

SYMPTOMATOLOGY FOLLOWING COVID-19 VACCINATION – A CROSS-SECTIONAL STUDY IN CENTRAL INDIA

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ABSTRACT

Objective: A successful COVID-19 vaccine should survive the safety, efficacy, and potency testing phases without causing any negative side effects, especially in high-risk individuals, such as the elderly, pregnant women, people with comorbidities, health-care workers, and others. The present study was conducted to determine common symptoms following the COVID-19 vaccine, the intensity of symptoms after the first and second doses, and estimate the prevalence of acquiring COVID-19 infection after getting vaccinated with the COVID-19 vaccine.

Methods: An observational cross-sectional study was conducted in the rural field practice area, including 445 participants from 19 villages. The statistical analysis was done using Microsoft Excel, and the data were represented in frequency and graphs.

Results: In the present study, the maximum (74%) of participants were Covishield recipients. The top three symptoms experienced after the first dose were headache (189), fever (130), and pain in the arm at which the vaccine was given (77). After the second dose, the top three symptoms were fever (281), headache (137), and fatigue (73). The top three psychosomatic symptoms were increased sleep (162), decreased sleep (122), and the third ranker was anxiety (93). More participants reported having severe symptoms after the first dose than after the second. Three percent of research participants contracted COVID-19 infection after the first dose, and 2% after the second.

Conclusion: Fever and headache were common symptoms after the first and second doses, but symptoms were more severe after administration of the first dose of the COVID-19 vaccine. Following vaccination, COVID-19 infection was extremely rare among participants.

Keywords: COVID-19 disease, COVID-19 vaccine, Post-vaccination symptoms.

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INTRODUCTION

A pandemic kills thousands of people, has a catastrophic impact on the economy, and has long-term health and fiscal repercussions [1]. In India, the first instance of COVID-19 was reported in January 2020. Since then, the government has issued numerous measures (lockdowns, social withdrawal, and mask wear) to monitor the populace. Countries from all over the globe were continuously collaborating to develop the COVID-19 vaccine quickly [2,3]. A successful COVID-19 vaccine should survive the safety, efficacy, and potency testing phases without causing any negative side effects, especially in high-risk individuals, such as the elderly, pregnant women, people with comorbidities, health-care workers, and others.

Although considerable effort is put into creating and implementing vaccines [3], the population's coverage rate is also a key element in determining the effectiveness of immunization. Normally, developing a vaccine would take years, if not decades. As a result, vaccine hesitancy [4,5] may pose a significant obstacle to successful immunization against the ongoing COVID-19 pandemic and the acceptance of a novel vaccine for the disease is still up in the air. The rapid spread of the virus and the absence of a specific treatment for COVID-19 infection makes vaccination a crucial weapon in the battle against the SARS-CoV-2 pandemic.

Widespread vaccination campaigns employing a range of anti-COVID vaccinations got underway in late 2020 and early 2021 to combat the COVID-19 pandemic. The Indian government began a widespread immunization campaign on January 16, 2021 [6]. Three COVID-19 vaccines Covishield by the Serum Institute of India, Covaxin by Bharat

Biotech, and Sputnik V by Zydus India and Gamelia Institute of Russia have been certified for use nationally. According to official figures, both the first and second doses of the vaccine have been administered in India a total of 79 crore times as of September 2021 [7].

A lot of professionals are investigating and studying data regarding COVID-19, and some have focused on vaccines. Adverse responses to a vaccine or any other drug, show the effectiveness of the vaccine and the immune system's reaction to it. Although adverse effects from immunizations are common and expected, each person reacts differently to different vaccines. There are conflicting views regarding the vaccine's effectiveness, one's degree of satisfaction, and capacity to stop pandemics, even though producers warn about the potential negative effects of their medicines. These represent existential perspectives on caring for one's family and oneself throughout the current pandemic. In addition, many describe how much they and their loved one's fear of getting COVID-19 disease.

Hence, this study was conducted to determine common symptoms following the COVID-19 vaccines, including various somatic and psychosomatic side effects after the first and second doses, the intensity of symptoms after the first and second dose and estimate the prevalence of acquiring COVID-19 infection after getting vaccinated with the COVID-19 vaccine.

