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An observational study on AEFI in relation with COVID vaccine

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Abstract
Background: Corona virus disease COVID-19, a respiratory disease which is caused by SARS-CoV 2 virus causing respiratory tract infections that can range from mild to lethal. Spreading of the disease is mainly by person contact to each other by air droplets infected persons exhalation. As a prevention for the disease should practice the sanitizing, wearing of mask, and practicing of social distancing. If affected with the disease should take or given with the symptomatic treatments, as a definite therapy was not yet established. Preventing of the disease should be considered in front step to stop the fast spreading, so as the first step world was urged for the development of the vaccines for the safety of public.
Aim: To assess the AEFI and identify the high risk population and also the occurrence of COVID after immunization in a tertiary care hospital.
Methods: The prospective observational study was conducted in a tertiary care hospital for a period of 6 months. A total of 217 participants who had taken the vaccination were included in the study. The details on age, gender, past medical history, adverse event after vaccination were collected. The data collected were analysed by using simple graphical method.
Results and Discussion: The study population included 217 participants who had taken COVID-19 vaccination. Participant responses were collected by telephonic interview and Google forms. The data was analysed using statistical methods. In this study, we found females were more prone to AEFI. Mean age group with more occurrence of AEFI was found in 19-60. Participants with comorbidities showed more incidence of adverse events than other individuals.
Conclusion: COVID virus disease 2019 is the respiratory disease which affects the people regardless of the age and gender. The adverse events after immunization was the major concern among public which reflected in the acceptance of vaccines. Along with that the studies regarding adverse event after vaccination and it's awareness will improve the percentage of vaccinated people. The adverse events following immunization are pain at injection site, fever, headache, fatigue, body pain, nausea and vomiting. Mild to moderate severity are observed among the affected ones. In rare cases serious AEFI like vaccine induced thrombocytopenia are also been reported. Even though we found high adverse event occurrence in middle aged and people with morbidity, there is need of further large population studies to confirm the high risk population.

Keywords: COVID -19, AEFI, SARS-COV-2

Introduction
COVID-19 infection originated in Wuhan, China in December 2019 and crippled human health globally in no time. The public health emergency required urgent efforts to develop and test the efficacy and safety of vaccines to combat the COVID-19 pandemic [1].
COVID-19 is a disease caused by a virus named SARS- COV -2. Countries around the world are rolling out COVID 19 vaccines, and a key topic of interest is their safety. COVID 19 vaccines are crucial tools in the pandemic response and protect against severe disease and death. Nowadays, People are very concerned towards the risk involved with vaccines. AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.
An infectious disease disaster in late 2019 and still contagious as on date occurred. One of the main reasons for decrease in the number of cases reported and mortality is Covid vaccine.

There are few vaccines released into the market claiming that improve the immune response against SARS-COV-2. But the mechanism by which they act differs from one another [2].

COVID -19 vaccines are crucial tools in the pandemic response and protect against severe disease and death. But they are also having risks or adverse effects which can be prevented. Adverse event following immunisation is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of vaccine. Commonly reported AEFI include fever, myalgia, headache, pain at injection sit [3]. The older population, people with comorbidities are more prone to adverse effects. Several studies have shown that AEFI incidence was higher in the first dose when compared to second dose [4]. An SAE was defined as an adverse event that results in any of the following conditions: death; life-threatening at the time of the event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly/birth defect; medically important event, based on medical judgment [5]. Taking into the account of benefit risk ratio, even though there are some adverse events after vaccination, considering their severity level, vaccines are more safe as it protects the individual from pandemic viral disease. A meta-analysis found that people with asthma may appear to have lower risk of COVID-19 than the general population. It is possible that the airway effects of asthma or immune effects of inhaled corticosteroids may affect the response to COVID-19 or COVID-19 vaccine [6].

Methodology

A prospective observational study was conducted by collecting data from tertiary care hospital for a period of 6 months. Participants aged 15 and above who took vaccination was included in the study. Pregnant, lactating mothers were not included in the study. Vaccination details was collected from hospital records. Specially designed data entry form was prepared to collect required data for the study. It included patient's demographic details, past medical history, past medication history, name of vaccine, vaccination details (date of vaccination, adverse effect, number of vaccines taken, duration of effect). A computerised literature and manual search was conducted to identify relevant studies related to AEFI following immunization.

