

Vaccine hesitancy after taking the first dose of COVID-19 vaccine: A challenge for the COVID-19 vaccination program in India

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ABSTRACT

Background: Coronavirus disease 2019 (COVID-19) vaccination campaigns are trying to curb the pandemic by vaccinating as many individuals and as quickly as possible. The speed of immunization depends upon the availability of the vaccine and vaccine uptake by the communities, which in turn is related to vaccine hesitancy, the safety/efficacy profile of the vaccines, and adverse events following immunization (AEFI). **Objectives:** (i) To study the AEFI experienced by vaccine recipients and (ii) to assess the subjective effect of these AEFI on the vaccine recipients, that is, perceived disability and opinion regarding taking the vaccine's second dose. **Methods:** This was a cross-sectional study conducted at a tertiary care hospital where a questionnaire was distributed to the medical students who had taken at least one dose of a COVID-19 vaccine. **Results:** Out of 208 participants, more than three-quarters ($n = 169$, 81.2%) experienced AEFI symptoms within 12 hours of vaccination. The commonest symptoms were pain at the injection site ($n = 173$, 83.2%), body aches ($n = 91$, 43.8%), fever ($n = 88$, 42.3%), weakness ($n = 86$, 41.3%), and headache ($n = 72$, 34.6%). A majority of the participants reported complete recovery within 13-24 hours. Complete recovery was seen in all the study participants, and no serious event was seen. Twenty (10%) participants reported that they were not confident in taking the second dose of the vaccine. **Conclusions:** The disability perceived by the vaccine recipients should be taken into consideration in a vaccine with a multi-dose schedule. Pitfalls in alleviating the immunization-related anxiety should be identified and addressed.

Keywords: Adverse events following immunization, COVID-19 vaccine, perceived disability, vaccine acceptance, vaccine hesitancy

Introduction

Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was officially declared a global pandemic by the World Health Organization (WHO) on 11 March 2020.^[1] In response to this global health care challenge,

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a global effort to create a safe and effective vaccine saw vaccine development and emergency use authorizations in record times in an attempt to achieve herd immunity against SARS-CoV-2. India started its vaccination campaign in January 2021 with Covishield (ChAdOx1 nCoV-19 recombinant live attenuated vaccine by Serum Institute of India based on the AstraZeneca-Oxford vaccine) being the only vaccine having emergency use authorization,^[2] whereas the other vaccine was licensed for restricted use under the clinical trial mode.^[2,3]

In order to achieve herd immunity, it is necessary to vaccinate a substantial fraction of the population. This depends upon

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factors such as vaccine availability, infrastructure and manpower to vaccinate such a large population, and vaccine uptake by the public. The biggest challenge to the uptake of the vaccine by the public is contributed by vaccine hesitancy.^[4] WHO has identified three factors that contribute to vaccine hesitancy, that is, difficulty in accessing the vaccine, a perception that the vaccine is not required owing to an underestimation of the disease severity, and the lack of confidence in the vaccine or fear of the vaccine owing to apprehensions such as potential side effects of vaccination or vaccine-induced infection.^[5]

The side effects of the vaccination manifest in the form of adverse events following immunization (AEFI), which is defined as any untoward medical occurrence seen in a vaccine recipient following immunization and which does not necessarily have a causal relationship with the usage of vaccines.^[6] Apart from the vaccine safety and efficacy-related data made public by the regulatory authorities, clinical trials, and vaccine developers,^[7-11] a few studies have analyzed AEFI during the COVID-19 vaccination campaigns,^[12-14] whereas others studied the vaccine hesitancy to assess the expected vaccine uptake trends in the population.^[15-17]

There are limited data on the subjective effect of AEFI experienced after the first dose on the COVID-19 vaccine recipients. The present study was planned in January 2021 when the vaccination campaign started in India with health care workers (HCWs) and frontline workers (FLWs) being vaccinated in the first phase.^[18] The study was conducted with the following aims and objectives: (i) to study the AEFI experienced by vaccine recipients and (ii) to study the subjective effect of these AEFI on the vaccine recipients, that is, perceived disability and the confidence in taking the second dose of the vaccine.

Materials and Methods

The present study was a prospective, cross-sectional study conducted over a period of 2 months from March 2021 to April 2021 at a tertiary care hospital of North India after obtaining due ethical clearance from the Institute's ethics committee vide letter no. MC/IEC/2021/11. The study was a questionnaire-based study in which medical students of the institute, receiving the COVID-19 vaccine, were recruited as the study participants. Those who had received at least one dose of the vaccine and gave their written consent for participation were included in the study. Those who did not give consent to participate in the study were excluded.