METHODS

An observational cross-sectional study was conducted in the rural field practice area from January 2023 to February 2023. The field practice area consists of 19 villages, around 1900 households, and 18000 population.

From each village, using convenient sampling around 24 participants were selected who belonged to the 18–70 years age group, were vaccinated with the COVID-19 vaccine dose either once or both and were willing to participate in the study. A sample size of 445 was calculated using the formula $Z^2 \times p(1-p)/d^2$ [8] considering estimated $p=52\%$ [9], with $Z\alpha=1.96$ for a 95% confidence interval and a predicted acceptable margin of error $d=5\%$ and taking 15% as the non-response rate.

The questionnaire was developed based on a review of the relevant literature [10-19]. It was then tested on 20 participants and adjusted for accuracy and clarity. Participants were informed about the study's purpose, the duration of the self-administered questionnaire, the identity of the researchers and how the data would be stored in a section at the beginning of the form. Filling out the complete questionnaire and submitting it successfully was contemplated as individuals consent. The self-administered questionnaire was translated into the local language (Hindi) to collect the information. The questionnaire consists of sociodemographic information and the vaccine side effects the individuals experienced after receiving the vaccine. The study data were entered and analyzed in Microsoft Excel. Categorical variables were expressed as percentages and frequencies.

Ethical clearance

It was granted by the institutional ethics committee.

RESULTS

In the present study, 445 recipients, were included, and out of those 334 (74%) were Covishield and 88 (19.8%) were Covaxin recipients, respectively.

Sociodemographic detail shows that about 53% of participants were in the age group 31–50 years with almost equally distributed between males and females. Rural participants from the nearby villages of the rural field practice area was included. Participants had varying levels of education and literacy (83%), and 88% had monthly incomes of <50,000/month (Table 1).

The COVID-19 disease and vaccine-related perceptions show that 85% of participants had received both the first and second doses of COVID-19 vaccine, 10.1% were administered with only first dose whereas 4.7% were not vaccinated (irrespective of type and brand of vaccine). Among the available vaccines, maximum (74%) of the participants were vaccinated with Covishield, followed by Covaxin (19.8%) and Sputnik V (1.3%). About half (45%) of participants had some health-related risk (like HTN, DM II, CVD, smoking, asthma, lung infection, or drug allergy). Nine percent of participants encountered COVID-19 infection before vaccination, 3.4% contracted the disease after the first dose and 2.2% after the second dose. More than half (75.7%) of participants had faith that the vaccine will control the pandemic. Fear related to possible long-term side effects of the vaccine, 33.5% responded yes, 20.5% responded no, whereas a majority (46%) had no opinion regarding the same. The biggest fear of death after vaccination, a maximum number of participants (67.4%) denied death fear, whereas 20.7% of participants had the perception that a vaccine can lead to death. The maximum (83%) participants were willing to motivate peers to get vaccinated (Table 2).

Participants were allowed to respond with more than one option as they can experience various symptoms simultaneously. Regarding the various symptoms experienced by study participants after the first dose of the COVID-19 vaccine, the top three side effects experienced were headache (189), fever (130), and pain in the arm where the vaccine was administered (77). Other symptoms following vaccination had lower reporting frequency (Fig. 1).

*Participants were allowed to respond with multiple choices of symptoms, so the total will not represent the sample size

Symptoms following the second dose of the COVID-19 vaccine, top three symptoms reported by study participants were fever (281), headache (137), and fatigue (73). Other symptoms had a lesser reporting frequency (Fig. 2).

Table 1: Sociodemographic characteristics of the study respondents (N=445)

| Age group | Frequency (%) |
|-----------------------|---------------|
| 18–30 years | 145 (32.6%) |
| 31–50 years | 237 (53%) |
| 51–67 years | 63 (14.1%) |
| Gender | |
| Male | 183 (41%) |
| Female | 262 (59%) |
| Education | |
| Illiterate | 77 (17%) |
| Matric pass | 72 (16.2%) |
| Higher secondary pass | 55 (12.4%) |
| Graduate | 169 (37.9%) |
| Post graduate | 57 (12.8%) |
| Other courses | 15 (3.4) |
| Income | |
| <50000 | 394 (88.5%) |
| >50000 | 51 (11.5%) |

