ORIGINAL ARTICLE

Profile of adverse events following COVID-19 vaccination: Insights from Covishield, Covaxin, and Corbevax beneficiaries in India

Shivaji B. Kashte[1], Rakesh Kumar Sharma[2], Sachin Kadam[3]*

[1]Department of Stem Cell and Regenerative Medicine, Centre for Interdisciplinary Research, [2]D. Y. Patil Medical College Hospital and Research Institute, D. Y. Patil Education Society (Institution Deemed to be University), Kolhapur-416006 (Maharashtra), India, [3]Sophisticated Analytical and Technical Help Institute, Indian Institute of Technology, New Delhi-110016 (New Delhi), India

Abstract

Background: The most common reasons for decline in COVID-19 vaccination coverage were the post-vaccine scare of adverse health effects and embracing the information propagated through social media. The adverse effects after taking the vaccine are termed Adverse Events Following Immunization (AEFI). *Aim and Objectives:* This study aimed to analyse AEFI after COVID-19 vaccination reported by Covishield, Covaxin and Corbevax beneficiaries. *Material and Methods:* The AEFI report data between January 2021 and June 2022 were collected from the Department of Health and Family Welfare, Ministry of Health and Family Welfare, Government of India. These AEFI reports for Covishield, Covaxin and Corbevax were collected and analyzed. *Results:* Covishield, Covaxin, and Corbevax vaccine recipients (N=1279, N=245, and N=46, respectively) experienced AEFI. Among recipients of both Covishield and Covaxin vaccines, the occurrence of C-type AEFI was the highest, while A3 and B2 types were minimal. Moreover, C-type AEFI was more pronounced in the higher age groups (above 60 and 45-60 years) compared to the younger age groups. In terms of gender, males experienced a higher incidence of C-type AEFI than females for both Covishield and Covaxin vaccines. In Corbevax vaccine beneficiaries, A4 type AEFI was highest, followed by C type AEFI among the 12-14 age group. *Conclusion:* The study observed that there are negligible reports of AEFI as compared to total vaccination beneficiaries. The benefits of COVID-19 vaccine are more than the small risk of harm. Therefore, more awareness and data on the safety and efficacy of vaccines should be made available.

Keywords: SARS-CoV-2, COVID-19 vaccine, Covishield, Covaxin, Corbevax, Adverse Events

Introduction

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) infections and the resulting disease, Coronavirus Disease 2019 (COVID-19), have affected 44,983,152 people and caused 531,794 deaths in India. There have been 766,440,796 confirmed cases and 6,932,591 deaths worldwide until May 18th 2023 [1]. The World Health Organization (WHO) declared COVID-19 a pandemic in March 2020 [2]. COVID-19 has negatively impacted the health and lifestyle of people as well as the economy throughout the world [3].

Mass vaccination efforts hold the most significant promise for ending the current pandemic [4]. Vaccines, in general, are considered the most economical healthcare intervention [5]. On January 16, 2021, India initiated the world's most extensive COVID-19 vaccine programme to vaccinate its 900 million population phase-wise. More than 200 crore COVID-19 vaccine doses were administered,

including more than 100 crore dose one and more than 95 crore dose two in India [6]. A total of 30 million healthcare and frontline workers were scheduled to be vaccinated in phase one. The bulk vaccination began in May 2021, starting with the elderly, those with comorbidities, and those in the age groups of 45 to 60 years and subsequently among 18 to 44 year old population [4, 7, 8]. In the later phase, precautionary doses were scheduled for those who had taken both doses of vaccine after six months, firstly to healthcare workers, the elderly and those with comorbidities. At the very beginning, only two COVID-19 vaccines, i.e., Covishield (Oxford-AstraZeneca vaccine, ChAdOx1nCoV-19 or AZD1222) and Covaxin (Bharat Biotech) were approved for restricted emergency use in priority-based vaccination programmes. Later, Sputnik V and Corbevax also got approval [2].

