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Study on Adverse Event Following COVID 19 Vaccination at Tertiary Care Hospital, Karwars

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SUMMARY

Introduction: Coronavirus Disease 2019 (COVID-19) as pandemic has caused massive crisis to global public health and also has turned into global economic devastation. In India, regulatory authorities had given permission for two vaccines. Covaxin, an inactivated vaccine developed and manufactured by Bharat Biotech and Covishield, the Oxford AstraZeneca vaccine is being manufactured locally by Serum Institute of India.
Aim: The present study has been proposed against this backdrop with the aim to study the adverse drug event post vaccination at our vaccination center and to compare the adverse drug event post first and second dose of COVID-19 vaccinations.
Material and Methods: This is a cross-sectional study done among the health care professionals and Students of Karwar institute of medical sciences, Karwar, Karnataka. A self-administered questionnaire was distributed amongst the participants.
Results: Out of 766 participants, 672 individuals received Covishield vaccine, 79 participants received Covaxin. Among the total participants, 665 had received both the doses of vaccines, 97 had received only the 1st dose. The most common adverse event at the injection site was pain/tenderness and apart from injection site, the commonest adverse event documented was fever.
Conclusion: As the study site is an Adverse drug monitoring center (AMC), higher reporting rate of Adverse effect following immunization (AEFI) was noted. The adverse events noted were not of serious nature and there was significant reduction in Adverse event (AE) for both the vaccines following 2nd dose across all age groups, in both the gender and for all adverse event except diarrhea, indicating that the vaccine used in India are safe.

Keywords: Adverse Event, Adverse Effect Following Immunization, Coronavirus Disease 2019, Covaxin, Covishield

INTRODUCTION

Coronavirus Disease 2019 (COVID-19) as pandemic has caused massive crisis to global public health and also has turned into global economic devastation. World Health Organization had declared COVID-19 as pandemic on March 11, 2020 [1]. In India, government acted very quickly, implemented lockdown measures, blocked international travel and enforced many other public restriction measures to reduce the COVID-19 morbidity and

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mortality [2]. As of February 15, 2021, there were 108153741 confirmed cases and 2381295 deaths according to Word Health Organization (WHO) [3]. From the day one, there has been extensive search for an effective pharmacological agent against COVID-19, agents like Remdesivir have been advocated in the treatment. To stop the pandemic, we need the drug to be at least 95% effective but most of the present available drugs are not that effective. Hence these and other agents may save lives but less likely to bring back the normalcy [2]. Because of the continued spread of the virus in spite of the government-imposed restriction, everyone understood at the initial stages that this chaos can be addressed by only an effective and safe; 10 (3) Vaccine. A vaccine has a power to produce herd immunity in the community, which will decrease the incidence of the COVID-19 and prevent the transmission, thus allowing the lockdown and social distancing to be relaxed [4]. This eventually will help in reducing the social and economic burden of COVID-19.

In India, regulatory authorities have given permission for two vaccines. Covaxin, an inactivated vaccine developed and manufactured by Bharat Biotech and Covishield, the Oxford AstraZeneca vaccine is being manufactured locally by Serum Institute of India [5]. There are innumerable evidence-based benefits of vaccine as an agent to provide immunity against preventable diseases, still there has been growing opposition for the use of vaccine and more so for COVID-19 vaccine because of the fast-track process involved in its research and development, and its approval. [6] The online dissemination of false and misleading information regarding vaccine safety, effectiveness and adverse event post vaccination will affect the vaccine drive initiated by Government of India on January 16th 2021. Health care providers can effectively counter this misinformation by providing the evidence based up- to-date information [6,7].

AIM

The present study has been proposed against this backdrop with the aim to study the adverse drug event post vaccination at our vaccination center and to compare the adverse drug event post first and second dose of COVID-19 vaccinations.

