

# COVID-19 Vaccination: An Observational Study on Postvaccination Infections and Side-effects

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## ABSTRACT

**Introduction:** Given the mortality and morbidity caused by the Coronavirus Disease 2019 (COVID-19) and the lack of therapeutic options, the need for vaccines has become inevitable. Knowledge about covid infection after vaccination and vaccine-related side-effects are essential to educate people and avoid myths about vaccination.

**Aim:** To evaluate the side-effects and incidence of COVID-19 in vaccinated people, and to compare the side-effect profile and postvaccination incidence of the infection.

**Materials and Methods:** This cross-sectional, email-based, survey was done from 1<sup>st</sup> July 2021 to 31<sup>st</sup> July 2021 at Guntur Medical College, Guntur, Andhra Pradesh, India. A total of 920 people were sent emails about the details and questionnaire of the study. All COVID-19 vaccinated and those who were more than 18 years of age were included in this study. A total of 506 subjects responded. Total 18 questions in the English language were there. The questions were about demographics, co-morbidities, the name of vaccine taken, postvaccination adverse effects, and COVID-19 positivity.

**Results:** Of the 506 vaccinated subjects, 287 (56.71%) received Covaxin<sup>®</sup>, 203 (40.11%) received Covishield<sup>®</sup> and 16 (3.16%) received other vaccines (BioNTech COVID-19 Vaccine-8, Sputnik V-3, Spikevax-5). The mean age of the participants was 37 years, and 45.2% (229) were females and 54.8% (277) were males. Side-effects were reported by 73.1%, and 65.17% of individuals after the first and second doses of Covaxin<sup>®</sup>, respectively, compared to 84.7% and 62.5% after Covishield<sup>®</sup>. Local pain and tiredness were the most common symptoms after Covaxin<sup>®</sup> and Covishield<sup>®</sup>.

**Conclusion:** Local pain and tiredness were the most common side-effects of Covaxin<sup>®</sup> and Covishield<sup>®</sup> vaccines. The number of participants in other vaccine groups was very minimal to study and compare their effects. Overall, the vaccines are safe and seem to show protection, although mild side-effects can be observed, which are usually non fatal. No difference in the incidence of infections was observed between vaccine groups.

**Keywords:** Coronavirus disease 2019, Pain, Fever, Covaxin<sup>®</sup>, Covishield<sup>®</sup>

## INTRODUCTION

The novel beta coronavirus Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) is believed to have emerged in December 2019 in Wuhan from bats. Crossing the species barrier, it entered human beings with the furtherance of infection through human-to-human transmission spreading rapidly throughout the world and declared by World Health Organization (WHO) as a pandemic in March 2020 [1]. Various clinical trials targeting therapeutic potential have been conducted bringing steroids into the picture as the only effective choice in hypoxic patients. At this point, development of a vaccine was the only choice to prevent the further spread of infection, decreasing the severity and mortality of the disease [2].

Almost 52 vaccine candidates entered the trials by the end of December 2020, and 13 vaccines were developed on four platforms [3]. The SARS-CoV-2-Delta (B.1.617.2) was identified in India in December 2020. The study by Twohig KA et al., showed higher hospital admission or emergency attendance rate for Delta variant patients in the unvaccinated population [4]. However, vaccination has shown to decrease infectivity in Delta variants rd in terms of effectiveness, only modest differences were found between Delta and Alpha variants after two doses of vaccination [5,6].

In India Covishield<sup>®</sup> and Covaxin<sup>®</sup> were available since January 2021, followed by Sputnik and, Janssen COVID-19 vaccine. Covaxin<sup>®</sup> uses a whole virion inactivated Vero cell platform developed by Bharat Biotech in association with ICMR and NIV. Covishield<sup>®</sup> is a non-replicating viral vector-based, ChAdOx1 nCoV-19 coronavirus recombinant vaccine developed by Oxford, and manufactured by the Serum Institute of India.

