



# Covid Vaccine Side Effects and Covid Infection after Vaccination: A Cross Sectional Study in Hubballi, Karnataka

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## ABSTRACT

**Introduction:** Vaccination against Covid-19 has become the promising strategy in controlling rise in Covid cases. Covishield and Covaxin were the two vaccines initially available in India which have been administered to all those >18years of age. These vaccines exhibit a spectrum of side effects, which may affect vaccination rates. The study was conducted to estimate the frequency of side effects of Covid vaccines in India and their relationship with co-morbidities and prior Covid-19 infection.

**Methodology:** A cross sectional questionnaire-based online survey was conducted for duration of one month among 1800 participants who had received at least one dose of Covid vaccine at KIMS Hospital, Hubballi, Karnataka, selected using systematic random sampling and information about vaccination, co-morbidities and covid infection after vaccination was collected.

**Results:** The most common side effects were fever, headache and generalised body ache. The prevalence of infection after complete vaccination with Covishield (4.45%) was higher than Covaxin (1.08%) and difference was statistically significant. The prevalence of side effects and Covid-19 infection after vaccination did not vary with co-morbidities.

**Conclusion:** The side effects reported were not serious and the prevalence was similar in both the vaccines. The prevalence of infection still remains high after vaccination; hence Covid Appropriate Behaviour should be continued.

**Key words:** side effects, Covid-19 vaccines, co-morbidities, re-infection, breakthrough infection

## INTRODUCTION

Since December 2019, an increasing number of cases of novel coronavirus (2019-nCoV)-infected pneumonia (NCIP) has been identified in Wuhan, a large city of 11 million people in central China.<sup>1-3</sup>

After its worldwide spread and increasing cases, World Health Organisation declared Covid 19 emergency as pandemic on March 11<sup>th</sup> 2020.<sup>4</sup>

Globally, as of 9:42am CEST, 23 August 2021, there have been 211,373,303 confirmed cases of COVID-

19, including 4,424,341 deaths, reported to WHO. As of 20 August 2021, a total of 4,562,256,778 vaccine doses have been administered.<sup>5</sup>

Covishield and Covaxin were the two vaccines initially available in India, which is now joined by Sputnik and Pfizer. These vaccines have been administered to all those 18+ years of age.<sup>6</sup>

In India a total of 58,25,49,595 doses of Covid-19 vaccine have been administered, which include 45,15,13,534 1<sup>st</sup> doses and 13,10,36,061 2<sup>nd</sup> doses.<sup>7</sup>

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The most common side effects of both the vaccines include injection site pain and tenderness, headache, fatigue, myalgia, malaise, pyrexia, chills, nausea and arthralgia. Giddiness, dizziness, tremor, sweating, cough and cold.<sup>8</sup>

The third wave is predicted in the coming months and the only promising strategy to fight against it is vaccination. Side effects of the vaccines and infection rates after vaccination are the important predictors of vaccine acceptance.<sup>9</sup> However, the literature regarding this is limited and scarce in this region of the country. Hence this study was aimed evaluate the prevalence of various side effects and infection rates after vaccination.

## MATERIALS AND METHODS

A Cross sectional survey was conducted among individuals >18years of age who have received at least one dose of Covid vaccine (Covishield or Covaxin) at KIMS, Hubballi for the duration of one month during from 24<sup>th</sup> June 2021 to 23<sup>rd</sup> July 2021.

**Sample size calculation:** A total of 56,000doses (36,000 first doses and 20,000 second doses, to 36,000 individuals) of Covid vaccines were administered at KIMS, Hubballi till date which included both Covishield and Covaxin. This research aims to cover at least 5% of the individuals who got vaccinated with at least one dose. The sample size turns out to be 1800.

**Study instrument:** Data was collected using an online questionnaire. The questionnaire had 4 sections.

Section A: Information on socio-demographic details such as age, occupation and place of residence.

Section B: Information about comorbidities and risk factors.

Section C: Details of Covid-19 infection prior to vaccination (tested positive either with Rapid Antigen Test or RT-PCR).

Section D: Details of vaccination, side effects experienced and Covid-19 infection after

Vaccination (tested positive either with Rapid Antigen Test or RT-PCR), duration between the second dose vaccine and positive Covid test among those who tested positive.

**Validation procedure:** The questionnaire was validated by two experts who are working in Covid research, modifications were made according to the suggestions and final approval was taken. The questionnaire was pilot tested on 20 individuals before finalizing.

**Ethical clearance:** The study was approved by the Institutional Ethical Committee of Karnataka Institute of Medical Sciences, Hubballi.