Covishield is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 S glycoprotein vaccinee developed by the Serum Institute of India (SII), Pune, based on the AstraZeneca-Oxford Model. According to the interim research, it is 70.4% effective in COVID-19 prevention with no significant side effects [9]. Covaxin, an inactivated vaccine, is the first indigenous COVID-19 vaccine, developed with the collaboration of the Indian Council of Medical Research, Government India and Bharat Biotech [9]. The immunisation regimen of Covishield and Covaxin consists of two doses; in the case of Covaxin, intramuscular injections are advised 28 days apart, and Covishield (0.5 ml in each dose) is administered 4-6 weeks apart. Both vaccines function by stimulating the immune system in the same way against the S protein of SARS-CoV-2, and both need two doses to achieve effective seroprotection [9]. According to the third-phase experiment, Covishield showed an effectiveness of nearly 90%, whereas Covaxin had an efficacy of about 80%. Both vaccine formulations in India have so far demonstrated satisfactory efficacy against numerous mutants variants of SARS-CoV-2 [9]. Corbevax (Biotechnological E vaccine) is a new vaccine in India similar to the Novavax vaccine. It is a form of protein subunit vaccination that requires two separate doses to be effective [9].

To achieve herd immunity, it is necessary to vaccinate a substantial fraction of the population [10]. However, vaccination rates in India remain low in comparison to other countries across the globe, with only around 68 % of Indians being fully vaccinated (May to June 2021) compared to 68 % in the United States, 76 % in Germany, 75% in the United Kingdom, 78% in France, 86% in South Korea and 89% in China [4].

The biggest challenge to universal coverage of eligible population is vaccine hesitancy Hesitancy and misinformation prevent the achievement of required vaccination coverage in India and other countries [5]. According to WHO, vaccinations' possible side effects contribute majorly to vaccine hesitancy [10]. These adverse effects after taking the vaccine are termed Adverse Events Following Immunization (AEFI). AEFI is defined as any untoward medical occurrence seen in a vaccine recipient following immunization and does not necessarily have a causal relationship with the usage of vaccines. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom, or disease. Apart from the vaccine safety and efficacy-related data made public by the regulatory authorities, clinical trials, and vaccine developers [11-14], a few studies have analyzed AEFI during the COVID-19 vaccination campaigns [15-16], others studied

vaccine hesitancy to assess the expected vaccine uptake trends in the population. The most common reasons for declining the COVID-19 vaccine were the post-vaccine scare of adverse health effects and believing the misinformation shared through social media [17]. Therefore, it was decided to study the adverse events after COVID-19 vaccination in Indian population. In this study, we collected and analyzed the causality assessment of reported serious AEFI cases following COVID-19 vaccination (Covishield, Covaxin and Corbevax) between January 2021 and June 2022 approved by the National AEFI Committee.

Material and Methods

The data regarding the AEFI were collected from the official website of Department of Health and Family Welfare, Ministry of Health and Family Welfare, Government of India [18]. All the AEFI reports for Covishield, Covaxin and Corbevax that were assessed and approved by National AEFI Committee between January 2021 and June 2022 were included in the study (Table 1). The data was processed, various type of AEFI and their diagnoses were analyzed in excel and graphs were plotted.

Table 1: Causality assessment of reported serious AEFI cases following COVID-19 vaccination, approved by the National AEFI Committee [18]

AEFI Classification	AEFI Meaning	Diagnosis
A1	Vaccine product-related reaction	Headache, dizziness, vomiting, fever, allergic reaction, anaphylaxis, etc.
A2	Vaccine quality defect-related reaction	Nil
A3	Immunization error-related reaction	Injection site abscess, left upper arm cellulitis, etc.
A4	Immunization anxiety-related reaction	Anxiety reaction, etc.
B1	The temporal relationship is consistent, but there is insufficient definitive evidence for vaccine-causing event	Seizure, deep vein thrombosis, gullain barre syndrome, etc.
B2	Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization	Bell's palsy with underlying diabetes mellitus, Steven Johnson Syndrome, polymyositis, extensive deep vein thrombosis, generalised tonic-clonic seizure with hypertension, encephalopathy with thrombocytopenia, thrombosis with venous infarct, etc
C	Coincidental-underlying or emerging condition or conditions caused by exposure to something other than a vaccine	Sudden cardiac death in a known case of diabetes and hypertension or past history of COVID-19 infection, pneumonia, COVID-19 disease, Sepsis, etc.
D	Unclassifiable	Unexpected death

