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ADR reporting in covid vaccines in coastal districts of Andhra Pradesh

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Abstract
Across the world, different vaccines are being used for the management of COVID-19. Among these vaccines, Bharat Biotech and Serum Institute of INDIA have developed Covaxin & Covishield respectively that are being used across India. Adverse events following immunization (AEFI) for all immunization programs is systematically analyzed by WHO. The common adverse effect of these vaccines is pain at the injection site. Other adverse effects include fatigue, headache, muscle aches, chills, joint pain, and fever. Usually, these symptoms sustain for about 24-48 hours and no more than a few days. We have conducted a prospective & retrospective study in and around Krishna and Guntur districts of Andhra Pradesh for months from April to August 2021. Vaccinated people of either sex or age group above 18 years were included in the study. A unique questionnaire was prepared and given to obtain data from the participants.
A total of 500 vaccinated people were enrolled to study the adverse events following immunization in which, no adverse event was reported for almost 90% of the vaccinated people, and the remaining 10% of the population includes 1.6% with thrombocytopenia, 1.4% with abscess, 1.4% with sepsis, 1.2% with encephalopathy, 0.4% with toxic shock syndrome, 4.0% were with fever, fatigue, body pains, 0.2% with heavy Menstrual bleeding for more than 10 days, and 0.2% with rashes. Anaphylactic reactions like pain, swelling at the site of injection, etc…noted in vaccinated people.
According to the study conducted, 349(69.8%) individuals had vaccinated with covisheild and 149(29.8%) individuals with covaxin. Adverse events following immunization with these vaccines were observed in covishield with 11.143%, covaxin with 6.03%, no reactions seen in 88.825%, and 93.95% of the population who preferred covishield and covaxin respectively.

Keywords: Covid-19, Covaxin, covishield, vaccines, adverse effect following immunization (AEFI)

Introduction
Coronavirus belongs to the family-Coronaviridae, it is enveloped, single-stranded, positive-sense RNA virus with the largest genome among RNA viruses. Scientists first identified coronavirus in 1965. The club-shaped spike (S) proteins on their surface are responsible for binding to the specific receptors in the human body such as the angiotensin-converting enzyme 2 receptors present in the oral and nasal mucosa, lungs, stomach, skin, etc., which has reported as functional SARS Co V receptor. The risk factors affecting mortality in COVID-19 patients include male gender, older age, diabetes, and other medical conditions. Symptoms of the patients infected with COVID-19 include fever, malaise, dry cough, and dyspnea [1].
Across the world, different vaccines are being used for the management of COVID-19. They are Pfizer-BioNTech, Moderna, AstraZeneca, Johnson & Johnson, Sputnik V, Sinovac Biotech, Novavax, Cansino Biologics, Bharat Biotech, Abdala, and Soberana 02.
Covaxin includes inactivated Corona Virus. Covishield is prepared using the viral vector platform in which a chimpanzee adenovirus - ChAdOx1-is modified to enable it to carry the COVID-19 spike protein into the cells of humans. This inactivated virus is incapable of infecting the receiver but prepares the immune system to act against such viruses [2, 3].
Primarily, these vaccines are produced using mRNA platforms which are highly effective and reactogenic as they cause a noticeable immune response. There is no direct correlation between side effects and protection. A vaccine cannot cause COVID-19. No vaccine contains a complete form of the virus responsible for the illness [4]. While the body's immunity varies from person to person, it is normal for a person to experience minor side effects.
The common side effect of these vaccines is pain at the injection site.

Other side effects include fatigue, headache, muscle aches, chills, joint pain, and fever. Usually, these symptoms sustain for about 24-48 hours and no more than a few days [5].

The chances of occurrence of these side effects after vaccination differ according to the type of vaccine. Few vaccines may cause more side effects after the first dose and other vaccines after the second dose. It is important to be vaccinated completely even the side effects were observed in the individual after the first dose.

