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Pharmacovigilance of Covid-19 Vaccination

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HUMAN

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ABSTRACT

Background: A COVID-19 vaccine is a vaccine intended to provide acquired immunity against severe acute respiratory syndrome coronavirus (SARS-CoV-2). The initial focus of SARS-CoV-2 vaccines was on preventing symptomatic, often severe illness2 .Currently many vaccines are under various phases of clinical trial and every country should ensure these newly developed vaccines are used within the framework of functioning, robust pharmacovigilance systems. Since these vaccines have undergone accelerated development and clinical trial3. Post marketing surveillance studies are mandatory. But as these vaccines are being used among large populations within a short time, detailed post-marketing studies may not be viable and hence safety largely depends on the country's existing pharmacovigilance system. **OBJECTIVES:** To assess safety in COVID-19 vaccine in CSI Holdsworth Memorial (Mission) Hospital Mysore, Karnataka. **METHODOLOGY:** This is an observational prospective study conducted over a period of 6 months from January 2021 to June 2021, in the CSI Holdsworth Memorial (Mission) Hospital Mysore, Karnataka. **RESULTS:** A total of 200 people monitored for Adverse Event after vaccination for COVISHIELD 170(85%) & COVAXIN 30(15%) and are followed for this study. A total of 814 non serious adverse events were reported within 24 hours of first dose of Covishield and Covaxin and a total of 252 non serious adverse events were reported within 24 hours of second dose of Covishield and Covaxin. No AEFI reported after 30 days of both the doses. We found no association of AEFI with vaccine type p. **CONCLUSION:** The short term adverse events for both the vaccines were observed in first 24 hours predominantly. And the adverse events decreased in subsequent weeks and one or two showed till a month of both the doses of vaccines. Symptoms were mild in severity and short lived. No serious adverse events attributable to vaccines were reported. Our study showed that the vaccines were safe and well-tolerated with a lower reactogenicity profile.

INTRODUCTION:

The new human viral pathogen, severe acute respiratory syndrome coronavirus-2 (SARS CoV-2), the cause of the coronavirus disease 2019 (COVID-19) pandemic, emerged in Wuhan, China in late 2019. The global COVID-19 pandemic continues to expand in many countries, including the India. A protective vaccine will be required to achieve sufficient herd immunity to SARS CoV-2 infection to ultimately control the COVID-19 pandemic[1].

A COVID-19 vaccine is a vaccine intended to provide acquired immunity against severe acute respiratory syndrome coronavirus (SARS-CoV-2). The initial focus of SARS-CoV-2 vaccines was on preventing symptomatic, often severe illness 2. Currently many vaccines are under various phases of clinical trial and every country should ensure these newly developed vaccines are used within the framework of functioning, robust pharmacovigilance systems. Since these vaccines have undergone accelerated development and clinical trial 3. Post marketing surveillance studies are mandatory. But as these vaccines are being used among large populations within a short time, detailed post-marketing studies may not be viable and hence safety largely depends on the country's existing pharmacovigilance system[4].

Pharmacovigilance is important for collecting, detecting, monitoring, adverse events which is the main objective. The adverse events reported should be assessed in order to know the casual relationship and avoid unnecessary effects on the recipient. Many people are vaccinating in a short period, so it is becoming much burden to the pharmacovigilance centres. Vaccine pharmacovigilance plays an important role when once vaccine is released into the market. The main objective of vaccine pharmacovigilance is the detection and monitoring of adverse events associated with vaccination. As a large number of people are vaccinating against COVID-19, it is very difficult for the pharmacovigilance centres to assess suspected adverse events in a short period of time. The understandings between patients, caregivers, private portioners, government doctors, field-level health care workers, personnel involved in the AEFI program, and pharmacovigilance program is more important than ever. INTRODUCTION PHARMACOVIGILANCE OF COVID-19 VACCINATION Page 2 The information about adverse reactions is imperative and should be reported immediately so that action can be taken, thus safeguard the vaccine recipients and avoid unnecessary reactions[5].

India began administration of COVID-19 vaccines on 16th January 2021. As of 28th August 2021, 5.24 billion doses of COVID-19 vaccine have been administered worldwide based on official reports from national public health agencies. India initially approved the Oxford–

AstraZeneca vaccine (manufactured under license by Serum Institute of India under the trade name Covishield) and Covaxin (a vaccine developed locally by Bharat Biotech). They have since been joined by the Sputnik V (manufactured under license by Dr. Reddy's Laboratories, with additional production from Serum Institute of India being started in September), Moderna vaccines, Johnson & Johnson vaccine and ZyCoV-D (a vaccine locally developed by Zydus Cadila) and other vaccine candidates undergoing local clinical trial[6].

Like many other vaccinations, COVID-19 vaccines also have a risk of causing side-effects. According to India's Union Ministry of Health and Family Welfare, the most common side effects include pain or swelling at the injection site, fever, irritability and headaches[7].

The UK Government also lists fatigue, nausea and joint pain as common side-effects of the Oxford vaccine (known as Covishield in India)[8].

Medical experts maintain that vaccines used are safe and their benefits outweigh the risks. It is also important to note that adverse cases do not necessarily have a causal relationship with the vaccines[9].

By 7th June, 26,000 adverse events had been reported following immunisation. Of this, 24,901 were minor, 412 were significant and 887 were serious. 488 deaths were also reported, including 301 men and 178 women (details of 9 deaths were not available). Both vaccines had an adverse reaction rate of about 0.01% and a fatality rate around 0.0001% - 24,703 events and 457 deaths from 210 million Covishield doses, and 1,497 events and 20 following 25 million Covaxin doses. Maharashtra reported the most adverse events (4,521), followed by Kerala (4,074), Karnataka (2,650) and West Bengal (1,456)[10].

On 15 June, the government published a review of case reports that had occurred between 5 February and 31 March 2021, focusing on 31 cases and one death from anaphylaxis that were believed to have been attributed to the vaccine, out of nearly 60 million doses administered in the time period. Only three of these cases, and the single death of a 68-year-old patient, were determined to be "vaccine-product related", with the remainder having been classified as coincidental, indeterminate, or unclassifiable[11].

The report stated that "mere reporting of deaths and hospitalisations as serious adverse events does not automatically imply that the events were caused due to vaccines[12].