The questionnaire was designed as per standard guidelines, involving open-ended as well as closed-ended questions,^[19] based on previously available literature. The questionnaire was divided into three sections. The first section gathered information about the basic profile of the study participants, namely, age, gender, date of vaccination, name of the vaccine administered, any illness at the time of vaccination, and prior medical history. No individual-identifiable sensitive information was used for data analysis.

The second section consisted of questions aimed at gathering information directly related to the adverse events experienced after vaccination. The list of AEFI included in the questionnaire was based on the COVID-19 AEFI list given on the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) website,^[20] WHO,^[21] and available literature.^[8-11] Factors related to AEFI included the following: type/symptom of AEFI experienced, time from vaccination to symptom onset, time from onset to recovery, type of management needed/done, and outcome. The AEFI experienced by the study participants were divided into two categories: mild and serious based on previous classification by the WHO.^[22] As per the classification, serious adverse events are the events that are life threatening or require in-patient hospitalization, thereby resulting in persistent or significant incapacity.

The final section consisted of questions related to perception of the study participants, that is, perceived disability to assess the subjective feeling of severity by individuals and their opinion regarding taking the second dose of the vaccine. For grading the perceived disability by the vaccine recipients, the grading included no disability (AEFI symptoms had no effect on the vaccine recipient's daily activity), mild disability (unable to perform heavy tasks that the study participants routinely undertook, such as exercising in the gym, running, playing outdoor sports, cycling, washing clothes manually, etc.), moderate disability (unable to perform ordinary tasks such as going to the market, attending college, etc.), or severe disability (vaccine recipients restricted themselves to bed for most of the duration of their symptoms).

The questionnaire was pre-tested by getting the form filled by a few test participants. Their recorded responses and experience of filling the form were assessed to validate the questionnaire. After pre-testing and validation, the questionnaire was distributed to the study participants and the filled forms were collected for analysis. The responses recorded were entered into Microsoft excel 2007. Statistical analysis was performed using SPSS version 23 (IBM Corporation, Armonk, New York, USA).

Results

A total of 208 participants were included in the study. The mean age of the participants was 20.6 years (range 17–26 years). Among the participants, 117 (56.2%) were males and the rest 91 (43.8%) were females. Two participants had a history of allergy to dust and pollens, whereas the rest of the participants had no significant medical history. None of the participants reported any active clinical symptom at the time of vaccination.

The AEFI symptoms experienced by the participants are shown in Table 1. Out of 208 participants, 205 (98.5%) reported at least one AEFI symptom, whereas three (1.5%) did not experience any symptoms. The most common symptom was pain at the site of injection ($n = 173$, 83.2%), followed by generalized body aches ($n = 91$, 43.8%), fever ($n = 88$, 42.3%), weakness ($n = 86$, 41.3%), and headache ($n = 72$, 34.6%).

Table 1: AEFI symptoms experienced by the study participants and their association with confidence in taking the second dose of the vaccine

AEFI	Number (n)	Confident (185)	Not confident (20)	P
Local AEFI				
Injection site - pain	173	155	18	0.46
Injection site - swelling	24	20	4	0.22
Injection site - stiffness in that limb	55	47	8	0.16
Injection site - weakness in that limb	35	29	6	0.10
Systemic AEFI				
Fever	88	79	9	0.84
Generalized body aches	91	81	10	0.59
Weakness	86	75	11	0.213
Headache	72	61	11	0.04*
Nausea	18	11	7	0.000013*
Vomiting	4	2	2	0.006*
Dizziness	29	23	6	0.03*
Breathing difficulty	2	0	2	-
Palpitations	4	2	2	0.006*
Loss of appetite	8	4	4	0.00009*
Sweating	21	14	7	0.0001*
Chills shivering	4	3	1	0.29

* $P < 0.05$ denotes significant

The time interval between vaccination and symptom onset is shown in Table 2. More than three quarters ($n = 169$, 81.2%) of the study participants experienced AEFI symptoms within 12 hours, whereas only one participant reported the onset of symptoms after 48 hours. All 205 participants who reported AEFI symptoms after vaccination undertook self-care at home, and none of the participants required hospital out-patient department visit or consultation, in-patient hospitalization, or emergency care, indicating that none of the participants suffered from any serious AEFI during the study. The time interval from vaccination to complete recovery is shown in Table 2. A majority of the study participants reported complete recovery between 13 and 24 hours, and more than 4/5th ($n = 170$, 81.7%) of the study participants recovered within 36 hours. Complete recovery was seen in all the study participants.

