CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.17307415

Available online at: http://www.iajps.com Research Article

ASSESS THE ADVERSE DRUG REACTIONS OF VARIOUS COVID VACCINES

Baddem Bhargavi, M.Madhavi Kumara, Dr.M.B.V.Raju

Department of Pharmacology, Avanthi Institute of Pharmaceutical Sciences
Cherukupally(vil), Chittivalasa (P.O), Bhogapuram(M),Vizianagaram (Dist.)-531162, A.P.

Abstract:

Background: *Adverse drug reactions (ADRs) following COVID-19 vaccination have been reported globally, but data on their incidence, severity, and associated risk factors remain limited. This study aimed to evaluate the occurrence and characteristics of ADRs among recipients of Covaxin and Covishield vaccines.*

Methods: *A total of 372 participants were enrolled. ADRs were assessed in relation to age, gender, concomitant medications, and clinical manifestations. Causality and severity were evaluated using the WHO-UMC scale and the modified Hartwig and Siegel scale, respectively.*

Results: *Among participants, 62 receiving Covaxin and 267 receiving Covishield experienced ADRs. The majority occurred in the 45–59 years age group (33.77%) and predominantly in males (Covaxin 60.94%, Covishield 71%). Participants on antihypertensive therapy reported the highest incidence of ADRs (43.33%), followed by proton pump inhibitors (15.5%) and hormonal drugs (12.5%). The most common ADRs included severe pain at the injection site (90.8%), weakness (87.54%), fever (87.21%), fatigue (61.9%), joint pain (57.3%), and muscle ache (54.75%). Organ systems most frequently affected were the skin and musculoskeletal system (25.87%) and gastrointestinal system (23.24%). Causality assessment revealed 20.38% probable, 37.54% possible, and 34.62% certain ADRs. According to the modified Hartwig and Siegel scale, 49.25% of ADRs were mild.*

Conclusion: *ADRs following COVID-19 vaccination were common, particularly among middle-aged males and those on antihypertensive therapy. Most ADRs were mild and involved the musculoskeletal and skin systems. These findings highlight the importance of monitoring ADRs and providing guidance for vaccine recipients to manage expected side effects effectively.*

Keywords: Adverse drug reactions, COVID-19 vaccination, Covaxin, Covishield

Corresponding author:
Baddem Bhargavi,
Department of pharmacology
8639900956
Bhargavibaddem01@gmail.com

QR CODE

Please cite this article in press ***Baddem Bhargavi*** *et al.,* ***Assess The Adverse Drug Reactions Of Various Covid Vaccines****, Indo Am. J. P. Sci, 2025; 12(10).*

INTRODUCTION:

Coronavirus disease 2019 (COVID-19) is a highly infectious illness caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus is primarily transmitted through respiratory droplets released when an infected person coughs, sneezes, or exhales. It can also spread indirectly when a person touches contaminated surfaces and subsequently touches their eyes, nose, or mouth.1 Since its emergence in late 2019, SARS-CoV-2 has rapidly spread across the globe, leading to a major public health crisis, infecting millions of individuals and causing over three million deaths worldwide within a year.1,2 The unprecedented scale and speed of transmission prompted an urgent need for effective preventive measures, including the rapid development of safe and efficacious vaccines.

India, like many other countries, faced significant challenges in controlling the spread of COVID-19 due to its vast population and densely populated regions. In response, researchers and pharmaceutical companies worked tirelessly to develop vaccines to reduce morbidity and mortality associated with the disease. Two Indian-developed vaccines received Emergency Use Authorization (EUA) early in the pandemic: Covishield, developed by Oxford-AstraZeneca and manufactured by the Serum Institute of India (SII), and Covaxin, an inactivated vaccine developed by Bharat Biotech Limited. These vaccines have played a pivotal role in India's COVID-19 immunization strategy.

Clinical Features of COVID-19

The clinical presentation of COVID-19 varies from mild symptoms to severe disease. Common symptoms include fever, cough, and shortness of breath, while more severe cases may progress to pneumonia or acute respiratory distress syndrome (ARDS).2,3 Less common manifestations include myalgia, sore throat, diarrhea, conjunctivitis, anosmia (loss of smell), ageusia (loss of taste), and dermatological signs such as rashes or discoloration of fingers and toes.3 In rare instances, COVID-19 can be fatal, particularly in older adults or those with underlying comorbidities. The symptoms of COVID-19 often resemble those of influenza or the common cold, which necessitates laboratory testing for accurate diagnosis.4

Epidemiology of COVID-19 in India

COVID-19 is highly transmissible, resulting in widespread infection in India. As of recent data, India has reported approximately 29.4 million cases, with 27.9 million recoveries and over 3.67 lakh deaths. The significant mortality associated with COVID-19 highlights the importance of vaccination as a public health intervention. Since its initial emergence, the SARS-CoV-2 virus has affected almost all regions of India, making COVID-19 a national as well as a global health crisis. Vaccination is considered the cornerstone of pandemic control, expected to reduce transmission, prevent severe illness, and contribute to herd immunity.4

The development and approval of COVID-19 vaccines occurred at an unprecedented speed, facilitated by global collaboration and streamlined regulatory pathways. However, the vaccines undergo authorization only after thorough evaluation of efficacy, safety, and quality.5 Clinical trials, particularly Phase 3 trials, involve a limited number of participants under controlled conditions, and certain rare adverse events may only be identified after widespread real-world use. Thus, post-marketing surveillance is critical for monitoring vaccine safety and effectiveness.5,6 The high uptake of COVID-19 vaccines in India is anticipated to generate extensive safety data, emphasizing the need for timely detection, evaluation, and communication regarding any adverse events.