Results

There were 89,83,29,422 total vaccine beneficiaries between January 2021 and June 2022. Among these 1570 reported AEFI of which Covishield vaccine (N=1279), Covaxin vaccine (N=245) and Corbevax (N=46) vaccine beneficiaries reported AEFI. Covishield was the most commonly administered vaccine and C-type AEFI was highest, while A3 and B2 were negligible in Covishield vaccine beneficiaries [Table 2, (Figure 1)]. C-type AEFI was highest among all age populations; 18-44, 45-60 and above 60 years. It was followed by A1, A4, B1 and D-type AEFI. C-type AEFI was highest in the age group above 60 years compared to the 45-60 and 18-44 years age groups. A1, A4 and B1 type AEFI were higher in the 18-44 age group as compared to 45-60 and above 60 years population. The A3 and B2 types AEFI were negligible among all age populations. Both males (n=627; 49.02 %) and females (n=652; 50.97%) who received the Covishield vaccine reported AEFI (Table 2). Among AEFI, C was highest in both genders (Figure 1). C-type AEFI was higher in males than females followed byA1, A4 and D-type AEFI. In females, A1 and A4 type AEFI was higher than in males. A3 and B2 type AEFI were negligible in both genders.

Table 2A: AEFI reports of Covishield, Covaxin and Corbevax

Type of vaccine		Covishield		Covaxin		Corbevax	
		N	%	N	%	N	%
Gender	Males	627	49.02	124	50.61	13	28.26
	Females	652	50.97	121	49.38	33	71.73
AEFI causality classification approved by the national AEFI committee	A1	213	16.65	30	12.24	4	8.69
	A3	6	0.46	1	0.40	0	0
	A4	125	9.77	54	22.04	30	65.21
	B1	112	8.75	29	11.83	3	6.52
	B2	18	1.40	2	0.81	2	4.34
	C	696	54.41	112	45.71	6	13.04
	D	109	8.52	17	6.93	1	2.17
Age (years)	12-14	NA	NA	NA	NA	46	100
	15-17	NA	NA	89	36.32	NA	NA
	18-44	508	39.71	66	26.93	NA	NA
	45-60	364	28.45	42	17.14	NA	NA
	>60	407	31.82	46	18.77	NA	NA
Total		1279	NA	245	NA	46	NA

Table 2B: Total vaccination (Covishield, Covaxin and Corbevax) and total AEFI (Covishield, Covaxin and Corbevax) reported between January 2021 and June 2022 [6, 18]

	N	%
Total Vaccination	898329422	100
Total Reported AEFI	1570	0.000175

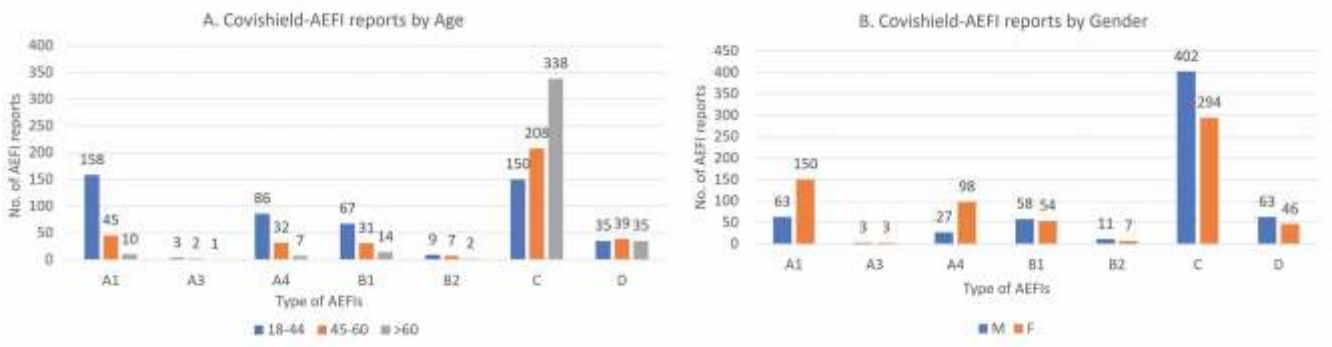

Figure 1A: AEFI reports of Covishield vaccine by age 18-44, 45-60 and above 60 years
Figure 1B: AEFI reports of the Covishield vaccine by gender

Covaxin (n= 245) reported the second most AEFI following Covishield vaccine. C-type AEFI was highest, while A3 and B2 were negligible in Covaxin vaccine beneficiaries (Table 2). C-type AEFI was highest among all age populations (Figure 2). C-type AEFI was highest in those above 60 years of age, followed by 45-60 and 18-44 age groups. Next to C-type AEFI, A4, B1, A1, and D were the commonest AEFI. A3 and B2 type AEFI were negligible in all age group populations.