An adverse event is any untoward medical occurrence in a patient. The vaccines may be administered in various settings such as primary health care centers in rural areas to sophisticated tertiary care hospitals. The vaccine may have different components like antigens, adjuvants, antibiotics, preservatives, stabilizers, and by-products all of which may be responsible for AEFIs [6].

Adverse events following immunization (AEFI) for all immunization programs are systematically analyzed by World Health Organization (WHO). The main aim of this surveillance is to reduce the negative impact of the general population on vaccine safety and to analyze the emerging adverse events after vaccination.

Among millions of people who are vaccinated with Moderna and Johnson & Johnson's Janssen (J&J/Janssen) in the United States, myocarditis and pericarditis, thrombosis with thrombocytopenia (TTS) have been rarely reported [7].

Temporary changes in the menstrual cycle have been reported in some women who are being monitored by MHRA & other experts. Thus, current evidence shows that all the above reported adverse events were found to be rare and with low risk.

It's common for a person to develop fever as a primary immune response after vaccination since the vaccine consists of inactive or dead antigens. The individual need not be isolated unless he/she experiences serious reactions or if they have come across a person tested positive for coronavirus. (8)

The age range was 17 to 52 years with a mean age of 28 years. 60% of the myocarditis-related COVID-19 vaccine cases were associated with the Pfizer-BioNTech vaccine, 33% with the Moderna vaccine, and 7% with the Johnson & Johnson vaccine. All the myocarditis cases related to the Moderna vaccine occurred following the second dose, whereas 66.7% related to the Pfizer-BioNTech vaccine occurred after the second dose of the vaccine [9].

Clinical trials have shown that both vaccines were associated with various mild to moderate side effects, such as pain, redness or swelling at the site of injection, tiredness, headaches, chills, muscle, and joint aches, and fever, the side effects that were reported by the individuals who received Oxford-AstraZeneca vaccine were significantly more compared to the individuals who received Pfizer-BioNTech (83% and 17%, respectively).

As a preventive measure, the Oxford-AstraZeneca's Covid-19 vaccine AZD 1222 was developed in the Serum Institute of India as a Covishield vaccine. This vaccine was vectored with the chimpanzee adenovirus and it was found to have an average efficacy of 70.4% in a peer-reviewed group and this can be stored in 2-8 ^{0}C [10].

Material and Methods

It was a prospective & retrospective study conducted in and around Krishna and Guntur districts of Andhra Pradesh for months from April 2021to August 2021. Vaccinated people of either sex or age group above 18 years were included in the study. A unique questionnaire was prepared and given to obtain data from the participants. Demographics of the vaccinated people who experienced adverse events after covid-19 vaccination & vaccination details were collected. Onset, duration of the adverse event, and management of adverse events by patients were collected. Outcomes were obtained. A questionnaire was forwarded through Whatsapp groups and data was collected. Collected data were analyzed and converted into pie charts.

Vaccinated people with age group above 18 years who were administered with Covishield, Covaxin, and Pfizer were included whereas, people with age less than 18years, pregnant women and who are vaccinated with vaccines other than Covishield, Covaxin, and Pfizer were excluded.

Results and Discussion

Table 1: Demographics

Gender	N value
Male	238(47.6%)
Female	262(52.4%)

In the subjective group of the population, 47.6% are males, and the remaining 52.4% are females. This study includes populations of coastal districts of Andhra-Pradesh

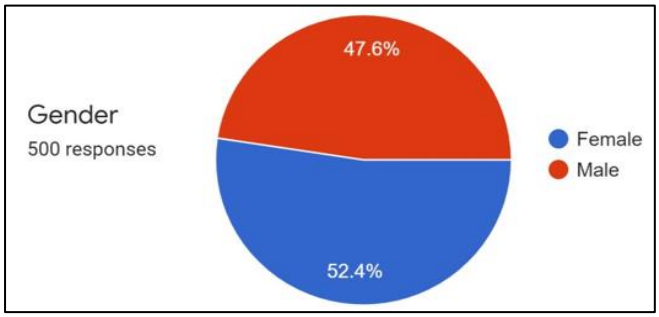


Fig 1: Demographics

Table 2: AGE

Age	Males (N value)	Females (N value)
18-45	136(27.2%)	204(40.8%)
45+	102(20.4%)	58(11.6%)

