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Original Research Article

Pattern of adverse effects following ChAdOx1 nCoV-19 COVISHIELD vaccination in adults in tertiary healthcare institution in North India: A retrospective observational study

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ABSTRACT

Introduction: Adverse effects following vaccination must be reported and assessed in order to promote the patient safety and well-being.

Objective: The aim of this study was to observe the pattern of adverse drug reactions (ADRs) following ChAdOx1 nCoV-19 (COVISHIELD) vaccination in adult patients.

Materials and Methods: Study was conducted at Dr. RPGMC, Kangra at Tanda, which has a dedicated COVID-19 hospital, ADR monitoring Centre, COVID-19 vaccination Centre & a hospital with 700 bedded multi-specialty tertiary healthcare Centre situated in North India. Assessment was carried-out for the pattern of ADRs reported by the volunteers receiving COVID-19; ChAdOx1 nCoV-19 (COVISHIELD) vaccine from January to December 2021. Data such as age, gender, vaccine administered, types of ADRs, treatment and outcome of the reactions were collected. Each reported patient was assessed individually. Causality assessment was done on WHO causality assessment scale. ADR profiling on the basis of site, onset, organ system affected, duration, whether urgent referral was required or not and resolution of signs & symptoms. The data is analyzed and expressed as mean ± standard deviation & percentages.

Results: A total of 21,115 volunteers got vaccinated at our Centre from 16 January 2021 to 31 December 2021. Less than 1% (201) vaccinees reported AEFIs and all those who reported AEFIs had mild symptoms and recovered. Immune system related adverse effects (55.2%) were most common. Fever, drowsiness, headache, vomiting, injection site pain/swelling/tenderness and body aches were the most commonly reported adverse effects.

Conclusion: Reporting of vaccine adverse effects and availability of safety data on public platform is an important factor in increasing the vaccine acceptability by the people and henceforth better health. ChAdOx1 nCoV-19 COVISHIELD vaccine is proved to be a safe vaccine against COVID-19 in adults.

1. Introduction

Corona virus is a type of virus which infects animals &humans and contains single-stranded positive-sense ribonucleic acid (RNA).[1] From various types of corona viruses, SARS (severe acute respiratory syndrome) corona virus and MERS (Middle East Respiratory Syndrome) corona virus outbreak were already seen in 2003 and 2012 respectively when viruses cross-over to humans from animals which lead to significant mortality.[2–4]

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COVID-19 disease causing pneumonia due to infection by novel corona virus, named 2019-nCoV, surfaced in December 2019 in Wuhan province of China. 2019-nCoV is a beta corona virus and 7^{th} member of coronavirus family infecting humans.[5] As of 28th Jan 2022, globally more than 418.6 million confirmed cases and over 5.8 million deaths were reported, in which 42.6 million confirmed cases and 0.50 million reports of deaths were reported from India and counting.[6]

The SARS-CoV-2 virion has diameter ranging between 60-140 nm.[5] A spectrum of systems including respiratory, neurological, skeletal system and cerebrovascular can be infected by coronaviruses in humans.[6]

COVID-19 infection, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) may be with asymptomatic and wide spectrum of symptoms of upper respiratory tract infection and even life-threatening sepsis as well.[7] SARS-CoV-2 is still continuing to unfold and has been widespread impacting world in every aspect, including substantial mortality among older adults and those with comorbid health conditions.[7,8]

Vaccines today are the backbone for the suppression of COVID-19 pandemic. They decrease the chances of severe form of disease, prolonged hospitalization and a fatal event occurrence.[9] It is expected that COVID-19 vaccines strengthen the immune system of the vaccine beneficiary and offers protection with more secured solution than treatment medications.[10] After COVID-19 pandemic breakdown world needed COVID-19 vaccine urgently to mitigate the COVID-19 pandemic. So national health regulators of various countries permitted various quickly developed COVID-19 vaccines usage under Emergency Use Authorization (EUA). In the United States of America, two mRNA vaccines (Pfizer and Moderna) were among the early ones to receive EUA. Initially COVISHIELD which is an adenovirus vector vaccine and COVAXIN an inactivated vaccine with matrix adjuvant have been approved early under EUA in India.[11,12]

