Factors of COVID-19 Vaccination Status and Identification of AEFI among the Populations with and without Comorbidities: A Prospective Cross-Sectional Observational Study

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Abstract

Vaccines are the most salient and inevitable biological product in improving public health in and around the world. COVID-19 vaccines are vaccines that protect against the virus that causes COVID-19, which is known as SARS-CoV-2. There are currently several COVID-19 vaccines that have been authorized for emergency use by various regulatory agencies around the world. All of these vaccines are highly effective at preventing severe illness, hospitalization and death from COVID-19. It is important to note that the benefits of vaccination far outweigh the risks of adverse events, as vaccines are highly effective in preventing serious diseases and their complications. The goal of the current study is to study the general population's perspective on COVID-19 vaccines and to identify AEFIs among vaccinated individual. It is a Prospective cross-sectional observational study conducted for a duration of 6 months, data collection from Nov 2022-April 2023.The study is conducted among the population visiting tertiary care teaching hospital located in the southern rural part of India. Among 413 participants, data were collected through a predesigned proforma and data was analysed using suitable statistical tools. Adverse events following immunization (AEFI)'s casualty assessment was done using WHO scale. About 82.9% of participants experienced side effects & 17.1 % experienced no side effects. 77 (19.3%) vaccinated individuals experienced Adverse Events (AE) in which 93.51% had serious AEFI and 6.49% had minor AEFI, under category A1, A4, B1, B2, C and D as per WHO scale. In conclusion, COVID-19 vaccination created a great impact among general population and the AE developed after vaccination must be taken seriously.

Keywords: Covid-19 vaccine, Side effects, AEFI, Adverse event, WHO scale

1. Introduction

WHO has declared that "The end of COVID-19 as a global health emergency is not the end of COVID-19 as a global health threat[1]." Since the disease is new and the virus is still mutating, there is no appropriate regimen to treat COVID-19. Vaccines are indispensable in the prevention of many community communicable diseases[2]. There are variety of COVID-19 vaccines are available in the market like: Covaxin, Covishield, Johnson & Johnson, Moderna, Sinopharm, Covax, Nuxovaxovid, Cansino and Pfizer have been launched due to the emergency with information from partly completed clinical trials[3]. Therefore, adverse events that could be identified in clinical trials could not be reported. COVID-19 vaccines show excellent efficacy in clinical trials and effectiveness in real-world data, but some people still become infected with SARS-CoV-2 after vaccination[4]. Post-vaccination adverse event monitoring is an important process in pharmacovigilance programs is still unknown even to healthcare professionals.

WHO defines AEFI as "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[5]." There are mainly two types of AEFIs that are minor (do not cause any health-related problems) and serious (events that lead to hospitalization or prolonged hospital stay or resulting in death/any physical incapacitation). Causality assessment refers to the systematic analysis of information on AEFI data. After vaccination, vaccination failure might also occur when the vaccinated person does not develop necessary immunity after vaccination due to immune system problems, incomplete vaccination, timing of vaccination and vaccine efficacy. In this article we have made an attempt to find out factors influencing COVID-19 vaccination status and identify AEFIs among populations with and without comorbidities after vaccination.

