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Adverse Effects Following Immunization (AEFI) with Covaxin™ and Vaccine Reluctance among Adolescent Teenagers (14-18 Years) and Their Parents: A Descriptive Cross-Sectional Study in Delhi, India

Research Article
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Abstract

Objective: Mild adverse effects following immunization (AEFI) are inevitable and generally tolerable. The primary objective of study is to know the prevalence of AEFI with COVID-19 vaccine (Covaxin™) in age group between 14-18 years. Study also aimed to assess the factors responsible for vaccine hesitancy among adolescents and their parents.

Methodology: The prospective observational study was conducted using self structured validated Google form questionnaire among the Covaxin™ recipients (N= 262) between June 2022 to August 2022. IBM-SPSS version 22 Chicago, USA was used for data analysis.

Observations and Results: Around 50% and 26.3% participants reported at least one of the AEFI following first and second dose of Covaxin™ respectively. No severe life threatening adverse events were reported with any dose. The common AEFI were pain at the injection site (13%, 7.3%), fever (37%, 19.1%), and generalized body aches (27.1%, 11.1%) respectively following first and second dose. The prevalence of AEFI was higher following the first dose compared to the second dose except for hair fall (7.2%). Hair fall was found statistically significant ($p<0.05$). Maximum duration of persistence of AEFI was 3 days (8.7%, 4.5%)) following first and second dose respectively. The main factor responsible for vaccine hesitancy was concern over immediate side effects (8%).

Conclusion: Adverse effects following immunization (AEFI) with Covaxin™ are mild and self limiting in nature. Precaution needs to be taken in individuals with a history of allergy and co-morbidity. Vaccine hesitancy can be reduced by addressing safety concerns using social media, print media and television campaigns.

Keywords: Covid-19 vaccination; AEFI; Adolescents; Vaccine Hesitancy

Introduction

Immunization against Covid-19 is relatively new to curb Corona virus pandemic, which originated in Wuhan, China in 2019 [1]. A variety of vaccines against Covid-19 were developed using fast track technology globally and received emergency approvals for use (EAU) including first indigenous vaccine (Covaxin™) of India. Covaxin™ (BBV152,

whole virion inactivated vaccine) was the second Covid-19 specific vaccine preceded by Covishield™ (adenovirus vector vaccine) in India [2].

Initially Covishield™ developed by Serum Institute of India and Oxford-AstraZeneca became part of vaccination drive with effect from on January 16, 2021 in Health care professionals (HCPs) and front line workers (FLWs) [3]. On Jan 3, 2021, 'Covaxin™ '(BBV152, Bharat Biotech) got approval for emergency use in adult population by DCGI [4]. The safety data on AEFI with Covaxin™ is required to educate public, avoid misinformation, which will overcome vaccine hesitancy [5].

AEFI can be defined as any untoward medical occurrence following immunization which does not necessarily have a causal relationship to the vaccine [5]. Vaccination against Covid-19 is new and therefore needs to be continuous monitoring of AEFI through post marketing as surveillance [6]. The purpose of vaccine surveillance is to identify serious and unexpected AEFI, to reduce the associated morbidity and mortality, to educate public, avoid misinformation and to overcome vaccine hesitancy among eligible population [5,7-8].

Till date adequate studies have been done on AEFI by Covid-19 vaccines in adult and elderly populations. But safety data on AEFI using Covaxin™ among children and adolescents is relatively inadequate. This is to note that only Covaxin™, which is made available for vaccinating Indian population under 18 years of age at the time of study proposal submission. There is an urgent need to generate safety data on Covaxin™ among teenagers in India.

Vaccine reluctance/hesitancy has also been seen among adolescents and parents. Vaccine reluctance is hesitancy of people to accept vaccine that has been made safe and effective to protect them against an Infectious disease [9].

The present study is a descriptive cross-sectional study conducted on Indian adolescent teenagers (14-18 years of age), willing to participate in the study. The primary objective of the study is to estimate prevalence of AEFI with Covaxin™ among adolescents between ages 14-18 years. The secondary objective is to determine factors responsible for causing vaccine hesitancy among adolescents (14-18 years of age) and their parents during mass vaccination drive in India. Study has been conducted to bridge the gaps in literature pertaining to AEFI and vaccine reluctance, targeted exclusively to 14-18 years of age group. The data generated will be beneficial to all stakeholders and policy makers for opting right decisions for strengthening mental and physical wellbeing of teenagers, following re-opening of schools almost after 2 years in India. This could also prove useful for motivating, creating awareness and convincing parents and school going children about benefits of getting vaccinated, to avoid future lockdowns in schools for their positive physical and mental health.