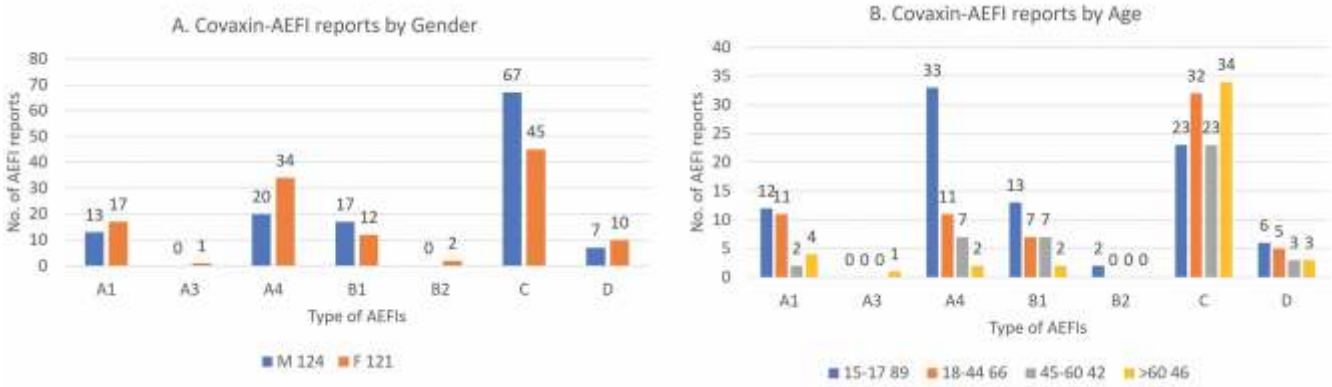

Figure 2A: AEFI reports of Covaxin vaccine by age 15-17, 18-44, 45-60 and above 60 years
Figure 2B: AEFI reports of Covaxin vaccine by gender

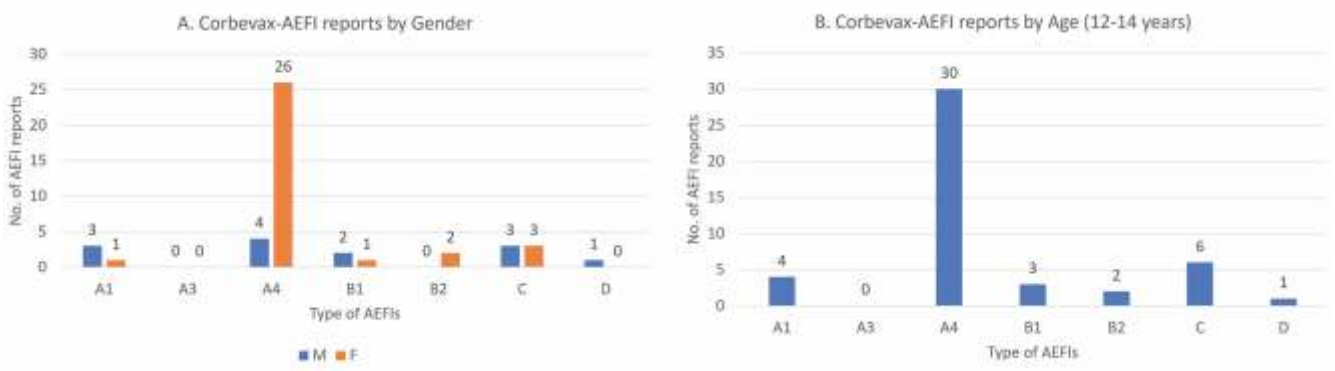

Figure 3A: AEFI reports of Corbevax vaccine by age 12-14 years
Figure 3B: AEFI reports of Corbevax vaccine by gender

AEFI reports of Covaxin by gender are shown in Figure 2. Males (n=124; 50.61 %) and females (n=121; 49.38%) reported Covaxin related AEFI. C-type AEFI was highest, followed by A4, A1, B1 and D. Males had higher C and B1 type AEFI than females. Females had higher A1 and A4 type AEFI compared to males. A3 and B2 type AEFI were negligible in both genders.