COVISHIELD is a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoded with S-glycoprotein of SARs-CoV-2 and is a monovalent type of vaccine. After its inoculation S-glycoprotein is expressed locally which stimulates and neutralizes antibody and cellular immune response. During post authorization use of COVISHIELD vaccine various adverse effects reported were injection site reactions, generally feeling unwell, fatigue, chills or feeling feverish, fever, headache, nausea, vomiting, joint pain or muscle ache, flu-like symptoms, feeling dizzy, decreased appetite, abdominal pain, lymphadenopathy, excessive sweating, itchy skin or rash.[13]

COVISHIELD vaccination drive began in India from 16^{th} January2021. In the beginning it was targeted for front line workers, peoples above 60 years and older than 45 years with any of the 20 comorbidities notified by Ministry of Health and Family Welfare, Govt. of India. Later COVISHIELD was rolled into next phases targeting other age groups as well.[14]

Usually, a vaccine development takes a long period of almost 10-15 years.[15] The unprecedented rapid development of COVID-19 vaccines (like COVISHIELD too) followed by their rapid administration under EUA with scarcity of safety data warrants close safety monitoring in post marketing phase. Timely detection & reporting of AEFIs with COVISHIELD is the step needed for strengthening more safety of vaccine. Since the COVISHIELD vaccination drive rolled out, the Adverse Drug Reaction Monitoring Centre (AMC), at Dr. R.P.G.M.C., Kangra at Tanda, HP, as per the guidelines of National Coordination Centre (NCC), Pharmacovigilance Programme of India (PvPI), is actively following-up for Adverse Events Following Immunization (AEFI) in COVID-19 vaccine recipients. The present retrospective study aimed at describing various trends observed in AEFI reports for COVISHIELD vaccine with regard to its safety profile.

2. Materials and Methods

This is a retrospective observational study done at adverse drug reaction monitoring Centre (AMC), Dr. R.P.G.M.C., Kangra at Tanda. The study was done on adverse events following immunization (AEFI) data collected at AMC following COVISHIELD vaccination. The approval to analyze and publish AEFI data was granted by National Co-ordinating Centre, Pharmacovigilance Program of India (PvPI), Indian Pharmacopoeia Commission, Ghaziabad.

The vaccinees were told regarding reporting of AEFI after administration of COVISHIELD vaccine free of cost, under National COVID Vaccination Program initiated by Ministry of Health & Family Welfare, Government of India. The data of the vaccinees who reported AEFIs to pharmacovigilance associate at the AMC was included in the study. The identification of the vaccinees was kept confidential and the data was also reported to NCC, PvPI. AEFI were recorded using preferred term (PT) & system organ classification, as under medical dictionary for regulatory activities (MedDRA)-a WHO medical terminology tool. The data was entered into Microsoft excel and analyzed using data analysis tool. The results were presented using appropriate tables & figures.

3. Results

Mean duration of AEFIs was 1.81 days and all the vaccinees have recovered.

No AEFI was of serious nature.