MATERIAL AND METHODS

This is anobservational, cross sectional, questionnaire-based, academic (noncommercial)study done after obtaining institutional ethical committee permission (IEC/KRIMS/O/20/2020-21) among the health care professionals (Doctors, Nursing staff, Paramedical staff) and Students (Medical students and Paramedical students) of Karwar institute of medical sciences, Karwar, Karnataka, India. A self-administered questionnaire was distributed amongst the participants. A briefing was given about the nature of the study, and the consenting participants will anonymously complete the questionnaire. The study questionnaire was pre-tested on a sample of volunteers. Ambiguities in the questions or responses was addressed before its implementation (as suggested by scientific/ethical committee). In case of students, briefing and Google form was shared with the class representative and was asked to share it in their respective class WhatsApp group. Similarly, in case of faculties respective department HODs/ In charge of the department were approached. Sample size was calculated using formula $4pq/d^2$, where p is prevalence of adverse event following COVID-19 immunization which is considered as 50% as it is a new study and no previous data available, q-100-p, d is 10% of p. Those participants who have consented and fully completed the proforma was included in the study. In the times of COVID-19 pandemic (to avoid gathering and to promote social distancing) and to promote environmentally friendly measures (paperless method to collect the data), Google forms was used to collect the data from the Participants. Data were analyzed using Microsoft office Excel and SPSS software and to compare the AE following 1st dose and 2nd dose of vaccination, Z – test for testing the difference in proportions was used. For estimating the factors associated with AE, odd's ratios were calculated using binary regression analysis.

RESULTS

The present study was conducted in Karwar institute of medical sciences, with the aim of studying the adverse events post COVID-19 vaccination.

In the present study 766 Health care professionals (Doctors, Nursing staff, Paramedical staff) and Students (Medical students

Table 1. Demographic characteristics of the study participants

Variable		Frequency (766)	Percent (%)
Gender	Female	417	54.44
	Male	349	45.56
Age Group	18 - 30	662	86.42
	30 - 45	85	11.10
	45 - 60	19	2.48

Table 2. Vaccination status of the Participants

Variable		Frequency	Percent (%)
Vaccinated	1st dose	97	12.66
	Both doses	665	86.81
	Not vaccinated	4	0.52
Vaccine	COVAXIN	79	10.31
	COVISHIELD	672	87.73
	Not Sure	11	1.44

The reasons for not vaccinating initially were Active covid 19 infection (3), Fear (1), Drug allergy (1) and Pregnancy (1), Planning for pregnancy (1), under age (1)

Table 3. Management of Adverse Event (AE) following Vaccination

Management of AE	Frequency (766)	Percent (%)
No adverse effects	77	10.05
Symptomatic management at the Hospital	13	1.69
Symptomatic management at home as suggested during vaccination	676	88.2

Table 4. Reporting of AE

Reporting	Frequency (689)	Percent (%)
Reported to adverse event following immunization center (KRIMS)	139	20.17
Reported to the vaccine helpline no.	6	0.87
Feedback link sent by Govt.	1	0.14
Not reported	543	78.80

and Paramedical students) participated. Out of the 766 participants 417 (54.44%) were female and 349 (45.56%) were male. 662 (86.42%) were in the age group of 18 to 30, followed by 85 (11.10%) in the age group of 30-45 and the participants in the age group of 45 to 60 accounted for 19 (2.48%).

DISCUSSIONS

This study aimed to analyze COVID-19 vaccination safety in the health care professionals (Doctors, Nursing staff, Paramedical staff) and Students (Medical students and Paramedical students) of Karwar institute of medical sciences, Karwar, Karnataka. Health care professionals and Students were considered as we had opted to collect the data via google form and participants should have access and ideally should have used these methods. Also, as our institute functions as the adverse drug reaction monitoring center (AMC) that supports the nearby hospitals toward routing their Adverse drug reaction/Adverse event following immunization (AEFI) to Pharmacovigilance Programme of India, hence participants can approach and report AE directly to AMC more conveniently.

Out of 766 participants, 672 individuals received Covishield vaccine, 79 participants received Covaxin. Among the total participants, 665 had received both the doses of vaccines, 97 had received only the 1st dose and 4 had not received any doses (Table 2). We observed higher vaccine number in Covishield when compared with Covaxin in our study as during the initial phases of vaccination healthcare workers/people working in hospital setup received Covishield whereas Covaxin was received by frontline workers working outside hospital [8]. It can also be due to different in timelines of introduction of these vaccines resulting in these differences.

