

A study on Adverse events following COVID-19 immunization(AEFI), Vaccination Awareness and Preference among people visiting vaccination centre, Shivamogga Institute of Medical Sciences, Shivamogga, Karnataka.

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ABSTRACT

INTRODUCTION: Corona virus Disease is a fatal viral disease that continues to trouble many countries around the world. Immunization is one of the most effective and cost efficient initiatives ever, saving millions of lives every year. COVID-19 vaccines are considered to be of great importance in preventing and controlling the disease. This study aimed to estimate AEFI, COVID-19 vaccine awareness, preference among people visiting vaccination centre, SIMS, Shimoga. **OBJECTIVE:** 1. To estimate AEFI among people visiting vaccination centre, SIMS, Shimoga. 2. To estimate COVID-19 vaccine awareness and preference among people visiting vaccination centre, SIMS, Shimoga. **MATERIALS AND METHODS :** A prospective longitudinal study was conducted for a period of one month – July 2021. People visiting COVID vaccination centre, SIMS, Shimoga were included in the study. Considering AEFI to be 30% after pilot study, sample size calculated was 336. Data was collected from 373 participants. Ethical clearance was obtained by Institutional Ethics Committee. Oral consent was taken from each participant. Each participant is interviewed telephonically, and the relevant information was collected. The collected data was tabulated in Microsoft excel sheet. Analysis is done by using epiInfo software. Descriptive statistics like percentages, mean were used, and the results were tabulated. **RESULTS:** Incidence of AEFI reported from our study population was 36%. Majority of it was after first dose of vaccination (47%), and the most common complaint was pain (64%) at the site of injection. Covishield was the most preferred vaccine as the availability was good. Awareness regarding vaccine was mostly from the discussion among friends, family members (25%) and from the health care provider (22%). **CONCLUSION:** Most of the AEFI reported was minor. Acceptability of the vaccine will increase if more vaccine is made available and choices of different vaccine is given to the people. “Conducting awareness camps” regarding vaccination at the work places will increase

the vaccine acceptance as discussion among friends and family members has major role in sharing information

Key words : AEFI, COVID -19, Vaccination

Introduction :

Corona virus Disease is a fatal viral disease that continues to trouble many countries around the world. SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) is a new coronavirus strain that has spread across the world and become a major public health problem.¹ The World Health Organization (WHO) declared the COVID-19 outbreak as a pandemic on 11 March 2020.² Because of the pandemic, more than a third of the worldwide people was confined under lockdown or curfew. The Government of India also took steps toward controlling the pandemic by a nationwide lockdown from 25 March 2020, it had an impact on a variety of facets of people's lives, including their physical, social, emotional, and behavioural well-being.³ At the time of writing (30 August 2021), this pandemic had affected 223 countries, with over 4.3 million confirmed cases and 67,726 deaths recorded globally.⁴ Immunization is one of the most effective and cost-efficient initiatives ever, saving millions of lives every year.⁵ COVID-19 vaccines are of great importance for preventing and controlling the disease. Indian Government composed the National Expert Group on Vaccine Administration for COVID19 (NEGVAC) to look after all aspects of COVID19 vaccine introduction in India. COVISHIELD™ (AstraZeneca's vaccine manufactured by Serum Institute of India) and COVAXIN™ (manufactured by Bharat Biotech Limited) are two vaccines that have been approved by the Central Drugs Control Organization (CDSCO) in India for confined use in emergency situation.^{6,7,8} As a part of control measures against COVID-19, in India vaccines have been launched from 16 January 2021, In the first phase, health care workers including medical students were targeted for vaccination with either of the two vaccines approved for restricted emergency use. As of March 1, 2021, vaccination against COVID19 has been extended to people over 60 years of age and those with comorbidities between 45 and 59 years of age.⁹ Then, with effect from April 1, 2021 and May 1, 2021, all people in India between the ages of 45-59 and 18-44 are eligible to be vaccinated. Post-vaccination adverse event (AEFI) is any unpredictable medical event that occurs following immunization that does not necessarily have a causal relationship with vaccine use. The COVID19 Vaccine Operations Manual clearly outlines everything, including AEFI monitoring, reporting and management procedures.^{10,11} As per the operational guidelines, each beneficiary needs to be observed at the

immunization centre for a minimum of 30 min for AEFIs or adverse events (AEs) of special interest (AESIs),¹² as the Covid vaccines were given emergency approval during pandemic while the vaccine are in phase III trials. As there were no phase IV trials, follow up of beneficiaries for any AEFIs after vaccination is crucial to see for safety of the vaccine and this data will contribute to available data/information. This study aimed to estimate AEFI, COVID-19 vaccine awareness, preference among people visiting Vaccination Centre, SIMS, Shimoga.