## METHOD OF DATA COLLECTION

The questionnaire was shared to the individuals selected by systematic random sampling from the vaccination register. Every 20th individual from the list, starting from serial number 1 was selected and the questionnaire Google form was shared to the contact number provided at the time of vaccination and also a phone call was made to inform about the same. If the individual was unaware about the online form submission, the data was collected by an oral interview on phone call and same was submitted in the Google form by the interviewer. If the individual didn't agree to participate in the study, then the next person in the list was included in the study. Daily review of the collected data was done, any participant who reported positive for Covid-19 infection was interviewed in detail through phone call to collect the details about the date of testing positive, type of test (Rapid Antigen Test or RT-PCR) and the reason for getting tested.

## DATA ANALYSIS

Data was entered and edited in Microsoft excel and analysed using Statistical Program for Social Sciences (SPSS) Version 25. Continuous data was expressed as mean and standard deviation. Categorical data was expressed as proportions. Student's t test was used to test the significance of continuous variables. Categorical data was analysed using Chi square test. A p-value of <0.05 was considered significant.

## RESULTS

Current study consisted of 958 (53.2%) males and 842 (46.8%) females, majority of them belonged to age group of 18-44years 966 (53.7%). Of 1800 participants, 489 (27.2%) of the participants were front-line workers and 386 (21.4%) were health care workers. Majority of the participants (71.2%) were residing in urban areas. The most common comorbidity reported by the participants was Hypertension (9.2%) followed by Diabetes Mellitus (7%). Other comorbidities reported were coronary artery disease (CAD) (1%), respiratory diseases (0.67%), chronic kidney disease (0.33%), others (0.67%). 4.9% of the participants reported that they had experienced at least one episode of Covid-19 infection prior to vaccination. 40.6% of the participants had taken Covaxin and 59.4% of the participants had taken Covishield. (Table 1).

The most common side effects experienced after vaccination for both the vaccines were pain at the site of injection, generalised body ache and fever. (Table 2).

**Table 1: Vaccination among participants**

Name of the Vaccine	First Dose	Second Dose
Covishield	1068 (59.3%)	471 (42.2%)
Covaxin	732 (40.66%)	645 (57.8%)
Total	1800 (100%)	1116 (100%)

**Table 2: Side effects of Covid vaccines**

Side Effects	Covishield	Covaxin
<b>Systemic side effect</b>		
Headache	413(38.6)	145(19.8)
Fever	539(50.5)	156(21.3)
Generalised Body ache	494(46.3)	168(22.9)
Joint pain	88(8.2)	40(5.5)
Chills	298(27.9)	93(12.7)
Diarrhoea	9(0.90)	5(0.7)
Vomiting	1(0.10)	7(0.96)
Dyspepsia	48(4.5)	22(30.05)
None	270(25.30)	437(59.7)
<b>Local side effects</b>		
Pain at the site of injection	693(64.8)	391(53.4)
Swelling at the site of injection	74(6.9)	25(3.4)
Enlarged axillary lymph nodes	6(0.60)	3(0.4)
None	329(30.8)	338(46.2)

Figure in bracket in indicate percentage.

**Table 3: Prevalence of Covid 19 infection after vaccination**

Name of Vaccine-Dose	Frequency (%)
<b>Covishield</b>	
After 1st dose (1068)	45 (4.25)
After both doses (471)	21 (4.45)
<b>Covaxin</b>	
After 1st dose (732)	13 (2.75)
After both doses (645)	7 (1.08)

**Table 4: Relationship between presence of comorbidities and side effects after vaccination**

Side Effects of Covishield & Covaxin	Comorbidities		Total (%)	Chi square	p value	OR (95% CI)
	Present (%)	Absent (%)				
<b>Systemic side effects</b>						
Present	173(55.8)	137(44.2)	310	3.794	>0.05	0.782 (0.611-1.002)
Absent	920(61.7)	570(38.3)	1490			
Total	1093(60.7)	707(39.3)	1800			
<b>Local side effects</b>						
Present	198(63.8)	112(36.2)	310	0.122	>0.05	1.046 (0.811-1.350)
Absent	936(62.82)	554(37.18)	1490			
Total	1134(63)	666(37)	1800			

**Table 5: Relationship between type of vaccine and Covid 19 infection**

Type of vaccine	tested positive		Total	Chi square	p value	OR (95% CI)
	Yes (%)	No (%)				
<b>After 1st Dose</b>						
Covishield	45(4.2)	1023(95.8)	1068	8.275	<0.01 Sign	2.433 (1.303-4.543)
Covaxin	13(1.8)	719(98.2)	732			
<b>After 2nd Dose</b>						
Covishield	21(4.45)	450(95.54)	471	12.664	<0.01 Sign	4.256 (1.794-10.097)
Covaxin	7(1.08)	638(98.92)	645			

