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Post-Vaccination Survey of Side Effects and Opinions Following COVID-19 Vaccination in India

Galani VJ*, Patel KB, Patel JB, Patel JK, Patel DV and Patel BH

Department of Pharmacology, Indubhai Patel College of Pharmacy and Research Centre, India

***Corresponding author:** Varsha J Galani, Department of Pharmacology, Indubhai Patel College of Pharmacy and Research Centre, Dharmaj-388430, Gujarat, India, Tel: +91 9429161203; Email: vrp173@yahoo.com

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Abstract

Objective: Vaccination is the ideal protocol to tackle pandemic coronavirus disease 2019 (COVID-19). COVID-19 vaccination campaign has been going on recently in several parts of the world including India. The protective efficiency of currently administered vaccines are frequently experience outside of clinical trial condition because of short period of testing. Thus, the present study was designed to study the post vaccination side effects and opinions following COVID-19 vaccination in India.

Methodology: The cross- sectional population based survey was conducted using Google form questionnaire.

Results: Out of 959 respondents, 51% were males and 49% were females with majority of that were below 50 years of age (77.9%) and very few were above 50 years of age (22.1%). About half (52.5%) of the participants had high school or less education and majority participants (57.7%) were from rural area. While, 77.1% participants received Covishield vaccine, 22.4% participants had Covaxin. 4.5% participants with single dose, 85.5% participants with two doses of vaccine and 10% participants with booster dose of vaccine had been recorded. 67.95% of participants opined that vaccine is safe and effective. After COVID-19 vaccination common side effects recorded were injection site pain (77.6%), Fever (62%), headache (54.8%), bone and muscle pain (47.9%), swelling and redness at the site of injection (13.8%). However, sleep disturbance (30.9%), chest pain (8.3%) and shortness of breath (6.3%) were attention seeking post vaccination side effects also observed in the present study. Prevalance of side effects like nausea, diarrhoea, loss of appetite, fever, sore throat, depression, shortness of breath, chest pain and bleeding are significantly ($p<0.05$) associated with number of doses of vaccine. Gastointestinal and cardiac side effects are significantly ($p<0.05$) associated with sex and age variables while, in addition to these psychological side effects are also significantly ($p<0.05$) associated with age variable.

Conclusion: The present study confirmed that all demographic diversities of people are participating in COVID-19 vaccination campaign of India. Further, the study participants had demonstrated a positive attitude towards vaccination. Most of the post-vaccination side effects experienced by the participants are mild to moderate, which are signs that body's immune system is building protection. Vigilance and further research is required for some of the reported potential post vaccination side effects of COVID-19 vaccines.

Keywords: COVID-19; Vaccination; Side Effects; Covishield; Covaxin; India

Abbreviations: SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus.

Introduction

The COVID-19 pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has infected more than 108 million people in over 150 countries [1,2]. The vigilance around physical distancing, wearing masks, public health interventions, and social gatherings has eased off, and some countries have been hit by second and third waves due to their hasty easing off of spatial distancing measures [3]. Regarding pharmacologic therapy for SARS-CoV 2, studies on the use of preexisting medications (e.g. Hydroxychloroquine and Remdesivir) for the treatment of COVID-19 were contradictory and did not confirm a conclusion [2,3]. This highlighted the need for specific antivirals against COVID-19 to be developed and authorized to control the pandemic [4]. To date, several vaccines have been developed and approved for emergency immunization [5,6]. This has given a glimpse of hope for preventing the spread of COVID-19 infection. Countries and governments worldwide have spent billions of dollars in preparing to immunise the population of their countries. India started the COVID-19 vaccination campaign on 16 January 2021. Vaccination drive in India is going on with the two vaccines namely, Covishield, which is the recombinant version of Oxford-AstraZeneca COVID-19 vaccine (ChAdOx1 nCoV-19, AZD1222) manufacturing by Serum Institute of India Pvt Ltd and Covaxin (BBV152), which is a whole inactivated virus-based COVID-19 vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research - National Institute of Virology [6,7]. Vaccination programmes can lead to herd immunity without requiring a substantial proportion of the community to be infected. However, such immunity requires a sufficient proportion of the population to be vaccinated. While vaccination is effectively recognized as an effective way to reduce and eliminate the burden of COVID-19, its effectiveness depends on the population's willingness to be vaccinated. Immunization programmers are only successful when there is a high acceptance rate of the vaccine [8-10]. Understanding the various side-effects that vaccination might cause is important for the different parties involved in the process, including the person receiving the vaccine, the caregivers, and the healthcare professionals [11]. Over 100 crore population in India was already been vaccinated. Studies conducted in several countries among the general population showed a high degree of acceptance of the COVID-19 vaccine [9,12]. COVID-19 vaccines are linked to various post vaccination adverse effects that continue to circulate and be debated at various social media sites. The present study was designed to assess the opinion and side effects of the COVID-19 vaccine among the general population of India.

