



**TO ASSESS THE EXPERIENCE AND SIDE EFFECTS AFTER COVID-19
VACCINATION IN HILLY POPULATION OF INDIA**

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ABSTRACT

Coronavirus disease 2019 (COVID- 19) is an illness caused by a novel coronavirus called severe acute respiratory syndrome corona virus -2 (SARS-CoV-2). Getting vaccinated prevents severe illness, hospitalizations and death. COVID- 19 vaccination programme has been started in India. There is paucity of real-world data available regarding post COVID vaccination side effects. In this study we aimed to determine post vaccination side effects and experience in hilly state of India. **Aims and objectives:** To assess experience of participants regarding COVID-19 vaccination at government designated centres. To determine the post vaccination side effects profile occurring within 72 hours **Material and Methods:** We examined self-reported post vaccination symptoms and experience using google meet forms (online survey). **Results:** A total of 902 people responded to the survey over 2 months from May to June 2021. Overall, 18% of respondents reported at least one post covid vaccination symptom occurring within 72 hours. Post-vaccination symptoms were more reported by women (20.48 %) compared to men (13.6%) The most common symptoms reported were myalgia followed by fever, headache, pain at the injection site, chills, sore throat and diarrhoea. 60% of lactating women reported side effects. **Conclusion:** As per our online survey, 18 percent of the participants reported post vaccination side effects. No serious adverse effect was reported after first dose of vaccine. Our results showed that maximum side effects were experienced in the age group 18-44 years and in women especially in lactating women.

KEYWORDS: Covid -19, Covishield vaccine, side effects.

INTRODUCTION

Coronavirus disease (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that can cause mild to severe respiratory illness including death. It first appeared in late 2019 in Wuhan (Hubei, China) and rapidly became a transnational peril affecting 220 countries.^[1,2] The first case of the COVID-19 pandemic in India was reported on 30 January 2020. Slowly, the pandemic spread to various states and union territories. The first case recorded in state of Himachal Pradesh was on 20 March 2020.^[3]

The plan of action followed by most countries around the world was to reduce the transmissibility of the disease by imposing masks, hands sanitization, social distancing, travel restrictions and lockdowns. But since this virus is highly contagious, it has rapidly spread globally. Till now there is no specific treatment available for this disease. Vaccines are the most hopeful and cost-effective public health interventions that can save millions of lives.^[4]

Two vaccines received approval for emergency use in India at the onset of programme that is covishield (a brand of the Oxford–AstraZeneca vaccine manufactured by the Serum Institute of India) and ii) Covaxin (developed by Bharat Biotech). Later in April 2021, Sputnik V (distributed by Dr Reddy's Laboratories) was approved as a third vaccine, which was deployed by May 2021. COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness. Few weeks after vaccination, our body produces T-lymphocytes and B-lymphocytes. When familiar antigens are detected, B-lymphocytes produce antibodies to attack them.^[5]

The government of India started its vaccination program on 16th January 2021 employing 3006 vaccination centres. The first phase of vaccination covered health workers and frontline workers. The next phase of the vaccine covered all residents over the age of 60, residents between the ages of 45 and 60 with one or more

qualifying comorbidities, and any health care or frontline worker that did not receive a dose during first phase.^[6]

Around four per cent of Himachal Pradesh's population has been vaccinated against Covid, according to the health bulletin released by the state as on 6th May, 2021. A total of 3.11 lakh people so far has received both doses of the Covid vaccine in the hill state, which has an estimated population of 76 lakh.

Health officials said that 90.3 percent of health workers in the state have been administered both the vaccine doses while 78 percent of people aged above 45 years have been given the first dose of the vaccine.^[7] The Himachal Pradesh government launched the third phase of the COVID-19 vaccination drive for the 18-44 years age group on 17th May 2021. Bi-weekly vaccination programmes for people in this age group was initiated.^[8]

The Covishield vaccine is made from a weakened version of a common cold virus (known as an adenovirus) from chimpanzees. The Oxford-AstraZeneca vaccine is being manufactured locally by the Serum Institute of India. When the vaccine is injected into a patient, it prompts the immune system to start making antibodies and primes it to attack any coronavirus infection. The jab is administered in two doses given between four and 12 weeks apart.^[9]

MATERIALS AND METHODS

The aim of our study:

To assess experience of participants regarding COVID-19 vaccination at government designated centers.

To determine the post vaccination side effects profile occurring within 72 hours

Objectives

To ensure that all eligible groups receive vaccine with self-confidence.

