Indian Journal of Pharmacy Practice., 2023; 16(4):353-359.
https://www.ijopp.org

Original Article

Assessment of Efficacy and Safety Associated with COVID-19 Vaccines: A Questionnaire Based Cross-Sectional Study

Sri Jahnavi Adusumilli, Hari Sai Gnana Lakshmi Gadu, Devi Priyanka Marni, Sri Raghu Bapiraju Mudunuri

Department of Pharmacy Practice, Shri Vishnu College of Pharmacy, Bhimavaram, West Godavari, Andhra Pradesh, INDIA.

ABSTRACT

Objectives: To evaluate the effectiveness and safety of different COVID-19 vaccines approved by CDSCO. The aim is to assess the safety and efficacy of COVID-19 vaccines through a questionnaire-based cross-sectional study. **Materials and Methods:** The Cross-Sectional Observational study has been carried out through a questionnaire-based survey followed by a telephonic interview. Microsoft Excel and GraphPad Prism version 9.3.1 were accessed to examine the statistics. Chi-square, Kruskal-Walli's, and Mann-Whitney tests were accessed to assess the effect of categorical variables, one independent variable on two or more dependent variables, and 2 independent groups respectively. **Results:** Significant difference seen between marital status and COVID infection status, age, and vaccination status. The older the age, number of vaccines taken increases. Significant differences were seen between age and severity of side effects. High-age people have less severe side effects. Vaccinated people were less infected with COVID-19 infection. Significant differences were seen between age and Covid infection status. Low-age people were less infected. **Conclusion:** In our study, 37.38% weren't infected. Among the infected 65.69% were before vaccination, 10.51% after the first dose and before the second dose, 20.22% after the second dose, 1.94% after the booster dose, and 1.61% both before and after vaccination. 41.86% experienced side effects like fever, pain at the injection site, body pains, and headache. Side effects being temporary only a few had to stop by a physician or taken to the infirmary. So, we conclude COVID-19 vaccines have shown better efficacy and safety.

Keywords: SARS-CoV-2, COVID-19, AEFIn, CDSCO.

Correspondence:
Ms. Sri Jahnavi Adusumilli
Department of Pharmacy Practice,
Shri Vishnu College of Pharmacy,
Bhimavaram, Andhra Pradesh, INDIA.
Email: jahnaviadu@gmail.com

Received: 02-04-2023;
Revised: 11-07-2023;
Accepted: 21-08-2023.

INTRODUCTION

The pharmacovigilance of vaccines is exceedingly prime and essential this day, as millions of people are immunized universally. Up to date vaccines with safety profiles emerging from clinical trials on a few samples size would require vigorous monitoring worldwide to evaluate current reactions post licensure.[1] while occurrence of vaccine averting diseases is diminished by increasing broadcast with the effective vaccine, immunization connected adverse events, regardless of causally linked become exceedingly eminent.[2]

COVID-19 epidemic held marvellous record on the well-being of the individuals globally, encompassing India, and is advancing with its effects. In spite the COVID-19 vaccines productively avert virus, still little occurrences of infections became outlined post- immunization, enhancing trouble their efficacy and safety.[3]

Here survey was focused to analyse safety associated with vaccination and the happening of SARS-CoV-2 infection among the immunized people.

The breakthrough infection is an infection with a bacteria, virus or other microorganism even after vaccination. This is an anticipated experience for a little proportion of those accepting any vaccine, as no vaccine is 100% productive in preventing infection in every individual who takes it.[4] Breakthrough coronavirus infections occur when anyone who has been fully immunized for COVID-19 happen to get contaminated with the SARS-CoV-2 coronavirus.[4]

Most of the studies probed the welcoming of COVID-19 vaccines and its fore casters besides the outlook towards these vaccines among communal. Even though the secure efficacy is often considered, little is familiar about the actual-world post-vaccination event outward of clinical trial circumstances. Very few studies have appraised the safety and efficacy of the COVID-19 vaccines building on the details available. Hence, this project has aimed to estimate the effectiveness of COVID-19 vaccines. To evaluate adverse events and complications occurred during and post vaccination period.