Corbevax was administered only to the age group 12-14 years, and 46 individuals reported AEFI (Table 2). The A4 type AEFI was highest, followed by C type AEFI among the 12-14 age group (Figure 3). A1 and B1, were less than 10%, while B2 and D were less than 5%. There was no report of A3 AEFI. Males (n=13; 28.26 %) and females (n=33; 71.33%) reported Corbevax related AEFI (Table1; Figure 3). A4 type AEFI was highest in both genders, followed by A1, C and B type AEFI. Females had higher A4 type AEFI as compared to males. Males had higher A1, C, B1 and D-type AEFI than females. There is only one report of D-type AEFI in males and no report of D-type AEFI in females. There was no report of A3-type AEFI in both genders.

Discussions

There were 89,83,29,422 total vaccine beneficiaries between January 2021 and June 2022. Among these 1570 reported AEFI of which Covishield (N=1279), Covaxin (N=245) and Corbevax (N=46) vaccine beneficiaries reported AEFI. The data were not available regarding the total vaccinated beneficiaries of Covishield, Covaxin and Corbevax separately. This is the limitation of the study. Even after taking this into consideration, reported AEFI were negligible with respect to the total number of vaccine beneficiaries. Among Covishield and Covaxin beneficiaries, C type AEFI were highest while A3 and B2 were negligible. In Corbevax vaccine beneficiaries,A4 type AEFI was highest, followed by C type AEFI among the 12-14 age group.

AEFI type C means coincidental- underlying or emerging conditions caused by exposure to something other than a vaccine. Coincidental events are reported following immunization, but a clear cause other than vaccination is found in the investigation. Therefore, though C-type reports were highest, these were not because of vaccine

effects. AEFI type A3 means immunization error-related reaction and B2 means reviewing factors resulting in conflicting trends of consistency and inconsistency with causal association to immunization. These AEFI were the lowest and, therefore, not significantly associated with vaccination. AEFI A1 means vaccine product-related reaction, A4 means immunization anxiety-related reaction, and D means unclassifiable. These AEFI were also noted. Vaccine product-related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc. Indeterminate reactions are those that occur soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analyses, and studies are required. Unclassifiable events have been investigated, but there is not enough evidence to assign a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment. Overall, the benefits of vaccination are overwhelmingly more significant than the small risk of harm. However, as a measure of utmost precaution, all emerging harm signals should be tracked and reviewed periodically.

Similar kinds of AEFI were also reported in a few other studies. A cross-sectional study was conducted on 208 medical students who had taken at least one dose of a Covishield vaccine. Among these, 81.2% experienced AEFI symptoms within 12 hours of vaccination. The most typical symptoms were pain at the injection site (83.2%), body aches (43.8%), fever (42.3%), weakness (41.3%) and headache (34.6%). A majority of the participants reported complete recovery within 13-24 hours. Full recovery was seen in all the study participants, and no severe event was seen [10]. A cross-sectional study was conducted among 606 Covishield-vaccinated healthcare professionals. Mean age of the participants was 35.6 years, and 52% were female. Almost 59% of participants were vaccinated with two doses, and around 54% took the Covishield vaccine. At least one local and systemic adverse event was reported by 54% and 62% of participants after the first dose and 37% and 49% after the second dose of Covishield. Injection site pain, swelling and tenderness at the injection site were the most frequently reported systemic AEFI. Almost 10% of individuals reported a post-vaccination SARS-CoV-2 infection, most of which occurred after taking the first dose of the vaccine [19]. A systematic review was carried out among fatal cases with post-mortem investigations, including 22 cases of Covishield. Based on these data, autopsy is very useful to define the main characteristics of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) after Covishield vaccination: recurrent findings were intracranial haemorrhage with diffused micro-thrombi located in multiple areas [19]. A prospective analytical study was conducted between January 2021 and May 2021 among 122 healthcare workers taking the Covishield vaccine and found that post-vaccination seropositivity was 69.67% in overall study participants. AEFI after the first and second doses was 72.9% and 27.8%, respectively. The most common symptoms after both doses of vaccination were local pain (73% and 88.2%), followed by fever (38.2% and 26.5%). The average duration of symptoms in both doses was 1.75 days. Of 122 participants, only 10 (8.19%) had a breakthrough infection after two doses of

