Original Article

Adverse events following Covaxin administration among adolescents (15–18 years) – A pharmacovigilance study in a district in Northern India

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Abstract

Introduction: The study was undertaken to observe the adverse event following immunization (AEFI) to the Covaxin vaccine in young adolescents in the age group of 15–18 years in a district in Northern India. The study was conducted to assess the safety profile of the COVAXIN vaccine. **Methodology:** This was a prospective observational study conducted at rural and urban health centers of a district in Northern India. We included the beneficiaries of the COVAXIN between the age of 15 and 18 years. The administration of the COVAXIN occurred in our district from January 2022. Periodic visits were conducted to the urban and rural health centers of the city to record any suspected adverse drug reaction following immunization in the defined population. The study was conducted for a period of 1 year (January 2022 to December 2022). **Results:** A total of 72,771 adolescents (15–18 years) received the first dose of Covaxin and 49,046 received the second dose. No adverse drug event following immunization was reported during the study. **Conclusion:** Thus, it can be concluded that Covaxin was found to be safe in adolescents (15–18 years).

Keywords: Adverse event following immunization, COVAXIN, pharmacovigilance

Introduction

All over the world, widespread vaccination campaigns were organized to stop Coronavirus disease-19 (COVID-19) from spreading. Although the majority of COVID-19 vaccines have demonstrated outstanding performance and safety profiles in clinical trials the veracity of these findings can only be proven by careful follow-up studies. On January 16, 2021, a large-scale vaccination program was started in India, and healthcare workers became the first beneficiaries.[1] In India, COVISHIELD and COVAXIN were the first vaccines to be approved for emergency use.[2] COVAXIN contains an inactivated virus vaccine developed in Vero cells. Inactivated virus is combined with Alhydroxiquim-II (Algel-IMDG), chemosorbed imidazoquinoline onto aluminum hydroxide gel, which is coupled with an inactivated virus and used as an adjuvant to increase immune response and extend immunity.[3] On December 28, 2021, the Ministry of Health and Family Welfare (MOHFW) released detailed recommendations for COVID-19 immunization of adolescents between the ages of 15 and 18 years as well as a preventive dose for healthcare personnel, frontline workers, and those 60 years of age and older. On January 3, 2022, these regulations came into effect.[4] The vaccination choice for beneficiaries between the ages of 15 and 18 was kept to be " COVAXIN " exclusively.[5] Fever, myalgia,

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and nausea are frequent side effects associated with vaccines that have been identified in clinical trials.[6] A primary justification for conducting the study was due to the vulnerability of children and the lack of comprehensive safety information about the use of COVAXIN as well as in this age group. Therefore, it is crucial to closely monitor any negative side effects of COVAXIN in the aforementioned age group at the early stage of the vaccination drive.

To the best of our knowledge, no such study was conducted in North India with the specific aim of observing adverse event following immunization (AEFI) following the COVAXIN vaccine in the age group of 15–18 years during the period.

Methodology

This was a prospective observational study conducted by the ADR monitoring center (AMC) located at Kalpana Chawla Government Medical College (KCGMC), Karnal, Haryana, India. We have included all rural and urban vaccination centers within the district. Adolescents (15–18 years) who received the COVAXIN in both the first and second doses were selected for the study. The study commenced shortly after the guidelines were issued by the government for initiating the drive on the administration of COVAXIN in adolescents in the age group of 15–18 years, in January 2022. The data was collected for 1 year (January 2022–December 2022).

The study was approved by the Institutional Ethics Committee of the Institute. The main objective of the study was to observe any AEFI in the defined age group receiving COVAXIN in both the first and second doses. The tool of data collection was the suspected adverse drug reaction reporting form and the case notification form as prescribed by the Pharmacovigilance Program of India (PvPI). All the minor as well as serious AEFI, were to be reported in the forms. The case notification form was to be filled for serious AEFI. Causality assessment of suspected ADRs was to be done using the WHO-UMC causality assessment scale. ADR reports with causality: Certain/Probable/Possible were considered for further analysis for the ADR profile. However, as no ADR report was received further assessment could not be done.

Results

During the study period 1,21,817 beneficiaries, in the age group of 15–18 years were vaccinated. Out of 1,21,817 beneficiaries, 72,771 (59.73%) received the first dose and 49,038 (40.25%) received the second dose of COVAXIN, as shown in Figure 1. The recipients of the first and second doses did not experience any adverse drug reactions/AEFI.

Discussion

With the emergence of the COVID-19 pandemic, the terrible consequences of the SARS-CoV-2 virus, which have disturbed life and made isolation, quarantine, and social seclusion the new norm, have been clear to everyone in the world. Over the past 18 months, the disease has infected about 200 million individuals, and over 4 million of them have died as a result.[7] It was believed that by allowing COVID-19 immunizations to be used in emergencies, the pandemic's subsequent waves would be minimized. Both the chimpanzee adenovirus-vectored Chad0x1 vaccine from Oxford-AstraZeneca and the full virion-inactivated BBV152 vaccine from Bharat Biotech (COVAXIN) were approved in India.[8] Individuals of the ages of 12 and 17 years, though not in India received the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccination, according to the participants in the Vaccine Adverse Event Reporting System (VAERS) report. It was recorded that there were 8.9 million recipients of this vaccine. Almost 9,000 adverse events were reported to VAERS; however, they were only moderately serious. Only a small number of youngsters were affected by major adverse effects including myocarditis.[9] In the current study, vaccine recipients aged 15–18 who were immunized by Covaxin did not report any AEFI.