To provide correct, consistent & timely information among people to proactively manage any vaccine hesitancy, myths, misinformation.

To provide post vaccination care and support.

We examined self-reported post vaccination symptoms and experience using Google Meet forms (online survey). Ethical approval was taken to conduct this study wide letter No. Health-A-B(15)3/2021, 2757 dated 27-07-2021.

METHODOLOGY

This is a cross sectional online survey which included questions pertaining to the immediate post vaccination experience conducted in 18 years and older residents of District Bilaspur of Himachal Pradesh. Study participants were taken amongst beneficiaries who came for vaccination at government designated centres. The study intended to identify type of side effects and which age group was most vulnerable to the short-term side effects.

The vaccine was administered in the deltoid region by the well-trained nurses with Covishield vaccine. After vaccination, people were asked to wait in the observation room for 30 min to check for any side effects.

The present study was conducted over the period of 2 months from May to June 2021. A questionnaire, designed on Google Forms, written in English and delivered to participants via WhatsApp. Communication between the investigators and the subjects participating in the study was established via social media like WhatsApp. The participants were not given any incentives to participate. The importance of the research in educating the community about the vaccine's side effects was clarified. The settings were adjusted so that each participant sent only one response.

The questionnaire comprised two categories of inquiries. The first one covers background data of the subject, such as nationality, gender, age, educational level, personal habits and comorbidities and previous infection with Covid-19. The second group of questions focused on post vaccination related side effects- systemic or local occurring within 72 hours. The survey asks what type of COVID-19 vaccine the participant received and whether the participant received one or two doses of the vaccine. Participation was voluntary and data was kept confidential. Those participants were included who had received at least one dose of Covid-19 vaccine (Covishield /Covaxin/ Sputnik).

We took total 902 participants more than 18 years of age and lactating mothers < 6 months after delivery.

Statistical Analysis: Descriptive statistics were performed for the collected data. The responses were displayed as frequency (counts and/or percentage).

RESULTS AND DISCUSSION

A total of 902 people belonging to district Bilaspur of hilly state Himachal Pradesh responded to the survey. Women were the majority of the participants (586, 65 %), while men constituted the minority of participants (316, 35%). It was found that 597 (66%) participants were in the age bracket 18-44 years, 247(27.3%) participants were in the age bracket of 45-60 years, only 6 (0.66%) participants were more than 60 years of age. 52 (5.7%) lactating mothers also participated. (Graph 1)

Most of the study population was made up of people with the graduate and postgraduate (519, 57.5%) while rest were matric and below matric (383, 42.5%) education levels.

The presence of habits such as smoking, alcohol and tobacco usage in the study population were 82 (9%) participants. The presence of co-morbidities like Diabetes, hypertension, lung disease, cardiac disease in the study population was in 52 (5.76%) participants. The study population's past medical history revealed that,

while a minority of them (56, 6.2%) had previously been infected with the SARS-CoV-2 virus, most participants (846, 93.8%) had never been infected. All study participants (902, 100%) had received their first COVID-19 vaccine dose of Covishield vaccine.

The number of participants who reported were satisfied with arrangements done at the vaccination centres were 798 (88.47%) participants while 104 (11.5%) were not satisfied. Of the total 902 respondents, only 163 (18%) individuals reported the presence of at least one post vaccination symptom within 72 hours. Post-vaccination symptoms were more reported by women (20.48%) compared to men (13.6%) out of total respondents.

Presence of side effects were reported in 106 (17.75%) participants out of total 597 in the age group of 18-44 year, 25 (10.12%) participants out of total 247 participants in the age group of 45-60 years, and only in 1 (16.6%) participant out of total 6 participants more than 60 years of age. The number of participants who reported post vaccination symptoms were highest in the age group of 18-44 years. (Graph 2)

In age group 18-44 years, 106 (65%) participants out of total 163 reported side effects out of which 26(24.5%) were male and 80 (75.5%) were female. The most common side effects reported was myalgia (64, 60%) and fever (68, 64%) followed by headache (19, 18%), chills (15, 14.1%), sore throat (4, 3.7%), pain in the injection site (4, 3.7%). Women also reported increase in heart rate/ tachycardia (14, 13.2%). In the age group of 45-60 years, 25 (15.3%) participants out of 163 reported side effects out of which 16 (64%) were male and 9 (36%) were female. The most common side effects reported were myalgia (25,100%), fever (12, 48%), pain in injection site (7,28%), headache (5, 20%) chills (8, 32%), diarrhoea (2,8%). Above 60 years only one male participant showed side effects that is fever and pain at the injection site. (Graph 3)

Out of 52 lactating women, 31 (59.6%) experienced side effects. Fever (17, 32.7%) was the most common side effect followed by myalgia (13, 25%), headache (7,13.5%), pain in the injection site (5, 9.6%) and chill (4, 7.7%).(Graph 4)

Habits of smoking, drinking was in 38 (23.3%) participants. Co morbidities like diabetes, hypertension was present in only 6 (3.68%) participants out of 106. 18 out of 163 (11 %) respondents who reported post vaccination side effects also had past history of COVID-19. Their symptom profile was not different to those who did not have a past history.

