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RESEARCH ARTICLE

A Cross-sectional Assessment of Gwalior Residents' Reports of Adverse Reactions to the COVID-19 Immunization

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Abstract

Objectives: Many people around the world are worried about the safety and adverse effects of the coronavirus SARS CoV2 vaccine. The study's goal was to document the side effects experienced by Gwalior residents who had received vaccinations. The other objective includes, to evaluate the potential risk factors associated with Covishield and Covaxin vaccination. **Methods:** Participants who had received one or both doses of any of the provided vaccines were surveyed using a cross-sectional survey (Covaxin, Covishield). The study enrolled 886 people in total. A large majority of those who received the vaccine had never been exposed to SARS CoV2 before (77.2 percent). Covishield (57.6%), followed by Covaxin (42.4%), was the most commonly prescribed medication in the study. **Findings:** There were several reported side effects following the first dosage of the vaccine, including discomfort at injection site (79.6%), weariness (52.8%), myalgia (36.5%), headache (34.2%), and chills (38.6%). (31.5 percent). Nausea was the most common gastrointestinal adverse effect, with 14.8% of patients reporting it, followed by appetite loss with 8.9% and diarrhea with 8.9%, respectively (5.7 percent). Each of the second doses of immunizations necessitated hospitalization in only one patient. People in Gwalior had higher side effects with the Covishield vaccine than the Covaxin vaccine, according to this research. **Novelty:** Large sample size and consideration of randomization technique distinguish this work from others. Analysis of Demographic information with GI distress is a newly performed task.

Keywords: Covid19; Vaccine; Side effects; Symptoms; Immunization

1 Introduction

The corona virus disease of 2019 is caused by SARS-CoV-2, a highly pathogenic corona virus (COVID-19). A global humanitarian catastrophe has ensued since its inception in December 2019, with negative consequences for the economy and education as well as other areas [1]. Protective precautions including wearing masks and staying at home have been implemented in many nations following the outbreak, although these measures are not expected to continue. So therapeutic and preventative measures are needed to control, decrease, and eliminate COVID-19 infection. Studies on the use of preexisting drugs (e.g., hydroxychloroquine and remdesivir) for the treatment of COVID-19 for SARS-CoV-2 were inconclusive and did not support a single conclusion [2]. SARS-COV-2 antivirals need to be developed and approved in order to control the pandemic. Once the disease has expanded to the point of pandemic proportions, it is impossible to stop it without achieving population immunity [3]. A herd-immunity strategy that relies solely on infecting a population with the virus is unethical and unacceptable. As a result, the only method now accepted for building population immunity is through long-term vaccination campaigns [4]. Within a year of the first reports of COVID-19, vaccinations for the virus had been created thanks to the tireless efforts of governments and scientists, as well as advances in biotechnology and interim studies.

1.1 What is a vaccine?

Infectious disease immunity can be gained through the use of a vaccine, which is a biochemical substance. Antibodies that look like disease-causing microorganisms and are made from weakened or killed microorganisms are commonly seen in vaccines. Both prophylactic and preventative vaccines can be used to protect against or lessen the effects of a natural or ”wild” pathogen (to fight a disease that has already occurred, such as cancer). To administer vaccines, a procedure known as vaccination is called ”vaccination” [5]. Vaccination is a safe, healthy, and effective method of preventing people from becoming sick with harmful diseases in the first place. By utilizing the body’s natural defenses to build resistance to specific illnesses, vaccinations help boost your immune system. Similar to when you are exposed to a disease, vaccination teaches your immune system to produce antibodies. Vaccines, on the other hand, are safe since they only include pathogens that have been killed or weakened, such as viruses or bacteria [6]. As a general rule, the majority of vaccines are given by injection, but some vaccines can be given either orally or nasally.

2 India’s Status of Covid Vaccines

Currently, India has provided more than 100 million doses of two authorized vaccinations, Covishield and Covaxin. Sputnik V was approved.