OBJECTIVE:

1. To estimate AEFI among people visiting vaccination centre, SIMS, Shimoga.
2. To estimate COVID-19 vaccine awareness and preference among people visiting vaccination centre, SIMS, Shimoga.

MATERIALS AND METHODOLOGY:

Study design: The study design was of a prospective longitudinal study.

Study area: The study conducted at Covid vaccination centre, Shimoga institute of medical science (S.I.M.S), Shimoga

Study participants: People who visited Covid Vaccination Centre, SIMS, Shimoga.

Study period: The study was conducted for one month from July 2021

Sample size: Considering AEFI to be 30% after pilot study, sample size calculated was 336. On adding non-response rate of 10% on total sample, the size was made to 369. Data was collected from 373 participants.

Methodology of data collection: Ethical clearance was obtained by Institutional Ethics committee. Oral consent was taken from each participant. Each participant was interviewed telephonically, and the relevant information was collected.

Methodology of data analysis: The collected data was tabulated in Microsoft excel sheet. Analysis is done by using epiInfo software. Descriptive statistics like percentages, mean were used, and the results were tabulated.

RESULTS: In this study, total of 373 participants were included. Out of 373 participants, 210 (56%) were > 45 years age group and 163 were from 18-45 years(44%) age group (Figure 1). Approximately females 55% are more compare to males (Table 1).Incidence of AEFI reported was 36% of study population (Figure 2). Majority of it was after both the doses of vaccination

47% (Figure 3), time of occurrence was within 3 days 93% (Figure 4) and the most common complaint was pain 64% at the site of injection (Figure 5). Covishield 71% was the most preferred vaccine as the availability was good (Figure 6). Awareness regarding vaccine was mostly from the discussion among friends, family members (25%) and from the health care provider (22%) (Figure 7).

GENDER	FREQUENCY	PERCENTAGE
MALE	167	45%
FEMALE	206	55%
TOTAL	373	100%

Table 1: Gender distribution of the participants (n = 373)

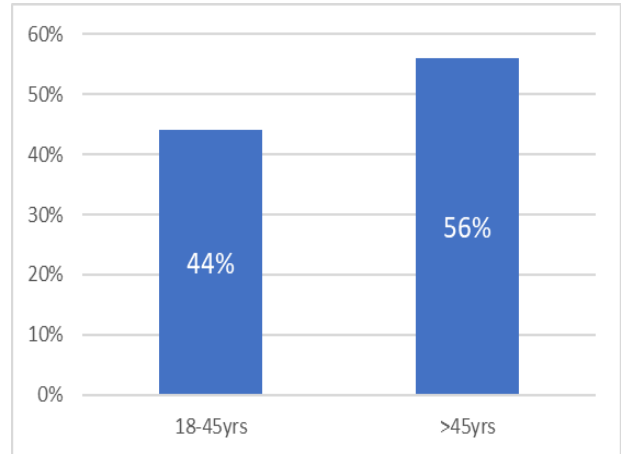


Fig 1: Age distribution (in percentage) of the participants (n = 373)