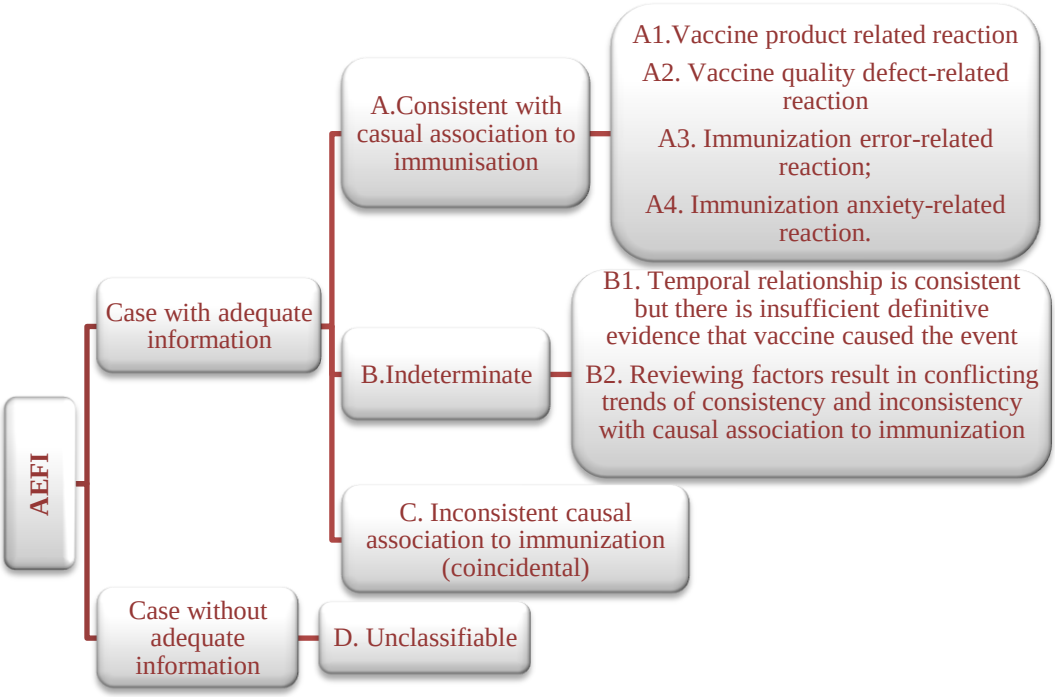

Figure-1. Categories of AEFI[5]

Improved understanding and characterization of vaccine effectiveness at longer dose intervals and of potential variation in effectiveness according to demographic factors, vaccination schedules and history of SARS-CoV-2 infection are urgently needed to inform vaccination strategies[6].

2. Aim and Objectives

2.1 - Aim

The aim of the current study was to study the pattern of side effects, adverse effects and factors influencing COVID -19 vaccination in COVID -19 vaccinated populations.

2.2- Objectives

The objectives of the study are as follows;

- To find out the vaccination status among the population attending outpatient department of Government Cuddalore Medical College and Hospital
- To find the factors influencing COVID -19 vaccines
- To find the side effect of COVID -19 vaccines
- To report the adverse events experienced after COVID -19 vaccinations.

3. Methodology

3.1 - Study design

This is a prospective cross-sectional observational study conducted among the population visiting tertiary care teaching hospital located in the southern rural part of India.

3.2 - Study duration

The study duration was 6 months and data were collected from November 2022 to April 2023 using predesigned proforma after obtaining informed consent from participants.

3.3 - Sampling technique

A convenience sampling technique was followed to select the participants and enrolled for the study. An interview was conducted for 10-15 minutes for all interested participants. Finally, the study was completed with 413 participants of different categories.

3.4 - Inclusion criteria and Exclusion criteria

The participants of all age groups, both the genders, vaccinated with one, two or both doses of COVID-19 vaccine, with or without comorbidities and not vaccinated were included in the study. Healthcare professionals and population not willing to participate were excluded.

3.5 - Sample size

Assuming that 50% of the population has a factor of interest and a population size of 1, 03,200; the study would require a sample size of 383, to estimate the expected proportion size of 5% absolute precision and 95% confidence interval. However, we obtained information from 413 participants. The following data were collected from the participants, which includes demographic details, type of vaccine, number of doses, vaccination method, factors affecting vaccination, side effects encountered, adverse effects encountered in pre-designed case report form after obtaining the informed consent.

3.6 – Ethical considerations

The present study protocol was approved by the Institutional Human Ethics Committee, of the participating site. [IHEC/1076/2022].

3.7 - Statistical analysis

Obtained data were analysed using single sample T-test, Chi-square test and linear regression with a significance level of 0.05 and confidence interval 95%. The statistical analysis was performed by using JASP V0.18.

