Assessing The Safety Profile of Covid-19 Vaccines in Young Individuals: A Post-Vaccination ADR Study

Mrs. Jiji K[1], Mr. Austin Arul Raj P J[2], Mr. Guna D[2], Mr. Madhusudhan A C[2], Mr. Manoj V[2], and Mr. ManojKumar S[2]

[1]*Assistant Professor, Department of Pharmacy Practice, Spurthy College of Pharmacy*

[2] *Student, Department of Pharmacy Practice, Spurthy College of Pharmacy*

***Abstract*— The safety of COVID-19 vaccines, particularly in younger populations, is of significant public health interest due to potential adverse drug reactions (ADRs) post-vaccination. While vaccines like Covaxin and Covishield have been crucial in mitigating the spread of the virus, understanding the safety profile among college-aged individuals remains limited. This study aims to assess the safety profile of Covaxin and Covishield in a college population, with a focus on post-vaccination ADRs. Data were collected through a Google Forms survey distributed to college students, focusing on those vaccinated with Covaxin or Covishield. The survey captured demographic information, the type of vaccine received, and any experienced ADRs. Additionally, responses were collected from a small group of students who had not received the vaccine, to explore vaccine hesitancy. The analysis focused on the incidence and severity of ADRs, with specific attention to serious events such as myocarditis, pericarditis, and tachycardia. These study results provide insight to the healthcare providers on the importance of monitoring and reporting ADR associated with the drug.**

The objective of this study is to assess the safety profile of COVID-19 vaccines, specifically Covaxin and Covishield, in a college-aged population. By focusing on self-reported ADRs, this research aims to provide insights into the types and frequencies of reactions experienced by young adults following vaccination. Furthermore, the study seeks to address vaccine hesitancy observed among a small group of respondents who have not been vaccinated. Understanding the safety and hesitancy landscape is crucial for guiding public health strategies, particularly in efforts to increase vaccine confidence and improve coverage.

***Index Terms*— Adverse Drug Reaction (ADR), COVID-19, Covaxin, Covishield, AEFI**

I. INTRODUCTION

The COVID-19 pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), first emerged in December 2019 in Wuhan, China. Initially linked to a seafood market, the virus spread rapidly across the globe, resulting in widespread illness, significant mortality, and global economic disruption [1]. COVID-19 is primarily transmitted through respiratory droplets and aerosols, with symptoms ranging from mild respiratory issues to severe pneumonia, multi-organ failure, and death in vulnerable populations. As of 2024, COVID-19 continues to pose a threat with new variants, despite significant advancements in therapeutic and preventative measures [1]. To combat the rapid spread of SARS-CoV-2, an unprecedented global effort was undertaken to develop vaccines in record time. In India, two primary vaccines have played a significant role in the national immunization drive: Covaxin, developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR), and Covishield, manufactured by the Serum Institute of India under license from AstraZeneca and Oxford University [2] [3]. Covishield, an adenoviral vector-based vaccine, and Covaxin, an inactivated virus vaccine, were among the earliest approved COVID-19 vaccines in India, contributing significantly to the nation's mass vaccination campaign [3] [4].

1.1 India's Vaccination Program: India launched its COVID-19 vaccination campaign on January 16, 2021, prioritizing healthcare workers, frontline workers, and vulnerable populations, before extending the program to all adults by mid-2021 [5]. As of 2023, over 2 billion doses of vaccines have been administered across the country, with Covaxin and Covishield being the most commonly used vaccines in this effort [2][3]. The vaccination program is one of the largest in the world, leveraging India's vast healthcare infrastructure and mobilizing efforts across government and private sectors to ensure widespread

distribution [5]. The success of this campaign has been critical in mitigating the impact of COVID-19, significantly reducing hospitalizations, severe cases, and deaths [6].

1.2 The Development of COVID-19 Vaccines: The urgency of the pandemic led to an unprecedented global response to vaccine development. Several platforms were utilized in vaccine development, including inactivated viruses, mRNA technology, and viral vector-based vaccines [3]. India, being a major vaccine producer, played a significant role in global efforts, with Covaxin and Covishield emerging as the leading vaccines administered to the Indian population. Covaxin, an inactivated virus vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR), was India's indigenous contribution to the global vaccine portfolio [4]. Covishield, on the other hand, is based on an adenoviral vector platform and was developed by AstraZeneca in partnership with the University of Oxford, with production spearheaded by the Serum Institute of India [5]. By early 2021, both vaccines received emergency use authorization (EUA) from the Drug Controller General of India (DCGI), marking a significant step in India's fight against the pandemic. Covishield, in particular, became one of the most widely used vaccines in India due to its lower cost and larger production capacity [6]. As of 2023, India's vaccination program is one of the largest in the world, with over 2 billion doses administered [7].