In the total sample of 500 collected for the study, males with an age group of 18-45years are 27.2%, 45+years are 20.4% and females with age group 18-45 years are 40.8% and 45+ years are 11.6%.

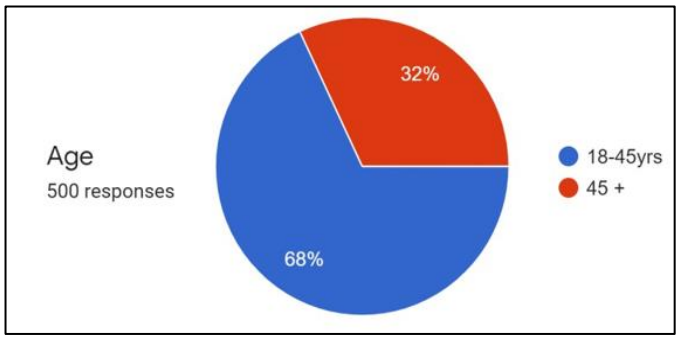


Fig 2: AGE

Table 3: Type of The Vaccine Taken

Gender	Age	Type of the Vaccine		
		Covishiled	Covaxin	Pfizer
Females	18-45	147(29.4%)	56(11.2%)	1(0.2%)
	45+	38(7.6%)	20(4%)	0
Males	18-45	88(17.6%)	47(9.4%)	1(0.2%)
	45+0	76(15.2%)	26(5.2%)	0

Different type of vaccines that are administered by the population in and around Vijayawada. According to the study majority of the people are vaccinated by covishield 69%; the remaining population preferred covaxin and Pfizer with 29.8% and 0.4% respectively.

