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A SYSTEMATIC REVIEW OF ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) REPORTED FROM JANUARY 2021 TO JANUARY 2022 FOLLOWING COVISHIELD VACCINATION IN INDIA.

Pharmacology

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ABSTRACT

The coronavirus disease – 2019 (COVID-19) was declared as pandemic on 11 March 2020 by the World health Organization (W.H.O. Safe and effective vaccines were the need of the hour to reduce the rapid transmission and mortality associated with it. The Committee of Central Drugs Standard Control Organization (CDSCO), India granted emergency approval of COVID-19 vaccine covishield (ChAdOx1 nCoV-19) on January 3, 2021. Adverse events following immunization (AEFI) should be promptly identified. In this study, which is a retrospective and observational study, we reported the AEFI by covishield in India from January 2021 till January 2022. The AEFI were collected from the database of PubMed. The common adverse events (AE) reported were pain at the injection site, mild fever, malaise (15%), headache, myalgia, diarrhoea, chills, and rigors. The other AEFI reported were dizziness, chest pain and rash. Few investigators reported rare cases of vaccine-induced erythema nodosum, episode of herpes zoster of both T10 dermatomes and a case of pityriasis rosea. The majority of the AEFI did not affect daily activities of the participants, which might indicate better tolerability and safe immunization.

KEYWORDS

Covishield, vaccination COVID-19, adverse event following immunization, immunization.

INTRODUCTION

The worldwide coronavirus disease – 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared as a pandemic on 11 March 2020 by the World health Organization (W.H.O).[1,2] The rapid surge in COVID-19 cases around the world produced a major healthcare crisis.[3] Various countries adopted preventive measures like facemask, hand washing, social distancing and a night or regional curfew to break the chain of virus transmission.[2] The Government of India also took steps to control the pandemic by a nationwide lockdown on 25th March 2020 with preventive measures.[1]

At the end of January 27, 2021 over 99.8 million people were diagnosed with COVID-19 globally with more than 2.1 million deaths. So, safe and effective vaccines was the need of the hour to reduce the rapid transmission thereby to decrease the burden and mortality of COVID-19.[4]

The Committee of Central Drugs Standard Control Organization (CDSCO), India granted emergency approval of COVID-19 vaccine covishield (ChAdOx1 nCoV-19) on January 3, 2021.[5] Covishield vaccine approved by WHO (Oxford-AstraZeneca) which is developed by Serum Institute of India (SII) is a monovalent vaccine composed of a single recombinant, replication – deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV2.[6] After intramuscular administration of covishield the S glycoprotein of SARS-CoV2 is expressed locally stimulating cellular immune response. Activation of cell-mediated immune response may lead to an adverse event following immunization (AEFI) like high-grade fever, pain at the injection site, dizziness etc.[6]

An AEFI is defined as any untoward medical occurrence following immunization and does not have a causal relationship with the use of the vaccine.[7] There are various AEFI reported in India by covishield by various database and journals. Hence, this present study was designed to provide evidence on AEFI following covishield vaccination in India.

AIMS AND OBJECTIVES

1. Adverse events following immunization by covishield vaccination in India.

MATERIAL AND METHODS

Study design

This is a retrospective and observational study conducted for AEFI by covishield in India from January 2021 till January 2022.

INCLUSION CRITERIA

1. Any participant above 18 years of age irrespective of the gender.
2. Pregnant participant.

EXCLUSION CRITERIA

1. Any history of recent vaccination.
2. Any participant less than 18 years old.

Study procedure

The AEFI were collected from the database of PubMed. The data was also collected from Vigibase, which is a database maintained by WHO Uppsala monitoring center (UMC), Uppsala, Sweden.

Ethics approval

This study had no direct interaction with human participants and this is a retrospective observational study so ethics approval was not required.