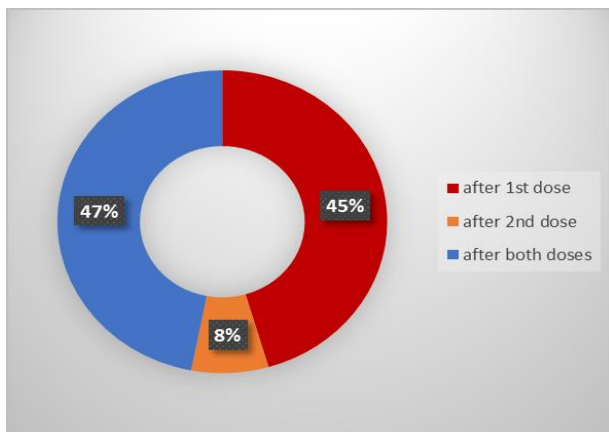


Fig 3: AEFI following vaccination dose

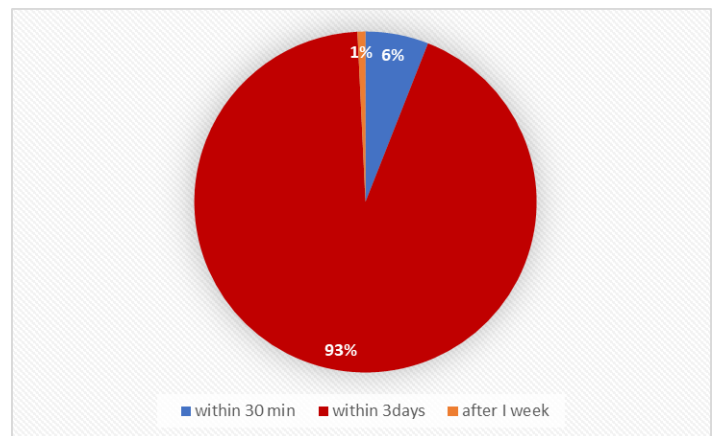


Fig 4 : Time of occurrence of AEFI

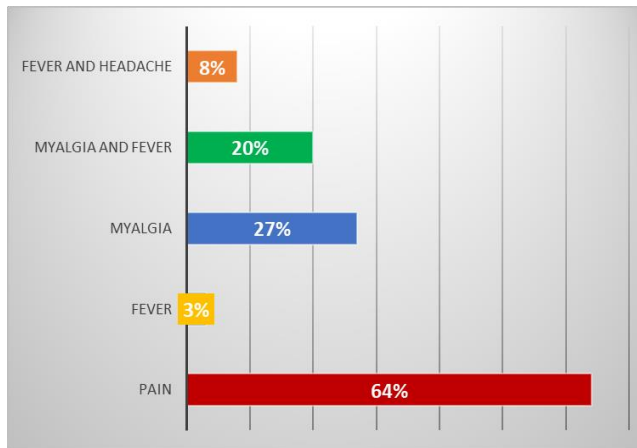


Fig 5: AEFI symptoms

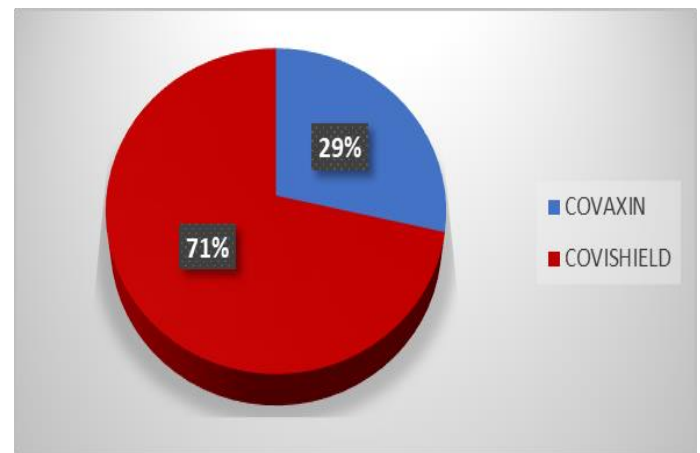


Fig 6 : Vaccine preference

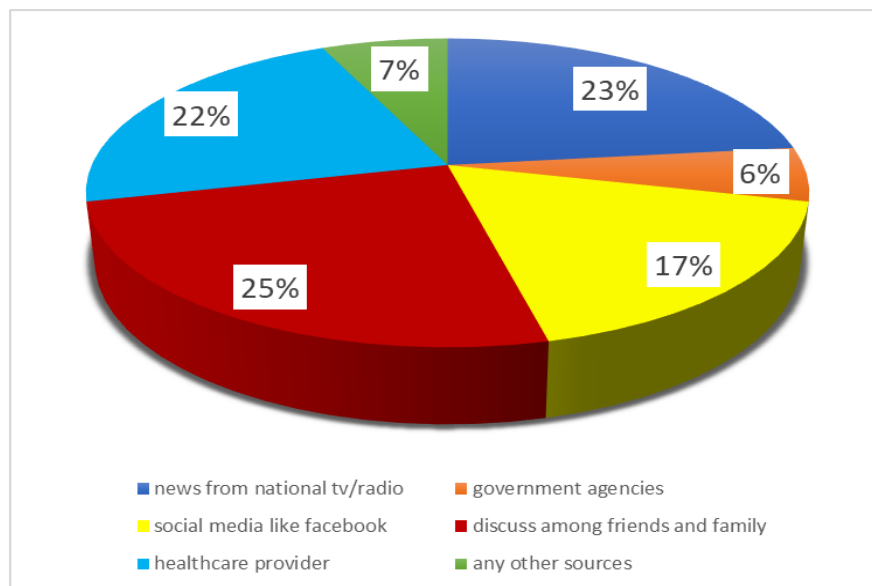


Fig 7: Source of information

DISCUSSION:

We observed an incidence rate of 36% of AEFIs among the study population, whereas the national incidence rate reported was 0.006%. This disparity in the incidence rate could be related to the fact that most vaccinators across the country prefer to vaccinate and educate their beneficiaries regarding AEFIs that are mild or severe. And health care workers /consumers may not spend their time to report any mild or moderate AEFIs, which were already known. Underreporting is one of the major concerns in the spontaneous reporting method of safety surveillance. But in our study, we followed vaccine recipients for a period of one month after vaccination for any of the AEFI occurrence.¹³

We found that 47% of participants reported AEFI following both the doses of vaccination. The percentage of AEFI occurred after first dose was 45% and after second dose it was 8%. The most common AEFI occurred was pain at the site of injection (64%) followed by myalgia(27%), myalgia and fever (20%), fever and headache (8%) and fever alone (3%). AEFI was more among older age group (>45 years) 38.5% compared to younger age group (18-44 years) 31.9%. All AEFI reported were mild to moderate in nature, and there were no severe AEFI reported during our study period. A study conducted by Jeon M et.al in Korea for a period of 14 days during March 2021 found that the AEFIs reported most commonly after the first dose of the ChAdOx1 nCoV19 vaccine. They were fatigue, malaise, tenderness, and pain at rest at the injection site. The severity of most AEFIs was mild-to-moderate, and the severity and number of AEFIs were less in the older age group. There were no serious events requiring hospitalization, and most AEFIs improved within a few days.¹⁴

The incidence rate of AEFIs reported within 30 min was 6%. A study conducted by Chetak Kadabasal Basavaraja et al for a period of 3 months from January to April 2021 showed incidence rate of AEFIs reported within 30 min was 0.66%. This could be due to less number of sample size and study population included only beneficiaries visiting SIMS vaccination centre.¹⁵

