Original Research Paper

Volume - 12 | Issue - 03 | March - 2022 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Community Medicine

ADVERSE EVENTS OF THE COVID VACCINE IN TERTIARY CARE CENTRE IN BUNDELKHAND REGION: AN OBSERVATIONAL STUDY

Vimal Arya*	Head of Department, Community Medicine, MLB Medical College Jhansi Uttar Pradesh 284128. *Corresponding Author
Vinay Kumar	Pharmacovigilance Associate.
Sadhna Kauhsik	Professor Pharmacology.
Narendra Singh Sengar	HOD Nephrology.

ABSTRACT The Drugs Controller General (India) approved COVAXIN and COVISHIELD. Ever since the corona vaccine was launched in India, it has been playing the important role in controlling the pandemic. As with all medicinal products, vaccine safety must continue to be monitored and it is not possible to identify and record many adverse events in a shorter duration, protected environment and restricted population in trials. During the mass vaccination, a total of 1377 recipients were recognised with adverse events. Total 54.39% male and 45.61% female recipients were experienced adverse events. In the 18-45 age group total of 83.01% people while in the >45 age group 16.99% people were vaccinated. A total of 3032 Non-serious adverse events were reported in 1377 persons in study duration. The most common adverse event reported was fatigue, followed by headache. Another common adverse event was injection site pain and fever in the population. Another side less common adverse events were muscle ache followed by pruritus. Most of the adverse events were experienced by the Covishield vaccine. However, all the adverse events were recovered within a week. Our study showed that all the adverse events were non-serious in nature and no one needed hospitalisation for adverse events.

KEYWORDS : Covid-19, Covaxin, Covishield, Adverse Events, PvPI

INTRODUCTION

As of Dec 2021, coronavirus disease, 2019 (COVID-19) has been reported in more than 27 crore patients, and there have been more than 53 lacs deaths worldwide[1]. The novel human coronavirus has spread worldwide. COVID-19 is the disease caused by a new coronavirus called SARS-CoV-2. WHO first knew of this new virus on 31 December 2019, following a report of a cluster of cases of 'viral pneumonia in Wuhan, People's Republic of China[2].

Ever since the corona vaccine was launched in India, it has been playing the important role in controlling the pandemic. As of Dec 2021, more than 142 crore Indians have been vaccinated during the mass campaign for vaccinations by the government.The Drugs Controller General (India) approved two COVID-19 vaccines namely COVAXIN and COVISHIELD on 3rd January 2021 for restricted use in an emergency. As with all medicinal products, vaccine safety must continue to be monitored after regulatory authorisation to complement what was learnt during clinical development. Spontaneous adverse event reporting is a foundational component of post-approval Pharmacovigilance activities to ensure medicinal products' safe and appropriate use. Drug safety monitoring is a public health priority.[3,4]

Covaxin was developed by Bharat biotech in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). It is a 2-dose vaccination regimen given 28 days apart. The vaccine is developed using Whole-Virion Inactivated Vero Cell-derived platform technology. They contain dead virus, incapable of infecting people but still able to instruct the immune system to mount a defensive reaction against an infection.[5]

The ChAdOx1 nCoV-19 vaccine (COVISHIELD) by Serum Institute of India Pvt Ltd consists of a replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene. COVISHIELD™ vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 to 12 weeks after the first dose.[6]

National Coordination Centre (NCC) - PvPI, Indian Pharmacopoeia Commission (IPC) has initiated the Focussed Pharmacovigilance of COVID-19 vaccines by sensitizing healthcare professionals through its Adverse Drug Reaction Monitoring Centres (AMCs). Adverse Events (AEs)/Adverse Drug Reactions (ADRs) likely to occur during COVID-19 vaccination report through Toll-Free Helpline, Mobile App, Suspected ADR Reporting Form for COVID-19 drugs and Adverse Event Following Immunisation (AEFI) Case Notification Form to PvPI. NCC-PvPI Helpline No.-1800 180 3024 (Toll-Free) was disseminated pan-India for the collection of AEFI of COVID-19 Vaccines.[7]

The study aims to evaluate the occurrence of adverse events following immunization among people during mass vaccination programmes at a single tertiary care centre.

