



A STUDY ON THE VACCINE SIDE-EFFECTS FOLLOWING COVID-19 VACCINATION AMONG THE RESIDENTS OF MAJOR CITIES OF GUJARAT, INDIA

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ABSTRACT

Background: COVID-19, caused by the SARS-CoV-2 virus, is a pandemic that started in Wuhan, China in 2019 and quickly spread globally. The WHO declared it a pandemic in March 2020. In India, Covishield and Covaxin have been granted emergency use authorization and the administration of COVID-19 vaccines began in January 2021. Immunization against Coronavirus has turned into the promising system in controlling ascent in Coronavirus cases.

Methodology: A cross-sectional survey study was conducted to assess COVID-19 vaccine side effects in major cities of Gujarat, India. The study used a descriptive research design and collected data from 420 participants over 18 years of age residing in Gujarat through an online questionnaire.

Result: Covishield vaccine has higher side effects (fever, pain, body pain, and headache) than Covaxin (fever, body pain). Side effects were less in 2nd dose and precaution doses compared to 1st dose. 7.2% people have experienced acute illness and some medical conditions. The prevalence of infection after vaccination was 20.34% among the participants.

Conclusion: Side effects were seen due to the COVID-19 vaccination. Some experienced acute illness and medical conditions. Few people noticed infection after COVID-19 vaccination.

Keywords: COVID-19, vaccination, side effects, illness, infection

1. Introduction

Covid 2019 (Coronavirus) is an infectious illness caused by a virus, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first case was recognized in Wuhan, China, in December 2019. The sickness quickly spread all over the world, approaching the Coronavirus pandemic.

The official names COVID-19 and SARS-CoV-2 were given by the WHO on February 11th, 2020. The Director-General, Tedros Adhanom made sense of that CO represents corona, VI for the virus, D for disease, and 19 for 2019, the year in which the outbreak was first recognized.

After its worldwide spread and increasing cases, WHO declared COVID-19 emergency as a pandemic on March 11th 2020. In the fight against most pandemics, vaccines were the most critical tool. Various companies have come forward to make vaccines against the COVID-19 pandemic.

In India, COVAXIN, COVISHIELD, and Sputnik vaccines are being administered to people at the initial stages. While two vaccines– Covishield (AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin (manufactured by Bharat Biotech Limited)--were granted emergency use authorization by the Central Drugs Standard Control Organization (CDSCO) in India.

India began the administration of COVID-19 vaccines on 16 January 2021. As of 1 August 2022, India has administered over 2.04 billion doses overall, including first, second, and preventative (supporter) dosages of the presently approved vaccines. In India, a total of 2,20,57,67,691 doses of the Covid-19 vaccine have been administered across the country by February 5th, 2022, which include 1,02,73,46,893 1st doses, 95,17,85,451 2nd doses, and 22,66,35,347 Precautionary (Booster) Dose.

Specifically, in Gujarat a total of 12,80,58,754 doses of the Covid-19 vaccine have been administered across the country by February 5th, 2022, which include 5,43,94,510 1st doses, 5,40,26,144 2nd doses, and 1,96,38,100 Precautionary (Booster) Dose. In taking the precautionary dose among the people Uttar Pradesh is leading state followed by Gujarat.

2. Literature Review

[1] (Andanigoudar, 2022) has investigated on a topic Covid Vaccine Side Effects and Covid Infection after Vaccination: A Cross Sectional Study in Hubballi, Karnataka. 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, comorbidities and covid infection after vaccination was collected. The most common side effects were fever, headache and generalized 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.

[2] (Ganesan, 2022) has conducted study on the vaccine side effects of COVID-19 vaccinations among the residents of UAE. A cross sectional study based on the online surveys and telephonic survey was carried out by the team to identify the side effects of vaccine. A sum of 1878 members finished the review, of which 1134 members were consulted through a telephonic interview and 744 members finished the internet based survey. They have compared the adverse effects on the basis of two different vaccines i.e. Sinopharm and BioNtech. The comparison based between Sinopharm and Pfizer BioNtech vaccine shows that the unfavorable impacts were more normal among beneficiaries of the mRNA Pfizer BioNtech vaccination than among beneficiaries of the latent Sinopharm vaccine.