vaccination with mild severity [20]. A prospective observational study was conducted among 804 participants (⩾ 18 years) receiving Covishield vaccination between February 2021 to May 2022. AEFI following the first dose were reported in 321 (40%; systemic involvement in 248). Among 730 participants who completed a 7-day follow-up post-second dose, AEFI occurred in 115 (15.7%; systemic in 99). The majority of AEFI, were mild-moderate and resolved spontaneously. Serious AEFI leading to hospitalisation was noticed in 1 (0.1%) participant with suspicion of Immunisation Stress-related Response (ISRR). AEFI of grade 3 severity (FDA) were recorded in 4 participants (0.5%). No deaths were recorded. Regression analysis showed an increased risk of AEFI in younger individuals, two times higher in females, those with hypertension or a history of allergy, and three times higher in individuals with hypo-thyroidism [21]. Covishield vaccine has an acceptable level of safety profile. Though it has not presented breakthrough infection, it has undoubtedly reduced the severity of infection [20]. Covishield carries an overall favourable safety profile with AEFI rates significantly lesser than other adenoviral vaccines. Females, those with hypertension, and individuals with a history of allergy and hypothyroidism may need watchful vaccine administration [21].

Another prospective observational study was conducted among the Covaxin beneficiaries between June 28 and September 6, 2021. A total of 1826 participants were assessed for any local or systemic adverse events after seven days of vaccination. Among these, 29.8 % reported at least one AEFI. No adverse events were reported, and about 1.6% had moderate AEFI. Pain at the injection site (14.6%), fever (9.7%) and myalgia (5.9%) were the everyday adverse events reported by the participants. AEFI incidence was higher after first dose (38.1%) when compared to second dose (26.4%), and this finding was significant ($p<0.001$). Major factors associated with AEFI were female sex, history of an allergic reaction, comorbidities, acute infection in the past three months, and intake of chronic medications [8].

A prospective observational study was conducted among 698 adolescents and 326 adults who received Covaxin. AEFI after the first dose were reported in 36.3%beneficiaries, with 21% reporting only local AEFI and 15.2% reporting systemic AEFI. Among 340 adolescents who had received the second dose of vaccine, 37.9% developed AEFI, with only local involvement in 20.3% and systemic involvement in 17.6%. Injection site pain and fever were the most common AEFI. The majority of AEFI were mild-moderate. Nearly 0.9% of adolescents receiving the first dose reported severe AEFI. Typical AEFI were observed in 0.6-0.9% of adolescents. Majority of the AEFI were resolved in 1-2 days. AEFI were persistent in >2% of adolescents at day 14 after the second dose and in 3.7% of adults at follow-up. No difference was observed in AEFI incidence and patterns between adolescents and adults. Females and those with a history of allergy had 1.6 times and three times increased risk of AEFI among adolescents, respectively [22]. A systematic review was conducted on the latest 25 studies published regarding Covaxinup to March 22, 2022. Pre-clinical, phase I, and II clinical trials showed appreciable immunogenicity. Both neutralising and binding antibody titers were significant, and T-cell responses were TH1-biased. Phase III trials showed a 93.4% efficacy against severe COVID-19. Data from the trials revealed an acceptable

safety profile with mostly mild-moderate local and systemic events. No serious adverse events or fatalities were seen, and most studies reported milder and lesser adverse events with Covaxin when compared with other vaccines, especially Covishield. The immunogenicity performance of Covaxin, which provided significant protection only after the second dose, was mediocre, and it was consistently surpassed by Covishield. There was some evidence of coverage against alpha, beta and delta variants. However, neither Covaxin nor Covishield showed sufficient protection against the omicron variant [23]. The safety and immunogenicity of Corbevax were analysed in phase-1/2 and phase-2 randomised clinical trials enrolling healthy adults (N= 460; 18-65 years of age). There was low evidence of adverse events after vaccination. Corbevax was well tolerated, with no observed safety concerns [24].