COVID-19 Vaccines in India

Initially, two vaccines were approved for emergency use in India: Covishield, the Oxford–AstraZeneca vaccine manufactured by SII, and Covaxin, developed by Bharat Biotech. In April 2021, the Russian Sputnik V vaccine, distributed by Dr. Reddy's Laboratories, was approved as a third option and began administration in May 2021.7,8 Covaxin is an inactivated whole-virus vaccine, which stimulates an immune response without causing infection. Covishield, on the other hand, is a viral vector vaccine that employs a modified chimpanzee adenovirus (ChAdOx1) to deliver the SARS-CoV-2 spike protein into human cells, inducing immunity. Both vaccines prime the immune system to recognize and combat SARS-CoV-2 in the event of future exposure.

Benefits of COVID-19 Vaccines

COVID-19 vaccination offers multiple benefits. Primarily, it reduces the risk of infection and prevents progression to severe disease, hospitalization, or death. Vaccination also contributes to herd immunity by increasing the proportion of the population protected, thereby reducing viral transmission. Furthermore, effective vaccination can limit viral replication and mutation, potentially mitigating the emergence of vaccine-resistant variants. India launched its COVID-19 vaccination program on 16 January 2021, initially targeting healthcare workers (Phase I), followed by frontline workers. Phase II prioritized individuals

over 60 years and those aged 45–59 with comorbidities.7

Adverse Drug Reactions (ADRs) of COVID-19 Vaccines

While COVID-19 vaccines have demonstrated robust safety profiles, mild to moderate adverse events have been reported. Common reactions include injection site pain, swelling, redness, fever, fatigue, headache, muscle aches, chills, and gastrointestinal disturbances. Covaxin-specific ADRs include localized pain, swelling, itching, stiffness, body aches, fever, rashes, nausea, and vomiting. Covishield has shown similar reactions, with more than 1 in 10 recipients reporting tenderness, pain, swelling, fatigue, chills, or headache. Less frequent events, affecting up to 1 in 100 people, include dizziness, abdominal pain, decreased appetite, lymphadenopathy, and rashes. Vaccines remain the most effective strategy for pandemic control, and ongoing surveillance ensures early detection of rare adverse events.

ADR Causality Assessment

Several scales and methods are used to assess the causality, probability, severity, and preventability of adverse drug reactions:

- **Causality Assessment:** WHO–UMC Causality Assessment Scale
- **Probability Assessment:** Naranjo Adverse Drug Reaction Probability Scale
- **Severity Assessment:** Modified Hartwig and Siegel Severity Assessment Scale, Karch and Lasagna Scale
- **Preventability Assessment:** Schumock and Thornton Scale

These tools are essential for evaluating the relationship between vaccination and adverse events, guiding clinical and regulatory decision-making.

Passive Surveillance of ADRs

Passive surveillance involves the unsolicited reporting of adverse events to central databases or health authorities. In India, such reports are collected in the IPC-Vaccines ADR Database, managed by the Indian Pharmacopoeia Commission (IPC). COVID-19 vaccine providers are required to report serious adverse events, enabling monitoring of both common and rare complications. Passive surveillance has been instrumental in identifying severe allergic reactions and other uncommon events associated with COVID-19 vaccination.

Active Surveillance of ADRs

Active surveillance entails proactive data collection and analysis from large healthcare databases to identify safety signals that may not be reported in passive systems. India's pharmacovigilance framework employs sentinel sites and collaborates with governmental and non-governmental partners to conduct active surveillance, ensuring continuous monitoring of vaccine safety and effectiveness.

In conclusion, the COVID-19 pandemic has underscored the critical role of vaccination in controlling infectious diseases. The rapid development and deployment of vaccines like Covishield, Covaxin, and Sputnik V have provided an effective means to reduce morbidity and mortality. Ongoing pharmacovigilance, through both active and passive surveillance, is essential to detect, evaluate, and mitigate potential adverse reactions, thereby maintaining public confidence in vaccination programs. Vaccination, coupled with other preventive measures such as masking and social distancing, remains central to India's strategy for controlling the spread of COVID-19 and safeguarding public health.

MATERIALS AND METHODS:

1 Study Design

This hospital-based retrospective observational study was conducted at King George Hospital, a 700-bedded multispecialty tertiary care teaching hospital, over a period of six months. The study aimed to evaluate adverse drug reactions (ADRs) associated with COVID-19 vaccination.

2 Study Population

The study included patients who had received COVID-19 vaccination. Data were collected from 100 patients over a three-month period.

3 Sampling Method

Patients aged 18 years and above who were willing to receive the COVID-19 vaccine were considered eligible. A total of 372 patients were selected based on these criteria.