[3] (J. Bawane, 2022) conducted a research on the topic of cutaneous adverse effects of the available COVID-19 vaccines in India. The study was a questionnaire based where survey was done through online forms. According to their research from 16 January 2021 to 16 August 2021, single or more cutaneous responses to COVISHIELD or COVAXIN COVID-19 vaccines were concentrated in 1029 medical health workers. According to their data findings the most common reaction, local injection site reaction, occurred primarily after the COVAXIN vaccination (50.8%) more than the COVISHIELD (34.93%). Delayed local arm reactions occurred primarily after the COVISHIELD vaccination (1.4%) more than the COVAXIN (0.7%) at a median of 4 days. Urticaria happened basically after the COVISHIELD inoculation. Pain other than at the site of injection occurred primarily after the COVISHIELD vaccination (10.3%) more than the COVAXIN (4.4%). Other cutaneous discoveries, which were less commonly seen with the two immunizations, included are 18 reports of swelling at different locales, 1 urticarial vasculitis and hair fall in 94 patients (9.1%). The data for post-vaccination systemic reactions revealed fever (49%), no reaction (37.4%), body ache (31%), headache (23.2%), arthralgia (12%), myalgia (9.1%), chills (9%) being more common than sore throat (6%) and diarrhea.

[4] (Ledford, 2021) has commanded a study on How could a COVID vaccine cause blood clots? Scientists race to investigate. The study includes the exceptionally interesting event of a mysterious blood-coagulating disorder among certain recipients of the Oxford-AstraZeneca COVID-19 vaccine has specialists scrambling to uncover whether and how the immunization could set off such a strange response. After weeks of investigation, the European Medicines Agency (EMA) declared on 7 April that there is a potential connection between the coagulations and the immunization. Eichinger was the first to notice the coagulating issue, a weird blend of blood clumps. The study proposes that the clusters additionally showed up in surprising parts of the body, such as brain and abdomen, as opposed to inlegs, where most profound vein blood clusters form. It may be due to the negatively charged heparin molecules combines to positively charged proteins- platelet factors.

[5] (Pokharel, 2021) conducted a study on the side effects of COVISHIELD Vaccine after second dose among Healthcare Workers. The descriptive cross-sectional study was conducted at Kathmandu Medical college and teaching hospital. Out of 220 cases who have taken second dosage of COVISHIELD antibody, 135 (61.36%) were male and 85 (38.63%). Among 220 cases, when they disseminated the cases as indicated by age 105 were between age bunch 25 to 34, 72 were between age 35 to 44 and 43 were between age bunch 18 to 24. According to the data collected, they side effects recorded were pain at injection site 178 (80.90%), fever 11 (5.00%), fatigue 97 (44.09%), headache 43 (19.54%), chills 18 (8.18%), diarrhoea 0 (0%), dizziness 6 (2.72%), and nausea 5 (2.27%) are the side effects complaint after second dose of COVISHIELD vaccination

3. Materials and Methods

3.1 Study Design

A Cross-sectional Survey based study was carried out from December 15th 2022 to January 30th 2023, to review the COVID-19 Side-effects among the individuals residing in the major cities of Gujarat, India. The study follows a descriptive research design. As it is concerned with describing the effects of vaccination in human beings and the efficiency of the vaccines in India. The survey was carried out through a Google Form – MCQs and data was collected by sharing the survey on social media applications.

3.2 Participants

Inclusion criteria for this study were individuals (i) above 18 years of age (ii) residing in the Gujarat state. A total of 420 participants were included. Participants in this study was not compensated financially or by any other incentives.

3.3 Study Instrument

The data was collected using online questionnaire. The questionnaire was divided into 5 main categories (i) demographic data included gender, age, and region; (ii) COVID-19 related anamnesis including vaccine type and number of doses; (iii) vaccine side effects after administration of 1st dose, 2nd dose, and Precaution dose; (iv)infected with COVID-19 after vaccination; and (v) acute illness and medical condition after vaccination.