A total of 21,115 volunteers got vaccinated at our Centre from 16 January 2021 to 31 December 2021. Less than 1%

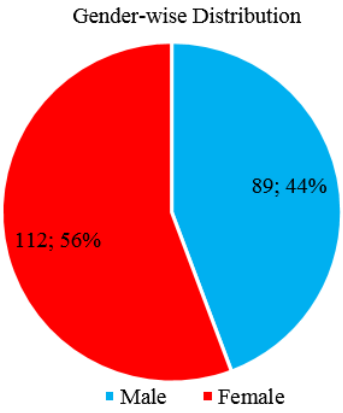

Fig. 1: Gender-wise distribution of patients reporting AEFIs

Table 1: Age-group-wise representation of vaccinees reporting AEFIs

Age-group	Vaccinees reporting AEFI	Males reporting AEFI	Females reporting AEFI
18-30 Years	51 (25.4%)	21	30
31-45 Years	89 (44.3%)	40	49
46-60 Years	42 (20.9%)	20	22
61-75 Years	18 (8.9%)	7	11
>75 Years	1 (0.5%)	1	0

Table 2: Organ-system involved as per reported AEFIs

System Involved	Number of AEFIs
Immune system	111 (55.2%)
CNS	38 (18.9%)
GI system	20 (10%)
Musculoskeletal system	19 (9.5%)
CVS	5 (2.5%)
Respiratory system	3 (1.5%)
Skin	2 (1%)
Eye	2 (1%)
Reproductive system	1 (0.5%)

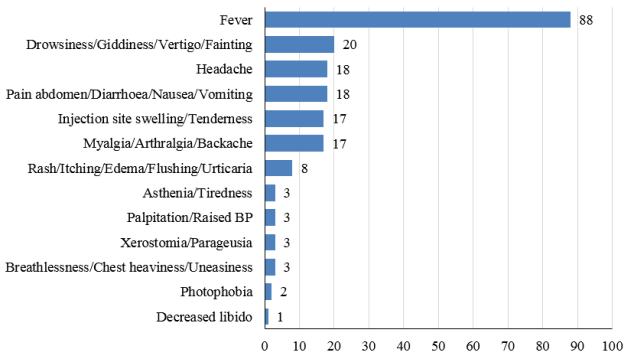

Fig. 2: Symptom-wise distribution of AEFIs

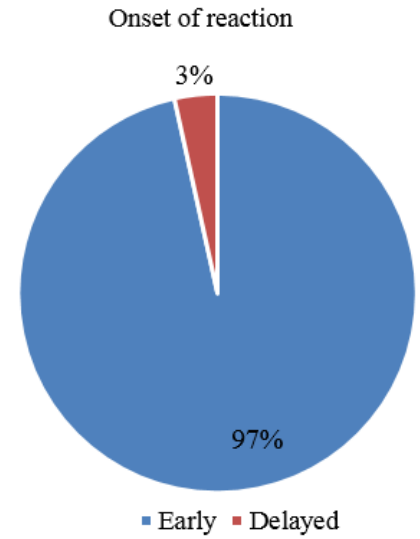

Fig. 3: Onset of reaction-wise distribution of AEFIs

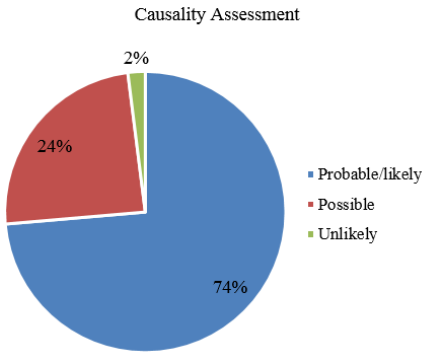

Fig. 4: WHO-causality assessment-wise distribution of AEFIs

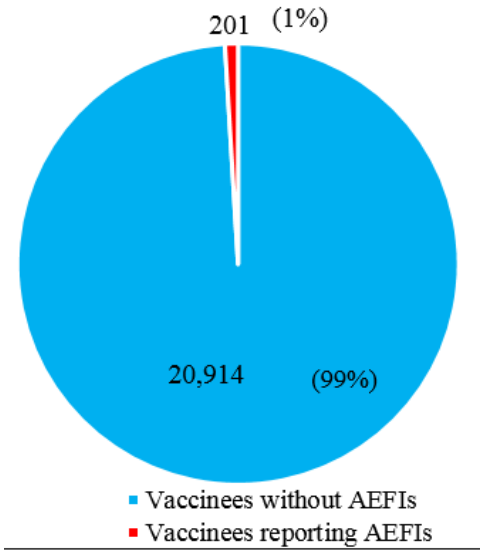

Fig. 5: AEFI-wise distribution of vaccines

vaccinees reported AEFIs and all those who reported AEFIs had mild symptoms and recovered.