Methodology

Cross-sectional (online survey) study was carried out including subjects of both gender and any age, who have been vaccinated with the first dose, two doses or booster dose of any of the administered vaccines in the India. Data collection was carried out between 23rd January and 27th February, 2022. A structured validated self-administered Google Form questionnaire was created after extensive review of the literature and later distributed through the social media platforms for the data collection. The form comprised III sections. Section I comprised 6 questions regarding the sociodemographic of the respondents. Participants of the present study reported their gender, age, education, occupation and residence. Section II included 7 questions asking the COVID-19 vaccine related information like types and number of doses, source of information about vaccine, opinion regarding vaccine. Section III comprised 7 questions concerning severity of side effects. All the questions in section III sough to identify the presence of side effects experienced post vaccination and their relationship with medical and non- medical factors. Incomplete Google form data were excluded from the study.

Statistical Analysis

According to Ministry of Health, Government of Gujarat, by January 18 2021, 9.4 crore individuals had been vaccinated in the Gujarat state. 48143082 (97.6%) of eligible persons above age of 18 years received the first dose of COVID-19 vaccines and 44292717 (94.6%) individuals had received the second dose. 2307645 (64.09%) individuals age group of 15-17 years had received first dose. 670025 individuals had received booster dose of the vaccine. Sample size was calculated for this study with 5% margin of error and a 95% confidence level via web-based sample size calculator (Raosoft®). The minimum recommended sample size was 384. Responses of participants were recorded in Microsoft Excel spread sheet. Data were analysed and descriptive statistics was calculated using frequencies and percentages. Associations between categorical variables were evaluated by performing chi-square test. The statistical significance level was set at $p < 0.05$.

Results

Socio-Demographics Characteristics

Out of 1032 respondents, 959 respondents had completed the self- administered questionnaire. Data of socio-demographics characteristics of the study participants are shown in Table 1. Results showed that almost equal number of males (51%) and females (49%) respondents were in the presence study. Majority of the participants (34.3%) belonged to the age group that extended between 20-29 years, while

individuals of age 60 years or more constituted only 8.9% of the study population. Participants had varying levels of education: High school or less (52.5%); Diploma (10.7%); Bachelor's degree (25.8%); Postgraduate degree (9.2%) and Ph.D (1.8%). Occupation wise distribution of respondents showed 11.6% businessman, 21.5% service persons, 24.6% homemakers and 41.3% students were recorded. 57.7% respondents were from the rural areas while 43.3% respondents were from the urban areas. In the history of any chronic disease question 817 (85.1%) respondents replied no disease, 56 (5.8%) with diabetes mellitus, 15(6.1%) with hypertension, 8 (0.9%) with cardiovascular disease,. 8 (0.9%) with obesity, 14 (1.5%) with joint inflammation, 10 (1.1%) with osteoporosis, 7 (0.7%) with autoimmune disease, 14 with (1.5%) thyroid disease, and 10 (1.1%) with other disease were reported.