The cause for breakthrough infections can be due to one or more of the following, i.e., due to differences in viral profile from the previous infection, the type and duration of immune response for the previous infection, properties of the vaccine received and general health status of the host. Long COVID-19 as well as a multi-inflammatory syndrome in adolescents may be significantly reduced in breakthrough infections [7]. Amidst the reports of breakthrough infections, vaccination significantly reduced mortality and severity of the disease.

The most common side-effects of vaccines have been reported to be fever and myalgia. Two dreaded complications reported were Vaccine-Induced Thrombotic Thrombocytopenia (VITT), and myocarditis [8-12]. The present study aimed to evaluate the side-effects and incidence of COVID-19 in vaccinated people, and to compare the side-effects profile and postvaccination incidence of the infection.

## MATERIALS AND METHODS

This cross-sectional, email-based, survey was done from 1<sup>st</sup> July 2021 to 31<sup>st</sup> July 2021 at Guntur Medical College, Guntur, Andhra Pradesh, India. Ethics committee approval was obtained from the Guntur Medical College and Government General Hospital (GMC/IEC/124/2021).

### Study Procedure

An online questionnaire was prepared. It had 18 questions in the English language which covered details about demographics, co-morbidities, the name of vaccine taken, postvaccination adverse effects, and COVID-19 positivity. A total of 920 members were sent links of the questionnaire via email or different WhatsApp groups.

Overall, 506 subjects consented and responded with the filled questionnaires. The data was entered into a Microsoft Excel sheet and were analysed manually.

All COVID-19 vaccinated people of more than 18 years of age were included in this study. All the participants were residents of Guntur city, data collected from different social platforms like WhatsApp groups and through emails. Authors shared the study details with the contacts they knew, and asked for propagation of the study details to everyone known. Those who were interested contacted us back.

## STATISTICAL ANALYSIS

The data was organised using Microsoft Excel version 10.0 and statistical tests were done using an online Chi-square calculator. Descriptive statistics were used to assess the baseline characteristics of the data. All the quantitative variables are represented as mean, and all the qualitative variables are represented as frequencies and percentages. For the comparison of categorical variables, the Chi-square test was used. Comparison of positivity rates and symptoms of Covaxin<sup>®</sup> and Covishield<sup>®</sup> vaccines was done. The details of 16 participants who received vaccines other than Covaxin<sup>®</sup> and Covishield<sup>®</sup> was excluded.

## RESULTS

A total of 506 people who responded to the survey had taken five different vaccines and 490 had taken Covaxin<sup>®</sup> and Covishield<sup>®</sup>.

Mean age of the study population was 37 years; 45.2% (229) were females and 54.8% (277) were males; 27.96% had a history of co-morbidities; 4.15% were smokers; 8.97% were alcoholics. Postvaccination symptoms were reported more by women (87.89%) compared to men (79.77%). The occurrence of symptoms decreased with advancing age, with the highest in the age group of 18-30 (90.33%) and lowest in the age group of >60 (66.6%). All patients who had a BMI of more than 35 kg/m<sup>2</sup>, had allergies and autoimmune diseases experienced [Table/Fig-1].

Variables	Number	Vaccine related symptoms <7 days of postvaccination (n,%)
<b>Age groups (years)</b>		
18-30	207 (42.24%)	187 (90.33%)
31-40	91 (18.57%)	74 (81.31%)
41-50	98 (20%)	79 (80.61%)
51-60	67 (13.67%)	52 (77.61%)
>60	27 (5.51%)	18 (66.66%)
<b>Gender</b>		
Male	267 (54.74%)	213 (79.77%)
Female	223 (45.26%)	196 (87.89%)
<b>Body mass index (kg/m<sup>2</sup>)</b>		
<18.5	13 (2.65%)	12 (92.30%)
18.5-24.9	193 (39.38%)	161 (83.41%)
25-29.9	220 (44.89%)	182 (82.72%)
30-34.9	54 (11.02%)	45 (83.33%)
>35	10 (2.04%)	10 (100%)
<b>History of chronic disease</b>		
Diabetes	43 (8.77%)	33 (76.74%)
Hypertension	56 (11.42%)	40 (71.42%)
Allergy, Asthma	3 (0.61%)	3 (100%)
Chronic kidney disease	3 (0.61%)	2 (66.67%)
Hypothyroidism	18 (3.67%)	15 (83.33%)
Others	9 (1.83%)	5 (55.55%)
Autoimmune	5 (1.02%)	5 (100%)
None	353 (72.04%)	281 (79.60%)