DISCUSSION

Kumar and his colleagues conducted a study to assess the safety of covishield in health care workers. It was an observational retrospective study. The adverse events (AE) reported by investigators were pain at the injection site (53.3%), followed by a mild fever (18.4%), malaise (15%), injection site swelling (3.8%), headache (4.4%), myalgia (2.1%), chills (1.3%), rigors and nausea (1% each). The mean duration of myalgia and arthralgia was 3 days, pain and fever lasted 2 days whereas other AEs like malaise, and pain at injection site and vomiting was seen upto 24 hours post vaccination. There was no serious adverse events leading to deaths, prolonged hospitalization or permanent disability.[8] Another study was conducted by Jaiswal and his colleagues to assess the AEFI of covishield in health care workers. It was a prospective, observational study done in central India. The common AEs reported in health care workers following covishield vaccination was mild fever (28.91%), myalgia (26.43%), cold and cough (8.16%), headache (6.74%), local pain and swelling at the injection site (3.37%). The few participants reported fatigue (0.35%), diarrhea (0.08%), rigors (0.07%), and joint pain in (0.08%) and nausea (0.07%). Only of recipients demonstrated severe symptoms (0.70%) that required admission and observation but were discharged after receiving treatment.No serious adverse events leading to prolonged hospitalization or death were repoerted[9].

In a study conducted by Mehta et al at Postgraduate Institute of Medical Education and Research, Chandigarh, reported three cases of minor cutaneous adverse effects following covishield vaccination. A 25 years old women was reported to have vaccine-induced erythema nodosum. She received covishield vaccination 7 days prior to the episode. Dermatological symptoms resolved completely at follow-up visit after 2 weeks. No recurrence was observed on receiving second dose after 4 weeks. Investigators reported another case of a 55-year-old man who presented with first episode of herpes zoster of both T10

dermatomes after covishield vaccination. The immunization was done 3 days prior to cutaneous eruption. Symptoms were resolved after 2 weeks. In another case, a 24 years old man developed pityriasis rosea following covishield vaccination. Patient received immunization 24 hours prior to onset of cutaneous lesions. Further progression of rash was not monitored as the patient was lost to follow-up.[10] Corresponding results were observed by Maurya and his colleagues following covishield administration at tertiary care hospital in Mumbai. A case was report of a 50-year-old elderly female of herpes zoster following two days after covishield vaccination. There was no history of varicella infection in the past. The herpes zoster lesions resolved on day 16 post - vaccination. Investigators also reported a case a 30-year-old female with pompholyx like skin lesion after 18 hours of second dose of covishield vaccine. The lesions resolved after a week. The third case reported by investigators was of a 48 years old female patient who developed fever with transient pancytopenia around six hours following vaccination. The blood counts restored to normal on day 6 of vaccination.[7]

Choudhary and his colleagues conducted a study on AEs following covishield administration in pregnant women in northeast state of India. It was observed that at the first dose no serious AE were reported apart from the mild fever and slight pain at the inoculation site. At the second dose of the vaccination participant only reported slight pain at the injection site.[11]

Remlabeevi and his colleagues conducted a study on adverse events after covishield vaccination in Kerala. A cross-sectional study observed that 56.7% (2495) participants reported adverse events following vaccination with either first or second dose of the vaccine. On administration of first dose of covishield the AE observed were fatigue (47%), low grade fever (46.5%), headache (41.4%), myalgia (33.8%), chills (23.6%), dry mouth (14.8%), lose stools (4.6%), vomiting (3.3%), chest pain (1.9%), rash (0.9%) and seizures (0.5%). It was also observed that female participants (59.9%) reported a higher incidence of AEs as compared to men (48.6%). On administration of second dose of covishield vaccination the AE observed were headache (25.5%) as the most common AE, followed by fever (20.9%), dry mouth (8.8%), chest pain (5%) and seizures (0.02%). It was also observed that female participants (26.4%) reported a higher incidence of AEs as compared to men (19.1%).[12] Corresponding results were observed in a study conducted at state of Haryana, India. Mahapatra and his colleagues conducted a study among healthcare professionals to assess the adverse events following covishield vaccination. It observed that study participants developed redness and pain at the site at injection site, body ache, headache, fever and chills. It was also observed that female participants developed more AEs than men ($p < 0.05$). The investigators reported that none of the participants reported any severe AEs.[6]

