INDIAN ASSOCIATION OF EPIDEMIOLOGISTS

Epidemiology International
Volume 7, Issue 2 - 2022, Pg. No. 13-16
Peer Reviewed & Open Access Journal

Research Article

Safety Profile of COVID-19 Vaccination among Adolescents in India - An Initial Experience

Poornima Tiwari[1], Amit Kumar[2], Jugal Kishore[3], Anirudh Saxena[4], Pranav Ish[5], Ravindra Nath[6], SJH Adolescent Vaccination Working Group[7]

[1]Director Professor,[3]Director Professor and Head, [4]Resident, [6]Post-Graduate Resident, Department of Community Medicine, VMMC and Safdarjung Hospital, New Delhi, India.
[2]Senior Medical Officer, Department of Pediatrics, VMMC and Safdarjung Hospital, New Delhi, India.
[5]Assistant Professor, Department of Pulmonary and Critical Care Medicine, VMMC and Safdarjung Hospital, New Delhi, India.
[7]SJH Adolescent Vaccination Working Group.
DOI: https://doi.org/10.24321/2455.7048.202208

I N F O

Corresponding Author:
Ravindra Nath, Department of Community Medicine, VMMC and Safdarjung Hospital, New Delhi, India.
E-mail Id:
rnath24.9@gmail.com
Orcid Id:
https://orcid.org/0000-0001-5082-935X
How to cite this article:
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(2):13-16.

Date of Submission: 2022-06-03
Date of Acceptance: 2022-06-29

A B S T R A C T

Introduction: The government of India announced a nationwide mass vaccination drive for adolescents 15-17 years of age from 3rd January 2022. This announcement was considered a welcome measure by public health experts to increase vaccination coverage throughout the nation. This study was undertaken to understand the safety profile of COVID-19 vaccination among initial adolescent recipients.

Methodology: The first 500 such beneficiaries (adolescents of age 15-18 years) who received COVAXIN were identified. All the vaccination beneficiaries were prospectively taken in the study. These children were telephonically called and assessed for AEFI occurring up to 2 weeks.

Results: Among the first 500 beneficiaries vaccinated over the first week of the vaccination drive, 68 (only 13.6%) subjects developed an AEFI. These AEFI were all after the first dose of the vaccine.

Conclusion: Our initial experience is that COVAXIN is a relatively safe vaccine in adolescents with the majority of AEFI being mild. It is necessary for documentation and knowledge of the AEFI profile as this will help decrease vaccine hesitancy and promote acceptance.

Keywords: COVID-19, COVAXIN, Adolscent

Introduction

Coronavirus disease (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused a global pandemic over the last nearly years, with countries and global health organizations constantly trying to come up with treatment and prevention strategies to combat this disease. With the development of various COVID-19 vaccines throughout the world, a new tool was added to our armoury in the fight against this deadly disease.

The Government of India launched a nationwide vaccination drive for adults in a phased manner from 16th January 2021. Adverse Events Following Immunization (AEFI) reports in adults were minor[1] and thus, gradually the acceptance for vaccines increased with over 80% of eligible adult beneficiaries vaccinated with the 1st and over 50% with 2nd dose of COVID-19 vaccine i.e., complete vaccination. In October 2021, the Subject Experts Committee of the country's apex drug regulatory organization Central Drugs

Standard Control Organisation had recommended granting Emergency Use Authorisation (EUA) to Bharat Biotech's COVAXIN (an inactivated vaccine) for the age group 2-18 years. This was based on a phase 2/3 open-label, multi-centre study among 2-18 years old children which showed efficacy and safety of COVAXIN.[2] This study found all minor AEFI with fever being the most common (5%) among the 176 children of age group 12-18 years. Following this, the government of India announced a nationwide mass vaccination drive for adolescents 15-18 years of age from 3rd January 2022.[3] This announcement was considered a welcome measure by public health experts to increase vaccination coverage throughout the nation. However, it is imperative to evaluate the safety of the vaccination in adolescent age-group prospectively in the real-world scenario in India. Globally, mRNA vaccines in adolescents are in use after initial phase 2/3 trial showing safety with injection site pain, headache and fatigue being the most commonly reported side effects.[4] Despite subsequent reports of myocarditis,[5] the recommendation for the use of these vaccines was continued due to favourable risk-benefit ratio.[6] However, such AEFI occurrence re-emphasise on the need for caution and strict vigilance for all vaccination, especially when launched for a naïve population on a nationwide or global scale.