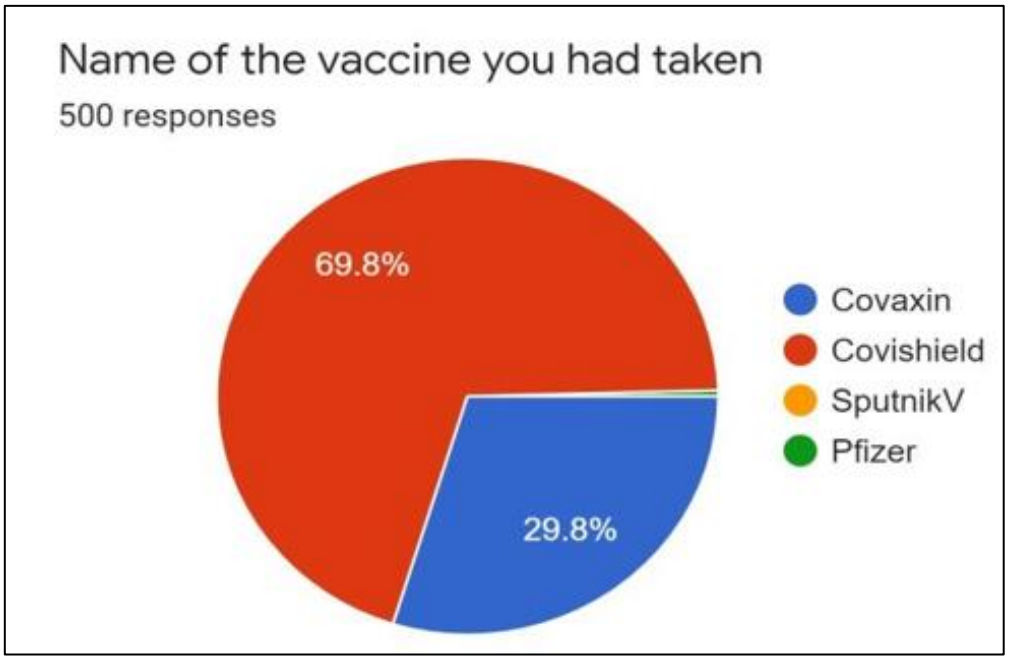


Fig 3: Type of The Vaccine Taken

Table 4: Frequency of ADR

S. No	ADR	Covishiled		Covaxin	
		Number of cases	Percentage	Number of cases	Percentage
1.	None	310	88.825%	140	93.95%
2.	Thrombocytopenia	6	1.7%	2	1.34%
3.	Abscess	5	1.43%	2	1.34%
4.	Sepsis	7	2.0%	0	0
5.	Encephalopathy	5	1.43%	1	0.67%
6.	Toxic shock syndrome	0	0	2	1.34%
7	Fever, body pains, fatigue, headache, weakness	14	4.011%	0	0
8.	Allergy	1	0.286%	1	0.67%
9.	Heavy menstrual bleed	1	0.286%	0	0
10.	Pain at injection site	0	0	1	0.67%

Out of the total number of vaccinated individuals who have participated in this study, it has been found that there are no adverse events observed in about 93.95% of individuals who have received covaxin when compared to covishield for which it is 88.825%. The following are the number of cases reported with their respective percentages for different adverse events in individuals vaccinated with covishield. These include thrombocytopenia - 6(1.7%), abscess - 5(1.43%), sepsis - 7(2.0%), encephalopathy - 5(1.43%), toxic shock syndrome - 0, fever, body pains, headache, weakness, fatigue - 14(4.011%), allergy - 1(0.286%), heavy menstrual bleed 1(0.286%), pain at injection site - 0 whereas for covaxin, thrombocytopenia - 2(1.34%), abscess - 2(1.34%), sepsis - 0, encephalopathy - 1(0.67%), toxic shock syndrome – 2(1.34%), fever, body pains, headache, weakness, fatigue - 0, allergy - 1(0.67%), heavy menstrual bleed -0, pain at injection site – 1(0.67%). Thus, it is observed that covishield has more number of adverse events when compared with covaxin.