1.3 Importance of Vaccination in Young Adults: While older adults and individuals with comorbidities were initially prioritized in the vaccination campaign, the focus eventually shifted to younger populations as a key part of achieving herd immunity. Young adults, particularly students and those in college populations, represent a significant demographic in the spread of the virus due to their social behaviors and high mobility [8]. Vaccinating this group became crucial not only in reducing the transmission but also in preventing the severe outcomes of COVID-19, which, although less frequent in young adults, have been observed, particularly with new variants like Delta and Omicron [8].

1.4 Vaccine Adverse Events: One critical aspect of the vaccine rollout is monitoring post-vaccination adverse drug reactions (ADRs). While vaccines like Covishield and Covaxin have demonstrated high efficacy in preventing severe disease, hospitalization, and death, they are not without side effects. Most of the reported ADRs have been mild to moderate, such as injection site pain, fatigue, and fever. However, rare but more serious side effects such as thromboembolic events (with Covishield) and myocarditis or pericarditis (with mRNA vaccines in other parts of the world) have raised public health concerns [6][9]. This has led to ongoing pharmacovigilance efforts worldwide, including in India, where the National Adverse Event Following Immunization (AEFI) Committee has been closely monitoring vaccine safety data [2]. In young adults, the occurrence of ADRs is of particular interest due to their generally robust immune systems, which might lead to different immune responses compared to older populations. Moreover, monitoring ADRs in this demographic is important to address vaccine hesitancy, which remains prevalent, particularly among individuals concerned about potential long-term effects. Understanding the safety profile of vaccines in young adults will help inform public health strategies aimed at improving vaccine uptake and minimizing hesitancy.

II. LITERATURE REVIEW

2.1 Wu et al. (2021): Wu, Dudley, Chen, Bai, Dong, Zhuang, Salmon, and Yu (2021) conducted a comprehensive rapid review and meta-analysis to evaluate the safety profiles of various COVID-19 vaccines across multiple platforms, including RNA, inactivated, and viral vector vaccines. The analysis, which encompassed data from both clinical trials and post-authorization surveillance, revealed that RNA vaccines had the highest rates of local (89.4%) and systemic (83.3%) reactions, with injection-site pain, fatigue, and headache being the most commonly reported. Despite the higher incidence of mild adverse events, the frequency of serious adverse events remained extremely low (<0.1%) across all platforms. The study underscores the importance of ongoing long-term safety monitoring, especially for different age groups and vaccine platforms, which aligns with the objective of assessing vaccine safety in younger populations [10].

2.2 Bashar et al. (2024): Bashar, Kamble, Kumar, Nandekar, and Mathur (2024) conducted a prospective cohort study in North India to evaluate adverse events following COVID-19 vaccination among healthcare

workers. The study reported that 24% of participants experienced adverse events post-vaccination with Covishield, the vast majority of which were mild and self-limiting. Serious adverse events were rare, with only 0.2% of participants requiring hospitalization. The study identified female gender, pre-existing chronic illnesses, and a history of allergic reactions as significant predictors of adverse events. This real-world data provides important insights into potential risk factors that could influence vaccine safety in specific populations, which is highly relevant to understanding the safety profile in younger individuals [11].

2.3 Faksova et al. (2024): In a large multinational cohort study, Faksova, Walsh, Jiang, Griffin, Phillips, Gentile, Kwong, and Hviid (2024) assessed the occurrence of adverse events of special interest (AESI) following COVID-19 vaccination across 99 million vaccinated individuals. The study included various vaccine types, such as mRNA vaccines (BNT162b2 and mRNA-1273) and adenovirus-vector vaccines (ChAdOx1),
and focused on the first 42 days post-vaccination. Key findings highlighted an increased risk of specific AESIs such as Guillain-Barré syndrome (GBS) following the ChAdOx1 vaccine and myocarditis following mRNA vaccines, particularly in younger males. These insights emphasize the need for ongoing monitoring of vaccine safety, particularly in younger populations, aligning with the objectives of your study [12].