Material and Methods

Study Type, Design and Sample Size

The present survey was an original research study with descriptive cross-sectional design using a self structured questionnaire. We used a sample size of 262 participants between age 14-18 years, with 10% adjustment for non responders/incomplete responses using the set formula.

Formula:

$$n = Z^2 p \frac{(1 - p)}{d^2}$$

Z= Confidence level (95%)
p= 20% (expected proportion from previous pilot studies)
d= 5% of true value (0.05)

Inclusion and Exclusion Criteria

Survey included adolescents (14-18 years), both male and female, who had received at least 1 dose of vaccine and belong to Delhi, India. Those who did not give consent and assent were excluded from study.

Time Frame of Study

The time frame for the study was 4-5 months. Sample collection was completed in 2 months from the date of receiving Ethical clearance and data analysis and STS-ICMR report writing was done in subsequent months.

Methodology

Questionnaire was validated for the content and face validation before conducting the study, by getting the questionnaire filled among 20 known participants. Questionnaire was edited and updated as per feedback by participants. These 20 participants were excluded from the main study. The final questionnaire was approved by Institutional Ethical Committee (IEC), Jamia Millia Islamia, and Delhi. (IEC approval no.2/6/390/JMI/IEC/2022).

A questionnaire link was generated and request message to fill the Google questionnaire form was shared in Whatsapp groups and emails among known and unknown contacts to achieve target sample size. Questionnaire with information regarding purpose of study and benefits of study was accessed by participants by clicking on the link shared as mentioned above. Participants were invited to participate

following acceptance to informed consent/assent as asked on first page of Google form. Each participant was asked multiple choice questions (MCQs) related to demography followed by MCQs related to CovaxinTM including reasons for any hesitancy/reluctance for vaccination at any time. Participants submitted their responses at last page after attempting questionnaire by clicking on 'Submit' icon. The acknowledgement was provided to each participant on submission of responses.

Responses received were saved in Google drive and downloaded in a Microsoft excel spread sheet which was later transferred to IBM-SPSS version 22 Chicago, USA for statistical analysis. Quality control of data collection was done and maintained by checking entries/ responses on daily basis by principal Investigator and co-investigator. Personal identity of participants was never revealed at any point of time of study conduct.

Data Analysis

Results from the data obtained were depicted in the form of tables, charts and graphs as percentages. IBM-SPSS version 22 Chicago, USA was used for analysis of results.

Results

Following are the observations and results depicted in the form of tables, pie charts and graphs as shown below.

The mean age of the participants (N=262) was 16 years (ranging from 14-18 years). Out of 262 participants, 7.3% reported history of pre-existing medical illness/co-morbidity. Around 100 (38.2%) participants had to take any form of analgesic drug before or after the vaccination. None of the participants reported any active clinical symptom at the time of vaccination (Table 1).

Demographic Variables	Observations	Prevalence, N= 262 (Percentage %)
Age	14 years	22 (8.4%)
	15 years	35 (13.4%)
	16 years	45 (17.2%)
	17 years	37 (14.1%)
	18 years	123 (46.9%)
Area of residence in Delhi	North Delhi	151 (57.6%)
	South Delhi	30 (11.5%)
	East Delhi	38 (14.5%)
	West Delhi	43 (16.4%)
Educational level	9th class	18 (6.9%)
	10th class	49 (18.7%)
	11th class	23 (8.8%)
	12th class	63 (24%)
	Undergraduate	94 (35.9%)
	Any other	15 (5.7%)
Pre-existing self-reported Co-morbidities (diabetes, hypertension, bronchial asthma, vitiligo, cutaneous allergy, polycystic ovarian disease PCOD, thyroid dysfunction, liver function abnormality, Recurrent infections, renal stones, migraine etc)	Present	19 (7.3%)
	Not present	243 (92.7%)
Analgesic, Antipyretic medicines use (pre or post vaccination)	Consumed	100 (38.2%)
	Not consumed	162 (61.8%)

Table I: Demographic details of participants.
N=Sample size

The AEFI symptoms following first and second dose of Covaxin™, experienced by the participants are shown in Figure 1. Out of 262 participants, 92 (35%) reported local symptoms of pain and swelling following first dose in contrast to 52 (20%) participants experiencing pain and swelling following second dose. The most common symptom was

fever in 97 (37%) and in 50, (19.1%) followed by generalized body ache in 71 (27.1%) and in 29, (11.1%) following first and second dose of vaccine respectively (Figure 1).