4. Discussion

This was a retrospective descriptive observational study of AEFIs following ChAdOx1 nCoV-19 COVISHIELD vaccination at our tertiary health care institution. Vaccination was done free of cost under national immunization programme by ministry of health and family welfare, government of India. The AEFIs collected and reported by the AMC of institute to NCC, PvPI, India were studied and analyzed. A total of 21115 people got vaccinated with either 1^{st} or 2^{nd} respective dose of their COVISHIELD vaccine between 16 January 2021 to 31 December 2021. Less than 1% (201) people reported AEFIs. A total of 430 AEFIs were collected and reported to to NCC, PvPI, Ghaziabad, India.

Out of total 20914 vaccinees 89 (44%) males and 112 (56%) females reported AEFIs post COVISHIELD vaccination. Mean age of men who reported AEFIs was 39.7±13.5 years and that of women was also 39.7±13.5 years. In a study done by Goldlin et al. 422 (31.4%) vaccinees developed adverse events out of which 213 (50.5%) were males with mean age 32.24±14.34 and 209 (49.5%) were females with mean age 29.95±11.42.[16] In a study done by Vijay Kumar et al. out of 349 vaccinees receiving COVISHIELD only 11.14% developed adverse events.[17] In a study done by Shukla et al. on evaluation of allergic reactions following COVID-19 vaccination in patients with documented allergies, only 1 recipient was found to develop rash out of 94 vaccine doses (1^{st} and/or 2^{nd} dose) of COVISHIELD vaccine.[18] In a study done by Kaur et al. 321(40%) and 122(5.4%) vaccinees developed AEFIs following 1^{st} and 2^{nd} dose of COVISHIELD vaccine respectively.[19] According to package insert of COVISHIELD vaccine by serum institute of India, Pune the safety data concludes that only 15 (1.25%) vaccinees developed AEFIs out of total 1200 vaccine recipients.[13] Rahat Kumar et al. reported 1694 adverse effects among all 2704 vaccinees who received COVISHIELD vaccine.[20] In a study done by Konda et al. 237 (6.2%) out of which 104 were men and 153 were women developed AEFIs following 1^{st} dose of COVISHIELD vaccine. After 2^{nd} dose 33 (2.3%) out of which 11 were men and 22 were women developed AEFIs.[21,22]

In the present study most of the vaccinees reporting AEFIs (44.3%) were between 31 to 45 years of age, which corresponds to age-wise population distribution of India.

5. Conclusion

AEFI reporting play vital role in contributing towards vaccine safety data, acceptance of vaccine and encourage more people to get vaccinated. Indian national immunization programme is the world's largest immunization programme and is still continuing with precautionary dose for adults with ChAdOx1 nCoV-19 COVISHIELD vaccine and COVAXIN vaccine for children between 12 to 18 years of age. Our study suggests that with ChAdOx1 nCoV-19 COVISHIELD vaccine less than 1% vaccinees developed AEFIs and those too were mild to moderate in intensity and resolved spontaneously. Most vaccinees who reported AEFIs had one or more symptoms of immune reaction which is expected of such a vaccine and are evidence for vaccine effectiveness. Therefore, it may be concluded that ChAdOx1 nCoV-19 COVISHIELD vaccine proved to be safe in adults. More people should get vaccinated to enhance cover from COVID-19 infection and to strengthen herd immunity. This will contribute more to such AEFI data.

6. Conflict of Interest

The authors declare no relevant conflicts of interest.

7. Source of Funding

None.

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