DOI: 10.5530/ijopp.16.4.61

MATERIALS AND METHODS

Source of data

- Questionnaire based survey followed by telephonic interview.
- Methods of collection of data Place of study Andhra Pradesh.
- Study design A Cross Sectional Observational Study.
- Sampling method the sample size was determined to be 405 (369 + 10% of drop-out rate) participants. The level of significance was set at 0.05, with a margin of error of 5% and a confidence interval of 95%. However, the actual sample size obtained for the study was 987 individuals.
- Incidence of AEFI (adverse event following immunization) with Covishield was observed to be 40%.[5] Our sample size is 987.

Inclusion criteria

- Partially COVID-19 vaccinated (vaccinated with only 1 dose) (or) Fully COVID-19 vaccinated (vaccinated with 2 doses or 3 doses) people.
- People who are willing to comply with all study requirements.
- People above or equal to 18 years.

Exclusion criteria

- Unvaccinated people.
- People who are not willing to comply with all study requirements.
- Vaccinated people other than in India.

Study Instruments

A questionnaire was designed to collect relevant data on demographics, COVID-19 infection status, vaccination status, and post-immunization adverse effects and complications. The questionnaire was validated to ensure its accuracy and effectiveness. Based on the inclusion and exclusion criteria, participants meeting the eligibility requirements were selected for the study. Adverse effects experienced by the participants post COVID-19 immunization were screened. The incidence of COVID-19 infection post-immunization was assessed among the participants. Participants underwent a detailed examination to gather comprehensive data for analysis. The collected data was validated to ensure its quality and reliability. Data analysis was performed using Graph Pad Prism 9.3.1 to generate results, which were then used to compile the final report.

Statistical Analysis

Data collected through personal / telephonic interview. MS Excel / Google Form was used for data entry. Graphs and analysis in graph pad prism 9.3.1. Demographics, COVID-19 infection status, vaccination status, side effects, and complications of COVID-19 vaccines were summarized using frequency and percentage to provide a clear overview of the study population. The Chi-Square test was employed to assess associations between categorical variables, such as gender, education status, profession, smoking, alcohol consumption, vaccination status, and COVID-19 infection status. This test helped identify potential risk factors. The Kruskal-Walli's test was utilized to analyse the relationship between the independent variable (age) and multiple dependent variables (vaccination status, severity of side effects, COVID-19 infection status, health-related problems). This non-parametric test was used when assumptions of other tests were not met. The Mann-Whitney test was used to compare two independent groups, specifically age and COVID-19 symptoms, and age and side effects onset. This test allowed for comparisons when the data did not meet the assumptions of parametric tests.

Ethics and consent

Institutional Ethical Committee of Shri Vishnu College of Pharmacy catalogued below SVCP/IEC/21/03 approved the survey. Chairperson of Institutional Ethics Committee gave permission to conduct the study.

RESULTS

Paramount of the participants in the study belong to age group 18-40 years (64%) followed by age group 41-60 years (30%), 61-80 years (6%) and >80 years (0.2%). Almost equal amount of male (51%) and female (49%) participated in the study and majority of them were married (56%) (Figure 1). A significant difference seen between marital status and COVID infection status. Married people were more contaminated with COVID-19 infection contrast to unmarried people. Among educational status, graduates were more contaminated with COVID-19 infection contrast to others. Among professions, professionals were more contaminated with COVID-19 infection contrast to others.

Majority of participants in our study are vaccinated with Covishield (74.56%) followed by Covaxin (25.22%) (Figure 2). A significant difference seen between age and vaccination status. The older the age, the no of vaccines taken increased. A significant difference seen between age and severity of side effects (Figure 3) especially in very low and moderate side effects. High age group people have less severe side effects. Due to low sample size of alcoholic's people taking alcohol has shown less severe side effects.

Married people were more vaccinated compared to unmarried people. Among professions, professionals were more vaccinated compared to others. Vaccinated people were less infected with COVID-19 infection (Figures 4 and 5). 41.13% of participants had encountered COVID-19 before receiving vaccination, whereas 21.4% experienced infection even after being vaccinated.