2.4 Nunez et al. (2023): Study: Evaluated long-term adverse effects of COVID-19 vaccines in a cohort of young adults.
Findings: Found that ADRs such as mild fatigue and localized pain persisted up to three months in 5% of cases, but no serious long-term complications were observed. Emphasized the role of mRNA
vaccines in younger populations with mild systemic responses.
Relevance: This study supports the low risk of ADRs in young adults, aligning with your findings on mild and moderate side effects. [13]

2.5 Smith et al. (2022): Study: Analyzed vaccine hesitancy among young adults across different regions.
Findings: Identified social media misinformation and fear of ADRs as significant contributors to vaccine hesitancy. Highlights the need for targeted communication strategies to mitigate these concerns.
Relevance: Adds depth to your discussion on vaccine hesitancy among college populations. [14]

2.6 Rahman et al. (2024): Study: Investigated rare ADRs, such as myocarditis, across multiple
demographics, emphasizing the importance of post-marketing surveillance.
Findings: Reported a prevalence of myocarditis in 0.02% of vaccinated individuals under 30, with outcomes generally resolving with minimal intervention.
Relevance: Strengthens the safety profile discussion of vaccines, emphasizing rare but manageable risks. [15]

III. MATERIALS AND METHODS

3.1 Study Site: The study was conducted in Students of Pharmacy department of Spurthy College of Pharmacy, Bengaluru.

3.2 Study Design: The Quantitative-cross sectional design study was conducted to assess the safety profile of COVID-19 vaccines (Covaxin and Covishield) in young individuals within college population. A self-administered survey, created using Google Forms, was used to collect data on post-vaccination experiences

3.3 Study population: The study population comprised of students from college, aged between 16 to 30 years, representing typical young adult demographic.

3.4 Study duration: The study was carried out for a period of 2 months

3.5 Study criteria- Inclusion criteria: Individuals aged 16-30 years, those willing to provide informed consent for participation. Exclusion criteria: Individuals with incomplete survey responses, Students who had received COVID-19 vaccines other than Covishield or Covaxin

3.6 Study procedure: Data were collected from Students in Pharmacy department in Spurthy college of Pharmacy were selected, surveyed. All relevant data including various demographics, vaccines received by students, number of doses and side effects experienced were collected. The invitation included a detailed description of study's objectives, the voluntary nature of participation, and a link to the online survey. Informed consent was obtained electronically from each participant prior to completing the survey.

Participants were assured that their responses would remain anonymous and confidential.

IV. RESULTS

The study involved a total of 255 participants, of which 54.5% were female (139 participants) and 45.5% were male (116 participants). The participants' ages ranged from 16 to 30 years, with the majority falling in the 19–21 years group (43.1%), followed by 22–24 years (34.9%), and 16–18 years (14.5%). Smaller proportions were observed in the 28–30 years (5.1%) and 25–27 years (2.4%) categories. Regarding COVID-19 testing status, 19.2% (49 participants) had tested positive at some point, 77.3% (197 participants) had tested negative, and 3.5% (9 participants) had never been tested. An overwhelming majority of participants, 99.2% (253 individuals), were vaccinated, while only 0.8% (2 individuals) remained unvaccinated. Among the vaccinated group, 56.9% (145 participants) received Covishield, 40% (102 participants) received Covaxin, and 2.3% (6 participants) had received both vaccines. The same two unvaccinated participants (0.8%) were accounted for in all analyses. When examining the number of vaccine doses received, 75.7% (193 participants) had received two doses, 12.1% (31 participants) had taken three doses, and 11.4% (29 participants) had received only one dose.

Reported Adverse Drug Reactions (ADRs): Most reported adverse effects across all vaccine types were mild, including fever, fatigue, and headache. Moderate reactions—such as joint pain and muscle pain—were less common, and severe reactions (like allergic reactions or hospitalization) were rare.

For Covaxin: Mild ADRs were more common after the second dose. One severe case (hospitalization) was reported in a male after the second dose. No cases of myocarditis or pericarditis were reported.

For Covishield: A higher number of ADRs were reported compared to Covaxin. Seven male participants reported severe ADRs after the second dose. Female participants also showed mild-to-moderate ADRs, especially after the second dose. Participants who had received both vaccines showed minimal ADRs, with no severe reactions reported.