4. Results

Table-1. Demographic details of study participants

DEMOGRAPHIC DETAILS	OBSERVED VALUE [n, (%)]	P-value
Gender		
Male	178 (43.1)	0.0059
Female	235 (56.9)	
Age		
12-19	11 (2.5)	< 0.0001
20-29	146 (35.4)	
30-39	82 (19.9)	
40-49	75 (18.2)	
50-59	52 (12.6)	
>60	47 (11.4)	
Education status		
Illiterate	73 (17.7)	< 0.0001
School	179 (43.3)	
Diploma	24 (5.8)	
Under graduate	82 (19.9)	
Post graduate	55 (13.3)	
P-value was calculated using Chi square test.		

COVID-19 vaccination data obtained from 413 participants attending outpatient department of tertiary care center, Cuddalore district implies that female participants were predominantly higher than male participants. Also, we infer that the age group of 12-19 are least vaccinated with 2.5%, 20-29 have highly are highly vaccinated with 35.4%, 30-39 have vaccinated with 19.9%, 40-49 with 18.2%, 50-59 with 12.6% and >60 with 11.4%. Based on the educational status, we infer that, among 413 participants, 179 (43.3%) have a school education, 82 (19.9%) are undergraduates, 73 (17.7%) are illiterates, 55 (13.3%) are post-graduates and 24 (5.8%) are diploma aspirants. According to study participants, media and healthcare professionals had created more awareness regarding vaccines.

To study the mentality of the population about COVID-19 vaccines, their opinion was obtained for the following statements “COVID -19 vaccines are safe and effective, vaccines are to protect ourselves from COVID-19 and COVID -19 vaccines can save our life” and their answers were of “agree, do not agree and neutral.” 58 – 68% of participants were optimistic about the statements, 26 - 34% of them were remained neutral and 3-6 % was against them.

Based on the factor influenced to take the vaccine, it was evident from the study that about 53% of vaccinated individuals were vaccinated for its safety & efficacy, 33% of them vaccinated for mandatory purpose and about 13% were vaccinated due to social influence, fear & anxiety.

On the factor of age for individual vaccines, greater than 60 years of age, 45 were vaccinated in which 32 participants were vaccinated with covishield, 7 with covaxin, 6 had mixed doses and 2 were non-vaccinated. Between age group of 50-59 years, 51 were vaccinated in which 37 participants were vaccinated with covishield, 9 with covaxin, 5 had mixed doses and 1 were non-vaccinated. In age group of 40-49 years, 71 were vaccinated in which 47 participants were vaccinated with covishield, 13 with covaxin, 9 had mixed doses, 2 had other vaccines and 4 were non-vaccinated. Among the age group of 30-39 years, 78 were vaccinated in which 47 participants were vaccinated with covishield, 17 with covaxin, 12 had mixed doses 2 had other vaccines and 4 were non-vaccinated. Between age of 20-29 years, 142 were vaccinated in which 101 participants were vaccinated with covishield, 34 with covaxin, 7 had mixed doses and 42 were non-vaccinated. In age group of 13-19 years, 10 were vaccinated in which 3 participants were vaccinated with covishield, 5 with covaxin, 2 had mixed doses and 1 were non-vaccinated.

Table-2. Details of COVID -19 vaccination along with side effects and AE category

Type of vaccine along with gender, side effects and AE category	COVI-SHIELD n=267 [n, (%)]	COVAXIN n=85 [n, (%)]	MIXED n=41 [n, (%)]	OTHERS n=4 [n, (%)]	Total vaccinated n=397 [n, (%)]	Non-vaccinated n=16 [n, (%)]	p-value
Male (n=178)	120 (69.7)	31 (18.0)	17 (9.8)	4 (2.3)	172 (96.7)	6 (3.3)	0.0014
Female (n=235)	147 (65.4)	54 (24.0)	24 (10.6)	-	225 (95.7)	10 (4.3)	0.0039
Fever	120 (44.9)	56 (65.8)	30 (73.2)	1 (25.0)	206 (51.9)	-	0.0017
Pain at injection site	102 (38.2)	44 (51.7)	26 (63.4)	1 (25.0)	173 (43.6)	-	0.0017
Fatigue	73 (27.3)	40 (47.0)	26 (63.4)	1 (25.0)	140 (35.3)	-	0.0011
Muscular pain	68 (25.4)	31 (36.4)	18 (43.9)	-	117 (29.5)	-	0.0017
Redness/ rashes	4 (1.5)	2 (2.4)	-	-	6 (1.5)	-	0.0007
Allergy	-	-	2 (4.9)	-	2 (0.5)	-	0.0041
Itching	1 (0.4)	-	-	-	1 (0.3)	-	0.0041
None	101 (37.8)	19 (22.4)	10 (24.4)	1 (25.0)	131 (33.0)	-	0.0052