In the present study most of the study participants preferred Covishield (71%) over Covaxin (29%). Similarly in a study conducted by Jyoti Jain et al, for a period of one and half months from 2 February to 7 March 2021, students thought it was necessary to pick between available COVID 19 vaccines among two available vaccines, Covishield was chosen over the other vaccine. Covaxin acceptance was shown to be low in general, and considerably lower among individuals who were hesitant to receive the vaccination. The acceptance of the vaccine has increased presently with the increase in the available information regarding efficacy and safety.¹⁶

It was also observed in the present study that the main source of information collected regarding vaccination and its awareness was through discussion among family and friends (25%), news from television and radio (23%), from health care providers (22%) and social media like Facebook, WhatsApp and Instagram(17%). A study conducted by Jyoti Jain et al showed the internet and social media are becoming more essential as sources of healthrelated information for medical students. Any future intervention aimed at reducing vaccine apprehension among students should take into consideration this shift in information sources. The use of social media

as a source of information was much higher among vaccine-hesitant students, which could be explained by anti-vaccination groups spreading unconfirmed and potentially misleading information.¹⁶

LIMITATIONS: Our study was conducted at SIMS vaccination centre alone, further studies with larger sample size and study area to be involved. This could affect the generalisability of our study results. Participants were followed up for a period of one month in our study, further studies are required to look for the long term adverse effects following vaccination.

CONCLUSION:

Most of the AEFI's reported were minor in nature. Acceptability of the vaccine would have been increased if more vaccine was made available and the choices of different vaccine was available to the people. "Conducting awareness camps" regarding vaccination at the workplaces will increase the vaccine acceptance as discussion among friends and family members has major role in sharing information. Door to door vaccination would be a most effective way for successful implementation.

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