Results

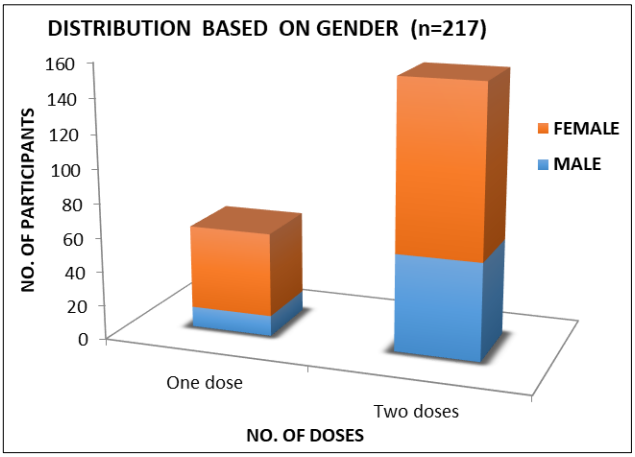

Fig 1: Distribution based on gender

The graph based on gender distribution depicts that 71.66% of the participants were females who had taken both doses.

Distribution based on age (n=217)

Table 1: Distribution based on age

Age category	Male		Female	
	No.	Percentage	No.	Percentage
15-18	4	5.71	16	10.88
19-60	61	87.14	125	85.04
Above 60	5	7.15	6	4.08

Distribution based on past medical history

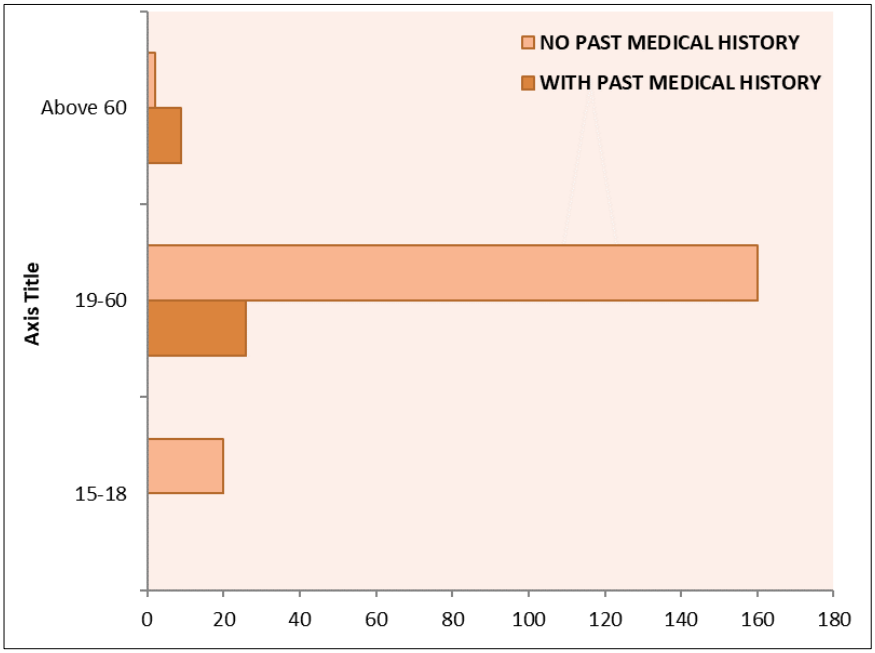

Fig 2: Distriution based on past medical history

The above graphical representation shows that in age category (19-60), 26 out of 186 participants had comorbidities. Whereas in age category above 60, 9 participants in total of 11 had comorbidities.