Serious	44 (16.5)	14 (16.5)	13 (31.7)	1 (25.0)	72 (18.1)	-	0.0019
Minor	5 (1.9)	-	-	-	5 (1.3)	-	0.0041
Category A1	8 (16.3)	3 (21.4)	1 (7.7)	-	12 (15.6)	-	< .0001
Category A4	2 (4.1)	-	-	-	2 (2.6)	-	< .0001
Category B1	5 (10.2)	1 (7.1)	-	-	6 (7.8)	-	< .0001
Category B2	1 (2.0)	-	-	-	1 (1.3)	-	< .0001
Category C	32 (65.3)	10 (71.4)	12 (92.3)	1 (100)	55 (71.4)	-	0.0005
Category D	1 (2.0)	-	-	-	1 (1.3)	-	< .0001
P-Value obtained using one sample T-test.							

According to survey done by Porus Rajpurohit (Pharmacovigilance officer), et al. out of 75 subjects, about an average of 88.66% of subjects experienced minor adverse events (which are described as side effects in our study) and 11.33% of subjects experienced no events[7]. In the survey study, fever was a most common AE with 53.33%. weakness and body ache were the second common AE, with 47.83%. Almost 44% of subjects experienced swelling and pain at the site of injection. Our study discloses that about 82.9% of participants experienced side effects and 17.1 % experienced no effects. We divulge that, fever was experienced by 26.37 % (44.7% of male and 57.7% of female) of participants, about 22.58% (44.1% of male and 43.1 % of female) of participants experienced pain at the injection site and 18.72 % (29% of male and 40% of female) experienced tired/ fatigue after COVID-19 vaccination.

Table-3. Correlation of age and gender with AE

Type of AE	No AE	Serious	Minor	Vaccination failure	A1 category	A4 category	B1 category	B2 category	C category	D category
Male [n, (%)]	125 (72.6)	45 (25)	1 (0.5)	3 (1.7)	7 (15.2)	2 (4.3)	2 (4.3)	1 (2.1)	34 (73.9)	-
Female [n, (%)]	194 (87.1)	27 (11.5)	4 (1.3)	2 (0.8)	5 (16.1)	-	4 (12.9)	-	21 (67.7)	1 (3.2)

Age >60 [n, (%)]	29 (64.45)	18 (23.3)	-	-	1 (0.12)	1 (0.12)	2 (2.5)	-	12 (16.8)	1 (0.12)
Age 50-59 [n, (%)]	36 (70.5)	16 (20.7)	-	2 (3.84)	4 (5.19)	-	-	-	12 (15.5)	-
Age 40-49 [n, (%)]	56 (78.8)	18 (23.3)	-	1 (1.34)	2 (2.5)	-	-	-	16 (20.7)	-
Age 30-39 [n, (%)]	71 (91)	10 (12.9)	-	2 (3.65)	3 (3.89)	-	-	-	7 (9)	-
Age 20-29 [n, (%)]	137 (96.4)	7 (9.0)	1 (0.12)	-	3 (3.89)	1 (0.12)	-	1 (0.12)	3 (3.89)	-
Age 13-19 [n, (%)]	7 (70.0)	4 (9.0)	-	-	1 (0.12)	-	-	-	3 (3.89)	-
p-value	0.0002	<0.0001	0.0041	0.0014	<0.001	0.005	0.004	0.004	<0.001	0.004
P-Value obtained using one sample T-test										

Apart from common side effects, 77 (19.3%) vaccinated individuals were experienced adverse events (AE) in which 93.51% had serious AEFI and 6.49% had minor AEFI. It was evident that 71.43 % were coincidental events and 15.58 % were vaccine product related reactions, 7.79% were indeterminate (insufficient definitive event), 2.60% were immunization anxiety related reactions, 1.30% were indeterminate (Definite events) and 1.30% were unclassifiable events which are based on the causality assessment scale by WHO[5] and 1% individuals had COVID-19 infection post vaccination.