Variables	Categories	Frequency	Percentage
Gender	Male	489	51%
	Female	470	49%
Age	Less than 20 years	99	10.30%
	20-29 years	329	34.30%
	30-39 years	152	15.90%
	40-49 years	167	17.40%
	50-59 years	127	13.30%
	60 years or more	85	8.90%
Education	High school or less	503	52.50%
	Diploma	103	10.70%
	Bachelor's degree	247	25.80%
	Postgraduate degree	89	9.20%
	Ph.D	17	1.80%
Occupation	Business	112	11.70%
	Service	209	21.80%
	Home maker	238	24.80%
	Students	400	41.70%
Place of Residence	Rural	553	57.70%
	Urban	406	43.30%
Are you suffering from any chronic Disease	No	817	85.10%
	Diabetes mellitus	56	5.80%
	Hypertension	15	6.10%
	Cardiovascular disease	8	0.90%
	Obesity	8	0.90%
	Joint inflammation	14	1.50%
	Osteoporosis	10	1.10%
	Auto immune disease	7	0.70%
	Thyroid disease	14	1.50%
	Cancer	0	0.00%
	Other disease	10	1.10%

Table 1: Socio-demographics characteristics of the study participants.

Covid-19 Vaccination Information

The two made in India vaccines Covishield and Covaxin are available for mass vaccination. All participants got vaccinated. As shown in Table 2, 738 (76.9%) participants had jabbed with Covishield and 221 (23.1%) participants had jabbed with Covaxin. 44 (4.6%) with single dose, 820 (85.5%) with two doses of vaccine and 95 (9.9%) with booster dose of vaccine had been recorded. 30 participants (15 male and 15 female) with single dose, 641 participants (322 male and 319 female) with two doses and 67 participants (43 male and 24 female) with booster dose of Covishield vaccine were reported. While, 14 participants (8 male and 6 female) with single dose, 179 participants (86 male and 93 female) with two doses and 28 participants (15 male and 13 female) with booster dose of Covaxin vaccine were reported (Table 3). 59.9% population received information from the government owned media platform. 63.8% of participants opined that vaccine is safe and effective. In contradictory to that very few people gave negative opinion that vaccine is not safe (2.4%) and having side effects (4.5%). The 28.3% participants reported that they had been infected with COVID-19 before vaccination (Table 2).

Variables	Categories	Frequency	Percentage
Type of vaccine	Covishield	738	76.90%
	Covaxin	221	23.10%
Doses received	Single dose	44	4.60%
	Two doses	820	85.50%
	Booster dose	95	9.90%
Source of information	Government owned media platform	575	59.90%
	Social media platform	245	25.50%
	Friends and medical webside	72	7.50%
	Scientic and medical website	33	3.40%
	I have no information	33	3.40%
Opinion regarding covid-19 vaccine	Safe and protective	612	63.80%
	Covid-19 is not dangerous	38	3.90%
	Lack of information	46	4.80%
	Not safe	23	2.40%
	Side effect	43	4.50%
Infected with covid-19 before vaccination	Yes	271	28.30%
	No	634	66.10%

Table 2: Covid-19 vaccination information of the study participants.

Dose Related Post Vaccination Side Effects

A wide spectrum of potential post vaccination side effects has been assessed among participants in the present study. Table 3 represents the frequencies of all side effects regardless of the type of COVID-19 vaccine received and association of post vaccination side effects with the number of doses of vaccine received. Data are further analysed for comparison between occurrence of side effects in both gender and age groups less than <50years and ≥ 50years (Table 4). 66 females and 98 males were not reported any post vaccination side effects. Hence, females (85.95%) had significantly (p=0.013653) greater side effects than males (79.95%).

The most common side effects were local symptoms like, injection site pain (77.6%), swelling and redness of injection site (13.8%), bone and muscle pain (47.9%). These side effects are not significantly associated with sex, age and number of doses of vaccine received (Table 3).

The gastrointestinal (GI) side effects like nausea (5.5%), diarrhoea (3.9%), vomiting (5.3%), abdominal pain (11.3%), loss of appetite (4.2%) and constipation (3.1%) were reported. Significant association of GI side effects with gender and age groups are observed. These side effects are more observed in male participants and in age group less than 50 years (Table 4). Further, nausea, diarrhoea and loss of appetite side effects are significantly associated with the number of doses of vaccine (Table 3).