The reasons for not vaccinating initially were active Covid-19 symptoms, followed by history of drug allergy, fear, underage, pregnancy planning and pregnancy. We observed that Covishield 1st dose had resulted in 2.67 time more AE as compared to Covaxin 1st dose and was statistically significant [9].

Table 5. Covid - 19 infection and status of Vaccination

Variable		Frequency	Percent (%)
Suffered from COVID	Before 1st dose	38	4.96
	After 1st dose	19	2.48
	After 2nd dose	49	6.40
	Not infected	660	86.16
COVID managed at	COVID care center / Isolation center	28	3.66
	Home isolation	68	8.88
	Hospitalized	10	1.31
	Not applicable (Not infected)	660	86.16

Among the 10 hospitalized for COVID - 19 infections, 6 had not taken any doses of the COVID19 vaccine, 3 subjects after receiving the 1st dose and 1 after both the doses of the vaccination.

Table 6. Adverse Events Experienced by the study participants after each dose of COVID-19 vaccine

Adverse Events	Time	After 1st Dose	After 2nd Dose	z-value	p-value
		n (%)	n (%)		
Tenderness / Pain at injection site	Within 30 min	140 (18.3)	74 (9.7)	4.85	<0.0001*
	Within 24 hours	385 (50.3)	169 (22.1)	11.48	<0.0001*
	Within 48 hours	36 (4.7)	17 (2.2)	2.68	0.0074*
	After 48 hours	5 (0.7)	3 (0.4)	0.79	0.4273
Redness/warmth at injection site	Within 30 min	47 (6.1)	17 (2.2)	3.83	0.00013*
	Within 24 hours	95 (12.4)	21 (2.7)	7.19	<0.0001*
	Within 48 hours	8 (1.0)	1 (0.1)	2.38	0.0172*
Swelling at injection site	Within 30 min	24 (3.1)	8 (1.0)	2.9	0.0037*
	Within 24 hours	87 (11.4)	22 (2.9)	6.46	<0.0001*
	Within 48 hours	7 (0.9)	3 (0.4)	1.22	0.2234
	After 48 hours	1 (0.1)	0 (0)	0.88	0.3813
Bruising at injection site	Within 30 min	9 (1.2)	3 (0.4)	1.76	0.0788
	Within 24 hours	20 (2.6)	5 (0.7)	2.92	0.0035*
	Within 48 hours	2 (0.3)	1 (0.1)	0.88	0.381
	After 48 hours	2 (0.3)	0 (0)	1.52	0.1293
Unwell /fatigue / weakness	Within 30 min	10 (1.3)	5 (0.7)	1.18	0.238
	Within 24 hours	337 (44.0)	47 (6.1)	17.12	<0.0001*
	Within 48 hours	41 (5.4)	8 (1.0)	4.89	<0.0001*
	After 48 hours	1 (0.1)	0 (0)	0.88	0.3813
Nausea / vomiting	Within 30 min	3 (0.4)	0 (0)	1.75	0.0797
	Within 24 hours	31 (4.0)	8 (1.0)	3.76	0.00017*
	Within 48 hours	5 (0.7)	2 (0.3)	1.11	0.2671
Headache	Within 30 min	16 (2.1)	3 (0.4)	2.99	0.0028*
	Within 24 hours	238 (31.1)	52 (6.8)	12.13	<0.0001*
	Within 48 hours	25 (3.3)	2 (0.3)	4.42	0.00001*
	After 48 hours	1 (0.1)	0 (0)	0.88	0.3813
Backache	Within 30 min	5 (0.7)	1 (0.1)	1.86	0.0628
	Within 24 hours	110 (14.4)	12 (1.6)	9.23	<0.0001*
	Within 48 hours	20 (2.6)	2 (0.3)	3.77	0.00017*
	After 48 hours	1 (0.1)	0 (0)	0.88	0.3813
Generalized Body ache	Within 30 min	5 (0.7)	1 (0.1)	1.86	0.0628
	Within 24 hours	300 (39.2)	56 (7.3)	14.78	<0.0001*
	Within 48 hours	39 (5.1)	8 (1.0)	4.67	<0.0001*
	After 48 hours	2 (0.3)	0 (0)	1.52	0.1293
Restricted Shoulder Movement	Within 30 min	21 (2.7)	5 (0.7)	3.03	0.0025*
	Within 24 hours	192 (25.1)	37 (4.8)	11.14	<0.0001*
	Within 48 hours	35 (4.6)	7 (0.9)	4.43	0.00001*
	After 48 hours	2 (0.3)	1 (0.1)	0.88	0.381
Joint Pain	Within 30 min	3 (0.4)	4 (0.5)	-0.29	0.77
	Within 24 hours	93 (12.1)	17 (2.2)	7.52	<0.0001*
	Within 48 hours	21 (2.7)	0 (0)	4.58	<0.0001*
	After 48 hours	2 (0.3)	0 (0)	1.52	0.1293
Sore Throat	Within 30 min	3 (0.4)	0 (0)	1.75	0.0797
	Within 24 hours	14 (1.8)	1 (0.1)	3.43	0.0006*