Out of the 205 participants who experienced symptoms, 137 (66.8%) did not perceive any disability. Thirty-three (16.1%) participants reported inability to do moderate to heavy tasks which they routinely undertook before vaccination such as exercise/working out and playing outdoor sports, etc.), whereas 26 (12.7%) participants reported inability to do ordinary day-to-day activities such as attending college, visiting the local market (s), etc., The remaining nine (4.4%) participants reported that they restricted themselves to bed for the duration they had symptoms.

The study participants were asked whether they felt confident in taking the second dose of the vaccine to complete their vaccination as per schedule. One-hundred-and-eighty-eight participants (90.4%) were confident of completing their vaccination by taking the second dose, whereas seven participants (3.4%) reported that they do not want to take the second dose owing to either an apprehension of experiencing a

similar degree ($n = 3$) of AEFI symptoms or an apprehension of experiencing greater symptoms ($n = 4$) than those experienced during the first dose. Thirteen (6.2%) participants were unsure whether they will take the second dose or not. This was attributed to apprehensions of facing a similar degree ($n = 8$) of symptoms or greater symptoms ($n = 1$) at the time of second dose. Four participants mentioned that they are not sure of the generation of adequate immune response after vaccination. The factors that showed significant association with the lack of confidence in taking the second dose were systemic AEFI symptoms such as headache ($P = 0.04$), nausea ($P < 0.001$), vomiting ($P = 0.006$), dizziness ($P = 0.03$), loss of appetite ($P < 0.001$), sweating ($P < 0.001$), and palpitations ($P = 0.006$) [Table 1]. Those participants in whom the symptoms appeared within six hours and those in whom the complete recovery from AEFI was seen in 49–72 hours after vaccination had a significant association with the lack of confidence in taking the second dose [Table 2].

Discussion

The COVID-19 vaccination program in India is one of the largest owing to its huge population, and COVID-19 vaccination AEFI surveillance committees have been created all the way up to the district levels across the country along with setting up of AEFI management centers at block levels.^[23]

The incidence of common AEFI observed in the present study was more as compared to the clinical trials of this vaccine,^[8-9,11,24] which can be attributed to the young age group in the present study. Jeon *et al.*^[12] had also observed that the ChAdOx1 nCoV-19 vaccine causes greater side effects in a younger population. A meta-analysis of the randomized controlled trials on safety of the SARS-CoV-2 vaccines has highlighted that vectored

Table 2: Parameters related to AEFI symptoms and their association with confidence in taking the second dose of the vaccine

	Number (n)	Confident (n=185)	Not confident (n=20)	P
Gender				
Male	117	107	10	0.72
Female	91	81	10	
Time from vaccination to onset of AEFI symptom (s)				
<1 hr	16	16	0	-
1-6 hr	71	60	11	0.04*
7-12 hr	82	74	8	1
13-24 hr	29	28	1	0.21
25-48 hr	6	6	0	-
>48 hr	1	1	0	-
Time from onset of AEFI symptom (s) to recovery				
<6 hr	31	31	0	-
7-12 hr	40	38	2	0.26
13-24 hr	62	55	7	0.63
25-36 hr	37	33	4	0.81
37-48 hr	13	12	1	0.79
49-72 hr	16	11	5	0.002*
>72 hr	6	5	1	0.56
Type of AEFI symptom (s) experienced				
Local AEFI only	48	46	2	0.13
Systemic AEFI with or without local AEFI	157	139	18	0.13

*P<0.05 denotes significant

vaccines have the highest incidence of AEFI among all the vaccine constructs such as mRNA vaccines, inactivated vaccines, and vectored/recombinant vaccines and people aged less than 55 years exhibit greater AEFI symptoms.^[24] In contrast, a study from southern India found significant AEFI in older age groups (>50 years).^[13]

A majority of the study participants in the present study reported AEFI symptoms within 12 hours of vaccination, which is slightly less than the time period in a study from Korea in which most AEFI were reported on day 1 (24–48 hours) of vaccination.^[12] The study from southern India reported most AEFI to present within 48 hours.^[13] A smaller interval between vaccination and AEFI symptom onset, that is, 1–6 hours, was found to have a significant association with hesitancy in taking the second dose of the vaccine in the present study. Vaccine recipients should be counseled regarding early appearance of AEFI symptoms that are usually mild and resolved within a day or two. Recent National AEFI committee report data from India show that 22 out of 88 serious AEFI cases reported were found to be related to immunization anxiety after causality assessment.^[25] Thus, a good pre- and post-vaccination support system is even more beneficial as it can also address immunization anxiety-related AEFI.