India is currently second only to the United States, which has registered more than 31 million cases, totaling more than 13.5 million. Brazil now ranks third with 13.4 million cases. India expects to have immunized 250 million ”priority citizens” by the end of July. However, experts warn that vaccine progress has been poor and that the deadline may be missed unless the campaign is scaled substantially (BBC, 2021). According to the statement, vaccines that have been licensed by regulators in the United States, the United Kingdom, the European Union, and Japan would be awarded expedited approval in India. The health ministry continued by stating that the first 100 people who received immunizations will be monitored for seven days before the remainder of the country could receive them (BBC,2021). This means that Indians will have access to Pfizer and Moderna vaccines [7–9].

2.1 Covaxin

Because Covaxin is an inactivated vaccine, the corona viruses in it have been eliminated, making it safe for injection (BBC, 2021). A corona virus isolate from India’s National Institute of Virology was used to develop the vaccine by Bharat Biotech, a 24-year-old vaccine company with a portfolio of 16 vaccines exported to 123 countries. Dead virus is still recognized by immune cells after injection, which prompts the immune system to produce anti-pandemic virus antibodies. Four weeks apart are the two doses. Between 2 and 8 degrees Celsius is the ideal temperature range for the immunization. Preliminary findings from the vaccines phase 3 trials show an efficacy rate of 81%. (BBC,2021). Bharat Biotech claims to have a stockpile of 20 million doses of Covaxin and plans to produce 700 million doses at four facilities in two cities by the end of the year (BBC, 2021) [10,11].

2.2 Covishield

The Oxford-AstraZeneca vaccine is produced on a national scale by India’s largest vaccine manufacturer, the Serum Institute of India. A monthly output of about 60 million doses is claimed by the company (BBC, 2021). Vaccines are created by altering

a common cold virus (referred to as an adenovirus) to make them more potent and useable in humans. Despite its inability to spread disease, it has been genetically altered to seem like a corona virus. A patient's immune system is strengthened and ready to fight off any corona virus infection after receiving the immunization. Two doses of immunization are given four to twelve weeks apart. At temperatures between 2 and 8 degrees Celsius, it can be kept in existing health-care settings, such as doctors' offices (BBC, 2021). Currently in use in a number of countries, the Pfizer-BioNTech vaccine must be stored at -70 degrees Celsius and can only be transmitted a few times — a particular difficulty in India, where summer temperatures can reach 50 degrees Celsius (BBC, 2021) [12,13].

2.3 SPUTNIK V

The Gamaleya Institute in Moscow created the vaccine, which sparked controversy when it was first rolled out before the release of the final trial results. The vaccination proved controversial. Scientists, on the other hand, claim that its benefits have been shown. In order to send a minimal amount of the corona virus to the body, it uses a non-pathogenic cold virus as the delivery vehicle (BBC, 2021). Because of this method of exposure, the body will learn to recognize and fight off the virus without being ill as a result. Antibodies specific to the corona virus begin to be produced shortly after immunization. This ensures that the immune system is ready to combat corona virus when it first comes into touch with it (BBC, 2021). To make it easier to transport and store, it can be held at temperatures between 2 and 8 degrees Celsius (a conventional refrigerator maintains a temperature of approximately 3-5 degrees Celsius). Six Indian vaccine makers have agreed to produce more than 750 million doses of Sputnik V for the Russian Direct Investment Fund, which is selling the vaccine. This year, the Hyderabad-based Dr Reddy's Laboratories will deliver the first shipment of 125 million pills to the United States (BBC, 2021) [14,15].

3 Data Collection

A cross-sectional (online survey) investigation was done on patients who had received the initial dosage or both doses of any of the vaccines provided in Gwalior (Covishield, Covaxin). Between June 13, 2021 and July 23, 2021, data collecting occurred.

3.1 Study instrument

After a thorough review of the literature, a Google Forms survey was created and then disseminated via a variety of social media outlets. Participants were permitted to take the survey if they replied "yes" when asked if they had had the COVID-19 vaccinations (Covishield, Covaxin). As a result of this, the authentication parameters of "Required" and "Limit to one response" were employed. Participants were made aware of the study's goals and assured that their answers would remain confidential and anonymous [16,17].