Table 2: COVID-19 disease and vaccine-related perception among the study participants (N=445)

| COVID-19 disease and vaccine-related perception | Frequency (%) |
|--|---------------|
| Health-related risk factor | |
| Yes | 200 (45%) |
| No | 245 (55%) |
| COVID-19 vaccination status | |
| Only first dose | 45 (10.1%) |
| Both first and second dose | 379 (85.2%) |
| Not vaccinated | 21 (4.7) |
| Name of COVID-19 vaccine received | |
| Covishield | 330 (74.2%) |
| Covaxin | 88 (19.8%) |
| Sputnik V | 6 (1.3%) |
| Not vaccinated | 21 (4.7%) |
| History of COVID-19 infection before and after vaccination | |
| Before COVID-19 vaccine | 40 (9%) |
| After first dose | 15 (3.4%) |
| After second dose | 10 (2.2%) |
| Not infected | 380 (85.4%) |
| Will the COVID-19 vaccine help the control of pandemic? | |
| Yes | 337 (75.7%) |
| No | 35 (7.9%) |
| Do not know | 73 (16.4%) |
| Can the COVID-19 vaccine lead to death? | |
| Yes | 92 (20.7%) |
| No | 300 (67.4%) |
| Do not know | 53 (11.9%) |
| Are there long-term side effects of the vaccine? | |
| Yes | 149 (33.5%) |
| No | 91 (20.5%) |
| Do not know | 205 (46%) |
| Will you motivate others for vaccination? | |
| Yes | 370 (83.2%) |
| No | 46 (10.3%) |
| Do not know | 29 (6.5%) |

*Participants were allowed to respond with multiple choices of symptoms so the total will not represent the sample size. Participants were permitted to choose more than one response because different symptoms can occur at once.

Related to the intensity of different symptoms experienced by the study participants with first and second doses of the COVID-19 vaccine study found that out of 445 participants, 286 participants said that the

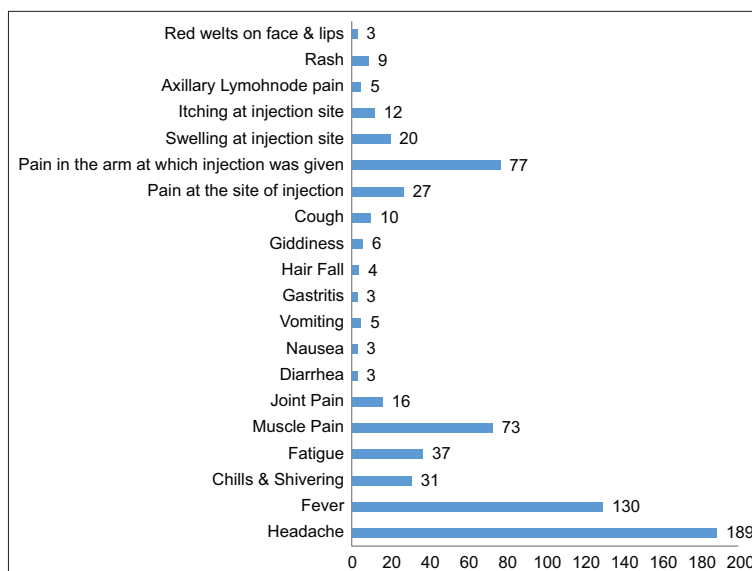


Fig. 1: Various symptoms experienced by study participants after the first-dose administration of the COVID-19 vaccine*