4 Study Criteria

A) Inclusion Criteria

- Patients of either sex aged ≥18 years.
- Patients who visited for COVID-19 vaccination.
- Patients willing to provide informed consent.

B) Exclusion Criteria

- Patients aged <18 years.
- Patients unwilling to provide consent.
- Unconscious or critically ill patients.

5 Study Materials

A) Informed Consent Form

Informed consent was obtained from all participants using a Patient Informed Consent Form (ICF). The form was prepared in English and local languages and explained in simple, understandable terms to ensure comprehension. Consent was obtained from the patient or guardian before inclusion in the study.

B) Patient Data Collection Form

Data were collected using a structured patient data collection form, which included demographic details, laboratory data, drug therapy, vaccination details, and relevant medical history.

C) Patient Medical Records

Patient medical records were reviewed to obtain demographic information, clinical history, general physical examination findings, laboratory data, and details of drug therapy.

6 Ethical Approval

The study protocol was approved by the Institutional Ethics Committee of King George Hospital. Confidentiality of patient data was maintained throughout and after the study.

7 Data Analysis

Collected data were analyzed for gender-wise distribution and other demographic characteristics. Information on comorbidities, drug therapy, and procedures was organized and analyzed using Microsoft Excel. Results were presented as mean values and percentages.

8 Experimental Methods

8.1 Materials

The primary materials used in the study included:

8.1.1 Patient Data Collection Form

This form was used to collect demographic details (age, gender, body weight, height, marital status) and information regarding the type of COVID-19 vaccine administered.

8.1.2 Suspected Adverse Drug Reaction Reporting Form

This form, part of the Pharmacovigilance Programme of India (PvPI), was used for voluntary reporting of ADRs by healthcare professionals. Key sections included:

- **Patient Information:** Initials, age or date of birth, sex, and weight.
- **Suspected Adverse Reaction:** Date of onset, date of recovery, description of the reaction.
- **Suspected Medication:** Vaccine name (Covaxin/Covishield), action taken, recurrence of reaction, relevant medical/medication history, seriousness, and outcome.
- **Reporter Details:** Name, professional address, and date of reporting.

8.1.3 ADR Assessment Scales

- **Causality Assessment:** WHO–UMC Causality Assessment Scale.
- **Probability Assessment:** Naranjo Adverse Drug Reaction Probability Scale.
- **Severity Assessment:** Modified Hartwig and Siegel scale, Karch and Lasagna scale.
- **Preventability Assessment:** Schumock and Thornton scale.

9 Study Procedure

Step 1: Collection of Patient Demographics and ADR Data

Patient demographics and ADR-related data were collected using the Suspected ADR Reporting Forms provided at the vaccination center. The forms captured detailed information, including patient initials, age, gender, onset and description of reaction, vaccination dose details, severity, outcome, de-challenge and re-challenge data, and reporter information. A detailed history was obtained from each patient to establish a potential causal relationship between vaccination and the reported ADR.

Step 2: Data Analysis

After collection, data were analyzed for patient demographics, vaccine type, and characteristics of the adverse reaction.

Step 3: Causality and Severity Assessment

Causality assessment was conducted by a team comprising medical graduates, clinical pharmacologists, and physicians. Consultant opinions from relevant departments were obtained when required. The assessment involved reviewing medical records, interviewing healthcare professionals, and monitoring patients until resolution of the ADR or discharge.

- **Causality:** Evaluated using the WHO-UMC scale and Naranjo scale, classified as probable or possible.
- **Severity:** Assessed using the Modified Hartwig and Siegel scale, categorized as mild (Level 1), moderate (Levels 3–4), or severe (Level 5).

- **Preventability:** Assessed using the Schumock and Thornton scale, classified as preventable or non-preventable.
- **Seriousness and Outcome:** Reactions were classified as fatal, life-threatening, causing hospitalization, disability, or congenital anomaly. Outcomes were recorded as recovered, recovering, continuing, fatal, or unknown as per the Indian Pharmacopoeia Commission 2014 guidelines.

All ADRs reported through spontaneous reporting and active surveillance were documented and submitted to the Adverse Drug Reaction Monitoring Centre (AMC) functioning at the tertiary care vaccination center.

10 Statistical Analysis

Data were entered and analyzed using Microsoft Excel (MS Office 2010). Descriptive statistics were applied, and results were presented as mean, percentages, and proportions. Epi-Info software was also utilized for data analysis and graphical representation of results.

Results

Table No.1: Distribution of demographic details among the study population

Age in years	Males		Females		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
18-24	07	3.53%	41	23%	48	12.9%
25-34	37	18.6%	19	10.9%	56	15%
35-44	41	20.7%	41	23%	82	22%
45-59	90	46.4%	66	37.9%	156	41.9%
60-75	23	11.6%	00	00%	23	6.1%
75<	00	00%	07	4.0%	07	1.8%
Total	**198**	**100%**	**174**	**100%**	**372**	**100%**
Mean	**33**		**29**		**62**	
Median	**30**		**30**		**52**	
Standard deviation	**32.23042**		**24.8274**		**52.9414**	

