

Factors associated with development of adverse events after taking COVID-19 vaccine in a tribal state of India: Regression analysis

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ABSTRACT

Background: Coronavirus disease (COVID-19) vaccination becomes a crucial weapon in the pandemic's control. Two vaccines, Covishield and Covaxin, are approved in India to vaccinate against the virus. Hence, the present study was done to determine the factors associated with the development of adverse events after taking the COVID-19 vaccine in a tribal state of India. **Materials and Methods:** This was a cross-sectional analytical study. All persons who were willing to participate in our study and had received the first or second dose of the COVID-19 vaccine from January 1 to March 31, 2021, were included. We got 1497 complete responses via (free, web-based Google Docs Editors suite offered by google, Founders- Larry Page Sergey Brin. Menlo Park, California, United States). So our final sample size came out to be 1497 in which analysis was done. The data was compiled in MS excel sheets (Microsoft version 2013, Microsoft Corporation, Redmond, Washington, United States) and a template was generated which was further analyzed in SPSS version 20 (version 25.0; IBM Corp., Armonk, NY, USA). **Results:** The total number of respondents who participated in the surveillance of adverse events following immunization (AEFI) was 1497. Among them, a majority have taken the Covishield vaccine followed by Covaxin. The majority of participants were female of age group less than 30 years and above 18 years with a mean age of 33.63 ± 51.51 . The most common AEFI was pain at the site of injection, after the first and second dose followed by fever after the first and second dose within 24 h following immunization. **Conclusion:** We conclude that factors like the type of vaccine, gender, and participants who have allergies have a higher risk of presenting the adverse events after the COVID-19 vaccination.

Keywords: Adverse events, COVID-19, factors, regression analysis

Introduction

The World Health Organization named the coronavirus disease (COVID-19) a global pandemic on March 11, 2020.^[1] It was clear that preventive measures like social distancing and mask-wearing would limit the spread of the virus, that

pharmaceuticals would help patients recover, but that only a vaccine could help stop the epidemic's extraordinary economic and social havoc. As a result, the COVID-19 vaccination becomes a crucial weapon in the pandemic's control. Two vaccines, Covishield and Covaxin, are approved in India to vaccinate against the virus. COVID-19 vaccine was introduced in a phased manner based on the guidance from NEGVAC (National Expert Group on Vaccine Administration for COVID-19); with the first phase focusing on health care workers and frontline workers, the population at higher risk is now underway in the state, district, and block level.^[2] The Serum Institute of India, the world's largest vaccine

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Received: 04-03-2022

Revised: 22-05-2022

Accepted: 30-05-2022

Published: 31-10-2022

Access this article online

Quick Response Code:



Website:
www.jfmpc.com

DOI:
10.4103/jfmpc.jfmpc_519_22

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How to cite this article: Kujur M, Kiran KA, Nag AR, Soren SK, Kujur A. Factors associated with the development of adverse events after taking COVID-19 vaccine in a tribal state of India: Regression analysis. J Family Med Prim Care 2022;11:6260-7.

factory, is producing the Covishield, Oxford-AstraZeneca vaccine locally. It is made from a chimpanzee adenovirus that has been attenuated. A chimpanzee adenovirus has been engineered to be replication-deficient. International clinical studies of the Covishield vaccine revealed that, compared to half-dose administration, full-dose administration resulted in a 90% efficacy rate. Covaxin, on the other hand, is a government-backed homegrown vaccine manufactured by Bharat Biotech, a 24-year-old vaccine manufacturer. Because it is an inactivated vaccination, it is safe to inject into the body. Bharat Biotech employed a coronavirus sample isolated by the National Institute of Virology in India. These COVID-19 vaccines have a number of adverse effects that people should be aware of to reduce vaccine apprehension and urge individuals to get the vaccine. Tenderness, discomfort, warmth, redness, itching, swelling or bruising at the injection site, weariness, malaise, feeling feverish, headache, nausea, joint pain, myalgia, and severe allergic reaction are some of the side effects.^[3] More than one in 10 people may have common side effects.^[4] In Kaur *et al.*,^[5] adverse events following immunization (AEFIs) of grade 3 severity (Food and Drug Administration (FDA)) were documented in four subjects (0.5%). Males, the elderly, the obese, and those with excess visceral fat have all been demonstrated to have a higher chance of developing problems after contracting COVID-19.^[6] Differences in vaccine response may also be determined by sex, age, and co-morbidities.^[7] According to a recent study, COVID-19 vaccine side effects are the result of a short burst of type I interferon (IFN-I) production combined with the activation of an efficient immune response.^[8] As a result, side effects might differ significantly depending on the recipient's age and gender, with females experiencing more severe side effects than males and younger persons experiencing more severe side effects than the elderly.^[9] In the literature, there has been evidence of a link between (type A, type B, type O, or type AB) blood groups and the likelihood of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. However, there is very little research on any possible link between vaccination reactogenicity and ABO blood type.^[10,11] It was discovered that people with different ABO blood types had varying degrees of reactogenicity to immunization. It is important to increase awareness and relevance of the adverse events reported post-immunization.