Two sections were included in the survey. There was a first portion that gathered demographic information about participants, such as their marital status and health status as well as their COVID-19 history. Participants were not asked if a polymerase chain reaction had been used to confirm their COVID-19 infection (PCR). Of all the methods for determining if a patient is infected with COVID-19, self-reporting was the most reliable. Compiling data on vaccination-related adverse events was the second phase in the process. Survey participants were asked if they had gotten one or two doses of the COVID-19 vaccine.

3.2 Data Analysis

Data was exported from Google Forms to a Microsoft Excel file and then loaded directly into IBMSPSS® 24.0 for statistical analysis [18]. The sociodemographic features of individuals were described using descriptive statistics. Pearson's chi-square test was used to determine associations between categorical variables. P.05. was chosen as the statistical significance level. Cronbach's alpha coefficient was used to determine the survey items' internal consistency.

4 Discussion

4.1 Characteristics of the general public

Table 1 summarizes the sample characteristics of the 886 participants enrolled in the study. The results indicated that the majority of participants (67.0 %) were male and held a diploma degree. Almost 80.7% of participants reported having no chronic conditions. A small proportion of participants (19.8 %) had previously been infected with the SARS-CoV-2 virus. In terms of vaccination type, more than a third of study participants (57.5 %) received Covishield, 42.5 % received Covaxin, and

the majority (74.8%) received only the first dose. After getting their first dose of the vaccination, 78.4% reported experiencing adverse effects, and 66.8% reported experiencing side effects after receiving their second dosage. However, none of the subjects required hospitalization following the first dosage, and just 0.6 % required hospitalization following the second dose of any of the COVID-19 vaccinations.

Table 1. Examining Population Features (N = 886)

Variable		N %	p value
Gender	Female	549 (62.0)	<0.001
	Male	337 (38.0)	
Age	18-24 years	137 (15.5)	<0.001
	25-65 years	717 (81.0)	
	>66 years	30(3.4)	
Education level	School	62 (7.1)	<0.001
	Diploma	67 (7.6)	
	University	727 (82.1)	
	Other	41 (3.8)	
Presence of chronic disease	No	715 (80.7)	<0.001
	Yes	170 (19.3)	
Allergy	No allergy	668 (75.4)	<0.001
	Seasonal allergy	54 (24.8)	
	Food allergy	20(2.3)	
	Penicillin allergy	12 (1.4)	
COVID19 vaccine	First dose only	663 (74.8)	<0.001
	First and second dose	222 (25.2)	
Type of COVID19 vaccine	Covaxin	509 (57.5)	<0.001
	Covishield	376 (42.5)	
History of COVID19 infection	No	593 (66.9)	<0.001
	Yes, before the vaccine.	205 (18.9)	
	Yes, after the dose	38 (3.5)	
	Yes, after the 2"d dose	5 (0 5)	
		1st dose	2nd dose	P Value
Having any side effect	No	110 (12.5)	210 (23.8)	0.101
	Yes	775 (87.5)	675 (76.2)	
Require hospitalization	No	867(97.9)	879 (99.4)	0.41
	Yes	19(2.1)	6 (0.6)	
Marital status	Single		503(56.8)	<0.001
	Married		382 (43.2)	

4.2 Consequences associated with the administration of Covid-19 vaccinations

As illustrated in Table 2, the majority of participants (76.2%) experienced pain in addition to swelling and redness at the injection site (17.3%). After the first dose, more than a third of subjects (38.1%) had bone and muscle pain. In comparison, after the second dose, lower proportions were seen.