Table No.2: Distribution of Type Of Vaccine Among The Study Population

Type Of Vaccine	Frequency		Percentage		Odds ratio	Chi-square	P value
	1st Dose	2nd Dose	1st Dose	2nd Dose			
Covaxin	12	55	5.3%	37.6%	0.09278	60.733	< 0.0001 **VHS**
Covishield	214	91	94.7%	62.4%	10.778	60.733	< 0.0001 **VHS**
Total	**226**	**146**	100%	100%			

Table No.3: Distribution of Marital Status amongthe Study Population

Marital Status	Frequency	Percentage
Married	296	79.5%
Un Married	61	16.4%
Separated\Divorced	04	1.1%
Widow	11	3%
Total	**372**	**100%**
MEAN	**93**	
MEDIAN	**36**	
STANDARD DEVIATION	**137.6929**	

Place	Frequency		Percentage	
	Covaxin	Covishield	Covaxin	Covishield
Rural	07	82	10.4%	27.1%
Urban	41	104	61.1%	34.4%
Semi Urban	19	119	28.3%	39.4%

Table No.4: Area Wise Distribution Of Study Population

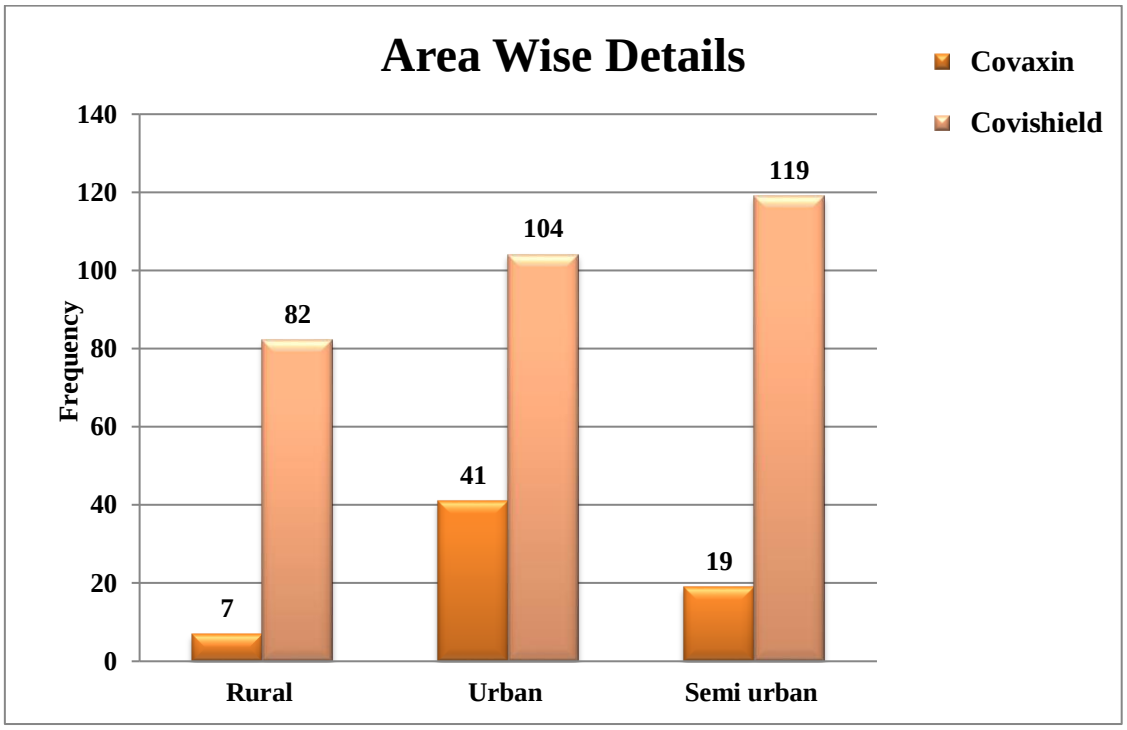

Table No.5: Implies the Period Of Vaccination Over The Year

Period Of Vaccination	Frequency		Percentage		MEAN	MEDIAN	Standard deviation
	1st Quarter 2021	2nd Quarter 2021	1st Quarter 2021	2nd Quarter 2021			
Covaxin	47	18	47%	18.00%	32.5	32.5	20.5061
Covishield	53	82	53%	82.00%	67.5	67.5	20.5061

Table No.6: Implies Body Mass Index of A Study Population

Body Mass Index(BMI)	Frequency		Percentage	
	Covaxin	Covishield	Covaxin	Covishield
Normal Weight	16	79	24%	26.1%
Under Weight	15	68	22.4%	22.2%
Over Weight	24	110	35.9%	36%
Obese	12	48	17.9%	15.7%
Total	**67**	**305**	**100%**	**100%**
Mean	**16.75**	**76.25**		
Median	**15.5**	**73.5**		
Standard deviation	**5.123**	**25.902**		

Table No.7: Socio Economic Status Wise Distribution of Sample Population

Socio Economic Status	Frequency		Percentage	
	Covaxin	Covishield	Covaxin	Covishield
Upper	22	08	32.8%	2.6%
Upper Middle	41	132	61.2%	43.3%
Middle	04	135	6%	44.2%
Lower Middle	00	23	00%	7.5%
Lower	00	07	00%	2.3%
Total	**67**	**305**	**100%**	**100%**
Mean	**13.4**	**61**		
Median	**4**	**23**		
Standard deviation	**17.1908**	**66.494**		