Knowledge about the AEFI among the family care physicians becomes more important when new vaccines are introduced for the immunization, as assessment of AEFI is incomplete without understanding the context of adverse effects. Only fewer studies have looked into the relationship between ethnicity, weight status (underweight, normal weight, overweight, and obesity), and the severity of side effects. So, the purpose of this study is to find out the factors associated with the development of adverse events after taking the COVID-19 vaccine in a tribal state of India.

Materials and Methods

Study design

This was a cross-sectional analytical study. All persons who were willing to participate in our study and had received the first or

second dose of the COVID-19 vaccine during the period of January 1 to March 31, 2021, were included. At the time these data were collected, third or booster doses were not yet recommended, so data on booster doses were not collected. Ethical approval was taken from the institutional ethics committee (IEC letter no 237 dated 31/05/21) of Rajendra Institute of Medical Sciences, Ranchi.

Study settings

The study site was two urban government vaccination centers in the Ranchi district. After taking permission from the nodal officers of both the vaccination centers via a proper channel, we got the contact details every day during our study duration period.

Sampling technique and data collection tools

Consecutive sampling was done. Pretested semi-structured questionnaire in the form of Google Form was prepared by the study team for collecting data. In the first part of the Google Form, the purpose of the study and study details were given along with the consent, in which the next part of the questionnaire only proceeds after the participants agreed to participate. The Google Forms were sent through WhatsApp or email to all vaccinees on the first day, the third day, and after 1 week to know any local and systemic adverse events. Well-trained nurses administered the vaccine in the deltoid region. The health care workers of the selected centers were also informed about the study and were advised to monitor and document any adverse events occurring within 15–30 min of taking the vaccine. Persons who had a history of allergic reactions were monitored for at least 30 min. After monitoring, vaccinees were advised to report to the outpatient clinic of the department of infectious diseases (IDs) or the emergency room (ER) if the adverse events persisted. We got 1497 complete responses via Google Forms. So our final sample size came out to be 1497 in which analysis was done. We included basic information like demographic data, vaccine details, weight, height, both local and systemic adverse events, and blood group in the questionnaire.

Statistical analysis

The data was compiled in MS excel sheets (Microsoft version 2013, Microsoft Corporation, Redmond, Washington, United States) and the template was generated which was further analyzed in Statistical Package for Social Sciences (SPSS) version 20 (version 25.0; IBM Corp., Armonk, NY, USA). During primary analysis, data cleaning was done and was expressed in frequency and proportions. Mean and standard deviation were calculated for all continuous variables. For categorical variables, Pearson's Chi-square test was applied to determine the association, and further, binary logistic regression was used to determine the significant influences of various associated factors resulting in AEFI. A *P* value of less than 0.05 was considered statistically significant and a 95% confidence interval (CI) was also documented for assessing statistical significance in our present study.

Results

The total number of respondents who participated in the surveillance of AEFI was 1497. Among them, a majority have taken the Covishield vaccine followed by Covaxin. The majority of participants were having a mean age of 33.63 ± 51.51 . Mean height was found to be 163.29 ± 10.44 , mean body mass index (BMI) was found to be 24.02 ± 9.36 , and mean weight was found to be 64.08 ± 24.11 . The most common AEFI were body ache, headache, malaise, pain at the site of injection, and fever within 24 h following immunization [Figure 1].

Most adverse effects were mild, but studies reported approximately 50% to 90% of participants experienced some adverse effects. Type of vaccine, age, gender, weight, and participants who have allergies were found to be statistically associated with AEFI [Table 1].

Blood groups were not found to be significantly associated with AEFI after the first dose of the vaccine [Table 2]. On applying logistic regression, the presence of allergy was found to be 1.950 times associated with AEFI with 95% CI (1.379–2.757), and the type of vaccine was found to be 1.8 times associated with AEFI with 95% (1.408–2.322) and are found to be statistically significant [Table 3].

Type of vaccine, gender, weight, and participants who have allergies were found to be statistically associated with AEFI [Table 4]; B negative blood groups were found to have more AEFI that was found to be statistically significant [Table 5].