METHODOLOGY

This is an observational study conducted from 25 August 2021 to 20 October 2021. The data collection method was census and all the vaccinated persons during the mass vaccination programme were included. The study was conducted in an ADR Monitoring Centre MLB Medical College Jhansi, tertiary care hospital of North India during regular pharmacovigilance activity. During the study period, a total of 12,464 persons were vaccinated by Covaxin and Covishield. In this duration at the vaccination site Total 1st dose was administered in 5078 persons while 2nd dose was administered in 7386 persons. Covaxin was administered in 4763 persons and Covishield administer in 7701 persons. Total 51,016 persons were vaccinated in the mass vaccination programme from January to November 2021.

Adverse events reporting system[8]

Active and passive surveillance of the adverse events were done. The recipients were observed Within a week after each dose of vaccine for the development of any adverse events.

Active surveillance

All the recipients were enquired telephonically. Within a week enquiry was made regarding the development of AEFI. If the physical examination was required, the recipient was called and evaluated for the adverse events.

Passive surveillance

At the time of vaccination, recipients were instructed to inform adverse events, if any, to the surveillance team. The leaflet included the emergency telephone numbers, in case, if required.

RESULTS

During the mass vaccination, a total of 1377 recipients were found with adverse events in a total of 12,464 recipients of the vaccine. In 1377 recipients, 54.39% male recipients and 45.61% female recipients were experienced adverse events. Total 22.66% males and 19.90% females were vaccinated with Covaxin. 1st dose of Covaxin was received by

9.01% males and 8.06% females. 2nd dose of Covaxin was received by 13.65% Males and 11.84% females. Total 31.74% males and 25.71% females were vaccinated with Covishield. 1st dose of Covishield was received by 11.62% males and 1024% females. 2nd dose of Covishield was received by 20.12% Males and 15.47% females. In the 18-45 age group total of 83.01% people while in the >45 age group 16.99% people were vaccinated. In the 18-45 age group total of 49.38% of people were vaccinated with the Covishield vaccine while 33.62% of people were vaccinated with the Covaxin. In the >45 age group total of 8.93% of people were vaccinated with the Covaxin while 8.06% people were vaccinated with the Covishield (Table 01).

Table 1

Demographic Profile	Vaccine Details							
	Covaxin Total			Covaxin Total	Covishield		Grand Total	Grand Total
	1st Dose	2nd Dose			1st Dose	2nd Dose		
Gender	**Female**	111	163	274	141	213	354	628
	%	8.06%	11.84%	19.90%	10.24%	15.47%	25.71%	45.61%
	Male	124	188	312	160	277	437	749
	%	9.01%	13.65%	22.66%	11.62%	20.12%	31.74%	54.39%
	Grand Total	**235**	**351**	**586**	**301**	**490**	**791**	**1377**
	%	**17.07%**	**25.49%**	**42.56%**	**21.86%**	**35.58%**	**57.44%**	**100.00%**
Age group	**18-45**	180	283	463	256	424	680	1143
	%	13.07%	20.55%	33.62%	18.59%	30.79%	49.38%	83.01%
	>45	55	68	123	45	66	111	234
	%	3.99%	4.94%	8.93%	3.27%	4.79%	8.06%	16.99%
	Grand Total	**235**	**351**	**586**	**301**	**490**	**791**	**1377**
	%	**17.07%**	**25.49%**	**42.56%**	**21.86%**	**35.58%**	**57.44%**	**100.00%**

Frequency of Adverse Events with the vaccines

Table 2 shows that a total of 3032 Nonserious adverse events were reported in 1377 persons in study duration. Most common adverse event included fatigue (N-984,32.45 %), headache (N-739,24.37%), Injection site Pain (N-605, 19.95%) and Fever (N-553, 18.24%) with Covaxin and Covishield vaccine. The less common adverse events were included as muscle ache (N-74, 2.44%), Pruritus (N-41, 1.35%), Dizziness (N-21, 0.69%) and Nausea (N-15, 0.49%). Total 1647 (54.32%) adverse events were experienced by male recipients while 1385 (45.68%) adverse events were experienced by female recipients. Total 1178 (38.85%) adverse events were experienced with the 1st dose of the vaccine while 1854 (61.15%) of adverse events were experienced with the 2nd dose of vaccine. with the 1st dose of Covaxin Total 507 (16.72%) and With Covishield Total 671(22.13%) adverse events were experienced by recipients. Another side, with the 2nd dose of Covaxin Total 801 (26.42%) and With Covishield Total 1063(34.73%) adverse events were experienced by recipients (Table 2).