Table No.8: Educational Status Wise Distribution Of Sample Population

Education	Frequency Of Population		Percentage	
	Covaxin	Covishield	Covaxin	Covishield
Primary Schooling	06	26	9%	8.5%
Secondary Schooling	12	53	17.9%	17.3%
Intermediate	05	28	7.5%	9.2%
Degree Level	31	131	46.3%	43%
University Level	06	33	9%	10.8%
Illiterate	07	34	10.4%	11.1%
Total	**67**	**305**	**100%**	**100%**
Mean	**11.166**	**50.83**		
Median	**7**	**30**		
Standard deviation	**10.028**	**40.424**		

BNN Table No.9: Implies the Condition of Patient Regarding Smoking and Alcohol Habit

Habits	Frequency Of Population		Percentage	
	Covaxin	Covishield	Covaxin	Covishield
Current Smoker	27	123	23%	19.3%
Ex- Smoker	08	39	6.9%	7.3%
Non-Smoker	32	143	27.3%	26.9%
Alcoholic + Smoker	26	119	22.2%	22.3%
Non-Alcoholic	24	109	20.5%	20.4%
Mean	**23.4**	**106**		
Median	**26**	**119**		
Standard deviation	**9.099**	**39.759**		

Table No.10 Implies the Monthly Income of an Individual ofa Study Population

Monthly Income	Frequency Of Population		Percentage	
	Covaxin	Covishield	Covaxin	Covishield
<1000-5000	15	64	22.0%	20.9%
5000-10000	07	32	10.29%	10.4%
10000-15000	09	51	13.2%	16.7%
15000-25000	19	94	27.9%	30.8%
25000-50000	11	37	16.1%	12.1%
50000<	07	27	10.29%	8.85%
Mean	**11.333**	**50.833**		
Median	**10**	**44**		
Standard deviation	**4.802**	**25.1031**		

Table No.11 Implies the Comorbidities Associated with an Individual in a Study Population

Co-Morbidities Associated	Frequency		Percentage		Suffered ADR				
	Covaxin	Covishield	Covaxin	Covishield	Covaxin	Covishield	P value	Chi-square	Odds ratio
Hypertension	07	62	7.77%	18.18%	03	23	0.0303 (S)	4.690	0.3889 (0.1693 to 0.8718)
Migrane	07	14	7.77%	4.1%	05	06	0.2343 (NS)	1.415	1.994 (0.7795 to 5.101)
Spondylitis	01	05	1.12%	1.46%	01	05	0.8061 (NS)	0.06024	0.7636 (0.0880 to 6.624)
Fatty Liver	01	01	1.12%	0.29%	01	01	0.8803 (NS)	0.02266	3.8640.2391 to 62.427)
Gastric	18	23	20%	6.74%	12	20	**0.0003 (VSH)**	13.346	3.505 (1.796 to 6.839)
Gout	01	01	1.11%	0.29%	01	01	0.8061 (NS)	0.02266	3.8640.2391 to 62.427)
Thyroid	08	13	8.88%	3.81%	08	12	0.0816 (NS)	3.033	2.492 (0.9991 to 6.215)
Asthma	08	04	8.88%	1.17%	08	02	**0.0003 (VSH)**	13.142	8.321 (2.445 to 28.320)
No Comorbidities	12	158	13.3%	46.33%	05	103	**< 0.0001 (VSH)**	30.504	0.1805(0.09594 to 0.348)
Pregnancy	00	00	00	00	00	00	-	-	-
Arthritis	02	09	2.22%	2.63%	01	07	0.8347 (NS)	0.04353	0.8480 (0.1799 to 3.998)
Epilepsy	03	05	3.33%	1.46%	02	03	0.4571 (NS)	0.5530	2.344 (0.5492 to 10.005)
Diabetes	22	46	24.4%	13.48%	16	35	0.0154 (NS)	5.868	2.106 (1.187 to 3.736)
Total	**89**	**341**	**100%**	**100%**	**63**	**218**	-	-	-

Table No. 12: Occupational Wise Distribution among Sample Population

Occupation	Frequency	Percentage

	Covaxin	Covishield	Covaxin	Covishield
Employed	36	153	53%	51%
Un Employed	16	79	23.8%	25%
Students	5	19	7%	6%
Business	10	54	14%	17%
Total	**67**	**315**		
Mean	**16.75**	**76.25**		
Median	**13**	**66.5**		
Standard deviation	**13.598**	**56.7766**		

No.13: Information About Comorbidities in Each Patient of A Sample Population

Comorbidities number in Each Patient	Frequency		Percentage		Suffered ADR				
	Covaxin	Covishield	Covaxin	Covishield	Covaxin	Covishield	P value	Chi - square	Odds ratio
01	12	52	41%	41.6%	13	56	0.8315 (NS)	0.007287	0.8788 (0.3781 to 2.043)
02	15	53	13%	42%	12	35	0.3268 (NS)	0.9614	1.691 (0.7163 to 3.994)
03	02	14	6%	11%	02	14	0.6517 (NS)	0.2037	0.5429 (0.1157 to 2.548)
04	00	06	00	4%	00	04	0.7082(NS)	0.1400	0.4263 (0.02226 to 8.164)