On applying logistic regression, the presence of allergy was found to be 1.9 times associated with AEFI with 95% CI (1.400–2.787) and the type of vaccine was found to be 1.8 times associated with AEFI with 95% (1.408–2.322) and are found to be statistically significant with the second dose of vaccine [Table 6].

Discussion

We studied the adverse events following COVID-19 vaccination on 1497 participants who will take either Covaxin or Covishield

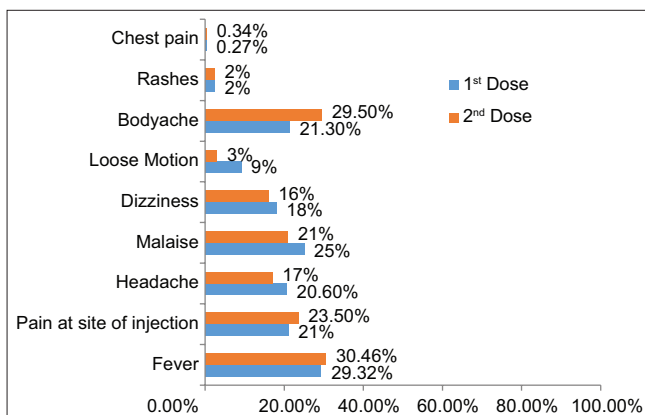


Figure 1: Showing the adverse events following immunization

Table 1: Showing the factors for adverse events following immunization after the first dose among the study participants (n=1497)

Variables	Adverse Event First Dose		Total	P
	Yes	No		
Type of vaccine				
Covaxin				
Count	129	445	574	
%	22.5%	77.5%	100.0%	
Covishield				
Count	310	613	923	<.001*
%	33.6%	66.4%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Age				
<30 years				
Count	270	665	935	0.639
%	28.9%	71.1%	100.0%	
>30 years				
Count	169	393	562	
%	30.1%	69.9%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Gender				
Male				
Count	167	528	695	<.001*
%	24.0%	76.0%	100.0%	
Female				
Count	272	530	802	
%	33.9%	66.1%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Ethnicity				
Tribal				
Count	129	292	421	0.488
%	30.6%	69.4%	100.0%	
Non-tribal				
Count	310	766	1076	
%	28.8%	71.2%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Weight				
<60 kg				
Count	214	490	704	0.394
%	30.4%	69.6%	100.0%	
>60 kg				
Count	225	568	793	
%	28.4%	71.6%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Height				
<160 cm				

Contd...

Table 1: Contd...

Variables	Adverse Event First Dose		Total	P
	Yes	No		
Count	322	741	1063	0.234
%	30.3%	69.7%	100.0%	
>160 cm				
Count	117	315	432	
%	27.1%	72.9%	100.0%	
Total				
Count	439	1056	1495	
%	29.4%	70.6%	100.0%	
BMI				
<25				
Count	277	717	994	0.047*
%	27.9%	72.1%	100.0%	
>25				
Count	162	341	503	
%	32.2%	67.8%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Allergy				
Yes				
Count	73	95	168	<.001*
%	43.5%	56.5%	100.0%	
No				
Count	366	963	1329	
%	27.5%	72.5%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	
Disease				
Yes				
Count	67	137	204	0.247
%	32.8%	67.2%	100.0%	
No				
Count	372	921	1293	
%	28.8%	71.2%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	

*Significant P value by Pearson's Chi-square

in this analytical cross-sectional study conducted in recipients of COVID immunization done in Jharkhand.

The vaccine recipients reported AEFI in 29.3% (1st dose) and 30.5% (2nd dosage), respectively, however in the Konda *et al.*^[12] research, 58.9% AEFI was documented regardless of doses. AEFI after vaccination was found to be higher in Covaxin than in Covishield, according to Basavaraja *et al.*,^[13] who reported AEFI after vaccination to be 4.32% and 0.57% in Covishield and Covaxin, respectively. The fact that the first groups to receive vaccination were health care professionals and frontline workers, who were mostly in this age group, may explain why AEFI is more common in people over 30 years old. Females experience/report more side effects due to a more powerful immune system and create higher antibody titers after being vaccinated in the

Table 2: Showing adverse events following immunization after the first dose among the study participants according to blood group (n=1497)