Another factor that was associated with hesitancy in taking the second dose of the vaccine was a perception of the vaccine recipient feeling moderate to severe disability as a result of AEFI symptoms experienced after the first dose of vaccine. The loss of confidence for vaccine uptake in such study participants was found to have a significant association with the presence of systemic AEFI symptoms, namely, headache, nausea, vomiting, dizziness, loss of appetite, sweating, and palpitations.

A study conducted during the early phase of the COVID-19 pandemic in June 2020 had reported that 74.5% people in India were willing to get vaccinated.^[26] An expedited development of the vaccine can induce fear regarding its safety profile,^[17,24] which coupled with the spread of misinformation has the potential to increase the vaccine hesitancy.^[27] People generally have a low tolerance to AEFI symptoms,^[22] and the vaccination experience of the medical students, being part of the first phase of vaccination, is important as their feedback to other people in their family and network can have a driving influence on them regarding the decision to take the vaccine.

The latest data provided by MoHFW, GoI, on 28 August 2021 show that 19.6% HCWs (2,031,472 out of 10,356,871) and 29.2% FLWs (5,357,104 out of 18,316,341) are currently inoculated with only one dose of the COVID-19 vaccine.^[28] This priority group has been eligible for the COVID-19 vaccine for more than 8 months now. The vaccine availability does not appear to be a causative factor in this gap between the first and second doses among HCWs and FLWs, considering the fact that around 263,103,851 doses have been given to the 18–44 year age group since the time they became eligible for the COVID-19 vaccine in the last phase of the campaign. Therefore, this gap in vaccination is attributable to either late acceptance of the vaccine or non-compliance with the second dose of the vaccine. The latest Government data show that the second dose is not taken by a large fraction of the population, despite 10 crore (100 million) people eligible for the same amid adequate stock of the vaccine, which can put the COVID-19 mitigation efforts at risk.^[29]

The second wave of COVID-19 put heavy burden on the Indian health care system and HCWs, causing stress, burnout,

and hospital-acquired COVID-19 infections.^[30] Addressing vaccine hesitancy and alleviating apprehensions regarding AEFI symptoms leading to a perception of heightened disability can go a long way in increasing vaccine uptake, thereby increasing the protection of the HCWs/FLWs along. This may, as mentioned above, benefit vaccine recipients by addressing anxiety-related AEFIs as well.^[23] The role of the primary care physicians and the primary health care set up is indispensable in this regard since they have access to the far-to-reach and rural areas where access to tertiary level health care is limited, thereby making high vaccination coverage an important aspect of reducing COVID-19 morbidity and mortality burden.

Key points and highlights

1. More than 75% study participants experienced systemic AEFI symptoms after one dose of the vaccine.
2. The presence of systemic AEFI symptoms such as nausea, headache, vomiting, dizziness, palpitations, loss of appetite, and sweating was associated with the lack of confidence in taking the second dose of the vaccine.
3. No serious AEFI was seen during the study, and all participants recovered completely, indicating a good safety profile of the vaccine.
4. The study highlights the importance to reassure vaccine recipients regarding the commonly seen systemic AEFI symptoms that generally last less than 72 hours, followed by a complete recovery.

Conclusions

The present study shows that the ChAdO × 1 nCoV-19 vaccine is safe and the systemic AEFI, although very common, are well tolerated and there was no incidence of serious adverse events in the present study. This study also highlights that the disability perceived by the vaccine recipients as a result of AEFI symptoms should be taken into consideration and campaigns to address this perception should be undertaken to ensure good compliance with the dosage schedule of a multi-dose vaccine.

Author contributions

Y.B. and P.C. were involved in study conception. Y.B., P.C., and N.B. were involved in study design and preparation of the data acquisition tools. Y.B., N.B., and P.S. did the literature search. P.C. and Y.B. conducted the study. Y.B. and P.C. prepared the manuscript. N.B. and P.S. did the proof reading and corrections of the manuscript. The manuscript has been read and approved by all the authors. All authors account for all aspects for the manuscript.

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Conflicts of interest

There are no conflicts of interest.

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