<b>Additions</b>		
Smoking	19 (3.87%)	19 (100%)
Alcohol	44 (8.97%)	35 (79.54%)
<b>Type of vaccine</b>		
Covaxin <sup>®</sup>	287 (58.57%)	227 (79.09%)
Covishield <sup>®</sup>	203 (41.43%)	183 (90.14%)

**[Table/Fig-1]:** Incidence of postvaccination symptoms with age, gender, associated comorbidities and addictions and type of vaccines (N=490).

There was no significant difference in postvaccination infection incidence after first dose of vaccine. But after the 2<sup>nd</sup> dose, infection incidence was significantly low with Covishield<sup>®</sup> compared to Covaxin<sup>®</sup>. While calculating the infection incidence, the number of participants who got infected before vaccination were subtracted. If infection was positive after the 1<sup>st</sup> dose of vaccine, they were not administered the 2<sup>nd</sup> dose for 6 months after infection due to vaccination guidelines. In the time frame when the study was conducted, the participants who were tested positive after 1<sup>st</sup> dose, did not receive the 2<sup>nd</sup> dose of vaccination [Table/Fig-2]. The positivity after vaccination was low with Covishield<sup>®</sup> for both the 1<sup>st</sup> and 2<sup>nd</sup> doses [Table/Fig-3].

Time interval	Covaxin <sup>®</sup>	Covishield <sup>®</sup>	p-value
Before vaccination	76/287 (26.48%)	42/203 (20.69%)	
1 <sup>st</sup> dose	12/211 (5.68%)	4/161 (2.48%)	0.131
2 <sup>nd</sup> dose	27/191 (14.14%)	6/126 (4.76%)	0.0074
None	172/287 (59.93%)	151/203 (74.38%)	

**[Table/Fig-2]:** COVID-19 infection before and after vaccination.

Name of vaccine	Before vaccination	After two doses of vaccination	p-value
Covaxin <sup>®</sup> (287)	76 (26.4%)	27 (14.14%)	<0.001
Covishield <sup>®</sup> (203)	42 (20.6%)	6 (4.76%)	<0.0001

**[Table/Fig-3]:** Showing COVID-19 positivity before and after 2 doses of vaccine.

The infection rate was commonly observed within 1 month of vaccination and was more common after Covaxin<sup>®</sup> compared to Covishield<sup>®</sup>. The difference is statistically significant following 2<sup>nd</sup> dose of vaccine, but not after 1<sup>st</sup> dose. There was a significant reduction in positivity after two doses of vaccination for both vaccines (p<0.00001) [Table/Fig-4].

Duration	Covaxin <sup>®</sup>		Covishield <sup>®</sup>	
	After 1 <sup>st</sup> dose (12)	After 2 <sup>nd</sup> dose (27)	After 1 <sup>st</sup> dose (4)	After 2 <sup>nd</sup> dose (6)
1 week	2 (16.67%)	4 (14.81%)	None	2 (33.33%)
1 week to 1 month	8 (66.67%)	9 (33.33%)	4 (100.00%)	1 (16.67%)
1-2 months	1 (8.33%)	8 (29.63%)	None	2 (33.33%)
2 to 3 months	None	3 (11.11%)	None	None
3 to 6 months	1 (8.33%)	3 (11.11%)	None	1 (16.67%)