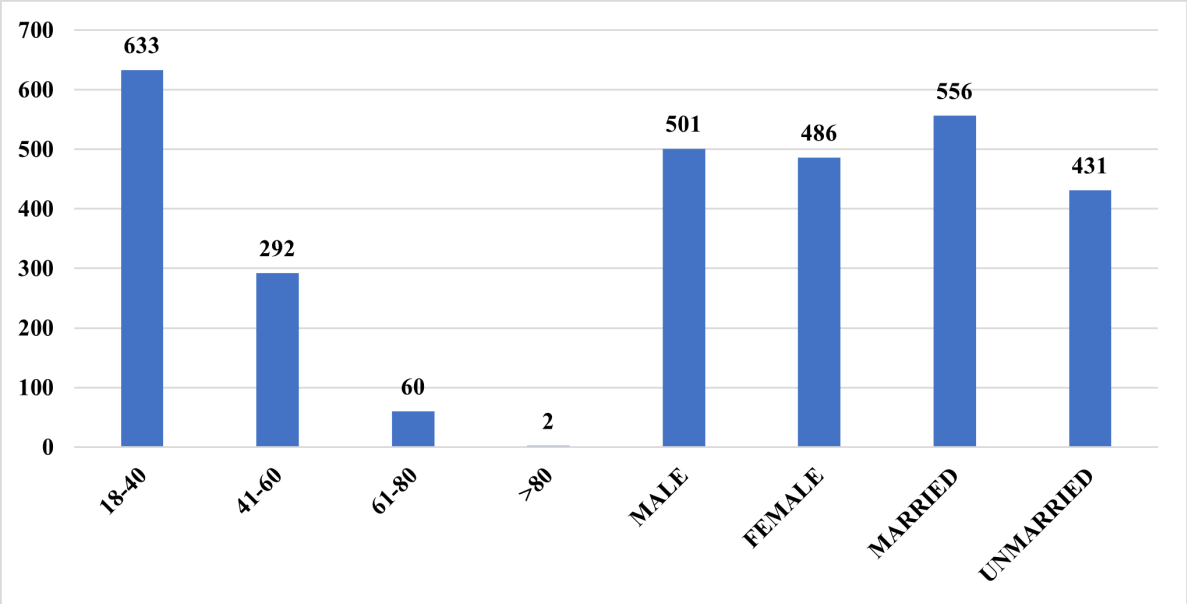

Figure1: Demographics classification of the subjects. Paramount of the participants in the study belong to age group 18-40 years. Almost equal amount of male and female participated in the study and majority of them were married.

Higher age people were seen to have less health-related problems post vaccination compared to lower age group. Higher age group people have shown symptoms than lower age group people. Higher age group people have immediate onset of symptoms compared to low age people.

A significant difference seen between age and Covid infection status (Figure 6). Low age group people were less infected than high age group. Side effects observed in about 40% participants, and in those experienced side effects, more were seen in patients vaccinated for 1 dose (58.13%) (Figure 7).

Within our study, distinct patterns emerged: 37.38% remained uninfected, 41.13% contracted COVID-19 prior to vaccination, and 21.4% experienced infection post-vaccination. Among those who were infected, 65.69% were affected before vaccination, with 10.51% encountering infection after the first dose but prior to the second, 20.22% after the second dose, 1.94% post-booster dose, and 1.61% both before and after vaccination. Notably, 41.86% of participants reported experiencing side effects, with fever (24.05%), pain at the injection site (22.31%), body pains (16.56%), and headache (12.3%) being the most common complaints. Remarkably, the majority of side effects were temporary, lasting 1-2 days (76.88%) or 3-4 days (16.88%), with only a minority seeking medical attention.