**Table 6: Relationship between comorbidities and Covid 19 infection after vaccination**

Comorbidities	tested positive		Total (%)	p value	OR (95% CI)
	Yes (%)	No (%)			
<b>After 1st dose</b>					
Present	5(1.6)	305(98.4)	310	3.11	0.444 (0.176-1.121)
Absent	53(3.6)	1437(96.4)	1490		
Total	58(3.2)	1742(96.8)	1800		
<b>After 2nd dose</b>					
Present	6(2.3)	260(97.7)	266	0.095	0.866 (0.348-2.160)
Absent	22(2.6)	826(97.4)	848		
Total	28(2.5)	1086(97.5)	1114		

The reinfection rates after vaccination were higher for Covishield compared to Covaxin and the difference was statistically significant. (Table 3 and Table 4). There was no significant relationship of the comorbidities with side effects and reinfection after vaccination. (Table 5 and Table 6)

A vaccine breakthrough infection is defined as the detection of SARSCoV-2 RNA or antigen in a respiratory specimen collected from a person  $\geq 14$  days after receipt of all recommended doses of an approved COVID-19 vaccine (10) The breakthrough infection rate in the current study was found to be 1.25% (2% for Covishield and 0.6% for Covaxin), of which 70.1% were vaccinated with Covishield. The difference in the breakthrough infection rates of the two vaccines was found to be statistically significant (Chi square: 4.9642,  $p < 0.05$ ).

## DISCUSSION

In this hospital-based study conducted in Hubballi, Karnataka, adverse effects and infections rates following administration of the two COVID-19 vaccines that are in use in India i.e Covishield and Covaxin were evaluated. In the current study 59.33% of the participants had received Covishield and 40.66% of the participants had received Covaxin.

The Current study reported that the most common systemic side effects of the Covishield and Covaxin were pain at the site of injection, followed by fever and headache. These side effects may be attributed to the immunological response for Covid vaccines. The prevalence of side effects and Covid-19 infection after vaccination did not vary with comorbidities. The breakthrough infection rate was found to be significantly higher for Covishield compared to Covaxin, which may be because of the difference in the efficacy rates of the two vaccines and also the duration between two doses. The finding may also be attributed to the individual immunological response to Covid vaccines, adherence to the Covid appropriate behaviour (CAB) and susceptibility to the infection after vaccination.

In a study conducted by Rimple Jeet Kaur, the common adverse effects were pain at the injection site (15%), headaches (3%), fatigue (3%), fever (2%), nausea and vomiting (2%) and after 2nd dose they reported 2% participants had pain at the site of injection, 0.5% individuals developed fever and chills.<sup>11</sup> The percentage of people who experienced adverse effects in current study was higher.

In comparison with study conducted at Wroclaw Medical University, Mikulicza-Radeckiego, Poland, by Izabela et al, 78% of people who received 1st dose of Covishield, the most common side effect was soreness at the injection site. Presence of comorbidities did not affect the side effect prevalence and pattern as well as the reinfection rates after vaccination.<sup>12</sup>

A study by Ahlam A Alghamdi in Saudi Arabia reported that the most common side effects of Covishield were Myalgia (49%), fever (42%) and headache (40%) after the first dose.<sup>13</sup>

A study by Haya Omeish at Jordan reported Myalgia (84%), fatigue (76%) and fever (56.7%) as the side effects of Covishield after the first dose.<sup>14</sup>

A study by Hamed Zare at Iran reported that the pain at the site of injection was the most common side effect with first dose of either of the vaccines (71% in Covishield recipients, 83% among Covaxin recipients).<sup>15</sup>

A study by Dash GC et al in Odisha reported that among 274 individuals with confirmed breakthrough infection, 35 (12.8%) individuals received Covaxin and 239 (87.2%) individuals received Covishield. As COVID-19 vaccines do not provide 100% protection, post vaccination breakthrough infection is possible but rare.<sup>17, 18</sup> A study has suggested that COVID-19 vaccines might protect against the occurrence of severe illness and might help in preventing infection.<sup>19</sup>

## CONCLUSION

The most common side effects were similar with Covishield and Covaxin. Further independent studies on vaccine safety are strongly required to strengthen

the public confidence in the vaccine, and to provide a better understanding of the potential risk factors of vaccine side effects. Re infection rates after vaccination were higher after complete vaccination with Covishield in comparison with Covaxin. Hence further research is needed.

## LIMITATIONS

Limited sample size, with disproportionate distribution of urban and rural population. Infection rate after vaccination is underestimated, since people who tested positive only were reported in the study.

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