Table No.14: Medication Using by Study Population During Vaccination

Class Of Drugs	Frequency		Percentage				
	Covaxin	Covishield	Covaxin	Covishield	P value	Chi-square	Odds ratio
Anti-Diabetic Drugs	22	08	32.83%	6.66%	< **0.0001 (VSH)**	19.961	6.844 (2.838 to 16.505
Anti-Hypertensive Drugs	05	52	7.46%	43.33%	< **0.0001 (VSH)**	24.442	0.1055(0.03957 to 0.281)
Nsiads	08	07	11.94%	5.83%	0.2327 (NS)	1.424	2.189(0.756 to 6.333)
Anti-Oxidants	03	01	4.47%	0.83%	0.2608 (NS)	1.265	5.578 (0.568 to 54.75)
Proton Pump Inhibitors	15	18	22.38%	15%	0.2843 (NS)	1.146	1.635 (0.7626 to 3.504)

Xanthan Oxidase Inhibitors	01	01	1.4%	0.83%	0.6743 (NS)	0.1766	1.803 (0.1109 to 29.31)
Harmones	02	15	2.98%	12.5%	0.0568 (NS)	3.629	0.2154(0.04768 to 0.972)
Anti-Inflammatory	08	13	11.94%	10.83%	0.8182 (NS)	0.05285	1.116 (0.4375 to 2.847)
Anti- epileptic drugs	03	05	4.47%	4.16%	0.9197 (NS)	0.01015	1.078 (0.2494 to 4.661)
Total	**67**	**120**					

Table No.15: Condition of Sample Population Regarding ADR

	Frequency				**Percentage**			
	Self-Medication		**On Prescribed Medication**		**Self-Medication**		**On Prescribed Medication**	
	Covaxin	Covishield	Covaxin	Covishield	Covaxin	Covishield	Covaxin	Covishield
Mono Therapy	07	39	19	68	70%	61%	86.3%	49%
Dual Therapy	03	25	03	51	30%	39.06%	13.6%	37.2%
Triple Therapy	01	02	00	18	00	00	00	13.1%
Total	10	66	22	119	100%	100%	100%	100%
Mean	**3.66**	**22**	**7.333**	**45.66**				
Median	**3**	**25**	**3**	**51**				
Standard deviation	**3.055**	**18.681**	**10.214**	**25.423**				

Table No.16: Implies Reporting of ADR to Any Health Care Staff after Vaccination

	Frequency	**Percentage**
ADR Reported to The Health Care	112	38.48%
ADR Not Reported to The Health Care	227	61.52
Total	339	100%
Mean	**169.5**	
Median	**169.5**	
Standard deviation	**81.31728**	

Table No.17: Information About Effecting ADRAfter Vaccination in A Sample Population

Category	Frequency Of Population **Developed** ADR				Frequency Of Population **Didn'tDeveloped** ADR			
Drug	**Covaxine**		**Covishield**		**Covaxin**		**Covishield**	
	Male	Female	Male	Female	Male	Female	Male	Female
	26	36	131	136	03	02	27	11
Total	**62**		**267**		**05**		**38**	
Percentage	42%	58%	49%	51%	60%	40%	71%	29%

Table No.18: Classification of ADR

Type Of ADR	Covaxin	Covishield
Type A	**25**	**67**
Type B(Bizarre)	**12**	**42**
Type C(Continuing)	**15**	**38**
Type D(Delayed)	**10**	**22**

Table No 19: Distribution of Assessed Adverse Drug Reactions among Study Population

S.No	Various Assessed ADRs	Frequency Of Assessed ADR's		Percentage Of Assessed ADR's (%)		P value	Chi-square	Odds ratio
		Covaxin	Covishield	Covaxin	Covishield			
1.	Hypertension	23	75	34.3%	24.5%	0.1374(NS)	2.206	1.603 (0.9085 to 2.828)
2.	Fast Heart Beat	25	91	37.3%	29.8%	0.2934(NS)	1.104	1.400 (0.8055 to 2.433)
3.	Headache	20	86	29.8%	28.19%	0.9028(NS)	0.01492	1.084(0.6068 to 1.935)
4.	Nausea	18	84	26.8%	27.5%	0.9107(NS)	0.01259	0.9665(0.6068 to 1.935)
5.	Insomnia	10	52	14.9%	17.04%	0.8093(NS)	0.05825	0.8536(0.4091 to 1.781)
6.	Vomitings	15	76	22.3%	24.9%	0.2876(NS)	1.131	0.6574 (0.4627 to 1.633)
7.	Difficulty In Breathing	12	50	17.9%	16.4%	0.9039(NS)	0.01456	1.113(1.573 to 7.434)
8.	Skin Swelling	28	125	41.8%	40.98%	0.9032(NS)	0.01479	1.034(4.208 to 17.638)
9.	Fever	46	266	68.66%	87.21%	**0.0004(VSH)**	12.645	0.3212(0.1734 to 0.594)
10.	Weakness	45	267	67.16	87.54%	< **0.0001(VSH)**	15.388	0.2911(0.1577 to 0.537)
11.	Joint Pain	35	175	52.2%	57.3%	0.5274(NS)	0.3994	0.8125(0.4780 to 1.381)
12.	Muscle Ache	35	167	52.2%	54.75%	0.8113(NS)	0.05703	0.9038(0.5321 to 1.535)
13.	Leg Cramp	18	127	26.8%	41.6%	**0.0351(S)**	4.439	0.5149(0.2864 to 0.9254)
14.	Severe Pain On Site Of Injection	48	277	71.6%	90.8%	**0.0013 (VSH)**	10.307	0.346(0.1845 to 0.6510)
15.	Dizziness	23	132	34.32%	43.27%	0.2268(NS)	1.461	0.6851(0.3941 to 1.191)
16.	Fatigue	36	189	53.73%	61.9%	0.2667(NS)	1.233	0.7127(0.4182 to 1.215)
17.	Sweating	11	77	16.4%	25.24%	0.1673(NS)	1.907	0.5816(0.2899 to 1.167)
18	Swelling	25	152	37.3%	49.83%	0.0848(NS)	2.970	0.5992(0.3455 to 1.025)

