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

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.

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 either once or both and were willing to participate in the study. A sample size of 445 was calculated using the formula \( Z^2 \cdot p (1-p)/d^2 \) [8] considering estimated \( p=52\% \) [9], with \( Z=1.96 \) 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)**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18–30 years</td>
<td>145 (32.6%)</td>
</tr>
<tr>
<td>31–50 years</td>
<td>237 (53%)</td>
</tr>
<tr>
<td>51–67 years</td>
<td>63 (14.1%)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>183 (41%)</td>
</tr>
<tr>
<td>Female</td>
<td>262 (59%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>77 (17%)</td>
</tr>
<tr>
<td>Matric pass</td>
<td>72 (16.2%)</td>
</tr>
<tr>
<td>Higher secondary pass</td>
<td>55 (12.4%)</td>
</tr>
<tr>
<td>Graduate</td>
<td>169 (37.9%)</td>
</tr>
<tr>
<td>Post graduate</td>
<td>57 (12.8%)</td>
</tr>
<tr>
<td>Other courses</td>
<td>15 (3.4%)</td>
</tr>
<tr>
<td>Income</td>
<td></td>
</tr>
<tr>
<td>&lt;50,000</td>
<td>394 (88.5%)</td>
</tr>
<tr>
<td>&gt;50,000</td>
<td>51 (11.5%)</td>
</tr>
</tbody>
</table>

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

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

*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
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
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Symptoms of the vaccine. Research from Ethiopia has concluded that at least one
the severity of symptoms was more severe following the second dose
21% of participants felt
specifically discussing the same. The study found that 64.2% of
symptoms after COVID-19 vaccination but could not find any study
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 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
cautious 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.

ACKNOWLEDGMENT

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their honest perceptions by participating in the present study.

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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REFERENCES

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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*