Sore Throat	Within 48 hours	4 (0.5)	0 (0)	1.96	0.0501
	After 48 hours	1 (0.1)	1 (0.1)	0	1
Cough	Within 30 min	3 (0.4)	0 (0)	1.75	0.0797
	Within 24 hours	11 (1.4)	3 (0.4)	2.07	0.0382*
	Within 48 hours	2 (0.3)	1 (0.1)	0.88	0.381
Fever	Within 30 min	17 (2.2)	4 (0.5)	2.88	0.0039*
	Within 24 hours	361 (47.1)	54 (7.0)	17.67	<0.0001*
	Within 48 hours	42 (5.5)	3 (0.4)	5.9	<0.0001*
	After 48 hours	3 (0.4)	1 (0.1)	1.18	0.2397
Chills	Within 30 min	3 (0.4)	2 (0.3)	0.33	0.7404
	Within 24 hours	228 (29.8)	24 (3.1)	14.09	<0.0001*
	Within 48 hours	23 (3.0)	2 (0.3)	4.15	0.00003*
	After 48 hours	1 (0.1)	0 (0)	0.88	0.3813
Diarrhea	Within 30 min	1 (0.1)	0 (0)	0.88	0.3813
	Within 24 hours	7 (0.9)	4 (0.5)	0.94	0.3478
	Within 48 hours	2 (0.3)	1 (0.1)	0.88	0.381
	After 48 hours	1 (0.1)	0 (0)	0.88	0.3813

Table 7. Factors Associated with the presence of Adverse events after 1st dose of COVID-19 vaccination

*Significant (Binary Logistic Regression (Multivariate) analysis is used to determine the factors associated with AE. Cox & Snell R2=0.079, Nagelkerke R2=0.166; Omnibus test of model coefficients was significant, x2=63.39 with p<0.001and according to Hosmer & Lemeshow test, the model was a good fit, x2=8.195 with P=0.146; Overall percentage accuracy in classification was 91.1%)

Factors		Didn't had any Adverse effect (77)	Had Adverse effect (689) (Ref)	Total (766)	OR (95% C.I)	p-value
Gender	Female	35	382	417	1 (Reference)	
	Male	42	307	349	0.648 (0.388-1.084)	0.098
Age (Years)	18 - 30	60	602	662	1 (Reference)	
	30 - 45	12	73	85	0.564 (0.28-1.135)	0.108
	45 - 60	5	14	19	0.342 (0.1-1.173)	0.088
Vaccine	COVAXIN	14	65	79	1 (Reference)	
	COVISHIELD	54	618	672	2.671 (1.385-5.151)	0.003*
	Not Sure	5	6	11	0.231 (0.059-0.901)	0.035*
	Not vaccinated	4	0	4	0	0.999
Constant					7.86E+08	0.999

Whereas 2nd doses of both the vaccines did not exhibit statistically significant differences (Table 2, 7, 8).