.								
19	Dry Cough	20	87	29.8%	28.52%	0.9457(NS)	0.004638	1.066(0.5973 to 1.903)
20	Dysuria	12	59	17.9%	19.34%	0.8599(NS)	0.03116	1.065 (0.4580 to 1.807)
21	Electrolyte Imbalance	16	54	23.88%	17.70%	0.3180(NS)	0.9970	1.458 (0.7735 to 2.749)
22	Mouth Sore	04	39	5.97%	12.78%	0.1709(NS)	1.875	0.4330 (0.1492 to 1.257)
23	Itching	14	56	20.9%	18.3%	0.7580(NS)	0.09492	1.175 (0.6091 to 2.265)
24	Mood And Behavioral Changes	20	52	29.8%	17.04%	0.0257(NS)	4.977	2.070 (0.9458 to 3.081)
25	Dehydration	13	109	19.4%	35.73%	**0.0149(S)**	5.930	0.4329((0.2261 to 0.828)
26	Hypotension	27	156	40.3%	51.14%	0.1406(NS)	2.171	0.6447 (0.3767 to 1.104)
27	Chest Discomfort	17	76	25.3%	24.91%	0.9379(NS)	0.006068	1.024 (0.5575 to 1.883)
28	Hot Flashes	03	36	4.47%	11.80%	0.1206(NS)	2.409	0.3503 (0.1045 to 1.174)
29	Diarrhea	04	40	5.97%	13.11%	0.1525(NS)	2.047	0.4206 (0.1451 to 1.219)
30	Heart Burn	07	22	10.44%	7.21%	0.5205(NS)	0.4129	1.501(0.6131 to 3.674)

DISCUSSION:

In the present study, adverse drug reactions (ADRs) following COVID-19 vaccination were evaluated among 372 patients. Among these, 62 participants who received **Covaxin** and 267 participants who received **Covishield** experienced ADRs. This is consistent with previous studies by Sneegdha et al. (37%) and Sandhiya et al. (21%). However, it contrasts with observations by Julie Birdie Wahlang et al., Harmet S. Rehan et al., Anima Rout et al., and Medhi B. et al., where the reported incidence of ADRs was 9.82%, 8.63%, 8.48%, and 87.35%, respectively.

The majority of ADRs in our study were observed in the **age group 45–59 years** (33.77%), which aligns with findings from Harmet S. Rehan et al. (27.4%), Vikneswaran Gunaseelan et al. (24.5%), Sneegdha Poddar et al. (26%), and Sapankumar Behera et al. (49.8%). The higher prevalence of ADRs in this age group may be due to decreased metabolic and excretory functions, leading to accumulation of vaccine metabolites and products, thereby increasing susceptibility to ADRs.

In terms of gender distribution, **males experienced a higher incidence of ADRs** (Covaxin: 60.94%; Covishield: 71%). This is consistent with studies by Meena Kumari K et al. (55.9%), Vikneswaran Gunaseelan et al. (60.7%), Seewunet Admasu Belachew et al. (58.6%), and Sneegdha Poddar (52%). The higher occurrence in males may be attributed to sex-based differences in pharmacokinetics and pharmacodynamics of vaccines.

Regarding concomitant medications, ADRs were most commonly reported in participants receiving **antihypertensive therapy** (43.33%), followed by **proton pump inhibitors** (15.5%) and **hormonal therapies** (12.5%). This is consistent with the findings of Anima Rout et al. (breast cancer 29.8%) and Harmet S. Rehan et al. (39.1%). Conversely, Meena Kumari et al. reported a lower incidence (12.8%), while Anju Prasad et al. observed 25% of hypertensive patients experiencing ADRs, and Renuka L. Kadam et al. reported only 2.86%.

The **most common adverse reactions** in this study included:

- Severe pain at the injection site: 90.8%
- Weakness: 87.54%
- Fever: 87.21%
- Fatigue: 61.9%
- Joint pain: 57.3%
- Muscle ache: 54.75%

These findings are in partial agreement with Harmet S. Rehan et al., who reported body pains (9.21%) and fever (7.89%), and Anima Rout et al., who observed pain at the injection site (17.37%) and muscle ache (13.98%). Similarly, Meena

Kumari et al. reported fever in 21.6%, Anju Prasad et al. reported injection site pain in 28.84%, and Medhi B et al. reported fever in 63.16%. Most ADRs affected the **skin and musculoskeletal system** (25.87%), followed by the **gastrointestinal system** (23.24%), consistent with findings of Harmet S. Rehan et al. (musculoskeletal 43.7%).