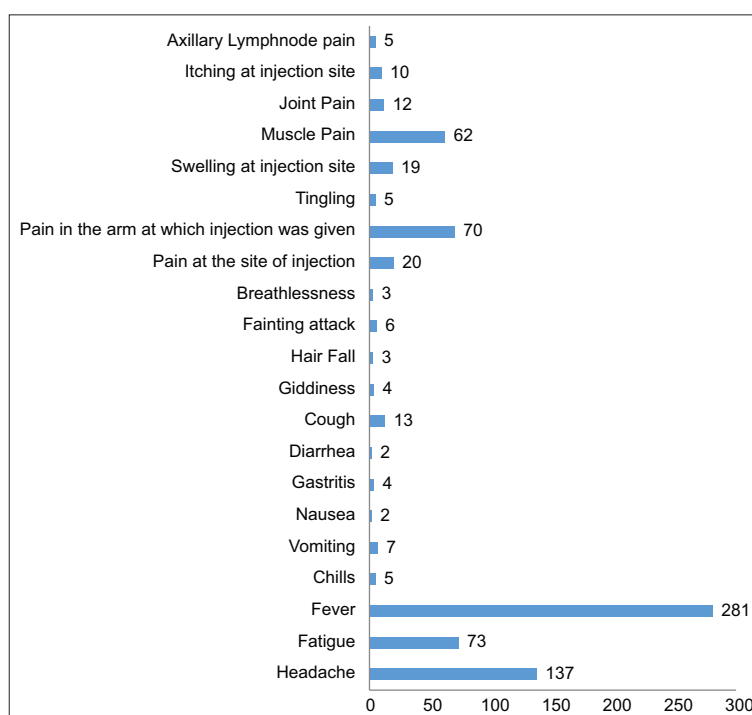


Fig. 2: Various symptoms experienced by study participants after the second-dose administration of the COVID-19 vaccine*

symptoms after first dose were more intense than second dose whereas 93 participants reported that symptoms with the second dose were more intense than the first dose of the COVID-19 vaccine (Fig. 3).

The most common reported psychosomatic symptoms (irrespective of the dose) were increased sleep (162), decreased sleep (122), and anxiety. Other psychosomatic symptoms had a lower frequency (Fig. 4).

*Participants were allowed to respond with multiple choices of symptoms so, the total will not represent the sample size.

DISCUSSION

Studies on the symptomatology and adverse reactions following the administration of varying doses of the COVID-19 vaccine has been conducted all over the world.

The current study had 53% of participants in the age group of 31–50 years similar distribution was seen in the UAE-based study with 50% of participants in the age group 35–55 years, but the male–female distribution in this UAE-based study is not the same as that of the current study where equal participation from male and female participants was observed [20]. Nearly half (45%) of participants had some or other health-related risk factor, whereas various studies around the globe had different percentages of health-related risk factors ranging from 28% to 52% [21,22].

The prevalent vaccine type in the current study is Covishield, but most of the studies conducted around the world are based on, Sinopharm, Pfizer (BNT162b2), Moderna, CoronaVac, and various other vaccines [21-25]. Participants in the studies conducted in Uganda and Ethiopia were received the AstraZeneca vaccine; the current

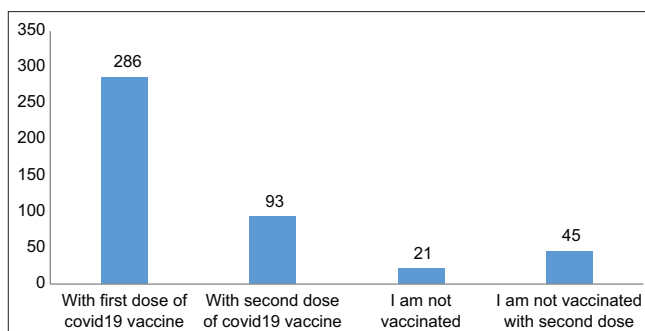


Fig. 3: Intensity of symptoms experienced by study participants after first and second dose of COVID-19 vaccine (N=445)

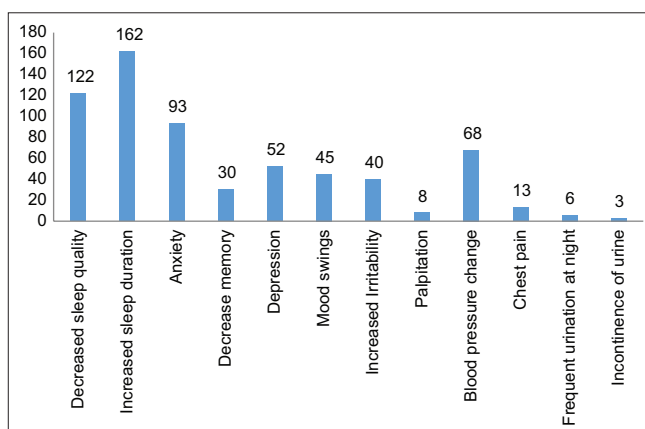


Fig. 4: Psychosomatic symptoms experienced by study participants following the COVID-19 vaccine*