Variables	Adverse Event First Dose		Total	P
	Yes	No		
Blood Group				
A-ve				
Count	4	7	11	0.337
%	36.4%	63.6%	100.0%	
A+ve				
Count	91	197	288	
%	31.6%	68.4%	100.0%	
AB-ve				
Count	0	6	6	
%	0.0%	100.0%	100.0%	
AB+ve				
Count	32	92	124	
%	25.8%	74.2%	100.0%	
B-ve				
Count	4	19	23	
%	17.4%	82.6%	100.0%	
B+ve				
Count	161	408	569	
%	28.3%	71.7%	100.0%	
O-ve				
Count	8	14	22	
%	36.4%	63.6%	100.0%	
O+ve				
Count	139	315	454	
%	30.6%	69.4%	100.0%	
Total				
Count	439	1058	1497	
%	29.3%	70.7%	100.0%	

study by Konda *et al.*^[12] which is similar to the current study. In randomized clinical trials with COVID-19 vaccinations, the most prevalent AEFIs were pain and fever, with uncommon major adverse events. Injection site events (e.g., pain, redness, swelling) and systemic effects (e.g., fatigue, headache, muscle or joint pain) were described as the most common AEFIs.^[14-16]

Individuals with type A blood groups reported more severe reactogenicity, according to Check *et al.*,^[17] and there was a statistically significant link between the ABO blood group and reactogenicity. In our investigation, the B negative (B-ve) blood group was more sensitive to AEFI following the second dose of vaccination. As a result, a link between B negative blood grouping and vaccination reactogenicity appears to be plausible.

The most prevalent AEFI was minor pain at the injection site and fever within 24 h of receiving both doses of the vaccination. Basavaraja *et al.*^[13] had similar findings.^[18] Gender, allergy, and vaccine type were the most strongly related to the outcome of AEFI. Non-overweight recipients had a higher risk of experiencing some side effects from the COVID-19 vaccine (fever, vomiting, diarrhea, and chills), according to Iguacel *et al.*,^[19] but we only found an association between BMI and

Table 3: Binary logistic regression for adverse events following immunization for the first dose among the study participants (n=1497)

Variables	P	AOR	95% confidence interval	
			Lower	Upper
Gender				
Male			Reference	
Female	0.000	0.491	0.358	0.674
Ethnicity				
Tribal			Reference	
Non-tribal	0.918	0.986	0.760	1.280
Weight				
<60 kg			Reference	
>60 kg	0.340	0.870	0.655	1.157
Height				
<160 cm			Reference	
>160 cm	0.089	0.744	0.529	1.046
BMI				
<25			Reference	
>25	0.409	0.995	0.984	1.006
Age				
<30 years			Reference	
>30 years	0.724	1.049	0.804	1.368
Blood Group				
Rh + ve			Reference	
Rh-ve	0.617	0.987	0.936	1.040
Allergy				
No			Reference	
Yes	0.000	1.950	1.379	2.757
Disease				
No			Reference	
Yes	0.926	1.017	0.714	1.449
Type of vaccine				
Covaxin			Reference	
Covishield	0.000	1.808	1.408	2.322

AEFI in the second dose of vaccine, which could be due to the presence of some confounder.^[13,18]

The factors most strongly associated with the outcome of AEFI were gender, allergy, and type of vaccine. Iguacel *et al.*^[19] reported a higher risk of presenting some side effects against the COVID-19 vaccine (fever, vomiting, diarrhea, and chills) in non-overweight recipients but we only found an association between BMI and AEFI in the second dose of the vaccine, which could be due to the presence of some confounder. In other studies, 34.1% of the study group with co-morbidities suffered AEFIs, and there were modest changes between strata of BMI and co-morbidities, Menni *et al.*^[20] also reported that there was no obvious pattern across vaccinations and doses.

Our present study provides factual information about the benefits and risks of the vaccines that will help primary care physicians to increase awareness in the community about the vaccination as they are the first to be connected with them. This study also validates data from randomized clinical trials and government-sponsored surveillance to give an essential

Table 4: Showing adverse events following immunization following second dose among the study participants (n=1497)

Variables	Adverse Event Second Dose		Total	P
	Yes	No		
Type of vaccine				
Covaxin				
Count	235	339	574	
%	40.9%	59.1%	100.0%	
Covishield				
Count	221	702	923	
%	23.9%	76.1%	100.0%	<.001*
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Age				
<30 years				
Count	298	637	935	
%	31.9%	68.1%	100.0%	0.132
>30 years				
Count	158	404	562	
%	28.1%	71.9%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Gender				
Male				
Count	188	507	695	0.008*
%	27.1%	72.9%	100.0%	
Female				
Count	268	534	802	
%	33.4%	66.6%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Ethnicity				
Tribal				
Count	115	306	421	0.105
%	27.3%	72.7%	100.0%	
Non-tribal				
Count	341	735	1076	
%	31.7%	68.3%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Weight				
<60 kg				
Count	232	472	704	0.049*
%	33.0%	67.0%	100.0%	
>60 kg				
Count	224	569	793	
%	28.2%	71.8%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Height				
<160 cm				

Contd...