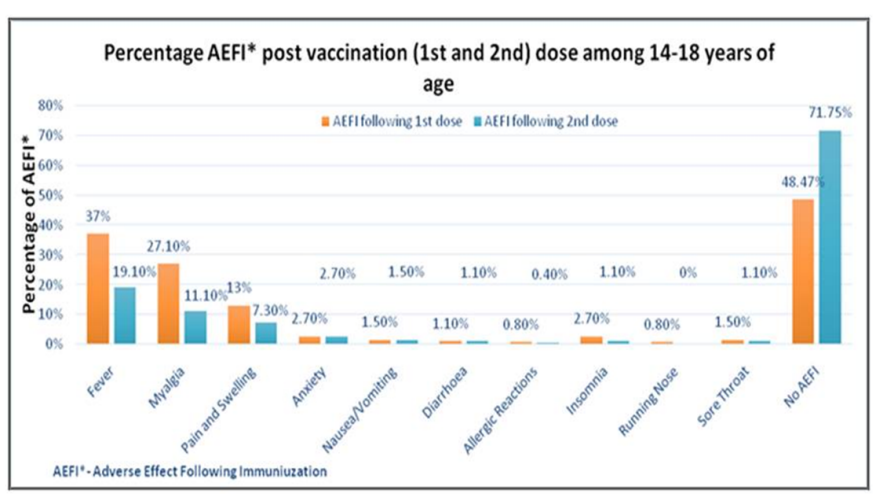

Figure 1: Percentage AEFI* post vaccination (first and second dose) among 14-18 years of age group.

Self-Reported AEFI by Participants

The self-reported AEFI were; Covid-19 positive status among 3 participants, (1.14%) and 2 participants (0.76%) following first and second dose respectively. Excess hair fall within 1 month of first and second dose of vaccination was reported by 5 participants (1.9%) and 19 participants, (7.2%) respectively. Hair fall after the second dose was found to be statistically significant at $p<0.05$. Altered taste sense was reported only after the first dose of Covid-19 vaccine among 6 participants (2.2%). Generalized fatigue and weakness was to the extent of 17 (6.4%) and 3 (1.14%) following first and second dose respectively (Figure 2).

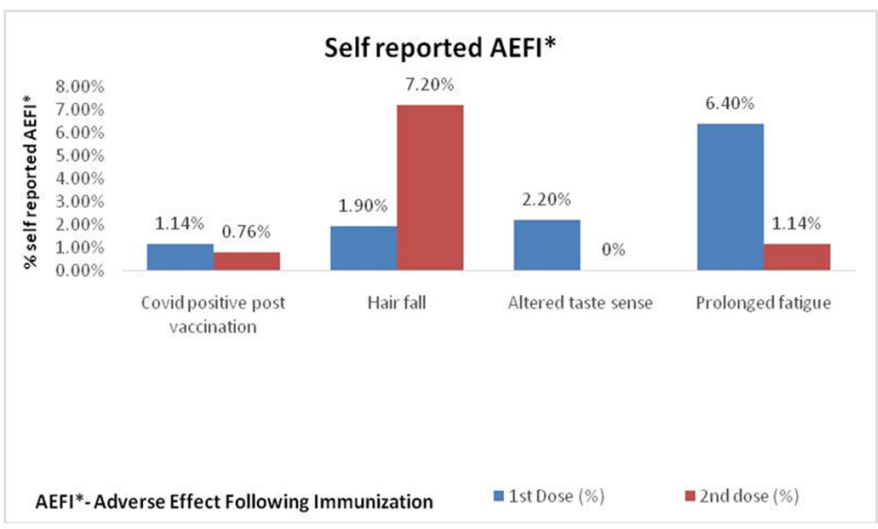

Figure 2: Self-reported AEFI by participants (14-18 years of age).

Duration of AEFI

Majority of the participants (22.3%) experienced AEFI symptoms up to 2nd day and very few 4.9% beyond 3 days following first dose of Covid-19 vaccine. Only 2.1% of participants experienced AEFI symptoms beyond 3 days following vaccination with the 2nd dose. Overall duration of persistence of AEFI was lower following 2nd dose of

vaccination. A majority of the study participants reported complete recovery within 24 hours following the first and second dose of vaccine. Complete recovery was seen in all the study participants maximum by 12-14 days post vaccination (Figure 3).