Only properly conducted investigations and causality assessments can help in understanding if any causal relationship exists between the event and the vaccine[13].

Karnataka Health Minister K. Sudhakar announced on 9 January that the state would be given 13.9 lakh (1.39 million) doses of Covishield in two batches[14].

6.3 lakh (630,000) health workers had registered for the vaccine[15].

Two people were admitted to hospital following complications, one person was later discharged[16].

On 31 July, Karnataka became the first state in South India to cross the 3 crore doses mark and in Bangalore, around 85% of the eligible population has been vaccinated with at least one shot, making the city the second highest after New Delhi[17].

GUIDE TO DATA READING:

This document describes the reports of reactions that have been observed after administration of the vaccine. This does not mean that such reactions were caused by the vaccine. They could be a symptom of another disease or they could be associated with another product taken by the person who was vaccinated. Investigating significance and causes of these reactions is the task of pharmacovigilance. As an aid to orientation in this investigation and analysis process, it is necessary to know that, an adverse event is any unfavourable episode that occurs after the administration of a medicine or vaccine, but which is not necessarily caused by taking the medicine or having received the vaccine. An adverse reaction, on the other hand, is a noxious and unintended response to a medicine or vaccine for which it is possible to establish a causal relationship with the medicine or the vaccine itself. In order to distinguish, therefore, whether we are facing an adverse event or an adverse reaction, we have to evaluate whether it is possible to trace a cause related to the medicinal product. It is not enough that the event occurred shortly after vaccination or taking the medicine. An undesirable effect is an unintended effect related to the properties of the medicine or vaccine, which is not necessarily harmful and has been observed in a number of people. This is therefore a known possible effect that has occurred over time and is considered acceptable. Investigating every event that appears after a vaccination, serves to gather as much information as possible and increase the possibility of identifying truly suspicious events whose nature is important to understand, or which have never been observed before, with the aim of ascertaining whether there is a causal link with the vaccination 18.

Objective (s):

Primary objectives:

To assess the adverse events of Covid-19 vaccination.

Secondary objectives:

¬ To identify and document the adverse events caused by Covid-19 vaccination.

¬ To perform systematic causality assessment of Adverse Event Following Immunization.

Methodology:

Source of data: ¬ Vaccination Centre: • Covid-19 vaccine centres register book: Collected vaccine recipients demographic and personal contact data such as name, age and contact number with the help of nursing-in-charge who was present at the vaccination centres. • Collected information about the vaccine type, batch no, manufacturing date, expiry date of vaccines by nursing-in-charge who was present at the vaccination centres. • Personal interview with the vaccine recipients and collected the information about their age, gender, co-morbidities, past and present medication history, vaccine type and allergy, if any. • Personal interview with the care taker of vaccine recipients of those who are not able to provide information by themselves. • Other documentations such as vaccine recipients prescriptions, case reports, if available. • Personal telephonic contact with the vaccinated recipients for further follow-up during study period. • Personal interview with the doctors, nurses and health care workers regarding adverse events observed.

Study site:

This study was conducted at various vaccination centres namely CSI Holdsworth Memorial (Mission) Hospital, Asha Kiran Hospital, Krishna Rajendra Hospital Mysore, Karnataka.

Study Period:

This study was conducted for a period of 6 months from January 2021 to June 2021.

Study design:

This is a prospective, observational and interventional study.

Study Approval: This study was approved by the Institutional Ethics Committee of Farooqia College of Pharmacy, Mysore.

Study material:

Adverse Events Documentation and Evaluation Form (APPENDIX-II) ¬ Questionnaire.

Study procedure:

Investigators visited vaccination centres on daily basis from morning 10 A.M. to evening 4 P.M. and collected all the relevant information mentioned in the source of the study.

¬ The vaccinated personals were followed-up from the time of administration of 1st dose vaccine till 4 months including 2nd dose of vaccine.

¬ All the vaccinated personals were advised to notify all the adverse events through telephone or to note it down in a record book.

. ¬ The first inquiry for the AEFI was done after 24 hours of vaccination for first dose as well as second doses of both the vaccine Subsequently, the weekly enquiry was made regarding the development of AEFI on days 8, 15, 28, we gathered all the and entered in our data collection form, we nearly collected 200 data of vaccinated personals.

¬ All the recipients were enquired telephonically after 24 hours, within one week and after one week to one month after vaccination.

¬ The reply of vaccinated recipients collected and assessed for the causality. Study Analysis: Statistical analyses were carried out with the help of statistician and data were analysed using SPSS 23.0 software. Categorical data related to adverse events (symptoms) of vaccine variables are presented as proportions. The associations between independent variables and primary outcomes were tested using p value test or Chi-square test as appropriate variables that are associated.

Data Collection:

All the relevant and necessary data of the patient were collected from Patients case sheet, Patient prescription, Medication/ Treatment Chart and dose division request form. A suitable data collection form was designed to store data for computation.

RESULTS:

A total of 200 people observed for Adverse event after vaccination for COVISHIELD 170(85%) & COVAXIN 30(15%) and are followed for this study and their details for the same are described below.

Gender Distribution:

The gender wise distribution of the people who have been vaccinated for both the COVISHIELD & COVAXIN is elaborated in (Table 1 & Figure 1).

Table 1

Gender	No. of people	Percentage %
Male	109	54.50%
Female	91	45.50%

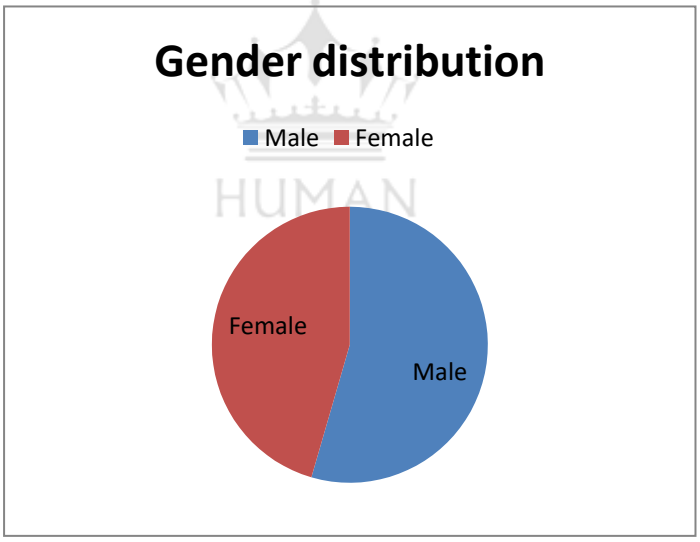

Figure 1

Comparison of gender according to vaccine type are described in given Table 2 & Figure 2 where COVISHIELD males 89(52.35%) and females 81(47.64%) followed by COVAXIN males20(66.66%) and females 10(33.33%).