**[Table/Fig-4]:** Duration of breakthrough infection after the first and second dose of vaccination.

One or more side-effects were reported by 73.1% and 67.6% of individuals after the first and second doses of Covaxin<sup>®</sup> respectively, compared to 84.7% and 68.7% after Covishield<sup>®</sup>. Local pain was the most common symptom reported, after the administration of Covaxin<sup>®</sup> followed by tiredness, muscle aches, headache, and low-grade fever. Tiredness was the most common symptom reported after the administration of Covishield<sup>®</sup> followed by muscle aches, local pain, low-grade fever, headache, and moderate fever. When comparing Covaxin<sup>®</sup>'s 1<sup>st</sup> dose with the Covishield<sup>®</sup> 1<sup>st</sup> dose, the adverse effects occurred more frequently after the 1<sup>st</sup> dose of Covishield<sup>®</sup> (p-value<0.005). Comparing the 2<sup>nd</sup> doses of both vaccines, there was no difference in rates of adverse events (p-value>0.005) [Table/Fig-5-7].

Time interval	Covaxin®	Covishield®	p-value
<b>First Dose</b>	n=287	n=203	
<24 hours	125 (24.7%)	82 (16.21%)	0.485
24 to 72 hours	76 (15.02%)	86 (17%)	0.0002
72 hours to 1 week	9 (1.78%)	4 (0.79%)	0.429
<b>Second dose</b>	n=267	n=168	
<24 hours	99 (19.57%)	62 (12.25%)	0.97
24 to 72 hours	71 (14.03%)	42 (8.3%)	0.712
72 hours to 1 week	4 (0.79%)	1 (0.2%)	0.389

**[Table/Fig-5]:** Duration of symptoms (vaccination side-effects) after the first and second dose of vaccination.

Dosage	Covaxin® (287)	Covishield® (203)	p-value
1 <sup>st</sup> dose	210 (73.1%)	172 (84.7%)	0.002
2 <sup>nd</sup> dose	174 (65.17%)	105 (62.5%)	0.57

**[Table/Fig-6]:** Incidence of side-effects after first and second doses of Covaxin® and Covishield® and p-value.

Symptoms	Covaxin®		Covishield®			
	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose	4 <sup>th</sup> dose
Tiredness	78 (27.18%)	72 (25.09%)	93 (45.81%)	52 (25.62%)		
Muscle aches	53 (18.47%)	55 (19.16%)	80 (39.41%)	28 (13.79%)		
Low-grade fever	27 (9.41%)	25 (8.71%)	59 (29.06%)	24 (11.82%)		
Moderate fever	5 (1.74%)	7 (2.44%)	37 (18.23%)	10 (4.93%)		
High fever	1 (0.35%)	2 (0.70%)	2 (0.99%)	1 (0.49%)		
Headache	35 (12.20%)	26 (9.06%)	56 (27.59%)	27 (13.30%)		
Joint pain	14 (4.88%)	13 (4.53%)	28 (13.79%)	5 (2.46%)		
Local pain	95 (33.10%)	72 (25.09%)	53 (26.11%)	34 (16.75%)		
Nausea or vomiting	2 (0.70%)	3 (1.05%)	5 (2.46%)	0	0	
Diarrhoea	1 (0.35%)	3 (1.05%)	4 (1.97%)	1 (0.49%)		
Swelling	16 (5.57%)	11 (3.83%)	25 (12.32%)	4 (1.97%)		
Itching	4 (1.39%)	3 (1.05%)	2 (0.99%)	1 (0.49%)		
Redness	3 (1.05%)	3 (1.05%)	9 (4.43%)	4 (1.97%)		
Tingling	2 (0.70%)	1 (0.35%)	3 (1.48%)	0	0	
cough or cold	2 (0.70%)	1 (0.35%)	0 (0.00%)	0	0	
Fainting or dizziness	4 (1.39%)	3 (1.05%)	1 (0.49%)	0	0	
Others	1 (0.35%)	1 (0.35%)	2 (0.99%)	0	0	
None	77 (26.83%)	93 (32.40%)	31 (15.27%)	63 (31.03%)		
Not taken	0	0	20 (6.97%)	0	0	35 (17.24%)

**[Table/Fig-7]:** Comparison of postvaccination symptoms of Covaxin® and Covishield®. (20 participants of Covaxin® and 35 participants of Covishield® did not take the 2<sup>nd</sup> dose, at the time of data collection) zero was mentioned in the 1<sup>st</sup> dose section because all our participants received the 1<sup>st</sup> dose, therefore, not taken 1<sup>st</sup> dose was zero.