Table-4. Correlation of comorbidities with vaccination and AE

COMORBIDITY	TYPE OF VACCINE							
	COVISHIELD		COVAXIN		MIXED		OTHERS	
	Vaccinated	AE	Vaccinated	AE	Vaccinated	AE	Vaccinated	AE
Diabetes (n=44)	27 (61.3)	9 (20.4)	6 (13.6)	2 (4.54)	8 (18.1)	4 (9.1)	1 (2.2)	0
Hypertension (n=41)	22 (53.6)	6 (14.6)	9 (21.9)	5 (12.1)	8 (19.5)	6 (14.6)	0	0
Heart Diseases (n=16)	11 (68.7)	7 (43.7)	2 (12.5)	2 (12.5)	3 (18.7)	3 (18.7)	0	0
Thyroid Disorder (n=11)	7 (63.6)	2 (18.1)	1 (9.1)	1 (9.1)	1 (9.1)	1 (9.1)	0	0
Others (n=18)	15 (83.3)	8 (44.4)	2 (11.1)	2 (11.1)	1 (5.5)	1 (5.5)	0	0
P-value	< .0001	< .0001	< .0001	< .0001	< .0001	< .0001	-	-
P-Value analysed using Linear Regression								

From the study, out of 93 participants with comorbidities 38 participants observed adverse events after vaccination. Of 44 participants with Diabetes, 34% experienced serious events under the categories A1, B1 and C, 2.3% experienced minor adverse event. Of 41 participants with Hypertension, 46% experienced serious adverse events (SAE) in categories A1 and C. Of 11 participants with Thyroid disorder, 36% experienced serious adverse events belonging to category C. Of 16 participants with Cardiac disease, about 69% experienced serious adverse events fall in category B1 and mostly in category C. Of 18 participants with other co-morbidities like Bronchial Asthma, Myasthenia gravis, COPD, psychiatric illness and Arthritis 67% of them experienced serious adverse events fall in categories A1, B1, C and category D.

5. Discussion

Vaccination against SARS-CoV-2 is a leading strategy to change the course of the COVID-19 pandemic worldwide[4]. COVID-19 vaccines have been found to be efficacious for preventing severe disease, yet breakthrough infections and deaths have occurred in a small proportion of vaccinated individuals[8]. In our study, 12-19 years of age were least vaccinated (are least vaccinated) with 2.5% and 20-29 years of age have been highly vaccinated in the study with 35.4%. This is in contrast to the other similar type of study which states that overall, 42.3% of children and 74.8% of adolescents were vaccinated[9]. According to the study results of one of the study, most participants were women (84%), and the median age was 46 years who have vaccinated with COVID -19 vaccines[6]. It was similar to the gender based reports of our study.

Among 413 participants, a huge population had completed two doses of vaccination and few with booster dose. More than half of the population had vaccinated with covishield followed by covaxin.
It was similar to the another study in which 90% of the subjects were vaccinated, majority (77%) of them had received 2 doses of vaccine with Covishield[10]. Amongst 413 participants, an average of 55% of participant has positive impact regarding COVID -19 vaccines, 4% deviate from this opinion.

From the gathered data, fever was the most common side effects of all vaccines followed by pain at injection site, muscle pain and tired/fatigue and the less common effects were rashes and itching. Another study from the literature review shows that the most commonly reported systemic side-effects were fatigue and headache. Tenderness and local pain around the injection site were the most frequently reported local effects, occurring most often on the day after injection. Other side-effects, including allergic skin reactions such as skin burning, rashes, and red welts on the lips and face were reported by 10,860 (1·7%) of 627,383 users across both types of vaccine[11].