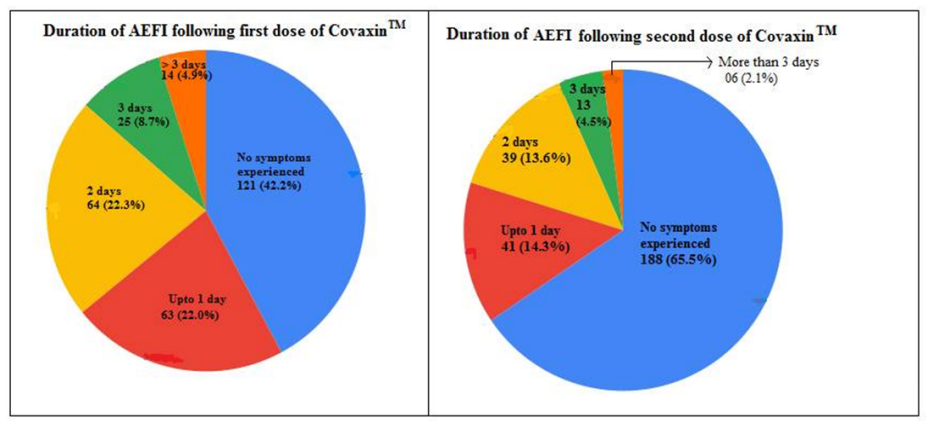

Figure 3: Duration of AEFI following first and second dose of Covid-19 vaccine (Covaxin™) among 14-18 years of age group.

There was statistically significant role of social media in 92 (35.1%), friends/relatives/family in 55 (21%) and television (news) in 16 (6.1%) in affecting the psychology of participants where $p<0.05$ found significant. Irrespective of completing the vaccine course (two shots), 52 (20%) of study participants were reluctant /hesitant to take vaccine shot pre or post first shot.

The rumors of adverse effects that led to vaccine hesitancy were irregular periods in 16(5%), heart attack in 12(4%), blood clot in 5(2%), bone growth retardation in 7(2%), genetic abnormality 11(4.2%), and sterility in 8 (3.1%) (Figure 4).

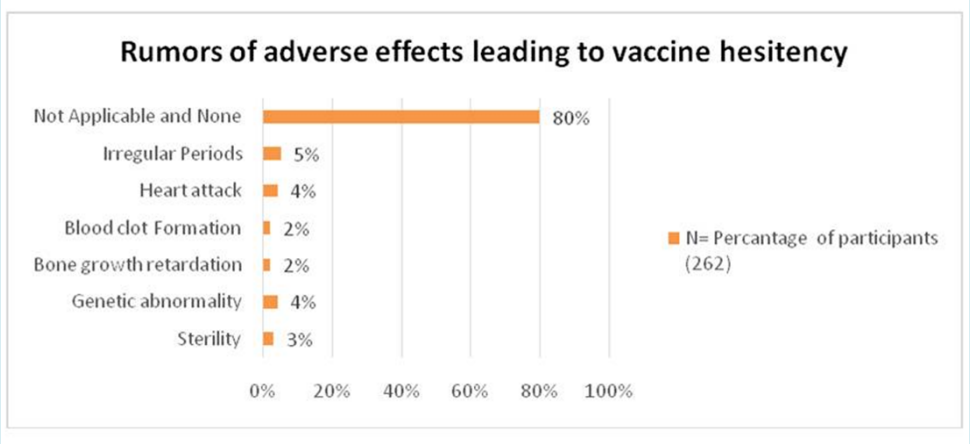

Figure 4: Nature of rumours around Covid-19 vaccination leading to Vaccine reluctance/hesitancy among 14-18 years age group and parents.

The factors which precipitated vaccine reluctance were unpleasant vaccination experience due to lack of confidence in vaccinators (nurse/technical staff at vaccination centre) and poor management at vaccine centre, 10(4%), lack of access to vaccine related information, 11(4.2%), apprehension about known and unknown immediate and delayed adverse effects post vaccination, 14(5.4%), doubtful vaccine effectiveness, 10(4%) (Figure 5).