The major flu like symptoms fever (69.6%), headache (40.5%), chills (4.1%), sore throat (1.8%), fatigue (3.5%), cough (3.0%), runny nose (3.9%), loss of taste (4.6%) and loss of smell (3.7%) were reported. No significant association are noted of these side effects with the number of doses of vaccine received except fever and sore throat (Table 3). Also, association of flu like symptoms with age and sex observed are not statistically significant (Table 4).

Some participants were reported psychological side effects like sleep disturbances (27.4%), anxiety and stress (5.3%) and depression (3.9%). Depression side effect was significantly associated with the number of doses of vaccine. Psychological side effects were significantly associated with age as more side effects observed in age group less than 50 years. No association is revealed between gender and psychological side effects (Table 4).

Cardiac side effects like shortness of breath (6.3%), palpitation (2.1%), chest pain (8.3%), loss of consciousness (2.5%), paleness (2.7%), bleeding (1.8%) were reported. Shortness of breath, chest pain and bleeding are found to be significantly associated with the number of doses of vaccine (Table 3). Cardiac side effects are significantly associated with gender and age of participants as more number of side effects observed in male and age group less than 50 years (Table 4).

38 (3.9%) participants had eye problems after vaccination and it was not significantly associated with sex, age or the number of doses of vaccine received (Tables 3,4). Statistical analysis revealed that no significant association is found between post vaccination side effects and types of vaccine (Covishield and Covaxin) received (data not shown).

Side effects	Categories	Frequency	Percentage	Single dose	Two doses	Booster dose	*P* value
Local symptoms	Injection site pain	744	77.60%	34	633	77	0.6939
	Swelling and redness of injection site	132	13.80%	1	117	14	0.0763
Bone & muscle pain	Yes	459	47.90%	23	387	49	0.6019
	No	403	42.00%	16	350	37	
GI side effects	Nausea	53	5.50%	7	45	1	0.0017
	Diarrhea	38	3.90%	5	31	2	0.0264
	Vomiting	51	5.30%	4	39	8	0.1674
	Abdominal pain	108	11.30%	1	96	11	0.1549
	Loss of appetite	40	4.20%	5	29	6	0.0222
	Constipation	30	3.10%	1	25	4	0.7825
Flu like symptoms	Fever	667	69.60%	29	583	55	0.026
	Headache	388	40.50%	12	338	38	0.1844
	Chills	39	4.10%	3	34	2	0.2109
	Sore throat	17	1.80%	-	12	5	0.0094
	Fatigue	34	3.50%	1	28	5	0.5859
	Cough	29	3.00%	-	25	4	0.5406
	Runny nose	38	3.90%	-	31	7	0.0971
	Loss of taste	35	4.60%	1	28	6	0.4383
	Loss of smell	29	3.70%	1	25	3	0.9549
Psychological side effects	Sleep Disturbance	263	27.40%	15	229	19	0.1559
	Anxiety and stress	51	5.30%	3	47	1	0.1417
	Depression	38	3.90%	5	28	5	0.0247

Cardiac side effects	Shortness of breath	60	6.30%	7	51	2	0.0075
	Palpitation	20	2.10%	-	17	3	0.4936
	Chest pain	79	8.30%	7	69	3	0.035
	Loss of consciousness	24	2.50%	2	17	5	0.1142
	Paleness	26	2.70%	2	20	4	0.4491
	Bleeding anywhere	17	1.80%	-	12	5	0.0094
Eye symptoms	Yes	38	3.90%	3	28	7	0.1094
	No	628	65.50%	31	543	54	

Table 3: Covid-19 post vaccination side effects experienced by the study participants and its association with number of doses of vaccine.

Side effects	Male	Female	*P* value	<50years age	≥ 50years age	*P* value
Local symptoms	401	406	0.07711	627	180	0.8144
Bone & muscle pain	227	232	0.39723	356	103	0.8723
GI side effects	149	118	0.00001	222	45	0.0189
Flu like symptoms	387	380	0.56136	597	170	0.9913
Psychological side effect	181	154	0.18961	282	53	0.0008
Cardiac side effects	111	78	0.02178	165	24	0.0007
Eye symptoms present	22	16	0.48194	33	5	0.2473

Table 4: Association of Covid-19 post vaccination side effects with gender and age of study participants.