3.4 Ethical Considerations

The study was reviewed and approved by the Faculty of Management Studies at Parul University, Vadodara.

3.5 Data Analysis

Data was entered in the Microsoft Excel. Then, the data was edited and analyzed using the Microsoft Excel. Side effects of both vaccines for the doses were analyzed using ANOVA single factor. The acute illness and medical condition of vaccine were analyzed using T-test.

3.6 Sample size calculation

The sample size was calculated using the formula,

$$n = Z^2 \times p \times q / e^2$$

$$= (1.96)^2 \times 0.5 \times (1-0.5) / (0.05)^2$$

$$\approx 384$$

Where, n = sample size

Z = 1.96 at 95% Confidence Interval

p = assuming expected outcome of 50%

q = (1-p)

e = margin of error, 5%

4. Result

4.1 Demographic Characteristics

In total, 420 participants are included in the study; the respondents' demographics are summarized in numbers and percentages in Table 1. In total, 244 (58.1%) participants were males and 176 (41.9%) were females. Majority of them belonged to the age group of 18-25 years; 185 (44.05%). The highest number of respondents were from Surat 145 (34.53%), followed by Ahmedabad 120 (28.58%).

Table 1. Participants Demographics

Characteristics	No.(%)
Age Group	
18-25 years	185 (44.05%)
26-35 years	134 (31.9%)
36-45 years	66 (15.72%)
Above 45 years	35 (8.33%)
Gender	
Male	244 (58.1%)
Female	176 (41.9%)
Residence Location	
Ahmedabad	120 (28.58%)
Surat	145 (34.53%)
Vadodara	113 (26.90%)
Rajkot	34 (8.09%)
Other	8 (1.09%)
Effects (Acute Illness and Medical Condition)	
Yes	29 (7.2%)
No	374 (92.8%)

4.2 Information of Vaccine Type and Vaccine Doses

Among the 420 participants, 403 (95.95%) have taken Covid-19 Vaccination; from that 265 (65.76%) have taken AZD1222/Covishield vaccine and 138 (34.24%) have taken BBV152/Covaxin vaccine.

On the basis of any vaccine taken; 403 participants have taken 1st Dose, 396 participants have taken 2nd Dose, and 171 participants have taken the Precaution Dose. Number of doses taken on the basis of vaccine type is summarized in Table 2 in the form of numbers and percentage.

Table 2. Vaccine Type and Doses among the cases

Taken any Covid-19 Vaccine	403 (95.95%)	
Unvaccinated Cases	17 (4.04%)	
Vaccine Type		
AZD1222/Covishield	265 (65.76%)	
BBV152/Covaxin	138 (34.24%)	
Others	0	
Vaccine Doses (Any Vaccine)		
1 st Dose	403	
2 nd Dose	396	
Precaution Dose	171	
Vaccine Doses		
	AZD1222/Covishield	BBV152/Covaxin
1 st Dose	265 (65.76%)	138 (34.24%)
2 nd Dose	261 (65.90%)	135 (34.1%)
Precaution Dose	124 (72.52%)	47 (27.48%)

4.3 COVID-19 Vaccine Reported Side Effects

The vast majority of the participants reported having at least one side effect following the COVID-19 vaccine. The prevalence of side effects were slightly higher in 1st Dose for both the vaccine type as compared to the 2nd Dose and Precaution Dose. The Covishield vaccination had significantly higher side effects than Covaxin vaccinae.

The most common side effect for Covishield vaccine 1st dose was pain at injection site (73.2%), followed by fever (71.3%) and body pain (50.9%) (Table 3). For the Covaxin vaccine 1st dose, the most common side effect was fever (76.1%), followed by body pain (31.8%) (Table 4). Gradually, the side effects in 2nd dose and Precaution dose were less as compared to the 1st dose for both the vaccine type.