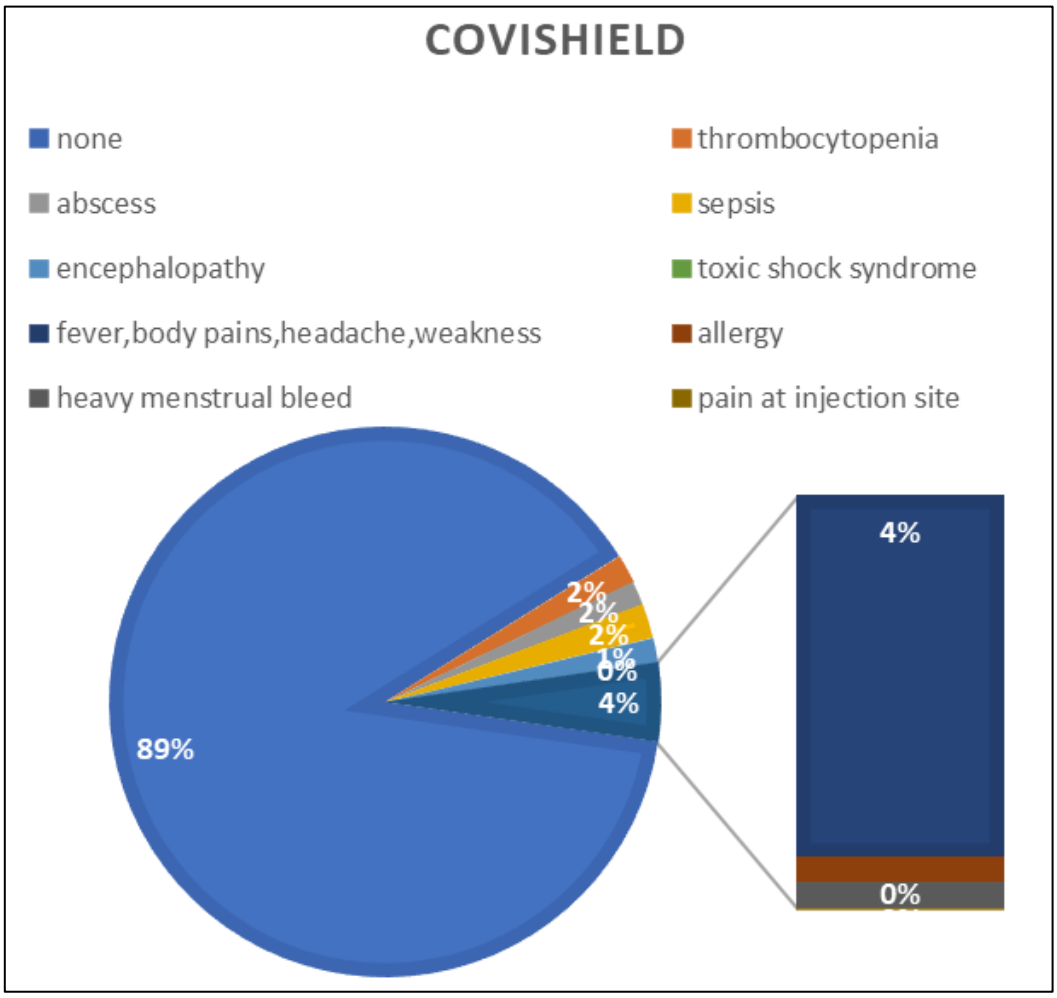


Fig 4: Pie Chart Representation of Adverse events Reported with Covishield

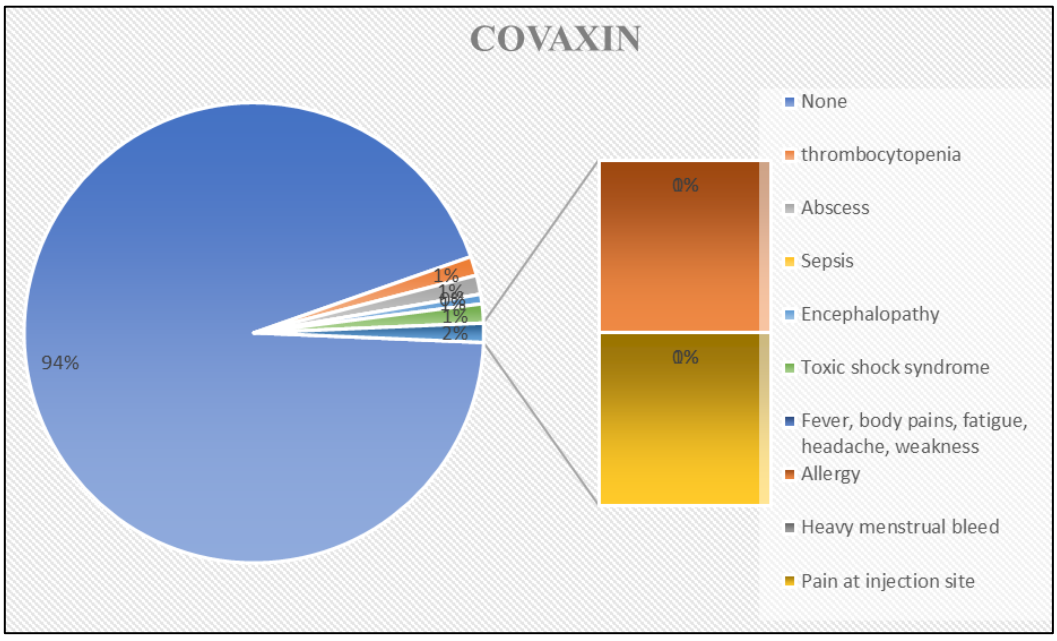
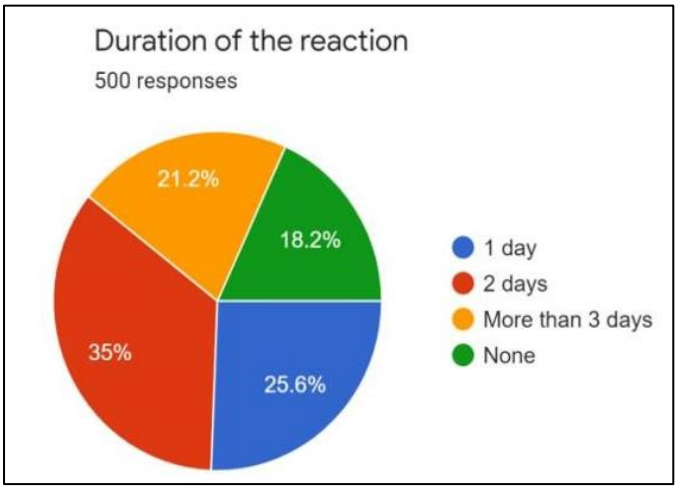