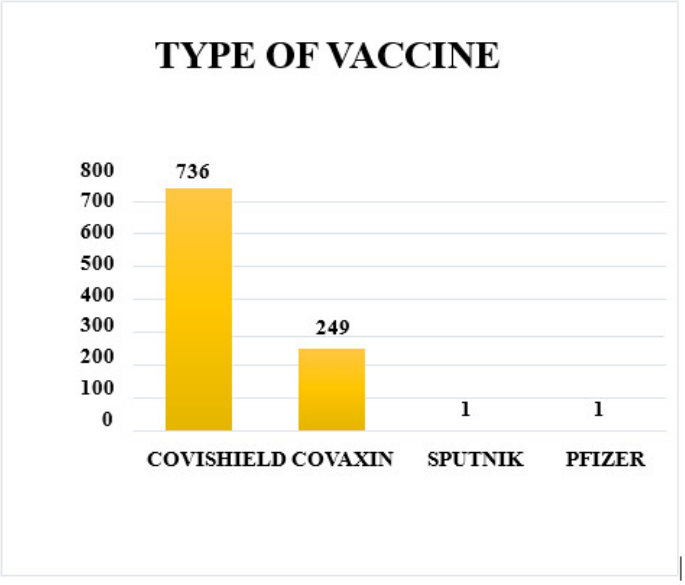

Figure 2: Graph of subjects based on the type of vaccination taken. Majority of participants were vaccinated with Covishield (74.56%) followed by Covaxin (25.22%). One participant each vaccinated with Sputnik and Pfizer.

DISCUSSION

The observation that only about one fourth of the individuals (21.4%) became infected with COVID-19 after receiving immunization is promising and aligns with the findings of other studies. Arifa Sultana *et al.* (2021) conducted a study that explored the temporary side effects of COVID-19 vaccines. Their research indicated that a substantial number of individuals experienced fever, pain at the immunization site, irritation at the injection site, body pain, vertigo, swelling, and drowsiness. Importantly, these side effects were generally temporary in nature, and only a small proportion of participants had to seek medical attention or hospitalization due to these effects.[2]

In line with the current study, a growing body of literature indicates that post-immunization COVID-19 infections are relatively infrequent. Similar observations were made by Raju Vaishya *et al.* (2021), where only a small fraction of participants reported infections after vaccination. This aligns with the notion

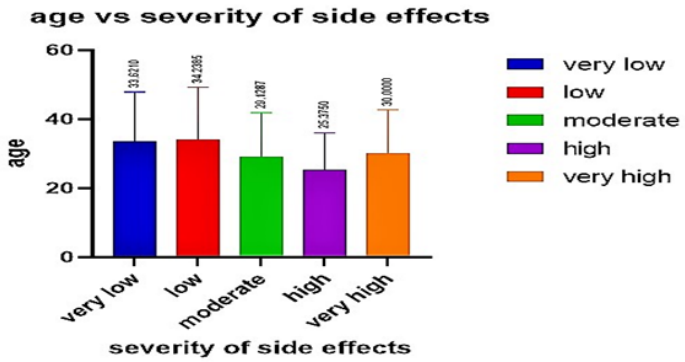

Figure 3: Graph of subjects based on comparison of age and severity of side effects. The severity of side effects increased with increase in age. Mean age 33-34 years experienced less severe side effects compared to mean age of 25-30 years who experienced more severe side effects.

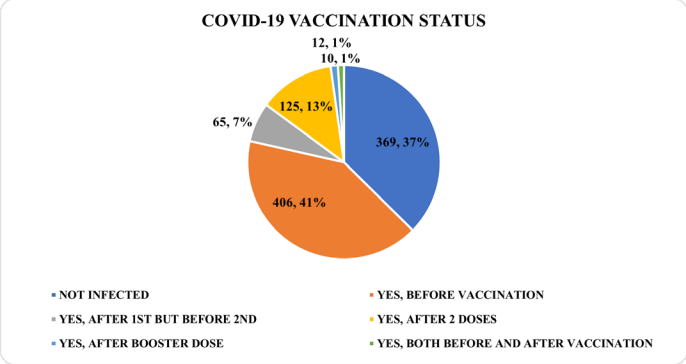

Figure 4: Pie chart based on COVID-19 infection status of subjects. 37.38% were not infected, 41.13% were infected before vaccination, 21.4% were infected after vaccination. This shows effectiveness of vaccines as majority were not infected after vaccination.