Details of past medical history

Table 2: Details of past medical history

Medical condition	No. of patients	Percentage of patients
Migraine	1	2.17
Psychiatric illness	1	2.17
CVD	4	8.69
HTN	10	1.73
DM	16	34.79
Hypothyroidism	5	10.87
Hyperthyroidism	1	2.17
Asthma	4	8.69
DLP	3	6.55
Rheumatic fever	1	2.17

Diabetes Mellitus and Hypertension were seen as the most common comorbidities

Distribution based on adverse event after vaccination

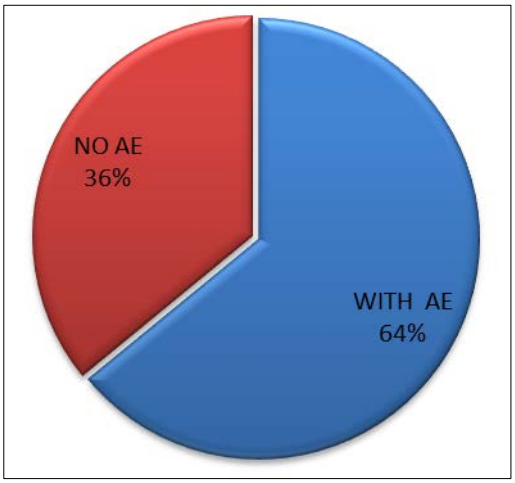

Fig 3: Adverse events reported after vaccination

The above chart shows in total of 217 persons who had taken vaccination 142(64.43%) participants had adverse events and 75(36%) had no adverse events.

Agewise Adverse Event Details

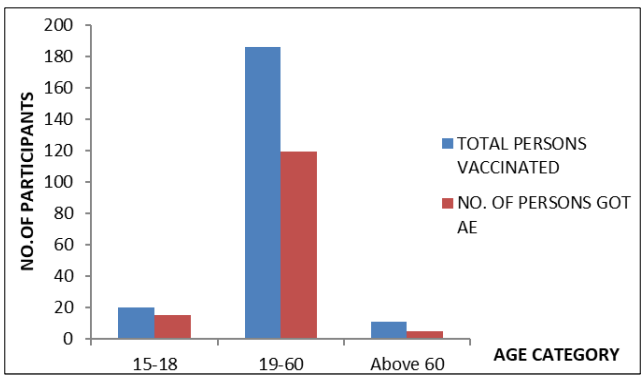

Fig 4: Agewise Adverse event details

This graph represents out of 20 persons in 15-18 age category 15 got AE, 119 out of 186 persons in 19- 60 age category and 5 out of 11 in above 60 category.

Types of adverse event (n=207)

Table 3: Types of adverse event

Types of adverse event	No. of persons	Percentage
Fever	92	44.48
Pain at site of injection	29	14
Body pain	29	14
Hand pain	7	3.4
Throat pain	1	0.48
Fatigue	10	4.84
Headache	16	7.73
Vomiting	3	1.44
Loss of taste and smell	2	0.96
Cough	7	3.39
Cold	1	0.48
Vertigo	1	0.48
Chest pain	1	0.48
Giddiness	2	0.96
Loss of consciousness	1	0.48
Alopecia	1	0.48
Blurred vision	2	0.96
Difficulty to sleep	1	0.48
Dyspnoea	1	0.48

Details of adverse event (n=207)

Correlation between morbidity and adverse event

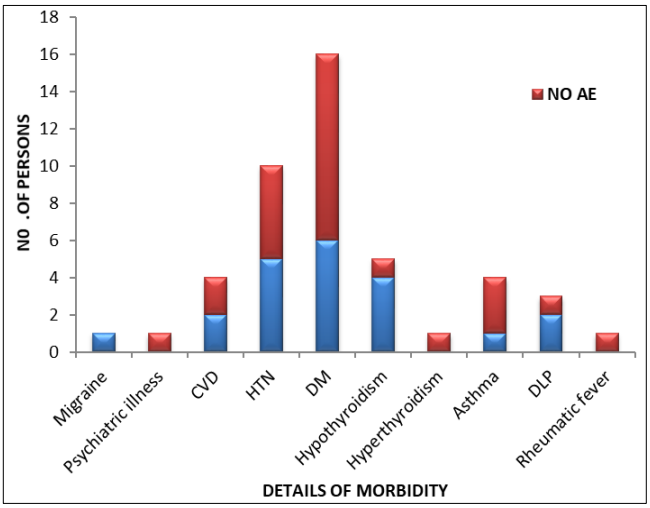

Fig 5: Correlation between morbidity and adverse event

Distribution based occurrence on of COVID after immunization

Table 4: Distribution based on occurrence of COVID after immunization

Age	Total persons got vaccinated		Persons got COVID after vaccination	
	No.	Percentage	No.	Percentage
15-18	20	9.21	5	6.02
19-60	186	85.72	77	2.78
Above 60	11	5.07	1	1.20

Discussion

A Prospective observational study was carried out for a period of 6 months in a tertiary care hospital to assess the AEFI after vaccination. The study included 217 participants. The data obtained by telephonic interviews and Google forms.