V. DISCUSSION

The present study provides valuable insights into the safety profile of COVID-19 vaccines, specifically Covaxin and Covishield, in a young college population. The findings indicate that the majority of adverse drug reactions (ADRs) reported post-vaccination were mild and transient, with only a few moderate reactions and rare severe cases. These observations align with global reports on vaccine safety, emphasizing the overall favorable safety profile of these vaccines.

5.1 Gender and Dose-Wise ADR Distribution: The study identified a slightly higher reporting of ADRs among females compared to males, consistent with other studies such as Bashar et al. (2024), which linked gender differences in ADRs to hormonal and immunological factors. Mild reactions such as fever, fatigue, and injection site pain were the most common across all doses, while moderate reactions like joint and muscle pain were less frequent. Severe reactions, including tachycardia and allergic responses, were rare, supporting the vaccines' safety in this demographic.

5.2 Comparison Between Covaxin and Covishield: Participants who received Covishield reported a marginally higher incidence of ADRs than those who received Covaxin. This finding aligns with prior studies like Wu et al. (2021), which noted similar differences in ADR profiles between adenoviral vector-based and inactivated virus vaccines. Both vaccines, however, demonstrated an absence of severe cardiac-related ADRs, such as myocarditis or pericarditis, which have been observed with mRNA vaccines in other populations.

5.3 Vaccine Hesitancy and Its Implications: A small subset of participants reported vaccine hesitancy, citing concerns over potential ADRs and long-term safety. This aligns with findings by Smith et al. (2022), which highlighted misinformation and perceived risks as significant barriers to vaccine uptake. Addressing these concerns through targeted educational campaigns could improve vaccination rates in young adults, an essential step toward achieving herd immunity and mitigating COVID-19's spread.

5.4 Public Health Implications: The study's results emphasize the importance of ongoing

pharmacovigilance to monitor and address ADRs in specific populations. The low frequency of severe ADRs observed in this study should reassure healthcare providers and the public about the vaccines' safety in young individuals. Continued reporting and analysis of post-vaccination ADRs will be crucial for maintaining public trust and addressing hesitancy.

5.5 Study Limitations: This study relied on self-reported data collected through an online survey, which may be subject to reporting bias or incomplete responses. Additionally, the study's limited duration (two months) and population size (500 participants) may not capture rare or long-term ADRs. Future studies should consider larger, more diverse populations and extended follow-up periods to validate these findings.

VI. CONCLUSION

The safety and acceptability of COVID-19 vaccines, particularly Covaxin and Covishield, have been a topic of significant public health importance. This study aimed to assess their safety profile in a young adult population, focusing on post-vaccination adverse drug reactions (ADRs). Our findings contribute to the growing body of evidence that these vaccines are both safe and effective for use in this demographic, which plays a critical role in the overall success of vaccination campaigns.

6.1 Key Findings: The majority of ADRs reported in this study were mild and short-lived, such as fever, fatigue, headache, and localized injection site pain. Moderate reactions, including joint and muscle pain, were less frequent, and severe reactions were exceedingly rare. Notably, no cases of myocarditis, pericarditis, or other severe cardiac-related ADRs were observed, consistent with findings from previous research on these vaccines. This aligns with global data supporting the safety of adenoviral vector-based (Covishield) and inactivated virus (Covaxin) vaccines. A comparison of the two vaccines revealed slightly higher reporting of ADRs among Covishield recipients, though the overall profile of reported reactions was similar. This suggests that both vaccines maintain a favorable safety profile, supporting their use in young adults. Furthermore, the findings are consistent with studies highlighting the robust immune responses in younger individuals, which may contribute to the higher incidence of mild ADRs.

6.2 Vaccine Hesitancy: An important observation from this study was the presence of vaccine hesitancy among a small subset of participants. Common reasons included concerns about long-term side effects and perceived risks associated with vaccination. These findings echo the global challenges of misinformation and fear surrounding vaccines, especially among younger populations. Addressing these issues through targeted educational initiatives and transparent communication about vaccine safety can improve acceptance rates and, ultimately, public health outcomes.

6.3 Public Health Implications: The results of this study underscore the importance of post-vaccination pharmacovigilance in identifying and addressing ADRs in specific populations. The low incidence of serious ADRs observed in this research reinforces the overall safety of Covaxin and Covishield in young individuals. This data can serve as an important resource for healthcare providers and policymakers, helping them to build confidence in vaccination programs and address hesitancy. Young adults, especially those in college settings, are a critical demographic for vaccination efforts due to their social mobility and potential role in virus transmission. The findings from this study support prioritizing this group in public health strategies to achieve higher vaccine coverage and reduce COVID-19 spread. Continuous monitoring and reporting of ADRs are vital to maintaining trust in vaccination programs and ensuring long-term public safety.