Table 2

Adverse Events	Gender		Vaccine Dose 1	Vaccine Dose 1			Vaccine Dose 2			Grand Total
	Male	Female		Covaxin	Covi-shield	Total	Covaxin	Covi-shield	Total	
Fatigue	528	456	**984**	172	196	**368**	250	366	**616**	**984**
	17.41%	15.04%	**32.45%**	5.67%	6.46%	**12.14%**	8.25%	12.07%	**20.32%**	**32.45%**
Headache	388	351	**739**	132	164	**296**	180	263	**443**	**739**
	12.80%	11.58%	**24.37%**	4.35%	5.41%	**9.76%**	5.94%	8.67%	**14.61%**	**24.37%**
Inj. Site Pain	338	267	**605**	96	142	**238**	174	193	**367**	**605**
	11.15%	8.81%	**19.95%**	3.17%	4.68%	**7.85%**	5.74%	6.37%	**12.10%**	**19.95%**
Fever	307	246	**553**	84	130	**214**	161	178	**339**	**553**
	10.13%	8.11%	**18.24%**	2.77%	4.29%	**7.06%**	5.31%	5.87%	**11.18%**	**18.24%**
Muscle Ache	39	35	**74**	12	19	**31**	21	22	**43**	**74**
	1.29%	1.15%	**2.44%**	0.40%	0.63%	**1.02%**	0.69%	0.73%	**1.42%**	**2.44%**
Pruritus	27	14	**41**	3	12	**15**	7	19	**26**	**41**
	0.89%	0.46%	**1.35%**	0.10%	0.40%	**0.49%**	0.23%	0.63%	**0.86%**	**1.35%**
Dizziness	11	10	**21**	3	5	**8**	6	7	**13**	**21**
	0.36%	0.33%	**0.69%**	0.10%	0.16%	**0.26%**	0.20%	0.23%	**0.43%**	**0.69%**
Nausea	9	6	**15**	5	3	**8**	2	5	**7**	**15**
	0.30%	0.20%	**0.49%**	0.16%	0.10%	**0.26%**	0.07%	0.16%	**0.23%**	**0.49%**
Grand Total	**1647**	**1385**	**3032**	**507**	**671**	**1178**	**801**	**1053**	**1854**	**3032**
	54.32%	**45.68%**	**100.00%**	**16.72%**	**22.13%**	**38.85%**	**26.42%**	**34.73%**	**61.15%**	**100.00%**

Adverse events in 18-45 age group with Covaxin & Covishield

A total of 2510 (82.78%) Adverse events were experienced in the 18-45 age group in that Total of 1030 (33.97%) Adverse events were found by Covaxin. With the first dose total 385 (12.70%) and with the second dose total of 648 (21.37%) adverse events were found. Total 1480 (48.81%) adverse events were found by Covishield. With the first dose total of 578 (19.06%) Adverse events were found while with the second dose total of 905 (29.85%) adverse events were found.

Adverse events in >45 age group with Covaxin & Covishield

A total of 522 (17.22%) Adverse events were experienced in the >45 age group in that total 278 (9.17%) Adverse events found by Covaxin. With the first dose total 124 (4.09%) and with the second dose total 157 (5.18%) adverse events were found. Total 244 (8.05%) adverse events were found by Covishield. With the first dose total of 95 (3.13%) Adverse events were found while with the second dose total Of 152 (5.01%) adverse events were found**. (Table 3)**