We observed that participants in the age group of 18 to 30 years constituted for 86.4% of the total participants [10], it is due to the large-scale participation by the students (Table1). Following 1st dose of vaccination 90.9% in the age group of 18-30, 85.8% in age group of 30-45 and 73.6% in the age group of 45-60 experienced one or the other adverse event, which was in line with VigiAccess [11] but the occurrences of adverse event in the age group were not statistically significant (Table 7). Similarly following 2nd doses of covid -19 vaccination 42.7% in the age group of 18 – 30, 55.2% in age group of 30-45 and 15.7% in the age group of 45-60 experienced AEFI. It was observed that age group of 30-45 years had 1.688 times higher chances of having adverse event as compared to age group of 18-30 years and was statistically significant (Table 8). However, based on these finding we cannot conclude that the AEFI is more in the age group of 30-45, as it is seen only in 2nd dose and also the initial phase of national wide vaccination was targeted against frontline workers [12]. It was noted that male participants had 0.73 times lesser occurrences of AE as compared to female following 2nd dose of vaccination similar

Factors		Didn't had any Adverse effect (433)	Had Adverse effect (333) (Ref)	Total (766)	OR (95% C.I)	p-value
Gender	Female	222	185	417	1 (Reference)	
	Male	211	138	349	0.734 (0.546-0.987)	0.041
Age (Years)	18 - 30	379	283	662	1 (Reference)	
	30 - 45	38	47	85	1.688 (1.059-2.69)	0.028
	45 - 60	16	3	19	0.301 (0.084-1.085)	0.066
Vaccine	COVAXIN	39	40	79	1 (Reference)	
	COVISHIELD	382	290	672	0.721 (0.446-1.167)	0.184
	Not Sure	8	3	11	0.352 (0.086-1.445)	0.147
	Not vaccinated	4	0	4	0	0.999
Constant					0.696	0.69

Table 8. Factors Associated with the presence of Adverse events after 2nd dose of COVID-19 vaccination

Significant (Binary Logistic Regression (Multivariate) analysis is used to determine the factors associated with AE. Cox & Snell R2=0.041, Nagelkerke R2=0.055; Omnibus test of model coefficients was significant, x2=32.21 with p=0.014 and according to Hosmer & Lemeshow test, the model was a good fit, x2=0.796 with P=0.939; Overall percentage accuracy in classification was 58.5%)

Factors		Study participants who had adverse effect after		Difference (Decrease in proportion)	z-value	Significance
		1st Dose	2nd Dose			
Gender	Female	382 (49.9%)	185 (24.2%)	25.7%	10.41	< 0.00001*
	Male	307 (40.1%)	138 (18.0%)	22.1%	9.53	< 0.00001*
Age (Years)	18 - 30	602 (78.6%)	283 (36.9%)	41.7%	16.52	< 0.00001*
	30 - 45	73 (9.5%)	47 (6.1%)	3.4%	2.48	0.013*
	45 - 60	14 (1.8%)	3 (0.14%)	1.7%	3.31	0.00094*
Vaccine	COVAXIN	65 (8.5%)	40 (5.2%)	3.3%	2.56	0.01046*
	COVISHIELD	618 (80.7%)	290 (37.9%)	42.8%	17.05	< 0.00001*
	Not Sure	6 (0.8%)	3 (0.4%)	0.4%	1.01	0.3125

Table 9. Comparison of 1st and 2nd dose of vaccination

*Indicates that P value was less than 0.05 and is statistically significant

to few Indian studies (Table 8) [13,14].

The most common adverse event at the injection site was pain/tenderness (73.89%-1st dose, 34.33%-2nd dose) followed by redness/warmth at injection site (18.77%-1st dose, 5.09%-2nd dose). Apart from injection site, the commonest adverse event documented was fever (55.22%-1st dose, 8.09%-2nd dose) followed by generalized feeling of unwell/fatigued/generalized weakness (50.78%-1st dose, 7.83%-2nd dose), generalized body ache (45.16%-1st dose, 8.48%-2nd dose). We observed on comparing the documentation of adverse event following 1st and 2nd dose of both the Covid-19 vaccines, that there was statistically significant reduction in AE following 2nd dose across all age groups, in both the gender, for all adverse event except diarrhea and for both the vaccines that is for Covishield and Covaxin [9]. AE documented in the study are reassuring as they are all predicted (as per clinical trial), mild, short lived and were responding to the symptomatic management suggested, hence reducing the vaccination hesitancy.