In general, 28.3% of people reported fever following the first dose of vaccine and 18.7% following the second dose. Almost half (63.7%) of individuals felt weariness following the first dose, and 40.2% following the second dose. Additionally, 32.8% of participants reported experiencing headache following the first dose of vaccine and 18.7% following the second dosage. Additionally, a greater proportion of subjects (33.4%) experienced chills following the first dose compared to the second dose (21.8%) The most often reported gastrointestinal adverse effect (14.5%) occurred following the first dose of immunization, while only 6.7% occurred following the second dosage. Vomiting, diarrhea, and constipation were observed less frequently following the first and second vaccine doses. In average, a greater proportion of participants experienced vaccine side effects following

Table 2. Detailing symptoms with p value

	First dose N $_{(at)}$ N = 1086	Second dose N (%) N = 299	P value
Local symptoms	851 (78.4)	200 (66.8)	0.004
Injection site pain	177 (16.3)	45 (15.0)	0.216
Swelling and redness of injection site			
Bone and muscle pain	453 (36.8)	94 (27.7)	<0.001
Flu like symptoms	306 (28.3)	54 (18.9)	<0.001
Fever	325 (32.8)	47 (18.4)	<0.001
Headache	301 (31.7)	68 (24.2)	<0.001
Chills	86 (7.9)	16 (5.9)	0.031
Sore throat	536 (52.8)	102 (41.1)	<0.001
Fatigue	94 (8.2)	9 (3.4)	0.048
Cough	78 (6.9)	13 (4.8)	0.115
Runny nose	15 (1.4)	1 (0.6)	0.264
Loss of taste	18 (1.7)	2 (1.1)	0.428
Loss of smell			
GI side effect	146 (14.2)	21 (74)	<0.001
Nausea	73 (5.9)	12 (4.6)	0.022
Diarrhea	28 (2.3)	7(2.3)	0.003
Vomiting	88 (8.8)	17 (6.2)	<0.001
Loss of appetite	66 (5.9)	6 (1.8)	<0.001
Abdominal pain	6 (0.5)	1(0.5)	0.431
Constipation			
Psychological side effect	109 (12.8)	19 (5.9)	<0.001
Sleep disturbance	60 (5.9)	7 (2.1)	0.003
Anxiety and stress	38(4.6)	5 (1.5)	0.007
Depression			

the initial dosage than following the second dose.

4.3 COVID-19 vaccine adverse events reported by participants and their association with their gender

Table 3. Gender-specific side effects of vaccinations

Symptoms	After 1^{M} dose of COVID-19 vaccine Frequency (96)		p Value	After 2 dose of COVID-19 vaccine Frequency (%)		p Value
	Female N = 399	Male N = 487		Female N = 114	Male N = 213	
Presence	27 (6.7)	65 (13.4)		54 (25.6)	28 (16.5)	0.065
No	372 (93.3)	417 (85.8)		7 (74.4)	175 (83.5)	
Yes						
Pain at the location of an injection	567 (82.1)	291 (71.5)	<0.001	116 (69.1)	74 (67.6)	0.784
	167 (19.3)	47 (10.8)	0.002	32 (14.8)	11 (12.0)	0.151
Pain in the bones and muscles	246 (36.8)	154 (36.8)	0.372	51 (34.5)	27 (24.5)	0.396
Symptoms resembling the flu	168(26.9)	132 (32.7)	0.026	32(16.0)	18 (16.3)	0
Fever	276 (37.2)	102 (26.7)	0.003	46(22.4)	13(11.7)	
Headache	233 (36.5)	107 (26.6)	0.002	45(21.1)	17(19.2)	
Chills	78 (11.2)	16 (3.9)	<0.001	14(6.2)	2 (1.4)	
Sore throat	361 (48.5)	176 (45.8)	0.004	78(39.1)	26 (22.0)	
fatigue	68(9.9)	19 (6.1)	0.003	6(2.4)	2(3.6)	