Causality assessment using the WHO-UMC scale showed:

- Probable ADRs: 20.38%
- Possible ADRs: 37.54%
- Certain ADRs: 34.62%

These findings align with Meena Kumari et al. (possible ADRs 34.4%) and Anima Rout et al. (possible 31.62%, probable 68.38%). According to the **modified Hartwig and Siegel severity scale**, 49.25% of ADRs were **mild**, comparable to Julie Birdie Wahlang et al. (30%) and Harmet S. Rehan et al. (86.97%). In contrast, moderate ADRs were more frequent in studies by Anima Rout et al. (39.31%) and Vikneswaran Gunaseelan et al. (17.9%).

CONCLUSION:

OurStudy concludes that Passive adverse drug reaction monitoring of Covid-19 Vaccine by observational research studies among south Indian context by healthcare professionals like Pharmacists, Physicians and other health care professionals will be vital in Collection of data on common and rare potential risks of Covid-19 Vaccines.

As a Preliminary observational research study on pharmacovigilance of Covid-19 Vaccines our study results will be more crucial for Rapid detection, prioritization and assessment of emerging safety information of Covid-19 Vaccines. In the Current Situation of Covid-19 Pandemic, our research study results on ADRs of Covid-19 Vaccines are collated and analyzed in real-time regionally can strengthen vaccine safety nationally and globally.

More effective pharmacovigilance research studies both active and passive pharmacovigilance is vital for safe use of COVID-19 vaccines among Indian Population who are at high risk of covid-19 Infections during Covid-19 2nd wave and hence the Covid-19 pandemic can be combated efficiently by safe and effective Covid-19 Vaccination programmes. Huge population observational research studies by health care professionals like Pharmacists and Physicians on Covid-19 Vaccines are needed in developing counties like India to strengthen pharmacovigilance systems during the Covid-19 Pandemic.

Our study highlights the huge need of prompt evaluation of the impact of detected safety issues on the benefit-risk balance of the covid-19 vaccines during post marketing surveillance and Prompt, effective communication of Covid-19 safety information is much needed for effective Covid-19 vaccination and fight Covid-19 Pandemic.

REFERENCES:

1. E. Ammirati, M. Frigerio, E.D. Adler, C. Basso, D.H. Birnie, M. Brambatti, *et al.* Management of acute myocarditis and chronic inflammatory cardiomyopathy: an expert consensus document Fail, 13 (11) (2020), 10.1161/CIRCHEARTFAILURE.120.007405 Google Scholar
2. S. Abu Mouch, A. Roguin, E. Hellou, A. Ishai, U. Shoshan, L. Mahamid, *et al.* Myocarditis following COVID-19 mRNA vaccination Vaccine, 39 (29) (2021), pp. 3790-3793, 10.1016/j.vaccine.2021.05.087 ArticleDownloadPDFView Record in ScopusGoogle Scholar [3]S.A. Huber, B. Pfaeffle
3. Differential Th1 and Th2 cell responses in male and female BALB/c mice infected with Coxsackievirus group B type 3 J Virol, 68 (8) (1994), pp. 5126-5132 CrossRefView Record in ScopusGoogle Scholar
4. U. Sahin, K. Karikó, Ö. Türeci mRNA-based therapeutics - developing a new class of drugs Nat Rev Drug Discov, 13 (10) (2014), pp. 759-780, 10.1038/nrd4278 CrossRefView Record in ScopusGoogle Scholar
5. Astier, A. Barton Pai, M. Bissig, D.J.A. Crommelin, B. Flühmann, J.D. Hecq, *et al.* How to select a nanosimilar nn N Y Acad Sci, 1407 (1) (2017), pp. 50-62, 10.1111/nyas.13382 CrossRefView Record in ScopusGoogle Scholar
6. S. Tinari The EMA covid-19 data leak, and what it tells us about mRNA instability BMJ, 372 (2021), Article n627, 10.1136/bmj.n627 CrossRefView Record in ScopusGoogleScholarc
7. J Montgomery, M Ryan, R Engler, D Hoffman, B McClenathan, L Collins, *et al.* Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military JAMA Cardiol (2021), 10.1001/jamacardio.2021.2833 Google Scholar
8. J Nelson, EW Sorensen, S Mintri, AE Rabideau, W Zheng, G Besin, *et al.*Impact of mRNA chemistry and manufacturing process on innate immune activation Sci Adv, 6 (26) (2020),

p. eaaz6893, 10.1126/sciadv.aaz6893 CrossRefView Record in ScopusGoogle Scholar
9. S. Mitra, The implications of COVID-19 for rural India, IDR 25 (2020). March, https ://idronline.org/the-implications-of-covid-19-for-rural-india/. [
10. Statistics Division, Ministry of Health & Family Welfare, Bulletin on rural health statistics in India.