Table No. 2: Comparison of Gender distribution among vaccinated recipients according tovaccine type

GENDER (n=200)	COVISHIELD	COVAXIN
MALE	89(52.35%)	20(66.66%)
FEMALE	81(47.64%)	10(33.33%)

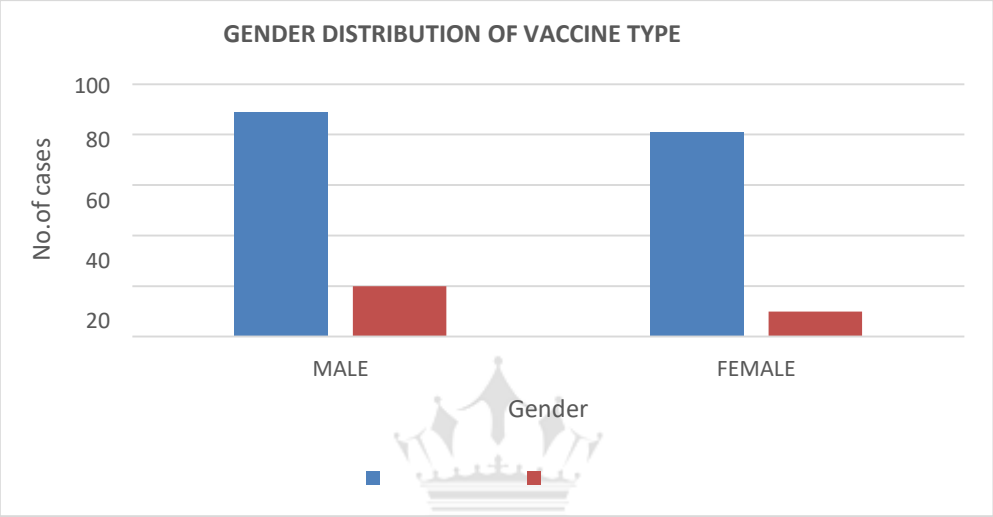

Figure No. 2: Comparison of Gender distribution among vaccinated recipients according tovaccine type

AGE DISTRIBUTION

Among 200 vaccinated recipients 30(33.70%) male and36(44.44%) female were of 18-30 years of age, 25(28.08%) male and 19(23.45%) female were of 31-40 years of age, 15(16.85%) male and 17(20.98%) female were of 41-50 years of age, 12(13.48%) male and 06(07.40%) female were of 51-60 years of age, 07(07.86%) male and 03(03.70%) female were of above 60 years of age. (Table 3 & Table 4)

Table No. 3: Age distribution details of vaccinated recipients for Covishield

Age Groups (years)	Male (n=89)	Percentage %	Female (n=81)	Percentage %
18-30	**30**	**33.70%**	**36**	**44.44%**
31-40	25	28.08%	19	23.45%
41-50	15	16.85%	17	20.98%
51-60	12	13.48%	06	7.40%
≥ 60	07	07.86%	03	3.70%

Table No. 4: Age distribution details of vaccinated recipients for Covaxin

Age Groups (years)	Male(n=20)	Percentage %	Female (n=10)	Percentage %
18-30	**08**	40%	03	30%
31-40	05	25%	03	30%
41-50	02	10%	02	20%
51-60	03	15%	02	20%
≥ 60	02	10%	01	10%

Co-morbidities details According to Vaccinated Recipients:

Our survey reveals that Hypertension (HTN) 40(20.00%) is a major disease in the people, followed by 23(11.50%) Diabetes Mellitus, 4(02.00%) Ischemic Heart Disease (IHD), 7(03.50%) Chronic Obstructive Pulmonary Disease (COPD), 2(01.00%) Tuberculosis (TB), 10(05.00%) Asthma, 5(02.50%) Hypothyroidism, 7(03.50%) Hyperthyroidism, 2(01.00%) Stroke (Figure 3).