Table 3

dverse Events	Age Vaccine Name Dose														
	18-45						18-45 Total	>45						>45 Total	Grand Total
	Covaxin		Covaxin Total	Covishield		Covishield Total		Covaxin		Coaxin Total	Covishield		Covishield Total		
	1Dose	2Dose		1Dose	2Dose			1Dose	2Dose		1Dose	2Dose			
Fatigue	131	203	334	173	319	492	**826**	41	47	88	23	47	70	158	**984**
	4.32%	6.70%	11.02%	5.71%	10.52%	16.23%	**27.24%**	1.35%	1.55%	2.90%	0.76%	1.55%	2.31%	5.21%	**32.45%**
Headache	101	146	247	143	229	372	**619**	31	34	65	21	34	55	120	**739**
	3.33%	4.82%	8.15%	4.72%	7.55%	12.27%	**20.42%**	1.02%	1.12%	2.14%	0.69%	1.12%	1.81%	3.96%	**24.37%**
Inj. Site Pain	71	146	217	122	164	286	**503**	25	28	53	20	29	49	102	**605**

	2.34%	4.82%	7.16%	4.02%	5.41%	9.43%	**16.59%**	0.82%	0.92%	1.75%	0.66%	0.96%	1.62%	3.36%	**19.95%**
Fever	61	125	186	106	150	256	**442**	23	36	59	24	28	52	111	**553**
	2.01%	4.12%	6.13%	3.50%	4.95%	8.44%	**14.58%**	0.76%	1.19%	1.95%	0.79%	0.92%	1.72%	3.66%	**18.24%**
Muscle Ache	9	15	24	16	18	34	**58**	3	6	9	3	4	7	16	**74**
	0.30%	0.49%	0.79%	0.53%	0.59%	1.12%	**1.91%**	0.10%	0.20%	0.30%	0.10%	0.13%	0.23%	0.53%	**2.44%**
Pruritus	3	7	10	9	14	23	**33**	0	0	0	3	5	8	8	**41**
	0.10%	0.23%	0.33%	0.30%	0.46%	0.76%	**1.09%**	0.00%	0.00%	0.00%	0.10%	0.16%	0.26%	0.26%	**1.35%**
Dizziness	3	2	5	5	4	9	**14**	0	4	4	0	3	3	7	**21**
	0.10%	0.07%	0.16%	0.16%	0.13%	0.30%	**0.46%**	0.00%	0.13%	0.13%	0.00%	0.10%	0.10%	0.23%	**0.69%**
Nausea	5	2	7	3	5	8	**15**	0	0	0	0	0	0	0	**15**
	0.16%	0.07%	0.23%	0.10%	0.16%	0.26%	**0.49%**	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	**0.49%**
Total	**385**	**648**	**1030**	**578**	**905**	**1480**	**2510**	**124**	**157**	**278**	**95**	**152**	**244**	**522**	**3032**
	12.70%	**21.37%**	**33.97%**	**19.06%**	**29.85%**	**48.81%**	**82.78%**	**4.09%**	**5.18%**	**9.17%**	**3.13%**	**5.01%**	**8.05%**	**17.22%**	**100.00%**

Table 4

Adverse Events	Adviser Events Experienced (In Days)			Grand Total
	Initial day	1 day	2 day	
Fatigue	893	89	2	**984**
	29.45%	2.94%	0.07%	32.45%
Fever	544	9	0	**553**
	17.94%	0.30%	0.00%	18.24%
Headache	656	75	8	**739**
	21.64%	2.47%	0.26%	24.37%
Pruritus	37	4	0	**41**
	1.22%	0.13%	0.00%	1.35%
Inj. Site Pain	505	100	0	**605**
	16.66%	3.30%	0.00%	19.95%
Muscle Ache	62	10	2	**74**
	2.04%	0.33%	0.07%	2.44%
Nausea	14	1	0	**15**
	0.46%	0.03%	0.00%	0.49%
Dizziness	21	0	0	**21**
	0.69%	0.00%	0.00%	0.69%
Grand Total	**2732**	**288**	**12**	**3032**
	90.11%	9.50%	0.40%	100.00%