## DISCUSSION

In this online questionnaire-based study, the adverse effects and COVID-19 infection rates following the administration of two common COVID-19 vaccines that are being used in India i.e. Covishield® and Covaxin® were analysed. In the current study 41.43% of the participants had received Covishield® and 58.57% of the participants had received Covaxin®.

The down-trending pattern of incidence of symptoms with advancing age, with the highest in the age group of 18-30 (90.33%) and lowest in the age group of >60 (66.6%) was observed, which is comparable to the study by Jayadevan R et al., [14]. The cause for this can be explained by vaccine reactogenicity, which is supposed to be correlated with inflammatory cytokines. But a severe vaccine reactogenicity is not considered a reliable sign of desirable immune response [15].

The positivity rate is high after 1<sup>st</sup> and 2<sup>nd</sup> doses of Covaxin® in present study compared to Andanigoudar KB et al., [16] and Ella R et al., study [13]. The positivity rate after Covishield® is comparable to Andanigoudar KB et al., study [16]. The disproportionately high occurrence of SARS-CoV-2 infection and COVID-19 in study by Kaur U et al., can be explained to some extent by the existence of variants such as the delta which might have escaped immune protection [Table/Fig-8] [17].

Vaccine		Present study	Andanigoudar KB et al., [16]	Kaur U et al., [17]	Ella R et al., [13]
Covaxin®	1 <sup>st</sup> dose	5.68%	2.75%	-	-
	2 <sup>nd</sup> dose	14.14%	1.08%	-	0-3%
Covishield®	1 <sup>st</sup> dose	2.48%	4.25%	41.5%	-
	2 <sup>nd</sup> dose	4.76%	4.45%	18.9%	-

**[Table/Fig-8]:** Postvaccination positivity of two vaccines compared to other studies.

The present study shows that pain at the injection site is the most common symptom following Covaxin® similar to others [13,16,20]. While with Covishield®, the present study reports fatigue and muscle aches to be the common side-effects similar to Jayadevan R et al., [14] study, but was in contrast to the other studies which showed pain at the injection site to be the most common symptom [Table/Fig-9] [13,14,16,18-21].

Previous studies	Covaxin®	Covishield®
Present study	Pain, fatigue, muscle aches	Fatigue, muscle aches, pain, fever
Andanigoudar KB et al., [16]	Local: Pain Systemic: Dyspepsia, bodyache, fever	Local: Pain Systemic: Fever, bodyache, headache
Jayadevan R et al., [14]	Tiredness, myalgia, fever	Tiredness, myalgia, fever
Pokharel K et al., [18]	-	Pain at injection site, fatigue
Kaur RJ et al., [19]	Headache, fatigue, fever	-
Ella R et al., [13]	Pain at injection site, headache, fever	-
Parida SP et al., [20]	Pain at injection site, fever	-
Khalil MM et al., [21]	-	Pain at injection site, fever

**[Table/Fig-9]:** Postvaccination side-effects compared to other vaccines [13,14,16,18-21].

## Limitations(s)

This is a questionnaire-based study. Postvaccination antibody response was not studied. Genetic analysis of breakthrough infections was not conducted.

## CONCLUSION(S)

Only mild symptoms were observed after vaccination. Local pain and tiredness were the most common symptom after both vaccines. Symptoms were more common in young and male individuals. Statistically significant side-effects were more observed after the first dose of Covishield® compared to Covaxin®. After the second dose, there was no statistical difference in side-effects between the two vaccines. Infections were more in number with Covaxin® although the difference is statistically insignificant after 1<sup>st</sup> dose, but significant after 2<sup>nd</sup> dose. Overall, both vaccines are safe.

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