A study done by Tiwari *et al.*, which was to observe COVAXIN's safety profile in youngsters between the ages of 15 and 18 years, was done in India. The primary side effects of vaccination were fever and soreness at the injection site, which could be treated with paracetamol and did not need hospitalization.[10]

Chen *et al.* conducted a meta-analysis of randomized control trials of COVID-19 vaccines that were conducted worldwide. It was concluded that inactivated COVID-19 vaccines are the safest with minimum AEFI as compared to other vaccine candidates. The risk ratio of the inactivated vaccine versus viral-vectored vaccine and mRNA vaccine were 1.34, 1.65, and 2.01, respectively.[11]

Conclusion

To sum up, based on our preliminary observations, COVAXIN is a relatively safe vaccination for adolescents. However, more long-term research and multi-centric investigations are needed to generalize the results to the entire population.

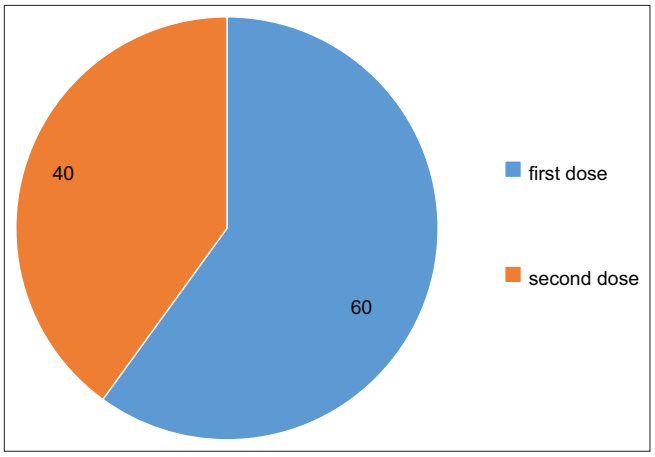

Figure 1: Ratio of adolescents who received the first dose of COVAXIN to those who received the second dose.

Ethics approval

The study protocol was approved by the Institutional Ethics Committee of KCGMC, Karnal, Haryana.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Covid-19 vaccination drive to begin from January 16 in India. India: Hindustan Times; 2021Jan 09. Available from: https://www.hindustantimes.com/india-news/covid19-vaccination-drive-to-begin-in-india-from-january-16-says-centre-101610189889889.html. [Last accessed on 2021 Feb 01].
2. Kaur U, Ojha B, Pathak BK, Singh A, Giri KR. A prospective observational safety study on ChAdOx1 nCoV-19 corona virus vaccine (recombinant) use in healthcare workers- first results from India. EClinMedicine 2021;38:101038.
3. Kumar VM, Pandi-Perumal SR, Trakht I, Thyagarajan SP. Strategy for COVID-19 vaccination in India: The country with the second highest population and number of cases. NPJ Vaccines 2021;6:60.
4. Health Ministry issues guidelines for Covid vaccination of children between 15-18 years and precaution doses. India: Economic Times (India times); 2021 Dec 28. Available from: https://economictimes.indiatimes.com/news/india/health-ministry-issues-guidelines-for-covid-19-vaccination-of-children-between-15-18-years/articleshow/88526372.cms. [Last accessed on 2022 Jan 12].
5. Guidelines for COVID-19 vaccination of children between 15-18 years and precaution dose to HCWs, FLWs and 60+population with comorbidities. Available from: https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationofChildrenbetween15to18yearsandPrecautionDosetoHCWsFLWs&60populationwithcomorbidities.pdf. [Last accessed on 2022 Jan 12].
6. Bharat Biotech Limited'. India: Fact Sheet Covaxin; 2021. Available from: https://www.bharatbiotech.com/images/covaxin/covaxin-fact-sheet.pdf. [Last accessed on 2021 May 11].
7. Abhilash KPP, Mathiyalagan P, Krishnaraj VRK, Selvan S, Kanagarajan R, Reddy NP. Impact of prior vaccination with CovishieldTM and Covaxin® on mortality among symptomatic COVID-19 patients during the second wave of the pandemic in South India during April and May 2021: A cohort study. Vaccine 2022;40:2107-13.
8. Press Statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID-19 virus vaccine. Available from: https://pib.gov.in/Pressreleaseshare.aspx?PRID=1685761. [Last accessed on 2023, Mar 02].
9. Hause AM, Gee J, Baggs J, Abara WE, Marquez P, Thompson D, *et al.* COVID-19 vaccine safety in adolescents aged 12-17 years-United States, December 14, 2020-July 16, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1053-8.
10. Tiwari P, Kumar A, Kishore J, Saxena A, Ish P, Nath R. Safety profile of COVID-19 vaccination among adolescents in India-An initial experience. Epidem Int 2022;7:13-6.
11. Chen M, Yuan Y, Zhou Y, Deng Z, Zhao J, Feng F, *et al.* Safety of SARS-CoV-2 vaccines: A systematic review and meta-analysis of randomized controlled trials. Infect Dis Poverty 2021;10:94.