An AEFI is defined as any untoward medical occurrence that follows immunization, not necessarily having a causal relationship with the vaccine. AEFI is reported as minor, severe, or serious. Minor AEFI are minor reactions which are common, self-limiting, e.g., fever, irritability, pain and swelling at injection site, malaise, etc. Severe AEFI are non-hospitalized cases with increased severity which can be disabling, e.g., non-hospitalized cases of anaphylaxis that have recovered, high fever (>102° F), hypotonic hyporesponsive episodes, sepsis, etc. Serious AEFI includes deaths, hospitalizations, clusters, disability, media reports, community or parental concern following vaccination.[7]

Methods

In our tertiary care centre, vaccination for adolescents started on 3rd January 2022, i.e., the same day as it was launched nationwide. Registrations for vaccination were made open online prior and walk-in-registrations were also allowed. The first 500 such beneficiaries (adolescents of age 15-18 years) who received COVAXIN were identified. Vaccination was done after verifying identity card of the adolescent where even school card was accepted. There was no requirement of fasting or any special instruction for vaccination for COVID-19. Vaccination was given in non-dominant arm intra-muscularly by a trained nurse. They were observed for 30 minutes at the vaccination site for any anaphylaxis or immediate AEFI. All the vaccination beneficiaries were prospectively taken in the study. Written informed consent was taken from the participants and the parents for the study. These children were telephonically called and assessed for AEFI occurring up to 2 weeks. Institutional ethical clearance was obtained for the study vide no. S. No. IEC/VMMC/SJH/Project/2021-03/CC-136.

Result

At the authors' current centre, among the first 500 beneficiaries vaccinated over first week of the vaccination drive, 68 (only 13.6%) subjects developed an AEFI. These AEFI were all after the first dose of vaccine. The profile of the vaccinated people and the Adverse Events Following Immunization (AEFI) revealed a relatively safe vaccine (Table 1). Among these 68 adolescents, 24 were males. Nearly 85% (59 of 68 cases) were reported on day 1 after vaccination, among which 2 were within 10 minutes of vaccination. Most (67 of 68 cases) were minor reported AEFI treated with paracetamol (45 of 68) or even verbal reassurance (25 of 68), with none of the cases requiring hospitalisation. The most common symptoms were pain at injection site (33 cases) and fever (27 cases). The recovery from the minor AEFI was within 1-3 days in most (65 out

Table 1.Adverse Event following Immunization with COVAXIN among first 500 Adolescent Beneficiaries

Total (n=68)	Pain at the injection site (n=33)	Fever (n=27)	Body aches (n=8)	Swelling of Arm (n=3)	Shivering, Itching, Headache, Anxiety (n=1)	Chest Pain (n=1)
Male (24)	12	10	3	2	0	1
Treatment	Tablet Paracetamol (3), reassurance (9)	Tablet Paracetamol (9)	Tablet Paracetamol (1), reassurance (2)	Tablet Paracetamol (2)	-	Tablet Diclofenac
Female (44)	21	17	5	1	1	0
Treatment	Tablet Paracetamol (10), reassurance (11)	Tablet Paracetamol (17)	Tablet Paracetamol (2), reassurance (3)	Tablet Paracetamol	Parenteral Dexamethasone, Oxygen support for 30 minutes	-

ISSN: 2455-7048
DOI: https://doi.org/10.24321/2455.7048.202208

of 67 mild AEFI) whereas two patients had persistent fever for 4 and 10 days which eventually resolved with symptomatic therapy. Only one patient developed an acute reaction (Severe AEFI) after vaccination requiring oxygen support and parenteral steroid, but she also recovered within thirty minutes.

Discussion

In the launch of vaccination drive in India, there has been apprehension regarding safety and efficacy. Similar doubts were raised when nationwide vaccination drive was started for adolescents in 2022 due to experience showing relatively lesser infections and fewer symptoms of COVID-19 among children.[8] Multisystem inflammatory syndrome in children (MIS-C) has also been a concern in COVID-19 infection among children. A similar MIS-V (post vaccination)[9] is theoretically a possibility with vaccination being launched for children.

However, vaccines which show a good safety profile, subsequent efficacy in preventing COVID-19, in preventing severe forms of COVID-19 and help reduce transmission can serve as the best weapon for control of this ongoing pandemic. Schools and colleges have been physically shut in India for the last 2 years and vaccination in children along with COVID-19 appropriate behaviours may pave for the reopening of the same in coming times. Thus, there is a need to expand the vaccination drive across children with strict monitoring for AEFI.

A recent meta-analysis of COVID-19 vaccines globally has shown that inactivated vaccines are the safest with minimum AEFI as compared to other vaccine candidates. Over seventy thousand patient data was analysed and it was concluded that risk ratios (RR) of AEFI for inactivated vaccine, viral-vectored vaccine and mRNA vaccine were 1.34, 1.65 and 2.01.[10] However, this analysis included all age groups and such data for adolescents is lacking due to recent approval and launch of vaccination drive. This initial data elicits that COVAXIN in adolescents majorly lead to minor AEFI with a single case of severe AEFI which was managed conservatively and did not require any admission or lead to any long-term sequalae.

Limitations

A major limitation of the study was that only AEFI following first dose of COVAXIN could be recorded as the second dose is administered 28 days apart as per national guidelines. It was a single-centre initial data, which eventually needs follow-up with safety and efficacy evaluation after the complete vaccination.