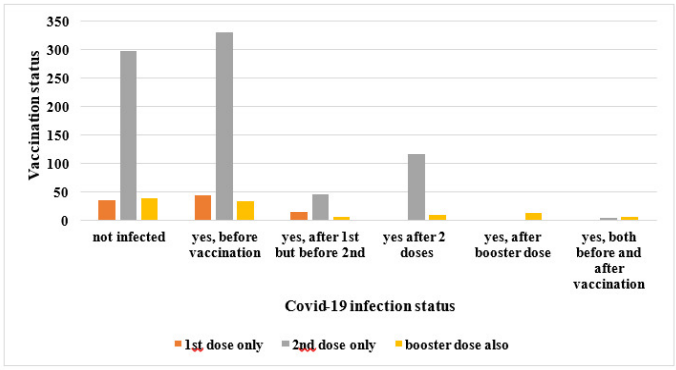

Figure 5: Graph of subjects based on comparison of COVID-19 virus infection status and immunization status. This shows vaccinated people were less infected with COVID-19 infection. Amidst those infected majority were before vaccination.

that immunization plays a substantial role in reducing the likelihood of infection.[3]

The reported side effects in the present study, such as fever, pain at the injection site, body pains, and headache, mirror the common short-term reactions reported in other investigations. Preethi Selvaraj *et al.* (2022) revealed that muscle ache, fatigue, weakness, and back pain were frequent complaints post-immunization, corroborating the transient nature of these effects.[6]

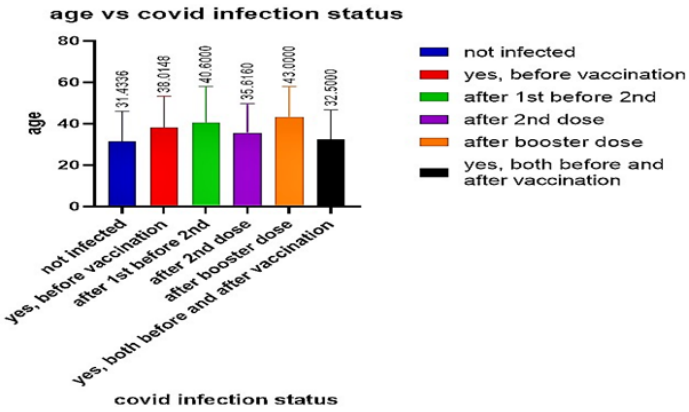

Figure 6: Graph based on comparison of age and Covid infection status. Lower age group people (mean age of 31years) were not infected compared to high age group people (35-40 years).

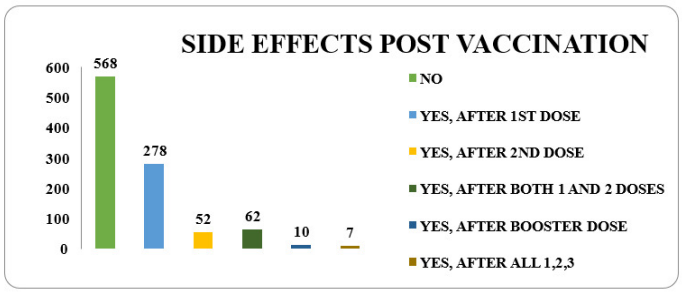

Figure 7: Graph of subjects based on side effects post vaccination. Majority of participants did not adventure any side effects post immunization. Amidst those adventured, paramount adventured after first dose, followed by after both doses, after 2nd dose, after booster dose, after all three doses.

Furthermore, research by Parameswaran *et al.* (2022) underscores this point, highlighting that breakthrough infections post-vaccination were observed in a minority of cases, and two doses of vaccines such as Oxford/AstraZeneca or Covaxin significantly lowered the incidence and severity of infections. This is consistent with a notable decrease in infection intensity subsequent to the administration of two vaccine doses contrasted with a solitary administration (Parameswaran *et al.*, 2022).[7]

Similarly, Sushila Kataria *et al.* (2021) found that side effects were generally self-limiting and resolved within a few days. These findings emphasize the tolerability of the vaccines and the temporary nature of the discomfort experienced by the majority of recipients.[8]

Addressing concerns about the long-term efficacy and safety of the vaccines, Stephen J. Thomas *et al.* (2021) conducted a study spanning six months and noted a sustained safety profile and efficacy of the Pfizer vaccine. This observation aligns with the continuous effectiveness of immunization in preventing COVID-19 cases over time. [9]