In this study, all the participants had taken first dose of Covishield vaccine only. Most of the participants (88.47%) were satisfied with arrangements and monitoring of side effects done at the government vaccine booths.

Overall, 18 % of the total participants reported side effects after taking vaccine. Post-vaccination symptoms were more reported by women (20.48 %) compared to men (13.6%) The most common symptoms reported were myalgia followed by fever, headache, pain at the injection site, chills, sore throat and diarrhoea. In the age group 18-44 years, 13.2% of women also reported fast heartbeat/tachycardia.

Our results showed that maximum side effects were experienced in the age group 18-44 years and in lactating women. Our results showed that there was not much difference in post vaccination symptom profile between participants who had history of alcohol/smoking, co-morbidities and past history of covid -19 to those who did not have.

As given on the website of manufacturers of Covishield vaccine -Serum Institute of India Pvt. Ltd, following side effects have been reported to occur commonly (more than 1 in 10 people) such as tenderness, pain, warmth, or itching where the injection is given, generally feeling unwell, fatigue, chills, fever, headache, nausea, joint pain or muscle ache with this vaccine.^[9]

Various studies have been done regarding post vaccination adverse events. A study by CDC researchers in United States of America showed that side effects appeared more commonly in women than men during the first month of vaccination. Reproductive hormones, such as estrogen and testosterone, may play a role in this sex discrepancy.^[10]

Another study was done in a hospital in Delhi, where 6,962 healthcare workers registered for Covishield vaccination. It was found that side effects were often reported two days after receiving a vaccine, and people older than 50 experienced less severe reactions. 66% had reported at least one symptom after vaccination. The most common side effects following vaccination were pain at the injection site and soreness.^[11]

In Nepal, post vaccination symptoms as reported by health workers were irritability in mood, myalgia, nausea, tenderness at the injection site and fever with chills.^[12]

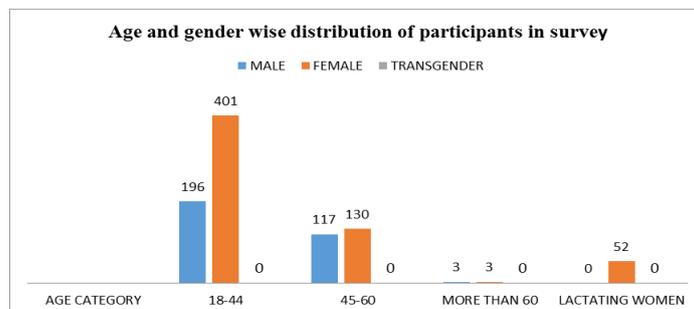
Another study done in Jordan where participants received Sinopharm, AstraZeneca, Pfizer-BioNTech, vaccines. About 10% of participants suffered from severe side effects; while 39% and 21% of participants had moderate and mild side effects, respectively.^[13]

A study of side effects of Pfizer-BioNTech COVID-19 vaccine among Saudi Arabia residents revealed the most common symptoms were injection site pain, headaches, flu-like symptoms etc. Flu-like symptoms were more common among those under 60 years of age, while injection site pain was more frequent among recipients who were 60 years and older. The study revealed a

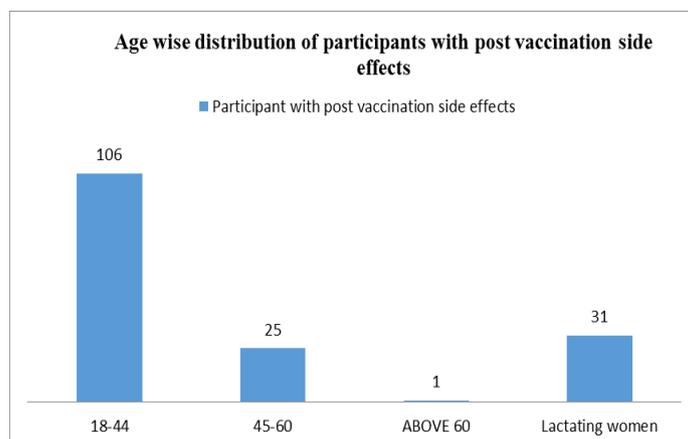
significant increase in the number of females who suffered from the vaccine side effects compared to males. Difficulty of breathing was more reported among recipients who had been previously infected with the coronavirus compared to those who had not been previously infected.^[14]