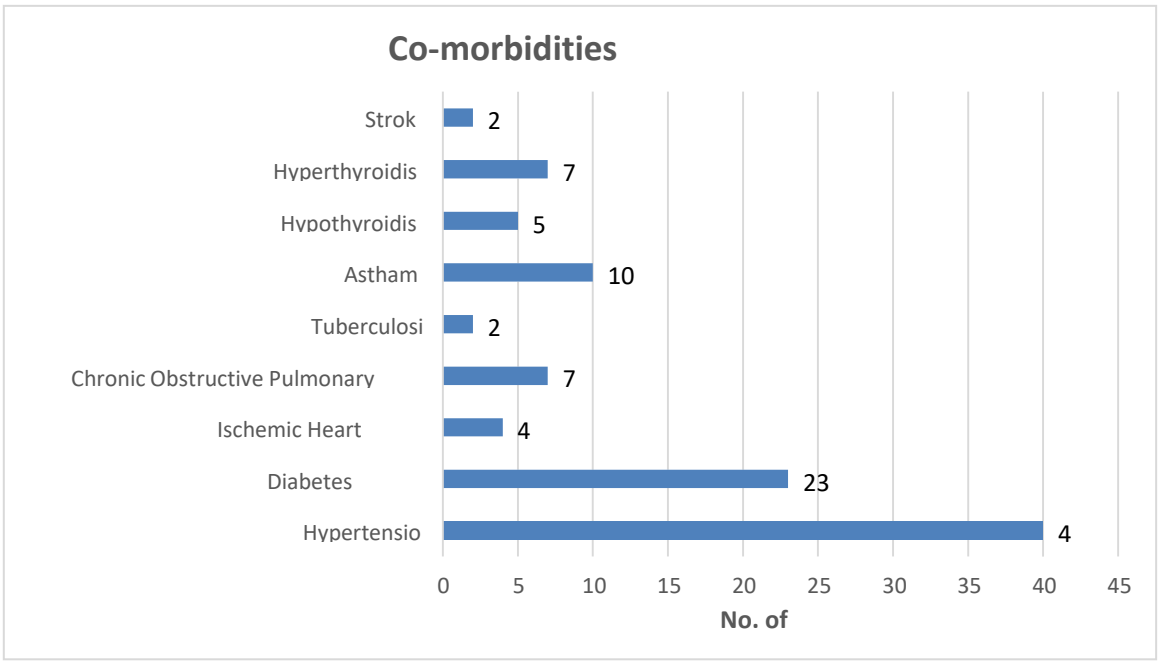

Figure No. 3: Details of Co-morbidities in vaccine recipient

DETAILS OF SOCIAL HISTORY AMONG VACCINATED RECIPENTS:

Among 200 Vaccinated personals majority of the people were Non-smokers 161(80.50%) and Non-Alcoholic 158 (79.00%) followed by 42(21.00%) people are Alcoholic and 39(19.50%) are Smokers (Table 5 & Figure 4).

Table No. 5: Details of Social history among vaccinated recipients

Social History	No. of cases(n=200)	Percentage %
Smoker	39	19.50%
Non-smoker	**161**	**80.50%**
Alcoholic	42	21.00%
Non-Alcoholic	**158**	**79.00%**

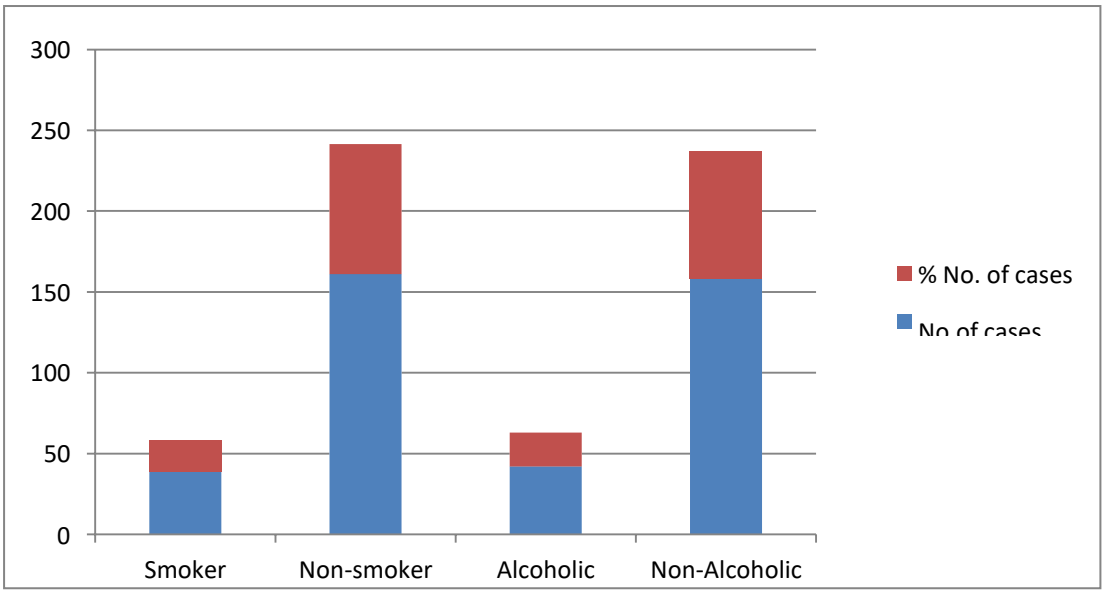

Fig No. 4: Details of Social history among vaccinated recipients

ALLERGIC DISTRIBUTION:

The Vaccinated recipients were grouped into different categories on Allergic history. Only 02(1.00%) were having history of Allergies followed by198(99.00%) were not prone to any Allergic history. (Table 6 & Figure 5)

Table No. 6: Allergic History of Vaccinated Personals

Allergic	No. of cases	Percentage %
Yes	02	1.00%
No	**198**	**99.00%**

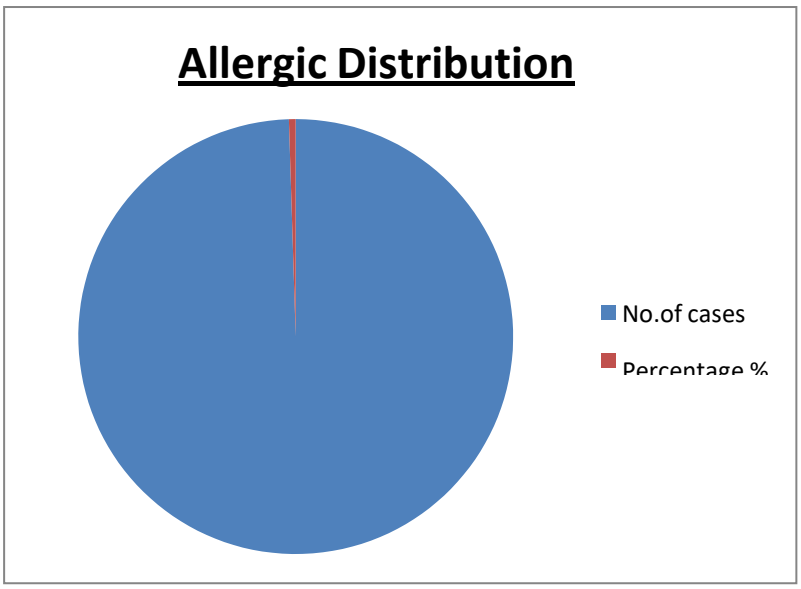

Figure No. 5 Allergic History of Vaccinated Personals

DETAILS OF ADVERSE EVENTS ACCORDING TO VACCINE TYPE:

Adverse events observed within 30 minutes of administration for both the COVISHIELD and COVAXIN after first and second doses along with their z value and p value are documented in the table 6, table 7,table 8 & table 9.