Table 3. Comparison of side effects after 1st, 2nd and Precaution doses of the Covishield (AZD1222) vaccine

Side Effects	1 st Dose (n=265)	2 nd Dose (n=261)	Precaution Dose (n=124)	P value
Fever	189 (71.3%)	23 (8.8%)	3 (2.4%)	0.06
Headache	55 (20.7%)	36 (13.7%)	8 (6.4%)	
Fatigue	31 (11.7%)	20 (7.6%)	7 (5.6%)	
Pain at injection site	194 (73.2%)	165 (63.2%)	46 (37.1%)	
Nausea	5 (1.8%)	2 (0.76%)	2 (1.6%)	
Body Pain	135 (50.9%)	29 (11.1%)	4 (3.2%)	
Breathing Problem	35 (13.2%)	2 (0.76%)	0	
Skin Infection	2 (0.75%)	0	1 (0.8%)	

Table 4. Comparison of side effects after 1st, 2nd and Precaution doses of the Covaxin (BBV152) vaccine

Side Effects	1 st Dose (n=138)	2 nd Dose (n=135)	Precaution Dose (n=47)	P value
Fever	105 (76.1%)	10 (7.4%)	0	0.26
Headache	20 (14.4%)	10 (7.4%)	4 (8.5%)	
Fatigue	6 (4.3%)	9 (6.6%)	2 (4.2%)	
Pain at injection site	17 (12.3%)	84 (62.2%)	20 (42.5%)	
Nausea	4 (2.8%)	0	0	
Body Pain	44 (31.8%)	17 (12.6%)	1 (2.1%)	
Breathing Problem	6 (4.3%)	0	0	
Skin Infection	0	0	0	

4.4 COVID-19 Infection after vaccination

Vaccine effectiveness is a measure of how well vaccination protects people against the infection. Around 20.34% participants were infected after taking vaccination. Out of 265 participants 12.83% were infected with COVID-19 after taking Covishield vaccination. The Covaxin vaccine had a significantly higher rate of COVID-19 infections after vaccination (Table 5).

Table 5. Covid-19 Infection in cases after taking Covid-19 Vaccination

Vaccine Type	Covishield	Covaxin	Total
Infected	34 (12.83%)	48 (34.78%)	82 (20.34%)
Uninfected	231 (87.17%)	90 (65.22%)	321 (79.66%)
Total	265 (100%)	138(100%)	403 (100%)

4.5 Effects reported after vaccination

After taking vaccination one may experience minor side effects which can be acute or chronic. Likewise, after taking COVID-19 vaccination 7.2% people have experienced acute illness and some medical conditions. (Table 1). People have suffered from acute illness such as pulmonary disease, chest pain and joint pain. Medical conditions have been noticed in the people such as hair fall, insomnia, pins and needles and anxiety (Table6).

Table 6. Cases noticed effects after taking Covid-19 Vaccine

Effects	Covishield (n=20)	Covaxin (n=9)	Total (n=29)	p value
Acute Illness				0.32
Pulmonary Disease	4 (20%)	5 (55.5%)	9 (31%)	
Chest Pain	3 (15%)	1 (11.1%)	4 (13.8%)	
Joint Pain	3 (15%)	2 (22.2%)	5 (17.2%)	
Medical Condition				0.20
Hairfall	10 (50%)	3 (33.3%)	13 (44.8%)	
Insomnia	1 (5%)	0	1 (3.5%)	
Pins and Needles	1 (5%)	0	1 (3.5%)	
Loss of Appetite	1 (5%)	0	1 (3.5%)	
Anxiety	0	1 (11.1%)	1 (3.5%)	

5. Conclusion

Vaccine have numerous positive effects including prevention of the diseases. But, many side effects have been faced by the vaccinated people. The most common side effects of the Covishield vaccine among the residents of major cities of Gujarat were fever, pain at injection site, body pain and headache. On the other hand, for Covaxin, common side effects were fever and body pain. Few people have experienced acute illness and some medical conditions after vaccination. The Covishield vaccine had a significantly higher rate of almost all side effects than the Covaxin vaccine.

6. Limitations of the Study

The number of participants with age above 45 was significantly low when compared to other age groups. The survey includes participants older than 18 years.

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