Additionally, Stefano Porru *et al.* (2022) found that breakthrough infections were significantly less likely among immunized healthcare workers compared to unimmunized individuals,

underlining the protective effect of vaccination even in cases of exposure.[10]

Balsam Qubais Saeed *et al.* (2021) also investigated the side effects of COVID-19 immunization. Their study revealed that after the first dose, common side effects included pain at the immunization site, fatigue, and headache. Interestingly, after the second dose, these researchers found that pain at the immunization site, headache, fatigue, and lethargy were the more common side effects. This supports the notion that the side effects might vary between the first and second doses, possibly due to different immune responses or dosage levels.[11]

Immunization not only reduces the likelihood of infection but also has a significant impact on the severity of the disease. Jamie Lopez Bernal *et al.* (2021) indicated that vaccination with a single dose of Pfizer or Covishield showed a connection with substantial decrease in typical COVID-19 cases, especially among elder individuals, and provided shielding from serious illness. This underscores the pivotal role of vaccines in preventing severe outcomes even in breakthrough cases.[12]

In a noteworthy development, the study conducted by Gunale *et al.* (2023) undertook a phase 2-3 study with observer-blinding and randomized clinical trial to evaluate the effectiveness and safety of a genetically engineered full-length spike protein COVID-19 immunization among children and adolescents. It exhibited noninferiority in terms of neutralizing anti-spike IgG antibodies and antibodies. The vaccine demonstrated its efficacy against various virus variants, underlining its potential in combating evolving challenges. Notably, common solicited adverse events encompassed reactions at injection site, fever, headache, malaise, and fatigue. Importantly, no notable adverse events were observed, and the investigation identified no causally related serious adverse events, bolstering the vaccine's safety profile.[13]

In a parallel pursuit, this study by Elgendy MO *et al.* (2022) investigated vaccine safety and efficacy in the Egyptian population to bolster public vaccine acceptance. Utilizing an online survey, participants receiving BBIBP-CorV, ChAdOx1, or BNT162 vaccines were assessed for side effects and responses. Common post-vaccine symptoms emerged, including discomfort at the injection site, muscle pain, fatigue, dizziness, fever, and headache. Interestingly, ChAdOx1 exhibited more side effects compared to BNT162 and BBIBP-CorV. Side effects primarily appeared within the initial 24 hr, lasting 1-2 days. Notably, prior coronavirus infections amplified immune responses. ChAdOx1's effectiveness surpassed BBIBP-CorV, with one ChAdOx1 dose akin to two BBIBP-CorV doses. This study underscores vaccines' safety and immunity-boosting potential, supported by mild-to-moderate side effects as markers of immune activation.[14]

This comprehensive study by Xing K *et al.* (2021) systematically assessed the safety and efficacy of COVID-19 vaccines, coinciding with our research focus. It included 13 trials involving 11 vaccines, conducted until December 2020. Like our study, it used quality assessment tools and a qualitative approach. Notably, many vaccines showed efficacy exceeding 80%, with two large trials achieving 95% and 70.4%. Adverse reactions were mostly mild and transient, aligning with our findings. Frequent side effects encompassed injection site pain and fatigue. The study, like ours, identified a positive link between vaccine dose and immune response, supporting double-dose vaccinations.[15]

Conducting a comprehensive review of COVID-19 vaccines' safety and efficacy, this study by Alhandod TA *et al.* (2023) aimed to alleviate public concerns about adverse reactions and protection duration. Focusing on AstraZeneca, Pfizer, Moderna, and Janssen vaccines approved in Saudi Arabia, the research systematically analyzed articles from key databases, aligning with our approach. Evaluated data showcased common local and systemic reactions, mirroring our findings of mild-to-moderate side effects like pain, redness, swelling, fever, chills, fatigue, headache, and muscle pain. Notably, vaccine efficacy surpassed WHO's threshold, echoing our shared observation of effectiveness. The study's emphasis on special population vaccination precautions resonates with our recognition of cautious administration for certain groups. Importantly, the call for additional research on rare post-vaccination adverse events mirrors our conclusion, highlighting the need for further investigation. These resonating objectives and outcomes underscore the significance of such studies in boosting public confidence in COVID-19 immunization.[16]

In the scope of the current study, the most frequently reported side effects were fever (24.05%), pain at the injection site (22.31%), body pains (16.56%), and headache (12.3%). These findings from various recent studies align with our observations, reinforcing the effectiveness and safety of COVID-19 vaccines. This consistency across studies lends further credibility to the observations made in the current study.