689 (89.94%) of participants had experienced one or the other adverse event. Among those participants who had experienced AE, 676 (88.2%) took symptomatic treatment as suggested at the time of vaccination and 13 participants were managed symptomatically at the hospital, all for fever with or without chills. out of the 689 participants, only 146 (21.19%) participants reported the adverse events. 543 (78.80%) of participants had not reported AE following covid -19 vaccination, whereas national AEFI reported was 0.007% [15]. Reason for underreporting may be as at vaccination site, beneficiaries were educated about the common expected AE and also the strategies to address them at home. Also, as AE experienced by the participants were not severe. Under reporting is major concern with respect to spontaneous report methos of pharmacovigilance. But the participants being

medical students, approach for the study participant, large number of participants should have reported AE. Even though the AEFI reporting by the study participants is better than the reported percentage in the COWIN portal, [15] under reporting in the study participants should be highlighted as participants being related to healthcare setup should have been aware of the importance of AE reporting especially of the recently introduced vaccines and should have taken the initiative to contact the AMC.

Out of the total participants 106 participants had suffered from Covid-19 illness, 38 participants before taking any doses of vaccines, 19 after 1st dose, 49 after 2nd dose. 64.15% of participants who had covid 19 illness were home isolated, 26.41% were managed at covid care center or at isolation center and 10 participants were hospitalized. Out of the 10 hospitalized, 6 participants had not received any doses of vaccine, 3 participants had received 1st dose of Covid-19 vaccine and 1 participant had taken both the doses of vaccine. In this study we noted that 15.78% of participants were hospitalized for Covid-19 illness even after taking 1st dose of vaccine but after taking both the doses 2.04% of participants were hospitalized, we noted significant reduction in hospitalization for covid 19 illness following both the doses of vaccine in this study, indicating reduction in the severity of infection when vaccinated with both the doses of Vaccine [16].

CONCLUSION

As the study site is an AMC, higher reporting rate of AEFI was noted. The adverse events noted were not of serious nature and there was significant reduction in AE for both vaccines following 2nd dose across all age groups, in both the gender and for all adverse event except diarrhea was noted and causality of each adverse reaction was not analyzed, hence the all-adverse events may or may not be related to the vaccines, indicating that the vaccines used in India are safe.

LIMITATIONS

As the study was a cross sectional study; comorbidity and the adverse event association was not analyzed as related data was not available. Representation across all the age groups was not achieved. There was large difference in the number of beneficiaries receiving each vaccine as the vaccines concerned in the study were introduced at two different time line. Causality of adverse event to the vaccines are not tested.

CONFLICTS OF INTEREST

All authors declare no conflict of interest.

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REFERENCES

1. Ong E, Wong MU, Huffman A, He Y. COVID-19 coronavirus vaccine design using reverse vaccinology and machine learning. Frontiers in immunology. 2020;11:1581.

2. Khuroo MS, Khuroo M, Khuroo MS, Sofi AA, Khuroo NS. COVID-19 vaccines: a race against time in the middle of death and devastation! Journal of clinical and experimental hepatology. 2020;10(6):610-21.

3. WHO Coronavirus Disease (COVID-19) Dashboard [Online]. World Health Organization [cited 2021 15 February 2021]. Available from: https://covid19.who.int.

4. Haque A, Pant AB. Efforts at COVID-19 vaccine development: challenges and successes. Vaccines. 2020;8(4):739.

5. Dubey AD. Public sentiment analysis of covid-19 vaccination drive in india. Available at SSRN 3772401. 2021.

6. Rodriguez-Nava G, Trelles-Garcia DP, Yanez-Bello MA, Imani-Ramos T, Trelles-Garcia VP, Bustamante-Soliz DS, et al., editors. MMR Vaccine Adverse Drug Reactions Reports in the CDC WONDER System, 1989–2019. Open Forum Infectious Diseases; 2020: Oxford University Press US.

7. Aagaard L, Hansen EW, Hansen EH. Adverse events following immunization in children: retrospective analysis of spontaneous reports over a decade. European journal of clinical pharmacology. 2011;67:283-8.