Fig 4.1: Pie Chart Representation of Adverse events Reported with Covaxin

Table 5: Duration of The Reaction

Gender	Duration of the Reaction	Type of the Vaccine		
		Covishield	Covaxin	Pfizer
Males	One day	40(8.0%)	14(2.8%)	1(0.2%)
	Two days	61(12.2%)	15(3.0%)	0
	>3 days	31(6.2%)	16(3.2%)	0
	None	32(6.4%)	28(5.6%)	0
Females	One day	63(12.6%)	10(2.0%)	0
	Two days	64(12.8%)	34(6.8%)	1(0.2%)
	>3 days	41(8.2%)	18(3.6%)	0
	None	17(3.4%)	14(2.8%)	0

Different types of reactions were caused after vaccination with the following frequencies, duration of 1day where males are of 11% and females are with 14.6%, 2days in males with 15.2% and females with 19.6%, more than three days in males with 9.4% and females with 11.8% and some of the males and females with 12% and 6.2% had no reactions respectively.



Duration of the reaction

Conclusion

According to the study conducted, 349(69.8%) individuals had vaccinated with covisheild and 149(29.8%) individuals with covaxin. Adverse events following immunization with these vaccines generally observed within 24 hours in 58.4% of individuals and between 24-48 hours in 22% of individuals and the duration of these reactions appeared to be one day in 25.6%, two days in 35%, and three or more days in about 21.2% individuals. These reactions occurred for the first dose in 39%, second dose in 9.6%, both doses in 21.6%, and 29.8% of individuals have no reactions. Injection site reactions such as pain and swelling occurred in 71% of individuals and these reactions were relieved within one day in 22.6%, in between 24-48 hours in about 40.6%, and in 48 hours in 22% of individuals. Adverse events such as fever, fatigue, body pains were observed in 4.0% of individuals. These reactions had recovered in 74.2% of the population, 6.2% are recovering.

It is the responsibility of the pharmacist to educate the population to get vaccinated against COVID-19. It is safe to be vaccinated and results in a reduced risk of getting ADR and mortality rate when compared to other populations who are unvaccinated. So, according to WHO guidelines, everyone needs to get vaccinated at the right time to prevent themselves from being infected with covid-19 or coronavirus.

Limitation

The study population that we have collected was low and the study was conducted in a smaller area. So, this could be expanded in terms of population and area to obtain the accurate result of the reported adverse events.

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