Table No. 7: Details of Adverse Events noticed within 30minutes of administration for theFirst dose of Covishield vaccine

Local and systemic reactions	Male (n=89)	%	Female (n=81)	%	Total (n=170)	%
Pain at the injection site	82	92.13	74	91.35	156	91.76
Redness	18	20.22	8	9.87	26	15.29
Swelling	8	8.98	9	11.11	17	10
Headache	12	13.48	17	20.98	29	17.05
Muscle pain	11	12.35	13	16.04	24	14.11
Dizziness	26	29.21	41	50.61	67	39.41
Fatigue	7	7.86	16	19.75	23	13.52
Nausea	10	11.23	6	7.4	16	9.41
Vomiting	0	0	1	1.23	1	0.58

Table No. 8: Details of Adverse Events noticed within 30minutes of administration for theSecond dose of Covishield vaccine

Local and systemic reactions	Male (n= 50)	%	Female (n=35)	%	Total (n=85)	%
Pain at the injection site	28	56	22	62.85	50	58.82
Redness	0	0	0		0	
Swelling	0	0	1	2.85	1	1.17
Headache	0	0	0	0	0	0
Muscle pain	0	0	0	0	0	0
Dizziness	0	0	0	0	0	0
Fatigue	0	0	0	0	0	0
Nausea	0	0	0	0	0	0
Vomiting	0	0	0	0	0	0

Table No. 9: Details of Adverse Events noticed within 30minutes of administration for theFirst dose of Covaxin vaccine

Local and systemic reactions	Male (n= 20)	%	Female (n=10)	%	Total (n=30)	%
Pain at the injection site	17	85	8	80	25	83.33
Redness	4	20	2	20	6	20.01
Swelling	3	15	1	10	4	13.33
Headache	1	5	2	20	3	10.01
Muscle pain	0	0	1	10	1	3.33
Dizziness	4	20	1	10	5	16.66
Fatigue	1	5	0	0	1	3.33
Nausea	1	5	1	10	2	6.66
Vomiting	0	0	0	0	0	0

Table No. 10: Details of Adverse Events noticed within 30minutes of administration for theSecond dose of Covaxin vaccine

Local and systemic reactions	Male (n= 20)	%	Female (n=10)	%	Total(n=30)	%
Pain at the injection site	11	55	6	60	17	56
Redness	0	0	0	0	0	0
Swelling	0	0	0	0	0	0
Headache	0	0	0	0	0	0
Muscle pain	0	0	0	0	0	0
Dizziness	0	0	0	0	0	0
Fatigue	0	0	0	0	0	0
Nausea	0	0	0	0	0	0
Vomiting	0	0	0	0	0	0

Details of adverse events noticed at different intervals of time:

Adverse events observed at different time intervals after vaccination for both the COVISHIELD and COVAXIN after first and second doses are documented in the table 10, 11, 12 & 13.

A total of 730 non-serious adverse events were reported within 24 hours of first dose of covishield vaccination Common adverse events included injection site pain (n=157, 92.35%), fever (n=111, 65.29%), myalgia (n=42, 24.70%), headache (n=56, 32.94%), weakness (n=52, 30.58%).111 non serious adverse events reported between 3 and 7 days. 36 non-serious adverse events were reported between 8-30 days.

Table No. 11: Details of Adverse Events noticed at different intervals of time after vaccination for the First dose of Covishield vaccine

Adverse effects	First 24 h		2-7 days		8-30 days	
(N= 170)	(Day-2)		(Day-8)		(Day-31)	
	No. of cases	%	No. of cases	%	No. of cases	%
Pain at the injection site	157	92.35	22	12.94	3	1.76
Fever	111	65.29	0	0	0	0
Fatigue	15	8.82	0	0	0	0
Giddiness	31	18.23	2	1.17	0	0
Myalgia	42	24.7	22	12.94	8	4.7
Arthralgia	27	15.88	9	5.29	5	2.94
Abdominal Pain	11	6.47	1	0.58	0	0
Nausea	20	11.76	1	0.58	0	0
Vomiting	13	7.64	0	0	0	0
Diarrhoea	13	7.64	0	0	0	0
Headache	56	32.94	17	0	4	0
Rashes	8	4.7	1	0.58	0	0
Chest Pain	16	9.41	5	2.94	0	0
Serious symptoms						
Weakness	52	30.58	28	16.47	16	9.41
Altered sensorium	11	6.47	3	1.76	0	0

A total of 203 non serious adverse events were reported within 24 hours of second dose of covishield vaccination Common adverse events included injection site pain (n=80, 94.11%), fever (n=46, 54.11%), giddiness (n=13, 15.29%), myalgia (n=8, 9.41%), weakness (n=13, 15.29%). 17 non serious adverse events reported between 3 and 7 days. 4 non-serious adverse events were reported between 8-30 days.

Table No. 12: Details of Adverse Events noticed at different intervals of time after vaccination for the Second dose of Covishield vaccine

Adverse effects (N= 85)	First 24 h (Day-2)		2-7 days (Day-8)		8-30 days (Day-31)	
	No. of cases	%	No. of cases	%	No. of cases	%
Pain at the injection site	80	94.11	3	1.76	2	2.35
Fever	46	54.11	0	0	0	0
Fatigue	5	5.88	0	0	0	0
Giddiness	13	15.29	0	0	0	0
Myalgia	8	9.41	3	1.76	0	0
Arthralgia	7	8.23	4	4.7	1	1.17
Abdominal Pain	0	0	0	0	0	0
Nausea	3	3.52	0	0	0	0
Vomiting	2	2.35	0	0	0	0
Diarrhoea	1	1.17	0	0	0	0
Headache	3	3.52	0	0	0	0
Rashes	0	0	0	0	0	0
Chest Pain	0	0	0	0	0	
Serious symptoms						0
Weakness	13	15.29	7	8.23	1	1.17
Altered sensorium	1	0	0	0	0	0