Continued on next page

Table 3 continued

cough	52 (8.7)	13 (3.9)	0.068	9 (4.6)	5(5.4)	
runny nose	10 (1.3)	1 (08)	0.043	1 (0.5)	0 (0.0)	
loss of taste loss of smell	12 (2.1)	1 (0.6)		2 (1.2)	0 (0.0)	
GI side effect	127(18.6)	37 (9.2)	<0.001	16 (7.5)	7 (6.4)	0.509
Nausea	52(7.6)	18(4.5)	0.043	9(4.2)	4(3.6)	0.639
Diarrhea	18(2.6)	12(3.0)	0.731	7 (3.3)	1 (0.9)	0.149
Vomiting	74 (11.1)	28 (7.2)	0.039	14(6.6)	5(4.5)	0.33
loss of appetite	53 (7.7)	12 (3.0)	0.001	4 (1.8)	3 (2.7)	0.748
abdominal pain constipation	6 (0.9)	1 (0.2)	0.211	1 (0.4)	1 (0.9)	0.703 I
Psychological SE	74 (10.8)	36 (9.0)	0.326	17(8.0)	5(4.5)	0.161
Sleep disturbance	47 (6.9)	21 (5.2)	0.279	6(2.8)	2(1.8)	0.48
Anxiety and stress Depression	35 (5.1)	13 (3.2)	0.145	4(1.8)	1(0.9)	0.43

The results in Table 3 indicate a significant difference (P =.001) between female participants who experienced COVID-19 vaccination adverse effects (92.3 percent) and male participants who did not (85.8 percent). However, no significant difference was observed following administration of the second dose. In comparison to males, there was a substantial increase (P.001) in the proportion of females (83%) who experienced pain at the injection site following the first dose of vaccinations (70.4 percent). Nonetheless, no statistically significant difference in response to the second dose was seen. Females experienced considerably more headache following the first dose (P =.003) and the second dose (P =.030). In terms of cardiac adverse effects, palpitation was substantially more prevalent in females than males (P.05).

Our investigation discovered that various adverse events have been observed following COVID-19 vaccination, most notably discomfort at the injection site, flu-like symptoms, and gastrointestinal symptoms, particularly following the first dose.

Our investigation discovered that the majority of symptoms associated with the delivery of either Covishield or Covaxin vaccines were not severe enough to need hospitalization, and that symptoms lasted just a few days following immunization. Numerous studies have observed a similar tendency, with the majority of side effects being mild to moderate in severity and typically resolving within a few days of vaccination.

5 Conclusion

After receiving the COVID-19 immunization, women were more likely than men to experience side effects. The most common side effects of vaccines were local, such as pain, redness, and swelling at the site of injection. In addition to a temperature, chills, tiredness, nausea and vomiting, and anxiety, there were also signs of musculoskeletal discomfort. Additional research into the long-term effects and safety profiles are needed, even if the observed symptoms were well tolerated.