The latest overall AEFI following COVID-19 vaccination was 0.006%, as per CO-WIN dashboard data [6]. Another study showed data upto September 20, 2021, the adverse events following COVID-19 vaccination were 0.005% [8]. However, these numbers may be grossly underestimated as the mechanism of AEFI reporting was not known to all or not all adverse reactions may have been reported [25]. Therefore, the limitation of this study is that the data available is restricted to vaccine beneficiaries who have reported adverse reactions.

This study emphasizes the importance of considering the perceived disability caused by AEFI and suggests conducting campaigns to address these concerns. It is crucial to ensure compliance with the recommended dosage schedule of multi-dose vaccines. Reports of severe adverse effects like thrombosis, thrombocytopenia, and myocarditis have had a negative impact on public opinion, resulting in a slowdown of the vaccine program. Therefore, it is recommended to conduct autopsies in cases where COVID-19 vaccination is associated with fatalities to determine causality. Measures such as providing clear information on vaccine safety and effectiveness are essential to reduce vaccine hesitancy in the general population. The scientific community must work diligently to address the growing reluctance to vaccinate following instances of fatal adverse reactions. It is necessary to tackle various issues related to vaccination approaches to establish an effective public health response and be prepared for future outbreaks.

Conclusion

The study findings indicate that COVID-19 vaccines are safe and effective, with minimal risk of harm from AEFI. However, the study had some limitations, such as the lack of data on specific vaccines administered and the possible under reporting of AEFI. The results are consistent with other studies that have shown acceptable safety profiles and high efficacy for Covishield, Covaxin, and Corbevax. To reduce vaccine hesitancy and increase compliance, public health campaigns should emphasize the benefits of vaccination and address any concerns regarding AEFI. Autopsies should be conducted in cases of fatalities associated with vaccination to establish causality. The scientific community should monitor and respond to any emerging harm signals from COVID-19 vaccination.

References

1. WHO Coronavirus (COVID-19) Dashboard. World Health Organization. [cited 2022 Sep 27]. Available from: https://covid19.who.int/
2. Kadam S, Sonawane T, Patil A, Tomar A. The best COVID-19 vaccine: understanding the conundrum behind comparing vaccines. *J Krishna Instit Med Sci Univ* 2022;11(1):1–13.
3. Kashte S, Gulbake A, El-Amin Iii SF, Gupta A. COVID-19 vaccines: rapid development, implications, challenges and future prospects. *Hum Cell* 2021;34(3): 711-733.
4. Bansal P, Raj A, Mani Shukla D, Sunder N. COVID-19 vaccine preferences in India. *Vaccine* 2022;40(15): 2242-2246.
5. Goel K, Sen A, Goel P, Satapathy P, Jain L, Vij J, *et al*. Community health workers willingness to participate in COVID-19 vaccine trials and intention to vaccinate: A cross-sectional survey in India. *Clin Epidemiol Glob Health* 2022;17:101113.
6. Co-WIN Dashboard. Ministry of Health and Family Welfare, Government of India. 2022 [cited 2022 Sep 27]. Available from: https://dashboard.cowin.gov.in/
7. Samanta S, Banerjee J, Kar SS, Ali KM, Giri B, Pal A, *et al*. Awareness, knowledge and acceptance of COVID-19 vaccine among the people of West Bengal, India: A web-based survey. *Vacunas* 2022;23: S46–S55.
8. Parida SP, Sahu DP, Singh AK, Alekhya G, Subba SH, Mishra A, *et al*. Adverse events following immunization of COVID-19 (Covaxin) vaccine at a tertiary care center of India. *J Med Virol* 2022;94(6):2453-2459.
9. Das S, Kar SS, Samanta S, Banerjee J, Giri B, Dash SK. Immunogenic and reactogenic efficacy of Covaxin and Covishield: A comparative review. *Immunol Res* 2022;70(3):289-315.
10. Bansal Y, Chand P, Bansal N, Singh P. Vaccine hesitancy after taking the first dose of COVID-19 vaccine: A challenge for the COVID-19 vaccination program in India. *J Family Med Prim Care* 2022; 11(5):2201-2206.
11. Gee J, Marquez P, Su J, Calvert GM, Liu R, Myers T, *et al*. First Month of COVID-19 Vaccine Safety Monitoring-United States, December 14, 2020–January 13, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:283-288.
12. Folegatti PM, Ewer KJ, Aley PK, Angus B, Becker S, Belij-rammerstorfer S, *et al*. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1 / 2 , single-blind , randomised controlled trial. *Lancet* 2020;396:467-478.
13. Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR, *et al*. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. *Lancet* 2020;396(10267): 1979–93.
14. Voysey M, Clemens SAC, Madhi SA, Weckx LY, Folegatti PM, Aley PK, *et al*. 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. *Lancet* 2021;397(10269):99–111.
15. Kamal D, Thakur V, Nath N, Malhotra T, Gupta A, Batlish R. Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study. *Med J Armed Forces India* 2021;77(Suppl 2):S283-S288.
16. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P, *et al*. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. *Lancet Infect Dis* 2021;21(7):939-949.
17. Umakanthan S, Patil S, Subramaniam N, Sharma R. COVID-19 vaccine hesitancy and resistance in India explored through a population-based longitudinal survey. *Vaccines (Basel)* 2021;9(10): 1064.
18. AEFI Reports. Departments of Health and Family Welfare, Ministry of Health and Family Welfare, Government of India. 2022 [cited 2022 Sep 16]. Available from: https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-welfare/immunization/aefi-reports
19. Rayamajhi S, Rafi MA, Tripathi N, Dongol AS, Pandey M, Rayamajhi S, *et al*. Adverse events following immunization with ChAdOx1 nCoV-19 and BBIBP-CorV vaccine: A comparative study among healthcare professionals of Nepal. *PLoS One* 2022;17(8): e0272729.