Dutta et al conducted a descriptive study based on serious adverse events (SAE) form covishield vaccination. Investigators observed that AEs following covishield vaccination were non-serious type. The AEFI reported post vaccination were pain at injection site, fatigue, and headache whereas nausea was observed as the most common AE.[3] Similar results were obtained in another study conducted by Mohakuda and his colleagues at Pune. Investigators reported myalgia and fatigue as the most common AE following covishield vaccination, which was observed in observed in 69 participants (25.7%). This was followed by fever in 59 (22.0%), pain at injection site in 56 (20.9%) which lasted for 24 to 48 hours, headache in 46 (17.1%), flu-like symptoms in 8 (2.9%), diarrhea in 3 (1.1%) and vomiting in 1 (0.3%) individual.[13]

Covishield vaccine, which is developed by SII have reported its adverse reactions on fact sheet. SII has classified AEFI of covishield as common adverse events (may affect up to 1 in 10 people) are reported as swelling or redness at injection site, fever, vomiting, diarrhea and flu like symptoms. Very common events (may affect more than 1 in 10 people) are reported as tenderness, pain at injection site, fatigue, headache and muscle pain. Uncommon adverse events (may affect up to 1 in 100 people) are reported as excessive sleepiness, abdominal pain, enlarged lymph nodes and rash. Very rare adverse events as blood clots with thrombocytopenia and anaphylaxis.[14]

Surya Pratap et al, reported that 7.7% (36/463) reported minor AEFI and none of the participant reported severe AEFI. Investigators reported fever (47.2%), fatigue (38.8%) and pain at injection site (27.7%) as the most commonly reported AEs. Two participants (5.5%) reported dizziness post vaccination and one participant reported diarrhea (2.7%). Investigators observed females were associated with higher AEs (9.9%) than the males (6.1%).[5]

In another study conducted by Usha Joshi and her colleague Preeti Joshi reported mild AEFI like transient headaches, light-headedness and dizziness on day one of covishield vaccination. Investigators also reported AEs as mood irritability, myalgia, nausea and pain at the injection site. Investigators observed that myalgia and pain at the injection site persisted on day two post vaccination. By the third day, it was observed that participants reported head heaviness and pain at the injection site which persisted.[15]

The various average adverse events following covishield vaccination are shown in figure 1.

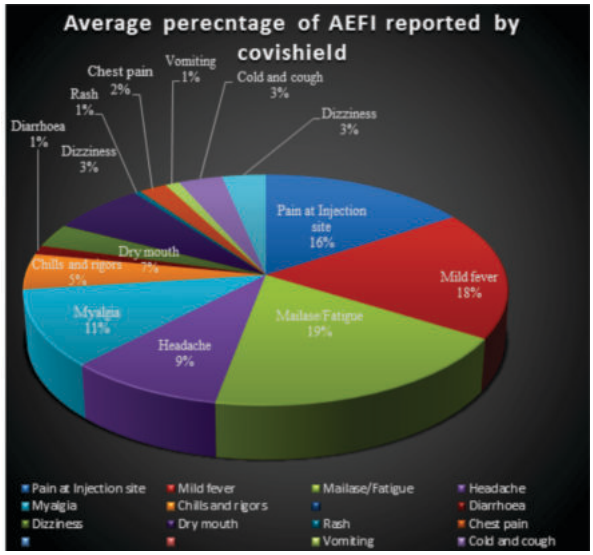

Figure 1: Average adverse events following covishield vaccination.

SUMMARY AND CONCLUSION

This study was conducted to address the adverse events following covishield vaccine after its emergency approval. The common AEs observed were fatigue, body pain, headache, fever and muscle aches. The other AEs, which cannot be overlooked, were chest pain, thrombocytopenia and seizures. But majority of the AEs did not affect the daily activities of the participants, which might indicate better tolerability and safe immunization. It was also observed in few studies that female participants reported higher AEs than men. With the present scenario, the long-term adverse events and its safety for covishield vaccination is still debatable.

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