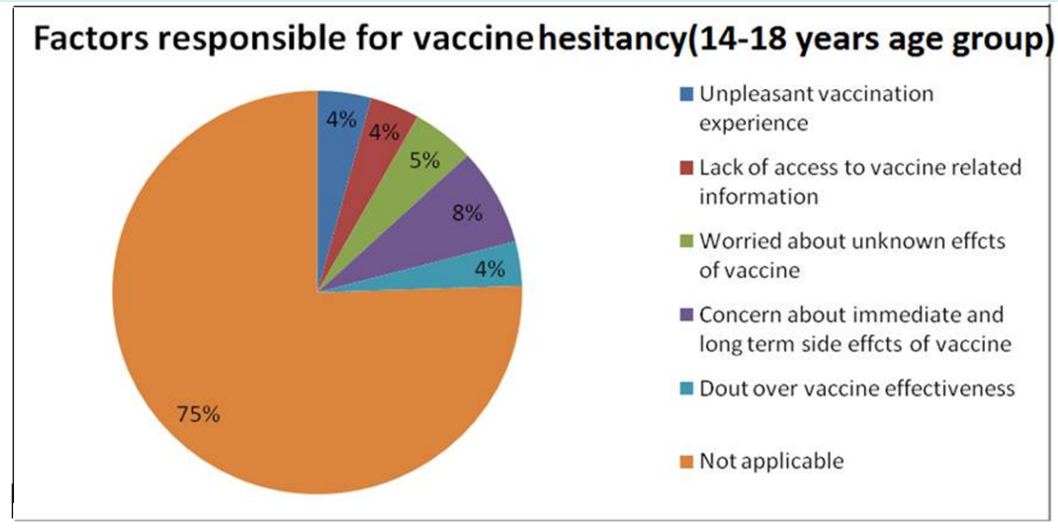

Figure 5: Factors potentiating Vaccine reluctance/hesitancy.

Statistical Analysis

Data Analysis was done using IBM-SPSS version 22 Chicago, USA.

Discussion

In India, only Covaxin™ was approved for vaccinating teenagers of more than 14 years till 18 years of age at the time of study proposal submission. Covaxin™ roll out for vaccinating adolescents was done on 10 January 2022 after undergoing through the rigorous, multistage testing process and phase III clinical trials to ensure it's the safety [10].

There are very limited studies on the AEFI with Covaxin™ on Indian population. We did not find any study on AEFI during literature search, for Covaxin™ among adolescent teenagers (14-18 years of age). The majority of the studies available in search literature were on Covishield™ (ChAdOx1) and BNT162b2.

In our study, the most common AEFI symptoms after the first and second dose were fever (37% & 19.1%) followed by generalized myalgia (27.1% & 11.1%) and local pain/ swelling at injection site (13% & 7.3%) and respectively. AEFI reported by subjects in our study are 2-3 times higher compared to available studies on Covaxin™. Houshmand B, et al in their study have shown similar adverse effects as found in our study except for very rare adverse effects in the form of diarrhea, arthralgia, nasal and oral bleeding with Covaxin™ in middle age adults [11]. The difference in response may be related to higher immune response seen in children and adolescents compared to adults and elderly.

In the study by Ella R, et al. (2021) in their phase III trials of Covaxin™, 12.5% adult participants experienced at least one AEFI. No serious adverse effects were reported by subjects except for Immune thrombocytopenia (1/5959) participants. Overall AEFI were lower following second dose (4.3%) compared to first dose (5.9%) of Covaxin™. Frequently reported local Adverse effects were local injection site pain, induration and erythema and common systemic adverse effects were headache, myalgia and mild to moderate grade fever. Around 9% subjects reported AEFI within 7 days post vaccination. Only 0.1% and 0.04% subjects reported immediate adverse effects within 30 minutes of vaccination following first and second dose respectively [12].

In contrast to study by Ella R et al, we in our study found that majority of subjects (22.3%) experienced adverse effects up to the duration of 24-48 hours following first and second dose of vaccine, the symptoms resolved after 2nd day post vaccination. Only 4.9% of subjects had AEFI symptoms beyond 72 hours (3 days) post first dose and 2.1% subjects had AEFI symptoms beyond 72 hours (3 days) post second dose of vaccine. In general, the AEFI were mild, self limiting and tolerable in most of the subjects following first in 127 (48.4%) and second dose in 181 (71.7%) respectively. AEFI symptoms were relatively more after first dose compared to second dose of Covaxin™. This finding was similar to a study conducted by Kaur, et al. (2021) in North India; they have reported 40% and 16.6% of the AEFI among first and second dose beneficiaries, respectively [13,14].