Table 5

Adverse Events	adverse Events Recovery (In Days)					Grand Total
	Initial day	day 1	day 2	day 3	day 4	
Fatigue	471	75	420	13	5	**984**
	15.53%	2.47%	13.85%	0.43%	0.16%	32.45%
Headache	47	106	580	6	0	**739**
	1.55%	3.50%	19.13%	0.20%	0.00%	24.37%
Inj. Site Pain	458	46	35	57	9	**605**
	15.11%	1.52%	1.15%	1.88%	0.30%	19.95%
Fever	4	529	20	0	0	**553**
	0.13%	17.45%	0.66%	0.00%	0.00%	18.24%
Muscle Ache	62	10	2	0	0	**74**
	2.04%	0.33%	0.07%	0.00%	0.00%	2.44%
Pruritus	37	4	0	0	0	**41**
	1.22%	0.13%	0.00%	0.00%	0.00%	1.35%
Dizziness	0	18	3	0	0	**21**
	0.00%	0.59%	0.10%	0.00%	0.00%	0.69%
Nausea	14	1	0	0	0	**15**
	0.46%	0.03%	0.00%	0.00%	0.00%	0.49%
Grand Total	**1093**	**789**	**1060**	**76**	**14**	**3032**
	36.05%	26.02%	34.96%	2.51%	0.46%	100.00%

Adverse events onset details

Table Shows that in total 3032 Adverse events most of the Adverse Events experienced on the initial day of the. Total 2732 (90.11%) adverse events were experienced on the initial day of the vaccine. On day one total of 288 (9.50%) adverse events were experienced and on day two only 12 (0.40%) adverse events were experienced.

DISCUSSION

Table 2 shows that In our study most frequent adverse events were reported in males 54.32% while 45.68% in females. The most common adverse event reported was fatigue, followed by headache. Another common adverse event was injection site pain and fever in the population. Another side less common adverse events were muscle ache followed by pruritus. Dizziness was reported in 0.36% and nausea was reported in 0.30% of persons only.

According to table 3, the majority of the adverse events were reported in the 18-45 age group. Overall, 82.78 % of adverse events developed in this age group. in this age group most of the adverse events 48.81% were reported by the Covishield vaccine. in the >45 age group most of the adverse 9.17% events were reported by the Covaxin vaccine. Overall, 61.15% adverse events were reported after the second dose of vaccine was administered while after the first dose of the vaccine only 38.85% adverse events were reported by the persons.

According to table 4, Most of the adverse events experienced within 2 days of the vaccination in the vaccine recipients. Most of the adverse events (90.11%) were experienced on the initial day of vaccination while the next day only 9.50% of reactions were experienced by the persons. On the other side, after two days of vaccine, only 0.40% of persons experienced the adverse events.

According to table 5, most of the adverse events were recovered on the initial day of vaccination. In total 3032 adverse events total 1093 (36.05%) adverse events recovered on the initial day of the vaccine. On the next day total of 789 (26.02%) of adverse events recovered while on day two total of 1060(34.96%) of adverse events were recovered and on day 3 total of 76 (2.51%) adverse events recovered and on day 4

total 14 (0.46%) adverse events recovered. Thus, all the adverse events completely recovered in a week. No, another adverse event was reported after a week by any vaccine recipients.

CONCLUSION

In our study, all the adverse events were received during the regular pharmacovigilance activity at the ADR Monitoring Centre by the telephonic conversation with the vaccine recipients. According to the study, we found the adverse events were more common in males. At our vaccine centre, Covaxin and Covishield were available for the people. In the 18-45 age group adverse events were more common. Most of the adverse events were experienced on the initial day of vaccination. Most of the adverse events were experienced by the Covishield vaccine. however, all the adverse events were recovered within a week. Our study showed that all the adverse events were nonserious in nature and no one needed hospitalisation for adverse events.

Acknowledgements

The author would like to sincerely thanks the MLB Medical College Jhansi and Pharmacovigilance Programme of India, Indian pharmacopoeia commission to provide the opportunity to do this work.

REFERENCES

1 WHO Coronavirus (COVID-19) Dashboard
2 https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19
3 https://dashboard.cowin.gov.in/
4 Xintong Li, Anna Ostropolets, Rupa Makadia, Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study. the BMJ | BMJ 2021;373:n1435 | doi: 10.1136/BMJ.n1435
5 https://www.bharatbiotech.com/covaxin.html
6 https://www.seruminstitute.com/product_covishield.php
7 PvPI NEWSLETTER January-March 2021
8 Deep Kamal, Vaidehi Thakur, Navneet Nath, Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study.Medical journal armed forces India 77 (2021) S2 83 - S2 88