CONCLUSION

In our comprehensive study, distinct infection patterns emerged: 37.38% of participants remained uninfected, 41.13% contracted COVID-19 prior to vaccination, and 21.4% experienced infection post-vaccination. Among those who were infected, 65.69% were afflicted before vaccination, with 10.51% experiencing infection between the first and second vaccine doses, 20.22% after the second dose, 1.94% post-booster dose, and 1.61% both before and after vaccination.

Furthermore, our investigation revealed that 41.86% of participants reported experiencing side effects, with prevalent

symptoms including fever (24.05%), pain at the injection site (22.31%), body pains (16.56%), and headache (12.3%). Notably, the majority of side effects were transient, lasting 1-2 days (76.88%) or 3-4 days (16.88%), with a minority requiring medical attention.

In light of these findings, we draw the conclusion that COVID-19 vaccines have demonstrated commendable efficacy and safety profiles. Immunization significantly reduces the incidence of infections, minimizes disease severity, and produces manageable short-term side effects. These collective insights emphasize the crucial role that vaccines play in curbing the consequences stemming from the COVID-19 pandemic and promoting public well-being.

Despite the ongoing global impact of COVID-19, continued efforts to combat its effects are essential. We advocate for thorough investigations into the efficacy and impact of existing vaccines on SARS-CoV-2 transmission. Furthermore, the importance of longitudinal assessments and comprehensive pharmacovigilance surveys cannot be understated, as they offer critical insights into potential long-term immunization effects.

ACKNOWLEDGEMENT

Herewith we take gratification in thanking everybody who made this project complete. We convey our gratitude to our respected Director Dr. Kumar. V. S Nemmani, and respected Principal Dr. K. S. Nataraj, Shri Vishnu College of Pharmacy by coming up with all facilities essential to undertake the study.

Ourselves also express our deep gratitude and regards to our Assistant Professor, Dr. M. S. Raghu Bapiraju, Department of Pharmacy Practice, Shri Vishnu College of Pharmacy. We are grateful to their encouragement and valuable guidance in completing our project work successfully by giving valuable suggestions. We are thankful for their everlasting patience. We would like to express our deep sense of gratitude and thanks to the Staff of the Department of Pharmacy Practice, for giving us valuable suggestions.

We would like to thank Mr. N. Apparao (librarian) and teaching and non-teaching staff who have indirectly contributed to complete this work successfully. Finally, we would express our love and thanks to our beloved parents, family, and friends for their constant encouragement and eternal affection during our project tenure.

We indebt gratitude to numerous people who assisted and braced us throughout the work. It obtains enormous delight to appreciate with high enthusiasm, their assistance, direction and back up contributed by bunch of people, whom we indebt a significant recognition for the triumphant fulfilment of this study.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FUNDING

The authors received no funding for the study or publication of this article.

ABBREVIATIONS

COVID-19: Coronavirus disease 2019; **SARS-CoV-2:** Severe acute respiratory syndrome coronavirus 2; **AEFI:** Adverse event following immunization; **CDSCO:** Central drugs standard control organization.

SUMMARY

In our study about one third of participants were not infected. Amidst those infection majority were infected before vaccination and little proportion infected after vaccination. About two fifth of participants experienced side effects post vaccination and only these side effects were temporary and little proportion had to stop by physician or taken to infirmary. Hence it shows COVID-19 vaccines have better efficacy and safety

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Cite this article: Adusumilli SJ, Gadu HSGL, Marni DP, Mudunuri SRB. Assessment of Efficacy and Safety Associated with COVID-19 Vaccines: A Questionnaire Based Cross-Sectional Study. Indian J Pharmacy Practice. 2023;16(4):353-9.