risk aversion perceived due to the COVID-vaccine side effects. The ChAdOx1 nCoV-19 vaccine (AZD1222) was developed at Oxford University and consists of a replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene [5]. As there are very few studies done regarding vaccine-related adverse drug reactions. So we did this study to ensure that this vaccine is safe and what the potential adverse drug reaction related to this vaccine.

MATERIALS AND METHODS

In India, healthcare workers received the highest priority for COVID-19 vaccination, followed by elderly people in long-term care facilities. This study was an open-label, non-comparative, non-interventional, observational study conducted by the department of pharmacology on healthcare workers including doctors, students, paramedical staff of BPS Govt. medical college for women and elderly people who received the first dose of COVID-19 vaccination ChAdOx1 nCoV-19 vaccine (AZD1222) by conducting their interviews and recording the data. This study aimed to identify adverse events occurring after the first dose of COVID-19 vaccination in 1907 participants. A total of 1907 healthcare workers received the AstraZeneca vaccine (chimpanzee adenovirus-vectored vaccine, 0.5 ml [5×10^{10} viral particles] per dose). This study protocol was approved by the Department of Pharmacology and subsequently by the Institutional Ethics Committee. Patients were made to understand the entire purpose of the study, their rights and the procedure of the study with the help of the patient information sheet, which was available in both Hindi and English. Patients who gave written informed consent were then included in the study. Participants were enrolled according to inclusion criteria i,e, those who are at high risk of SARS-CoV-2 infection and Medically stable, whereas exclusion criteria includes confirmed or suspected immunosuppressive or immune-deficient state, blood disorder like thrombocytopenia and coagulation disorders, received another COVID-19 vaccine, hypersensitivity to the active substance, pregnant and lactating females [6].

RESULTS

Between January and March 2021, 1907 participants were enrolled were included in this study. Out of 1907 recipients, 70 recipients reports adverse drug events. Consistent with data observed from this study, myalgia (0.629%), headache (1.31%), fever (≥ 37.5 °C, 0.839%) and fever with chills (≥ 37.5 °C, 1.048) were the most common adverse events among ChAdOx1 nCoV-19 vaccine (AZD1222) recipients [7]. as shown in table 1 and fig. 1. Throat irritation (0.209 %) and Generalised itching (0.262) were the least common adverse events.

Table 1: Adverse events reported within 7 d after the first dose of coronavirus disease 2019 vaccination

Adverse events	No. of recipients had this event	Percentage	The percentage of all participants who received the vaccine (first dose)
Fever	16	15.53	0.839
Fever with chills	20	19.41	1.048
Headache	25	24.27	1.310
Myalgia	12	11.65	0.629
Dizziness	8	7.77	0.419
Nausea/vomiting	7	6.79	0.367
Throat irritation	4	3.88	0.209
Generalized itching	5	4.85	0.262
Redness and pain at the injection site	6	5.58	0.314

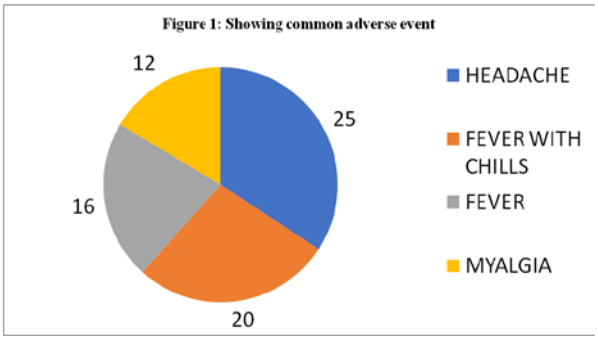

Fig. 1: Showing commonest adverse events reported within 7 d after the first dose of coronavirus disease 2019 vaccination

DISCUSSION

In this study, we synthesized the safety data or identified the adverse events occurring after the first dose of COVID-19 vaccination (Astrazeneca) in 1907 vaccinated healthcare workers, including doctors, students, paramedical and elderly people at BPS Govt. medical college for women and attached hospital. A total of 1907 participants received the AstraZeneca vaccine (chimpanzee adenovirus-vectored vaccine, 0.5 ml [5×10^{10} viral particles] per dose). Seventy recipients reported systemic adverse events (fever, chills, headache, myalgia, arthralgia, fatigue, and nausea/vomiting) that were resolved within 2 d after vaccination. More than 80% of vaccine recipients received medication for these adverse events, while approximately 20% of recipients not received any medications for these events and resolved them within 2 d on their own. In this study, we found fever, fever with chills and headache were the most common side effects after vaccination; these results were similar to a study done by Kaur *et al.*, [8]. A similar study done by Yamamoto K [9] also showed that fever and headache are common side effects after Covid 19 disease vaccination, similar to our study. Results similar to our study were also seen in a study done by Beatty AL *et al.*, [10], where common side effects were malaise, headache, and fever. A study was done by Menni C *et al.* [11] on Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID where common side effects were itching, pain, fever, and headache; these results were also similar to our study. As per the United States Food and Drug Administration guidelines for "Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry October 2020, it is recommended that pharmaceutical companies must inform the regulatory authority within 24 h of completion of any interim analysis which is intended to be used for attaining Emergency Use Approval (EUA) [12]. This data should be supplemented with the safety data of all safety data of phase 1 and phase 2, including the details of serious adverse events, adverse events of special events and cases of severe COVID-19 infection, and longer safety follow-ups [12]. A few shortcomings of this observational study were also there as this study was not a comparative study; ideally, a comparison with other covid 19 vaccines will be a good option to validate the side effects, and secondly study population was also not sufficient in view of covid infection.

CONCLUSION

Recognizing the urgent need for the COVID-19 vaccine, the safety data analysis of phases 1 and 2 is of prime importance for COVID-19 vaccines, and in this pandemic scenario when emergency use approval is being granted to COVID-19 vaccines. Thus, this study was conducted to assess the probability of adverse events with the COVID-19 vaccine and ChAdOx1 nCoV-19(Astrazeneca) has an acceptable safety profile as observed in this study. To our knowledge, very few studies are done that review the safety of COVID-19 vaccines. Further safety data from a larger sample size and of longer duration are warranted to establish safety.

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AUTHORS CONTRIBUTIONS

Dr. Arvind Narwat contributed in the interpretation of results, finalization of topic, Dr. Mitali Dua contributed in writing the manuscript whereas Dr. Abhinav goyal contributed in data collection and finding the supporting literature for this study.

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CONFLICT OF INTERESTS

None

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Yes

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