study's vaccine mixture was not used in those studies [26,27]. Around 21% of participants reported fear of death related to the vaccine, and 33.5% had the impression that the vaccine has long-term side effects. Similar findings are reported by a tweet-based study from India, which concluded that 21% of tweets were negative, including the fear of death and long-term side effects.[28] In the present study, the top three symptoms experienced after the first dose of the COVID-19 vaccine were headache, fever, and pain in the arm where the vaccine was given. The study from Uganda documented almost similar results with segregation as local and systemic side effects, headache, tiredness, and pain at the injection site as top rankers [26]. An Ethiopian study found that the top-ranked symptoms after the first dose are headache (48.8%), fever (38.8%), and muscle pain (38.8%), almost similar to the present study [27].

Common symptoms reported by study participants in the present study following the second dose of the COVID-19 vaccine were fever, headache, and fatigue. A study from Ethiopia [27] has reported injection site pain, headache, fatigue, tenderness, and fever as top symptoms following the COVID-19 vaccine. While researchers from Nepal have documented pain at the injection site, fatigue, and headache in order as common symptoms following the second dose of Covishield [29]. The minor variation in the findings may be attributed to the different study populations and individuals' perceptions and reporting of the symptoms of the vaccine.

The present study also had questions related to psychosomatic symptoms after COVID-19 vaccination but could not find any study specifically discussing the same. The study found that 64.2% of participants reported symptoms following the first dose of the COVID-19 vaccine to be more severe, whereas 21% of participants felt the severity of symptoms was more severe following the second dose of the vaccine. Research from Ethiopia has concluded that at least one

symptom is experienced by the respondents after the first (91%) and second (69.7%) doses of the AstraZeneca vaccine [27].

Studies related to symptoms following Covishield/AstraZeneca administration were fewer, and in the present study, the maximum (74%) of participants were recipients of Covishield.

A study from the UAE documented the common side effects of Sinopharm as normal pain at the site of vaccination (42.2%), fatigue (12.2%), and headache (9.6%) [21]. While research from Mexico has reported common side effects (health-care workers) after Pfizer-BioNTech vaccine administration as pain at the vaccination site (76.7%), headache (32.9%), and fatigue (30.3%). [23]. The current research discovered that 2.2% of participants contracted the disease after the second dose of the COVID-19 vaccine and 3.4% after the first dose. A study from Israel done on health-care workers who had received the Pfizer-BioNTech COVID-19 vaccine documented that 22 (0.54%) participants developed COVID-19 between 1 and 10 days (median 3.5 days) later [30]. The difference might be due to the exclusive inclusion of health-care workers, large sample size, and different vaccines.

CONCLUSION

Current research concludes that Covishield was the vaccine that was commonly received, whereas Covaxin and Sputnik V were received by fewer participants. The symptomatology following either dose of the COVID-19 vaccine is typical, and the prevalence of COVID-19 infection following any COVID-19 vaccine is incredibly uncommon among research participants.

Strengths and limitations

The research is more generalizable because the general population is included. The fact that the information was self-reported enhances its impartiality. Given that the gender distribution of the participants is not equal, the findings of this research should be interpreted with caution in terms of external validity. Due to the nature of self-reporting, the severity and intensity of adverse responses were not evaluated, meaning that they may have been overestimated or underestimated. The stated symptom duration was not determined.

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AUTHOR'S CONTRIBUTION

Vibha Arjaria - Concept, design, clinical protocol, data collection, definition of intellectual content, literature survey, implementation of the study protocol, and manuscript preparation. Deepika Badkur - Manuscript preparation, data collection, editing, and manuscript revision, preparing the first draft of the manuscript, review of manuscript, and submission of the article. Vikas Pandey - Data and statistical analysis, data interpretation, and review of manuscript.

CONFLICT OF INTEREST

No! conflict of interest is found elsewhere, considering this work.

AUTHOR'S FUNDING

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