- In this study, collected patient details (n- 217) depicts that 72% females and 28% were males. Of the participants, 5% (11) were senior citizens (60 years or above).in a study conducted by Ananya Chakraborthy showed that of 322 participants, 62.4% were females and 37.6%. the senior citizen participants in the study was found to be 3.4%. In short, there were more female participants and senior participants were comparatively low [7].
- Similar study by Dr. Rajeev Jayadevan *et al*, states that among the AEFIs reported, fever, myalgia, tiredness were more commonly reported. The study we conducted coincides with the above study and shows that AEFIs reported most were fever, pain at injection site, body pain [8].

And also in the cross-sectional study conducted by Arifa Sulthana states that side effects like swelling and pain at injection site were the observed localised symptoms and generalised symptoms include fever and dizziness, body and joint pain, irritation, burning sensation which were classified as musculoskletal symptoms were commolyrepoted AEFIs and GI symptoms such as diarrhoea, nausea, decreased appetite were reported after vaccination [9].

The study by Swayam Pragyan Parida *et al*, it was found that the population with co-morbidities had more incidence of AEFIs after COVID vaccination and on relating to our study conducted also been showed that the participants with comorbidities shows the more AEFIs on vaccination.

The study assessed adverse events following immunization of the COVID-19 vaccine in a large-scale sample. Females, individuals with a history of allergy, co-morbidities, acute infection in the past 3 months, and individuals taking chronic disease medication were having a higher chance of adverse events.

The younger population had more AEFI than the older ones. Individuals aged 60 years or more were 0.66 times. Individuals with any comorbidities were 2.08 times more likely to have AEFI than those having no co-morbidities less likely to have AEFI than those aged 18–29 years [10].

Study conducted by Khalil *et al* in Bangladesh also relates that Moreover, age and comorbidity had been significantly associated with the vaccine-related adverse events. Almost half of the participants had comorbidities. Among the comorbid populations, hypertension was the most prevalent (35.4%), followed by diabetes mellitus, which constituted one-fourth of the comorbid population (23.3%) [11].

- The study conducted by Amit S *et al*, states that Among 4,081 vaccinated healthcare workers in Israel, 22 developed COVID-19 from 1–10 days after immunization. Among the 22 COVID-19–positive HCWs, 11 had presumable community-related exposures, 4 of whom reported exposure incidents that occurred before or on the date of vaccination. An investigation conducted by the hospital's Infection Control and Prevention Unit identified 10 healthcare-related secondary exposures. By connecting to the study conducted also states that 5 of 20 of age group 15-18 and 77 of 186 of 19-60 group and 1 of 11 above 60 were affected with COVID after vaccination [12].
- To the date, no vaccine can be claimed to be completely free of adverse reactions, but the majority of them are either preventable or treatable. The rates of vaccine hesitancy and rejection are still high, which is associated with more negative beliefs that the vaccination will cause adverse reactions. Therefore understanding the adverse effects will aid in increasing the vaccine's success rate [13].

Conclusion

COVID virus disease 2019 is the respiratory disease which affects the people regardless of the age and gender. The adverse events after immunization was the major concern among public which reflected in the acceptance of vaccines. Along with that the studies regarding adverse event after vaccination and it's awareness will improve the percentage of vaccinated people. The adverse events following immunization are pain at injection site, fever, headache, fatigue, body pain, nausea and vomiting. Mild to moderate severity are observed among the affected ones. In rare cases serious AEFI like vaccine induced thrombocytopenia are also been reported. Even though we found high adverse event occurance in middle aged and people with morbidity, there is need of further large population studies to confirm the high risk population.

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