20. Mahadevaiah A, Doddamadaiah C, K S S, Cholenahalli NM. Study of immunogenicity, safety and efficacy of covishield vaccine among health care workers in a tertiary cardiac care centre. *Indian J Med Microbiol* 2022;40(2):200-203.
21. Kaur U, Ojha B, Pathak BK, Singh A, Giri KR, Singh A, *et al*. A prospective observational safety study on ChAdOx1 nCoV-19 corona virus vaccine (recombinant) use in healthcare workers- first results from India. *E Clinical Medicine* 2021;38: 101038.
22. Kaur U, Anju KL, Chauhan M, Joshi A, Das A, Kansal S, *et al*. A prospective observational study on BBV152 Coronavirus vaccine use in adolescents and comparison with adults: interim results of the first real-world safety analysis. *Drug Saf* 2022;45(10):1099-1109.
23. Ahmed TI, Rishi S, Irshad S, Aggarwal J, Happa K, Mansoor S. Inactivated vaccine Covaxin/BBV152: A systematic review. *Front Immunol* 2022;13:863162.
24. Thuluva S, Paradkar V, Gunneri SR, Yerroju V, Mogulla R, Turaga K, *et al*. Evaluation of safety and immunogenicity of receptor-binding domain-based COVID-19 vaccine (Corbevax) to select the optimum formulation in open-label, multicentre, and randomised phase-1/2 and phase-2 clinical trials. *E Bio Medicine* 2022;83:104217.
25. Frequently Asked Questions on Co-WIN, Co-Win Dashboard. Ministry of Health and Family Welfare, Government of India. 2022 [cited 2022 Sep 20]. Available from: https://www.cowin.gov.in/faq
26. Sessa F, Salerno M, Esposito M, Di Nunno N, Zamboni P, Pomara C. Autopsy findings and causality relationship between death and COVID-19 vaccination: A systematic review. *J Clin Med* 2021 15;10(24):5876.

Author for Correspondence:
Dr. Shivaji B. Kashte, PhD. Department of Stem Cell and Regenerative Medicine, Centre for Interdisciplinary Research, D. Y. Patil Education Society (Institution (Deemed to be University), Kolhapur-416006 (Maharashtra), India Cell:9518757400
Email: shivajikashte.cir@dypgroup.edu.in

How to cite this article:
Kashte SB, Sharma RK, Kadam S. Profile of adverse events following COVID-19 vaccination: Insights from Covishield, Covaxin, and Corbevax beneficiaries in India. *J Krishna Inst Med Sci Univ* 2023; 12(1):86-96

Submitted: *24-Sep-2022* ***Accepted:*** *30-Nov-2022* ***Published:*** *01-Jan-2023*