8. Basavaraja CK, Sebastian J, Ravi MD, John SB. Adverse events following COVID-19 vaccination: first 90 days of experience from a tertiary care teaching hospital in South India. Therapeu-

tic Advances in Vaccines and Immunotherapy. 2021;9:25151355211055833.

9. Kundawar A, Guralwar CO, Sontakke S. Study of Adverse Events following COVID-19 Vaccination: A cross-sectional Survey in India. The Journal of the Association of Physicians of India. 2022;70(7):11-2.

10. Mittal A, Jain B, Varshney AM, Garg G, Sachan D, Singh RB. Adverse effects after first and second dose of covishield and covaxin: A longitudinal study. Journal of Family Medicine and Primary Care. 2022;11(11):7339-45.

11. Reported potential side effects - Covid 19 vaccines [26th June 2023]. Available from: https://www.vigiaccess.org/.

12. Konda VCR, Gokul T, Poojitha M, Rao KU. Adverse Events Following Immunization to Covid-19 Vaccines in a Tertiary Care Hospital–A Descriptive Study. Biomedical and Pharmacology Journal. 2021;14(4):2149-56.

13. Kumar DR S, Patel AE. Covid-19 vaccination coverage and break through infections in urban slums of Bengaluru, India: A cross sectional study. medRxiv. 2021:2021.11. 21.21262716.

14. Jayadevan R, Shenoy R, TS A. Survey of symptoms following COVID-19 vaccination in India. Medrxiv. 2021:2021.02. 08.21251366.

15. Co-WIN winning over COVID-19 . Ministry of Health and Family Welfare. government of India [26th June 2023]. Available from: https://dashboard.cowin.gov.in/.

16. Gaind R, Gupta NK, Nath R, Srivastava N, Gahlot T, Ish P, et al. Effect of SARS-CoV-2 vaccination on severity and outcome of COVID-19 among health-care workers of a tertiary care hospital in India. Indian Journal of Medical Specialities. 2022;13(4):216.

Studija neželjenih dejstava nakon vakcinacije protiv COVID-19 u bolnici Karvar tercijernog nivoa zdravstvene zaštite

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KRATAK SADRŽAJ

Uvod: Koronavirusna bolest 2019 (COVID-19) kao pandemija izazvala je ogromnu krizu u globalnom javnom zdravlju i takođe se pretvorila u globalnu ekonomsku devastaciju. U Indiji su regulatorne vlasti dale dozvolu za dve vakcine. Covaxin, inaktivirana vakcina koju su razvili i proizveli Bharat Biotech i Covishield, Oxford AstraZeneca vakcina se proizvodi lokalno od strane Instituta za serume Indije.
Cilj: Ova studija je predložena u ovom kontekstu sa ciljem da se prouče neželjeni događaji nakon vakcinacije u našem centru za vakcinaciju i da se uporede neželjeni događaji nakon prve i druge doze vakcinacije protiv COVID-19.
Materijal i metode: Ovo je studija preseka sprovedena među zdravstvenim radnicima i studentima Karvar instituta medicinskih nauka, Karwar, Karnataka. Učesnicima je podeljen upitnik koji su sami ispunili.
Rezultati: Od 766 učesnika, 672 osobe su primile Covishield vakcinu, 79 učesnika je primilo Covaxin. Od ukupnog broja učesnika, 665 je primilo obe doze vakcine, 97 je primilo samo prvu dozu. Najčešći neželjeni događaj na mestu injekcije bio je bol/osetljivost, a osim na mestu injekcije, najčešći dokumentovani neželjeni događaj je bila povišena telesna temperaturaa.
Zaključak: Pošto je mesto istraživanja centar za praćenje neželjenih dejstava lekova (AMC), primećena je veća stopa prijavljivanja neželjenih događaja nakon imunizacije (AEFI). Zabeleženi neželjeni događaji nisu bili ozbiljne prirode i došlo je do značajnog smanjenja broja neželjenihg događaja (AE) za obe vakcine nakon 2. doze u svim starosnim grupama, za oba pola i za sve neželjene događaje osim dijareje, što ukazuje da je vakcina korišćena u Indija bezbedna.

Ključne reči: neželjeni događaj, neželjeni efekat nakon imunizacije, koronavirusna bolest 2019, Covaxin, Covishield

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