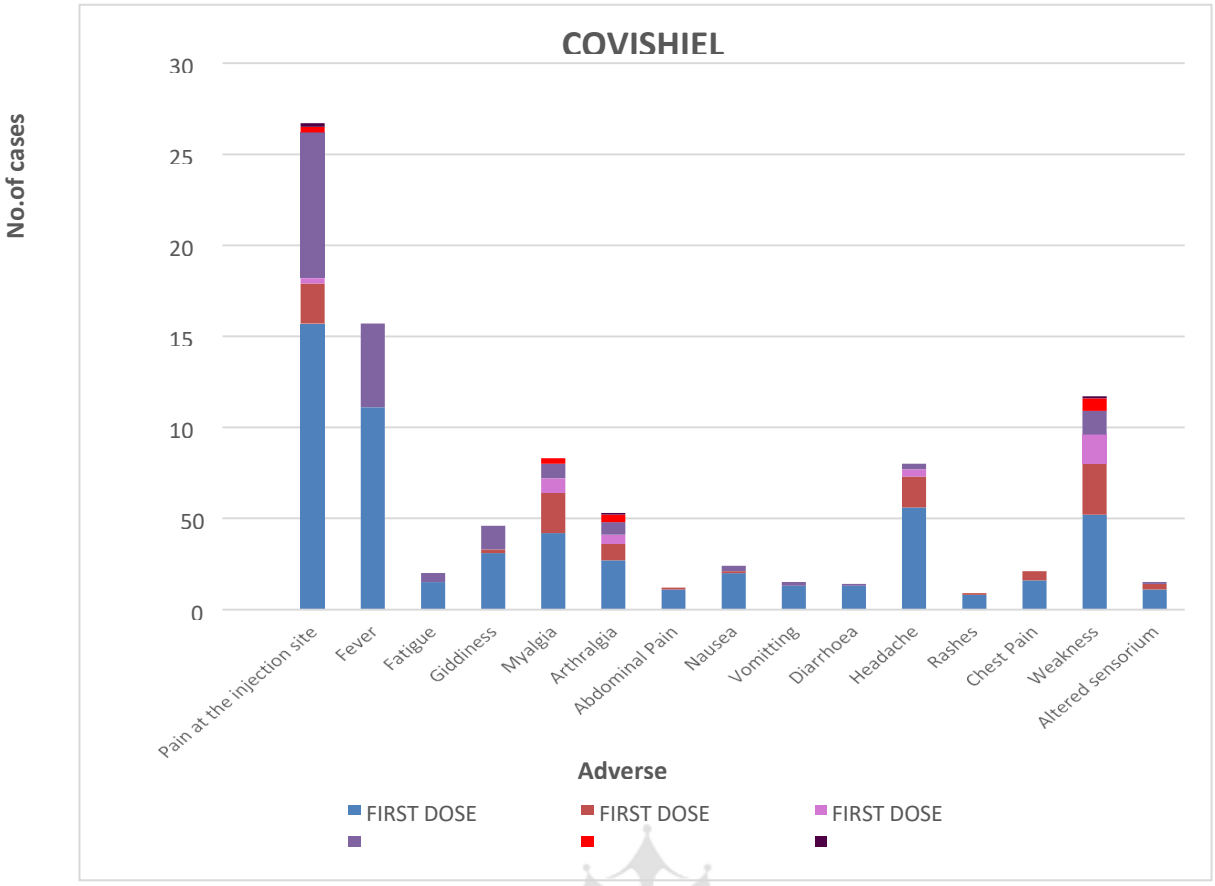

Figure No. 6: Details of Adverse Events noticed at different intervals of time after vaccination for Covishield vaccine

A total of 84 non serious adverse events were reported within 24 hours of first dose of covaxin vaccination Common adverse events included injection site pain (n=27, 90.00%), fever (n=15, 50.00%), giddiness (n=6, 20.00%), myalgia (n=4, 13.33%), weakness (n=7, 23.33%). 10 non serious adverse events reported between 3 and 7 days. No adverse events reported in 8-30 days.

Table No. 13: Details of adverse events noticed at different intervals of time after vaccination for the First dose of Covaxin vaccine

Adverse effects (N= 30)	First 24 h(Day-2)		2-7 days(Day-8)		8-30 days(Day-31)	
	No. of cases	%	No. of cases	%	No. of cases	%
Pain at the injection site	27	90	4	13.33	0	0
Fever	15	50	1	3.33	0	0
Fatigue	3	10	0	0	0	0
Giddiness	6	20	0	0	0	0
Myalgia	4	13.33	2	6.66	0	0
Arthralgia	3	10	1	3.33	0	0
Abdominal Pain	0	0	0	0	0	0
Nausea	1	3.33	0	0	0	0
Vomiting	1	3.33	0	0	0	0
Diarrhoea	1	3.33	0	0	0	0
Headache	6	20	0	0	0	0
Rashes	0	0	0	0	0	0
Chest Pain	0	0	0	0	0	0
Serious symptoms	0	0	0	0	0	0
Weakness	7	23	2	6.66	0	0
Altered sensorium	0	0	0	0	0	0

A total of 49 non serious adverse events were reported within 24 hours of second dose of covaxin vaccination Common adverse events included injection site pain (n=24, 80.00%), fever (n=9, 30.00%), weakness (n=8, 26.66%). 6 non serious adverse events reported between 3 and 7 days. 1 adverse events reported in 8-30 days.

Table No. 14: Details of Adverse Events noticed at different intervals of time after vaccination for the Second dose of Covaxin vaccine

Adverse effects (N= 30)	First 24 h(Day-2)		2-7 days(Day-8)		8-30 days(Day-31)	
	No. of cases	%	No. of cases	%	No. of cases	%
Pain at the injection site	24	80	0	0	0	0
Fever	9	30	0	0	0	0
Fatigue	0	0	0	0	0	0
Giddiness	1	3.33	0	0	0	0
Myalgia	0	0	0	0	0	0
Arthralgia	0	0	0	0	0	0
Abdominal Pain	0	0	0	0	0	0
Nausea	0	0	0	0	0	0
Vomiting	0	0	0	0	0	0
Diarrhoea	0	0	0	0	0	0
Headache	0	0	0	0	0	0
Rashes	0	0	0	0	0	0
Chest Pain	0	0	0	0	0	0
Serious symptoms	0	0	0	0	0	0
Weakness	8	26.66	6	20	1	3.33
Altered sensorium	0	0	0	0	0	0