References

1) British Broadcasting Corporation (BBC) News. Covid vaccine: WHO warns of "catastrophic moral failure". 2021.
2) Shadmi E, Chen Y, Dourado I, Faran-Perach I, Furler J, Hangoma P, et al. Health equity and COVID-19: global perspectives. *International Journal for Equity in Health*. 2020;19(104). Available from: https://doi.org/10.1186/s12939-020-01218-z.
3) Khuroo MS, Khuroo MS, Khuroo MS, Sofi AA, Khuroo NS. COVID-19 Vaccines: A Race Against Time in the Middle of Death and Devastation! *Journal of Clinical and Experimental Hepatology*. 2020;10(6):610–621. Available from: https://doi:10.1016/j.jceh.2020.06.003.
4) Yoo JH. What We Do Know and Do Not Yet Know about COVID-19 Vaccines as of the Beginning of the Year 2021. *Journal of Korean Medical Science*. 2021;36(6). Available from: https://doi:10.3346/jkms.2021.36.e54.
5) Jones D, Helmreich S. A history of herd immunity. *Lancet*. 2020;396(10254):810–811. Available from: https://doi:10.1016/S0140-6736(20)31924-3.
6) Sprent J, King C. COVID-19 vaccine side effects: The positives about feeling bad. *Science Immunology*. 2021;6(60). Available from: https://doi:10.1126/sciimmunol.abj9256.
7) Riad A, Pokorná A, Attia S, Klugarová J, Koščík M, Klugar M. Prevalence of COVID-19 Vaccine Side Effects among Healthcare Workers in the Czech Republic. *Journal of Clinical Medicine*. 2021;10(7):1428. Available from: https://doi.org/10.3390/jcm10071428.
8) Kewei X, Yuanyuan L. A-share Stock Reactions to the Approval of COVID-19 Vaccine Clinical Trial: An Event Study Model of Listed Pharmaceutical Firms' Returns. *2nd International Conference on Economic Management and Model Engineering (ICEMME)*. 2020;p. 404–407. Available from: https://doi.org/10.1109/ICEMME51517.2020.00086.
9) Chen L, Wang B, Wang Y, Wang X. Exploratory Data Analysis on the Usage of COVID-19 Vaccine. *6th International Symposium on Computer and Information Processing Technology (ISCIPT)*. 2021;p. 502–506. Available from: https://doi.org/10.1109/ISCIPT53667.2021.00107.
10) Yang X, Sornlertlamvanich V. Public Perception of COVID-19 Vaccine by Tweet Sentiment Analysis. *International Electronics Symposium (IES)*. 2021;p. 151–155. Available from: https://doi.org/10.1109/IES53407.2021.9594036.

11) Scarabaggio P, Carli R, Cavone G, Epicoco N, Dotoli M. Modeling, Estimation, and Optimal Control of Anti-COVID-19 Multi-dose Vaccine Administration. *IEEE 17th International Conference on Automation Science and Engineering (CASE)*. 2021;p. 990–995. Available from: https://doi.org/10.1109/CASE49439.2021.9551418.
12) Jackson EB, Dreyling R, Pappel I. Challenges and Implications of the WHO's Digital Cross-Border COVID-19 Vaccine Passport Recognition Pilot. *Eighth International Conference on eDemocracy & eGovernment (ICEDEG)*. 2021;p. 88–94. Available from: https://doi.org/10.1109/ICEDEG52154.2021.9530954.
13) Feng-Cai Z, Yu-Hua L, Xu-Hua G, Li-Hua H, Wen-Juan W, Jing-Xin L, et al. Safety, tolerability, and immunogenicity of a recombinan tadenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial. *The Lancet*. 2020;395(10240):1845–1854. Available from: https://doi.org/10.1016/S0140-6736(20)31208-3.
14) Zhai P, Ding Y, Wu X, Long J, Zhong Y, Li Y. The epidemiology, diagnosis and treatment of COVID-19. *International Journal of Antimicrobial Agents*. 2020;55(5):105955. Available from: https://doi.org/10.1016/j.ijantimicag.2020.105955.
15) Yoshimoto FK. The Proteins of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS CoV-2 or n-COV19), the Cause of COVID-19. *The Protein Journal*. 2020;39(3):198–216. Available from: https://doi.org/10.1007/s10930-020-09901-4.
16) Figueroa-hurtado E, Ortíz-farias DL, Sada-ovalle I, Maldonado-ortíz SY, Valdivieso-jiménez JA, Cortes-telles A. Humoral immune response in healthcare workers after two doses of a <scp>BNT162b2 mRNA</scp> vaccine in Yucatan, Mexico. *Respirology Case Reports*. 2022;10. Available from: https://doi.org/10.1002/rcr2.920.
17) Xu Z, Shi L, Wang Y, Zhang J, Huang L, Zhang C. Pathological findings of COVID-19 associated with acute respiratory distress syndrome. *Lancet Respir Med*. 2020;8(4):420–422. Available from: https://doi.org/10.1016/S2213-2600(20)30076-X.
18) Daniel W, Nianshuang W, Kizzmekia C, Goldsmith S, A J, Ching-Lin H, et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. *Science*. 2020;367(6483):1260–1263. Available from: https://doi:10.1126/science.abb2507.