Table 4: Contd...

Variables	Adverse Event Second Dose		Total	P
	Yes	No		
Count	334	730	1064	0.239
%	31.4%	68.6%	100.0%	
>160 cm				
Count	122	311	433	
%	28.2%	71.8%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
BMI				
<25				0.476
Count	309	685	994	
%	31.1%	68.9%	100.0%	
>25				
Count	147	356	503	
%	29.2%	70.8%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Allergy				
Yes				0.009*
Count	61	107	168	
%	36.3%	63.7%	100.0%	
No				
Count	395	934	1329	
%	29.7%	70.3%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	
Disease				
Yes				0.215
Count	64	140	204	
%	31.4%	68.6%	100.0%	
No				
Count	392	901	1293	
%	30.3%	69.7%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	

*Significant P value by Pearson's Chi-square

report for the public concerning AEFI. Indeed, massive digital cross-sectional studies may provide a technique for post-market surveillance of new pharmaceuticals and devices that are simple, inexpensive, and independent.

Conclusion

In the present cross-sectional analytical study, serious COVID-19 vaccine adverse effects were rare, and overall adverse effects were similar to the government reports. This independent evaluation enabled the comparison of adverse effects between the two vaccines. Adverse effects were more common with Covishield after the first dose, but after the second dose, adverse effects were more common with Covaxin. In our study, we conclude that factors like the type of vaccine, gender, and participants

Table 5: Showing adverse events following immunization following the second dose among the study participants

	Adverse Event Second Dose		Total	P
	Yes	No		
Blood Group				
A-ve				0.015
Count	1	10	11	
%	9.1%	90.9%	100.0%	
A+ve				
Count	85	203	288	
%	29.5%	70.5%	100.0%	
AB-ve				
Count	1	5	6	
%	16.7%	83.3%	100.0%	
AB+ve				
Count	28	96	124	
%	22.6%	77.4%	100.0%	
B-ve				
Count	14	9	23	
%	60.9%	39.1%	100.0%	
B+ve				
Count	178	391	569	
%	31.3%	68.7%	100.0%	
O-ve				
Count	8	14	22	
%	36.4%	63.6%	100.0%	
O+ve				
Count	141	313	454	
%	31.1%	68.9%	100.0%	
Total				
Count	456	1041	1497	
%	30.5%	69.5%	100.0%	

who have allergies have a higher risk of presenting the adverse events after the COVID-19 vaccination.

Take home message

Most of the AEFI reported are mild and this public knowledge on the nature and type of side effects and the factors associated with greater odds of side effects would instill confidence among them. It will also overcome vaccine hesitancy among the public that will further enhance vaccine coverage, which is the need of the hour to end this pandemic.

Acknowledgements

We are grateful to all the participants, nodal persons, and staff of the vaccination center for their assistance in carrying out the study in Ranchi, Jharkhand, India.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Table 6: Binary logistic regression for adverse events following immunization for the second dose among the study participants (n=1497)

Variables	P	AOR	95% Confidence Interval	
			Lower	Upper
Gender				
Male			Reference	
Female	0.000	0.544	0.389	0.759
Weight				
<60 kg			Reference	
>60 kg	0.966	1.008	0.714	1.423
Height				
<160 cm			Reference	
>160 cm	0.041	0.694	0.489	0.986
Age				
<30 years			Reference	
>30 years	0.735	0.955	0.734	1.244
BMI				
<25			Reference	
>25	0.024	0.714	0.533	0.956
Ethnicity				
Tribal			Reference	
Non-tribal	0.917	1.014	0.782	1.314
Blood Group				
Rh+ve			Reference	
Rh-ve	0.577	0.985	0.936	1.037
Disease				
No			Reference	
Yes	0.931	0.985	0.692	1.400
Allergy				
No			Reference	
Yes	0.000	1.976	1.400	2.787
Type of vaccine				
Covaxin			Reference	
Covishield	0.000	1.808	1.408	2.322

Abbreviations

- COVID-19: Coronavirus disease.
- AEFI: Adverse events following immunization.
- NEGVAC: National Expert Group on Vaccine Administration for COVID-19.
- SARS-COV-2: Severe acute respiratory syndrome coronavirus 2.

Author's contribution

MK, KAK, AK, ARN and SKS conceived the study and were involved in planning and formulating the study. KAK and MK guided and supervised the data collection. AK helped in analyzing the data and provided inputs in preparation of manuscript. MK, AK, and ARN prepared and aligned the manuscript. All the authors read, critically discussed and approved the final manuscript.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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