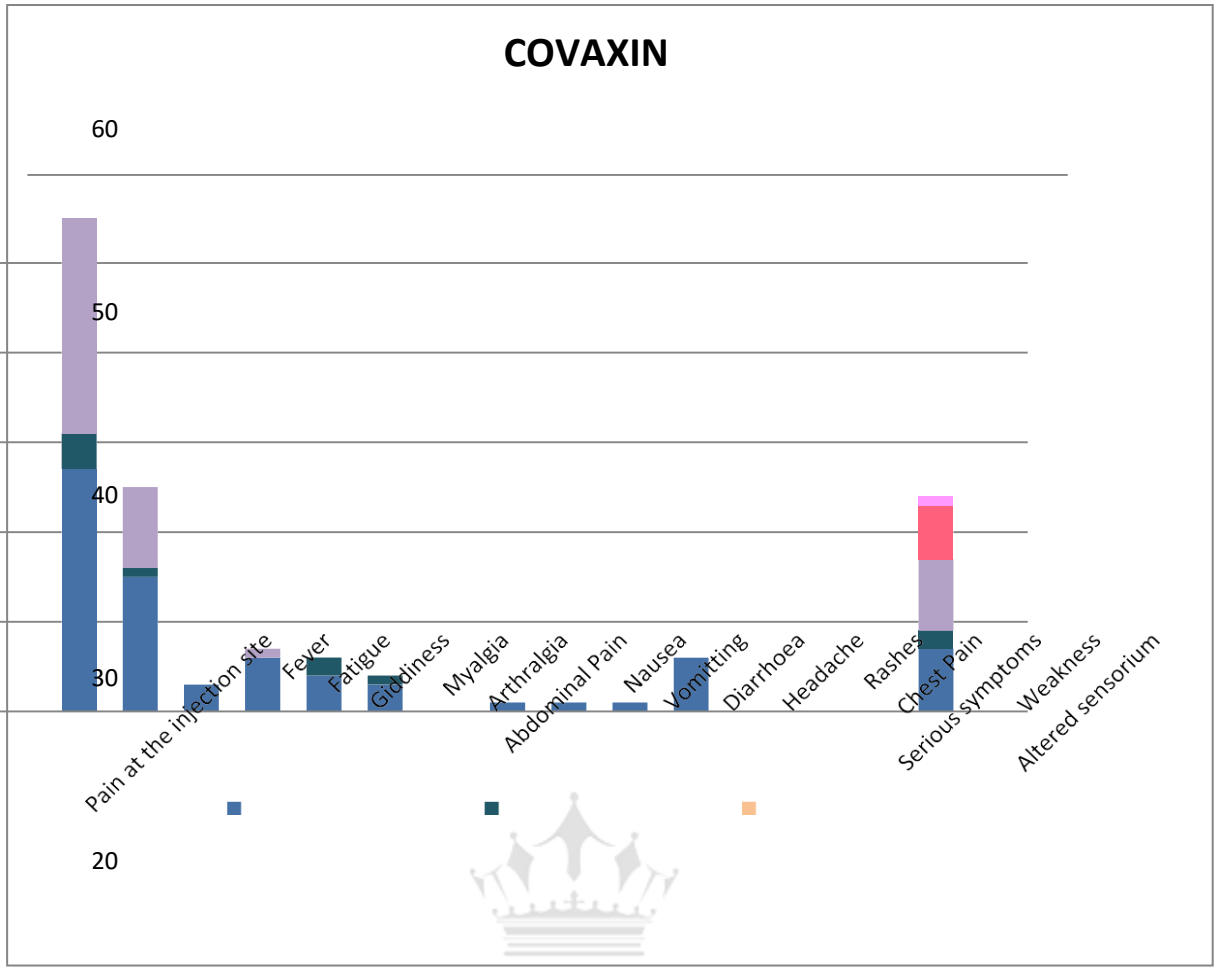

Figure No. 7: Details of Adverse Events noticed at different intervals of time after vaccination for Covaxin vaccine

Comparison of Adverse Events observed between COVISHIELD AND COVAXIN by

Statistical analysis:

We randomly selected 30 vaccinated recipients those who have been taken first dose of COVISHIELD AND COVAXIN (vaccines) and compared adverse events between them and the same is elaborated in the Table.14. We found significant difference ($p<0.05$) between Covishield and Covaxin for the following adverse events; myalgia ($p<0.01684$), vomiting ($p<0.0394$), diarrhoea ($p<0.02144$), headache ($p<0.00072$), weakness ($p< 0.0001$).

Table No. 15: Comparison of Adverse Events observed between First doses of COVISHIELD & COVAXIN by Statistical analysis

Adverse effects (N= 30)	COVISHIELD First dose		COVAXIN First dose			
	No. of cases	%	No. of cases	%	z value	p value
Pain at the injection site	29	96.66	27	90	0.9108	0.36282
Fever	14	46.66	15	50	-0.3101	0.75656
Fatigue	6	20	3	10	1.0847	0.28014
Giddiness	4	13.33	6	20	-0.7304	0.4654
Myalgia	11	10	3	13.33	**2.3928**	**0.01684**
Arthralgia	6	20	3	10	1.0847	0.28014
Abdominal Pain	3	10	0	0	1.777	0.07508
Nausea	1	3.33	0	0	0.9559	0.33706
Vomiting	6	13.33	1	0	**2.0638**	**0.0394**
Diarrhea	7	16.66	1	0	**2.3633**	**0.02144**
Headache	19	63.33	6	20	**3.38**	**0.00072**
Rashes	1	0	0	0	0.9559	0.33706
Chest Pain	1	0	0	0	0.9559	0.33706
Serious symptoms						
Weakness	22	73.33	7	23.33	**3.8761**	**0.0001**
Altered sensorium	1	3.33	0	0	0.9559	0.33706

We randomly selected 30 vaccinated recipients those who have been taken second dose of COVISHIELD AND COVAXIN (vaccines) and compared adverse events between them and the same is elaborated in the Table.14. We found significant difference ($p<0.05$) between covishield and covaxin for the following adverse events; fever ($p<0.04236$), headache ($p<0.00252$).