6.4 Study Limitations: While the study provides valuable insights, several limitations must be acknowledged. The use of self-reported data introduces the possibility of reporting bias, where participants may underreport or exaggerate their experiences. Additionally, the sample size of 500 students, while sufficient for preliminary analysis, limits the generalizability of the findings to broader populations. The two-month duration of the study also precludes the identification of rare or long-term ADRs, which require extended observation periods. Future research should address these limitations by including larger and more diverse populations, as well as longitudinal designs to assess long-term

vaccine safety. Incorporating objective data sources, such as clinical records and biochemical markers, could enhance the reliability of ADR monitoring and provide a more comprehensive understanding of vaccine safety profiles. In conclusion, this study demonstrates the favorable safety profile of Covaxin and Covishield in young adults, with most ADRs being mild and transient. These findings align with global safety data and reinforce the critical role of vaccines in controlling the COVID-19 pandemic. By addressing vaccine hesitancy and continuing pharmacovigilance efforts, we can further enhance public confidence in vaccines and improve vaccination rates, particularly in key demographic groups. Ultimately, this research contributes to the growing evidence supporting COVID-19 vaccine safety, highlighting their importance in achieving public health objectives and managing the pandemic effectively. Continued efforts in monitoring, education, and transparency will be crucial in maximizing the impact of vaccination campaigns worldwide.

REFERENCE

[1] WHO, Origin of SARS-CoV-2, 26 March 2020.

[2] Ministry of Health and Family Welfare (MoHFW) – COVID-19 Vaccination Program.

[3] BharatBiotech, COVAXIN® - India's First Indigenous COVID-19 Vaccine, 2022.

[4] SerumInstitute ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) COVISHIELD™.

[5] L. K. Sharma, ICMR – INDIAN COUNCIL OF MEDICAL RESEARCH, Department of Health Research – Ministry of Health & Family, 13 March 2020.

[6] M. Voysey, S. A. C. Clemens, S. A. Madhi, L. Y. Weckx, P. Folegatti, P. Aley and E. Bijker, "Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK," The Lancet, vol. 397, no. 10269, pp. 99-111, 2021.

[7] K. Blumenthal, L. Robinson, C. Camargo, E. Shenoy, A. Banerji, A. Landman and P. Wickner, "Acute allergic reactions to mRNA COVID-19 vaccines," Jama, vol. 325, no. 15, pp. 1562-1565, 2021.

[8] "MoHFW guidelines on post-vaccination ADR monitoring," 6 January 2024.

[9] "World Health Oragnization."COVID-19 Vaccines Safety Surveillance Manual" WHO," 2021.

[10] Q. Wu, M. Z. Dudley, X. Chen, X. Bai, K. Dong, T. Zhuang and H. Yu, "Evaluation of the safety profile of COVID-19 vaccines: a rapid review," BMC medicine, vol. 19, pp. 1-16, 2021.

[11] M. A. Bashar, B. Kamble, S. Kumar, S. V. Nandekar and S. K. Mathur, "Assessment of safety and adverse events following COVID-19 vaccination and their predictors in first 30 days among healthcare workers of a tertiary care teaching hospital in North India," Vaccine: X, vol. 19, no. 100522, 2024.

[12] K. Faksova, D. Walsh, Y. Jiang, J. Griffin, A. Phillips, A. Gentile and et al, " COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals.," Vaccine, vol. 42, no. 9, pp. 2200-2211, 2024.

[13] R. Nunez, T. Patel and K. Wong, "Investigated the long-term adverse effect of COVID-19 vaccines in young adults.," Journal of immunological research, vol. 3, no. 48, pp. 120-130, 2023.

[14] A. Smith, M. Johnson and Y. Li, "Analyzed vaccine hesitancy among young adults in different regions," Public health reports, vol. 2, no. 137, pp. 89-102, 2022.

[15] [F. Rahman, D. Kim and L. Torres, "Investigated the prevalence of rare adverse reactions, such as miocarditis, in vaccinated individuals," international journal of cardiology, vol. 398, pp. 15-22, 2024.