Legends

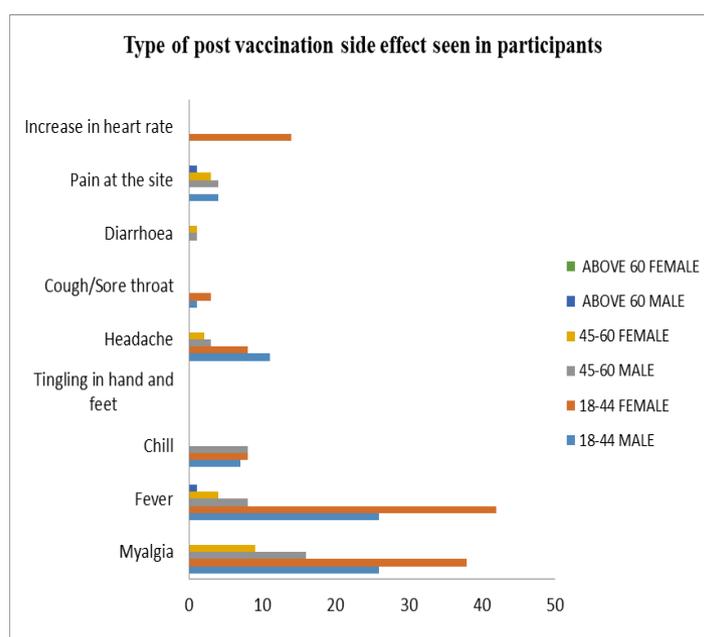
1. Graph 1: Age and gender wise distribution of participants in survey
2. Graph 2: Age wise distribution of participants with post vaccination side effects
3. Graph 3: Type of post vaccination side effect seen in participants
4. Graph 4: Type of post vaccination side effect seen in Lactating women



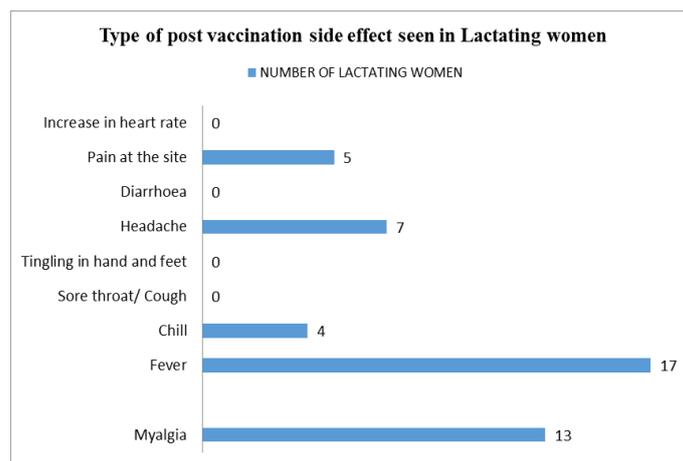
Graph 1: Age and gender wise distribution of participants in survey



Graph 2: Age wise distribution of participants with post vaccination side effects



Graph 3: Type of post vaccination side effect seen in participants



Graph 4: Type of post vaccination side effect seen in Lactating women

Limitation: Participants above 60 years of age were very less as they may not have been able to comprehend google form. Survey questions were in English, which might have posed some difficulty among those with limited proficiency in that language.

As the survey was done soon after initiation of vaccination, side effects within short term duration only could be documented. Delayed symptoms could not be assessed.

CONCLUSION

India government has started free COVID-19 vaccination on larger scale to provide acquired immunity against corona virus (SARS-COV-2).

Unvaccinated people should get vaccinated to protect from getting seriously ill, hospitalization and death. Beneficiary may have some side effects, which are normal signs that their body is building protection. These side effects may affect to perform daily activities which will go away in few days.

As per our online survey, 18 percent of the participants reported post vaccination side effects. No serious adverse effect was reported after first dose vaccine. Our results showed that maximum side effects were experienced in the younger age group and in women especially in lactating women. The most common symptoms reported were myalgia followed by fever, headache, pain at the injection site. These side effects were consistent with symptom profile as mentioned by the manufacturing company of the vaccine. Further studies are required to determine the long-term side effects.

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