Table No. 16: Comparison of Adverse Events observed between and Second dose of COVISHIELD & COVAXIN by Statistical analysis

Adverse effects (N= 30)	COVISHIELD Second dose		COVAXIN Second dose			
	No. of cases	%	No. of cases	%	z value	p value
Pain at the injection site	22	73.33	24	80	-0.6394	0.52218
Fever	17	56.66	9	30	**2.034**	**0.04236**
Fatigue	3	10	0	0	1.777	0.07508
Giddiness	2	6.66	1	3.33	0.5605	0.57548
Myalgia	6	20	3	0	1.0847	0.28014
Arthralgia	2	6.66	0	0	1.3622	0.17384
Abdominal Pain	1	3.33	0	0	0.9559	0.33706
Nausea	1	3.33	0	0	0.9559	0.33706
Vomiting	1	3.33	0	0	0.9559	0.33706
Diarrhea	1	3.33	0	0	0.9559	0.33706
Headache	10	30	1	0	**3.0243**	**0.00252**
Rashes	0	0	0	0	0	0
Chest Pain	0	0	0	0	0	0
Serious symptoms						
Weakness	5	20	8	26.66	-0.9509	0.34212
Altered sensorium	0	0	0	0	0	0

The chi-square test of independence was performed to examine the relationship between the adverse events observed between Covishield and Covaxin and the chi-square statistic is 0.8052. The p-value is 0.937747. The result is not significant at $p < 0.05$.

Table No. 17: Comparison of relationship between the significant Adverse Events observedbetween the Covishield and Covaxin by statistical analysis

Adverse effects(N= 30)	COVISHIELD		COVAXIN		p value	Chi-square
	No. of cases	%	No. ofcases	%		
Myalgia	11	10	3	13.33	0.937747	0.8052
Vomiting	6	13.33	1	0		
Diarrhea	7	16.66	1	0		
Headache	19	63.33	6	20		
Weakness	22	73.33	7	23.33		

CONCLUSION:

The major reason for conducting vaccine effectiveness assessments is to make sure a vaccine protects people from getting a disease under real-world conditions, outside of the strict setting of clinical trials. There are many factors that can affect a vaccine's effectiveness in real-world situations. Vaccine effectiveness can be affected by differences in the underlying medical conditions of people vaccinated in the real-world compared to those in the clinical trials. Vaccine effectiveness assessments can also provide important information about how well a vaccine is working in groups of people not included or not well represented in clinical trials. Our study shows that Covishield vaccine is taken by most of the people and Covaxin is the least and according to gender males (54.50%) are majority in number than compared to females (45.50%) and followed by age group 18-30 (33.70%) years are majority in number than compared to ≥ 60 years of age. The short term adverse events for both the vaccines were observed in first 24 hours predominantly. And the adverse events decreased in subsequent weeks and one or two showed till a month of both the doses of vaccines. Symptoms were mild in severity and short lived. No serious adverse events attributable to vaccines were reported. Our study showed that the vaccines were safe and well-tolerated with a lower reactogenicity profile.

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REFERENCES:

1. Mort M, Baleta A, Destefano F et al. World Health Organization. Vaccine safety basics learning manual. World Health Organization 2013; 1-207.
2. Corona Virus (Covid-19) Vaccinations – Statistics and Research https://ourworldindata.org/covid-vaccinations. Accessed on 7th February 2021; 1-25.
3. Nisha Jha, Subish Palaian, Pathiyil R Shankar et al. Pharmacovigilance of COVID-19 vaccines in the context of Nepal an assessment based on early adverse drug reaction reports. Journal of Pharmaceutical Health Services Research 2021; 20: 1-3.
4. Ali Elbeddini, Aniko Yeats, Stephanie Lee et al. Amid COVID-19: the importance of developing an positive adverse drug reaction (ADR) and medical device incident (MDI) reporting culture for Global Health and public safety. Journal of Pharmaceutical Policy and Practice 2020; 13(18): 1-4.

5. Deep Kamal, Vaidehi Thakur, Navneet Nath et al. Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study. Elsevier 2021; 77: 283-288.
6. Rimple Jeet Kaur, Siddhartha Dutta, Pankaj Bhardwaj et al. Adverse Events Reported From COVID-19 Vaccine Trials: A Systematic Review. Springer 2021; 1-13.
7. Anonymous 26000 Adverse Events, 488 Deaths Reported in India During Covid Vaccination Drive: Data. News 18 2021.
8. Bengaluru fares well with 85% of population getting at least one dose of vaccine. The News Minute 2021.
9. Government review of side effects confirms 1 death after vaccine dose. Hindustan Times 2021.
10. Barton F Haynes, Lawrence Corey, Prabhavathi Fernandes et al. Prospects for a safe COVID-19 vaccine. Sciences Translation Medicines 2020; 1-12. REFERENCES PHARMACOVIGILANCE OF COVID-19 VACCINATION Page 43
11. Helen Petousis Harris. Assessing the Safety of COVID-19 Vaccines: A Primer. Springer Nature Switzerland AG 2020; 43: 1205-1210.
12. Michel Kabamba Nzaji, Leon Kabamba N gombe, Guillaume Ngoie Mwamba et al. Acceptability of Vaccination Against COVID-19 Among Healthcare Workers in the Democratic Republic of the Congo. Pragmatic and Observational Research 2021; 11: 103- 109.
13. Peter Arlett. Safety monitoring of COVID-19 vaccines. European Medicines Agency Science Medicines Health 2021; 1-10.
14. Marwan ElBagoury, Mahmoud M Tolba, Hebatallah A Nasser et al. The find of COVID19 vaccine, Challenges and opportunities. Journal of Infection and Public Health 2020; 389-416.
15. Fernando P Polack, Stephen J Thomas, Nicholas Kitchin et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. The New England Journal of Medicine 2020; 1-13.
16. Carpenito L, Porta F, Di Blasi E et al. COVID-19 Vaccines. Safety Surveillance Manual. WHO Guidance for establishing AEFI surveillance systems in countries planning to use Ebola vaccines 2020; 1-232.
17. Samantha Artiga, Matthew Rae, Gary claxton et al. Key Characteristics of Health Care Workers and Implications for COVID-19 Vaccination. Kaiser Family Foundation 2021.
18. Roy L Soiza, Chiara Scicluna, Emma C Thomson et al. Efficacy and safety of COVID19 vaccines in older people. Oxford University Press on behalf of the British Geriatrics Society 2020; 1-5.