Study by Zhu F et al on AEFI of adenovirus vaccine, found a 69% overall AEFI incidence within 14 days post vaccination in subjects aging 6-17 years. Also overall AEFI in the vaccine

group was significantly higher than that in the placebo group (22%). In contrast to the RNA vaccine, fewer adverse events were reported in the adenovirus vector vaccine group following Dose 2 than after Dose 1. The most common adverse events with adenovirus vaccine were injection-site pain, fever, headache, and fatigue. Most adverse events were not serious and resolved in few days. Incidence of local and systemic adverse events, were higher in the vaccine group than in the placebo group [15].

The reported AEFI in our study was higher than that of the Phase 2 trial of Covaxin™. Ella et al reported 21% AEFI for BBV152 (Covaxin™) with 6 µg Algel IMDG and 17% with 3 µg Algel IMDG. However, Kamal, et al. (2021) reported a 57% rate of AEFI among the study participants. The difference may be due to the difference in vaccines [16,12].

Kaur, et al. (2021) in their study finding, shown majority of the AEFI to be among the younger age groups compared to elderly [13]. In our study 7.3% of participants had pre-existing medical conditions including diabetes, bronchial asthma, hypertension, cutaneous allergies, polycystic ovarian disease, liver and renal stones, thyroid dysfunction and migraine. Also hypersensitivity in the form of allergic rash within one week, were to the extent of 0.8% (2) and 0.4% (1) following first and second dose respectively.

In our study, few participants reported additional AEFI beyond study questionnaire. Self reported adverse effects in our study were positive Covid-19 test within 14 days of vaccination, excess hair fall, altered taste sensation, profound generalised weakness and fatigue. These AEFI symptoms were more following first dose compared to second dose except for hair fall (7.2% after second dose compared to 1.9% after first dose). Hair fall was significant with a $p < 0.05$ (Figure 2). Few studies have also reported similar adverse effects post vaccination [17,18].

We did not find any serious adverse events in our study. Kim, et al. (2021) in South Korea reported only one serious AEFI in the form of severe vomiting [19]. In our study, overall 38.2% of the participants had self-medicated with analgesic antipyretic (paracetamol) pre and post vaccination. Our finding was similar to a study by Shrestha, et al. (2021) [20]. In our study we also made an attempt to explore the factors responsible for vaccine hesitancy (Figure 5). Vaccine hesitancy rapidly rose due to growing number of cases who developed vaccine-related severe or permanent adverse events such as myocarditis, hypertension, acute respiratory failure, septic shock, sudden hearing loss, and thrombo-embolic events [21-23].

Our study present a well-documented safety profile of Covaxin™, even in co-morbid younger patients (14-18 years of age) may ameliorate the safety concerns associated with vaccine. Vaccination plays an important role in protecting the health of children. In the previous study by MacDonald NE, few determinants of vaccine hesitancy have been categorized as contextual influences (due to historic, political, environmental and health systems), individual and group influences arising due to personal/group perception of subject/subjects and vaccine-/vaccination-specific issues directly related to vaccine contents or vaccination process. We consider that these determinants are largely influenced by disseminating correct information about vaccine, AEFI reporting and causality assessment influences these determinants. Although vaccination should certainly not be made compulsory, it is important that parents make the right decision by allowing children to be vaccinated without hesitation [24].

Strengths and Limitations of Study

To our best of knowledge, present prospective observational study is the first ever study on AEFI of CovaxinTM and vaccine hesitancy among 14-18 years age, in India. Certain notable limitations in our study are probability of selection bias which could have risen due to incorporating subjects reporting more AEFI unintentionally.

Conclusion and Recommendations

Present study has indicated an acceptable safety profile of COVID-19 vaccine (Covaxin™) approved for 14-18 years of age group in India. The study will encourage children, adolescents and their parents to take vaccine shots to curb resurgence of pandemic. Overall, Covaxin™ is well tolerated and projects a good safety profile in young adolescents even with pre-existing co-morbidities. Since Covaxin™ is a killed (inactivated vaccine), it appears to be relatively safer compared to other available vaccines available in India. Monitoring and assessment of long-term adverse events needs to be done through active surveillance. There is a need to address safety concerns related to vaccine using Television, social media and print media. Adequate and valid explanation and preparation for expected adverse effects (AEs) is essential to promote widespread vaccination coverage.

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Conflict of Interest

None declared

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