SJH Adolescent Vaccination Working Group

The authors are thankful to Deepak Pandey (Resident, Department of Pharmacology), Nitesh Gupta (Assistant Professor, Department of Pulmonary and Critical Care Medicine), Shilpee Kumar (Professor, Department of Microbiology), Arshdeep Kaur (Senior Resident, Department of Pathology), Neeraj Kumar Gupta (Professor and Head, Department of Pulmonary and Critical Care Medicine), Rohit Kumar (Assistant Professor, Department of Pulmonary and Critical Care Medicine), Manu Madan (Assistant Professor, Department of Pulmonary and Critical Care Medicine), AJ Mahendran (Assistant Professor, Department of Pulmonary and Critical Care Medicine), RK Srivastava (Professor, Department of Plastic Surgery and Additional Medical Superintendent) of VMMC and Safdarjung Hospital, New Delhi, India for their support during the study and giving their valuable suggestion.

Conclusion

To conclude, our initial experience is that COVAXIN is a relatively safe vaccine in adolescents with majority of AEFI being mild. It is necessary for documentation and knowledge of the AEFI profile as this will help decrease vaccine hesitancy and promote acceptance in the form of an informed choice among the medical community and community at large including adolescents, especially in the era of emerging COVID-19 variants.[11,12] However, as there was a severe AEFI reported, it cannot be over-emphasized to maintain vigilance for any AEFI and carry out diligent monitoring of any symptom that the vaccine beneficiary may present with.

Financial Support: None

Conflicts of Interest: None

References

1. Srivastava RK, Ish P, Covid-Vaccination Group S. The initial experience of COVID-19 vaccination from a tertiary care centre of India. Monaldi Arch Chest Dis. 2021 Mar;91(4). [PubMed] [Google Scholar]
2. Vadrevu KM, Reddy S, Jogdand H, Ganneru B, Mirza N, Tripathy VN, Singh C, Khalatkar V, Prasanth S, Rai S, Ella R, Blackwelder W, Prasad S, Ella K. Immunogenicity and safety of an inactivated SARS-CoV-2 vaccine (BBV152) in children from 2 to 18 years of age: an open-label, age-de-escalation phase 2/3 study. Lancet Infect Dis. 2022 Sep;22(9):1303-12. [PubMed] [Google Scholar]
3. Covaxin receives approval for emergency use in 12-18 years old children. Available from: https://www.livemint.com/science/health/covaxin-receives-approval-for-emergency-use-in-12-18-years-old-children-11640480429321.html. Last accessed on 18 Jan 2022.
4. Ali K, Berman G, Zhou H, Deng W, Faughnan V, Coronado-Voges M, Ding B, Dooley J, Girard B, Hillebrand W, Pajon R, Miller JM, Leav B, McPhee R. Evaluation of mRNA-1273 SARS-CoV-2 vaccine in

adolescents. N Engl J Med. 2021 Dec;385(24):2241-51. [PubMed] [Google Scholar]
5. Kwan MYW, Chua GT, Chow CB, Tsao SSL, To KKW, Yuen KY, Lau YL, Ip P. mRNA COVID vaccine and myocarditis in adolescents. Hong Kong Med J. 2021 Oct;27(5):326-7. [PubMed] [Google Scholar]
6. Luxi N, Giovanazzi A, Capuano A, Crisafulli S, Cutroneo PM, Fantini MP, Ferrajolo C, Moretti U, Poluzzi E, Raschi E, Ravaldi C, Reno C, Tuccori M, Vannacci A, Zanoni G, Trifirò G; Ilmiovaccino COVID19 collaborating group. COVID-19 vaccination in pregnancy, paediatrics, immunocompromised patients and persons with history of allergy or prior SARS-CoV-2 Infection: Overview of current recommendations and pre- and post-marketing evidence for vaccine efficacy and safety. Drug Saf. 2021 Dec;44(12):1247-69. [PubMed] [Google Scholar]
7. WHO Classification of AEFIS. Accessed: 22 February 2021. Available from: https://vaccine-safety-training.org/classification-of-aefis.html. Last accessed on 18 Jan 2022.
8. Gupta S, Malhotra N, Gupta N, Agrawal S, Ish P. The curious case of coronavirus disease 2019 (COVID-19) in children. J Pediatr. 2020 Jul;222:258-9. [PubMed] [Google Scholar]
9. Iyengar KP, Nune A, Ish P, Botchu R, Shashidhara MK, Jain VK. Multisystem inflammatory syndrome after SARS-CoV-2 vaccination (MIS-V), to interpret with caution. Postgrad Med J. 2021 Aug;postgradmedj-2021-140869. [PubMed] [Google Scholar]
10. Chen M, Yuan Y, Zhou Y, Deng Z, Zhao J, Feng F, Zou H, Sun C. Safety of SARS-CoV-2 vaccines: a systematic review and meta-analysis of randomized controlled trials. Infect Dis Poverty. 2021 Jul;10(1):94. [PubMed] [Google Scholar]
11. Kunal S, Aditi, Gupta K, Ish P. COVID-19 variants in India: Potential role in second wave and impact on vaccination. Heart Lung. 2021 Nov-Dec;50(6):784-7. [PubMed] [Google Scholar]
12. Iyengar KP, Singh B, Vaishya R, Jain VK, Ish P. Should COVID-19 vaccination be made mandatory? Lung India. 2021 Jul-Aug;38(4):379-81. [PubMed] [Google Scholar]

ISSN: 2455-7048
DOI: https://doi.org/10.24321/2455.7048.202208