Discussion

COVID-19 pandemic has posed threats to human life across the globe, including India. Vaccination is an effective means of addressing the pandemic threat. It is necessary to raise the awareness in the people in a way they become not hesitant to receive the vaccine. The government of India has implemented a massive vaccination drive to save its citizens from the deadly virus. The COVID- mass vaccination inoculation campaign began in India on 16 January 2021. The amazing rate at which this vaccination drive is going on not only shows its efficiency and effectiveness but also demonstrated the widespread acceptability of the program [12].

In the present study, Covishield (77.1%) vaccine was more administered than Covaxin (22.4%). In other two studies, 74% Wang J, et al. [13] and 80.7% Shah, et al. [14] study population were inoculated with the Covishield.The study revealed that a significantly greater number of female participants suffered from post-COVID-19 vaccination side effects compared to males (p = 0.0136). Also, this is similar to the trend displayed by other adverse vaccine event monitoring study of COVID-19 vaccine [15]. Several factors might be responsible for this gender disparity in vaccine side effects [16].The younger age group had highest participation in the study. Similar result was also observed in the other studies [13,17,18]. In the present study, majority of respondents used government owned social platform for getting information regarding COVID-19 vaccine. Hence, maintaining acceptance of COVID-19 vaccines has also been linked to the level of trust towards information from government sources [13,14,19]. To achieve herd immunity, greater coverage of technology delivering accurate information will reflect collective attitudes and experiences towards vaccines through communication campaigns by the health authorities [20]. 63.8% of the participants had opined that vaccine is safe and effective, similar positive attitude was reported by 68% participant in the study of Jahan, et al. [16], 56.2% participants in the study of Christian, et al. [21] and 56.5% participants in the study of Shah, et al. (2021) [14].

After a vaccine administration, some side effects usually occur which indicates that the vaccine is activating the body's immune system to defend itself from the disease. These common side effects are short-lived and much less serious than developing COVID-19 or complications associated with COVID-19 [22]. Vaccine reactogenicity represents various local and systemic manifestations because of the inflammatory response to vaccination. The reactogenicity depends on various factors like the host characteristics (age, gender, etc.), type of vaccine, composition, route of administration, and many others [23]. Therefore, it is likely that most individuals would exhibit vaccine reaction

post-COVID-19 vaccination. In the present study, several side effects have been reported after receiving COVID-19 vaccination. Similar to findings of studies published Elnaem MH, et al. [24-26], the most common post-vaccination side effects present study were pain at injection site, fever, bone and muscle pain, headache and swelling and redness at the site of injection which are consistent with the clinical trial results of Oxford/AstraZeneca's ChAdOx1 nCoV-19 and BBV152 although the frequencies of the side effects were much lower in this study. This might have happened because of differences in ethnicity, geographical location and environmental factors of the study population [27]. However, sleep disturbance, chest pain and shortness of breath were attention seeking post vaccination side effects observed in the present study. Similar side effects were also observed in other studies [15,25,28,29].

The nature of the adverse effects reported were similar to the adverse events mentioned in the safety and efficacy study of the Covishield and Covaxin [30-34]. By comparing reported symptoms after receiving the first dose of vaccine with those reported after receiving the second dose, AstraZeneca vaccines showed that the prevalence of local and systemic side effects were higher after receiving the second dose compared to the first dose [31-33]. Similar pattern was also observed in the present study. With booster dose of both vaccines same side effects were reported in our study although frequency is less compared to second dose of vaccine [35]. Association of some of the post vaccination side effects were observed with demographic characteristics (age and sex) and number of dose of vaccine [23-25].

Conclusion

The present study confirmed that all demographic diversities of people are participating in COVID-19 vaccination campaign of India. Majority of the people positively opined that the vaccine is safe and protective and the present data can be used in creating awareness among the individual who are reluctant be vaccinated. The most prevalent side effects of Covishield and Covaxin vaccines were pain at injection site, fever, bone and muscle pain, headache and swelling and redness at the site of injection. However, further studies with a greater number of participants are still required in order to confirm some potential side effects observed in the present study.

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