Our finding was similar to other studies for e.g. a study from Czech republic reported fatigue, headache, muscle pain, and chills the most common side effects[12]. Similarly, a study from Wuhan showed fever, fatigue, headache, and muscle pain in vaccinated individuals by (46%), (44%), (39%), and (17%), respectively[13]. Pain at the injection site occurred in mRNA (66.9%), adenoviral vector (54.2%), and Sinopharm (54.5%) vaccine recipients. Another study showed, the Pfizer manufacturer reported a higher rate of local injection site reactions (83.1%); while, the same prevalence rate was reported in the adenoviral vector vaccine (54%)[13]-[14].

This study accentuates that any kind of vaccine be it covishield, covaxin or any others vaccines could produce AE. In some cases, AEs produced by covaxin is slightly more than covishield. Based on study observation, out of 77 participants experienced AEFI and some require hospitalization. Causality assessment was done according to WHO scale and those observed AEs were mostly coincidental events. The adverse events reported all around the world after vaccination range from minor events like fever, pain at injection site to serious events like MI requiring hospitalization. In a systemic review by Dana H. Baqi et al. 20 MI cases were reported[15].

Accordingly, 18 cardiac related adverse events which includes one AE from Mitral regurgitation, Cardiomyopathy, inferior wall MI were reported from this study[15]. Apart from the above mentioned AEs in this study, two cases of CAD (Coronary Artery Disease), Cardiogenic shock, unstable angina, TIA (Transient Ischemic attack) and 6 ACS-STEMI were also reported. A study done by Boby Varkey Maramattom et al. report 5 cases CNS (Central Nervous system) related AE after ChAdOx1 vaccination[16]. In the present study observed 12 CNS related AE among vaccinated individuals, which includes one AE from hemorrhagic stroke, BPPV (Benign paroxysmal positional vertigo), Peripheral motor neuropathy, Neurospasm and hemiplegia. Apart from the above AEs in the present study observed 4 seizures and 2 hemiparesis.

An AEFI report published by Government of India MoHFW (Ministry of Health & Family Welfare) Immunization Division listed the results of 254 reported AEFI of COVID-19 vaccines. The results include, 78 out of 254 cases for which causality assessment has been done were found to have a consistent causal association to vaccination. Of these 78 cases, 31 cases were vaccine product-related reaction including 2 deaths and 47 cases were immunization anxiety-related reaction. 122 cases have an inconsistent causal association to immunization (coincidental - not linked to vaccination), including 83 death cases. 33 cases were in the indeterminate category including 1 death case. There were 21 cases in the unclassifiable category[17]. Similar analysis was performed for our study (https://online.publuu.com/618836/1383027). Of these 77 cases with AE, 14 cases were vaccine product- related reaction, 55 cases have an inconsistent causal association to immunization, 7 cases were in the indeterminate category including 1 death case and 1 report falls under the "unclassifiable" category.

In this study, 93 participants were presented with co-morbidities. About 40 % of vaccinated individuals experienced SAEs (Serious Adverse Events), among them more SAEs were experienced by participants with cardiac disease, diabetes mellitus and hypertension. Considering the type of vaccine, covaxin produced more AEs comparing to covishield (though a smaller number of participants had covaxin vaccine in vaccinated individuals with comorbidities. Co-existing diseases such as bronchial asthma, hypertension, and diabetes were a recognized risk factor for post vaccine side effects[18].

6. Conclusion

In conclusion, COVID-19 vaccines provided a wide range of protection against corona virus infection. Even though the population had a positive opinion on the COVID-19 vaccine, there also arises fear of adverse effects of vaccines. Most individuals agree that vaccines are safe, effective and provide protection against Covid-19 and only few individuals differ. The most common side effects experienced include, fever & pain at injection and rare side effects include rashes and itching. Also, minority participants experienced no side effects. As the study preferably focused on the vaccinated individuals, a set adverse events were identified which weren't reported earlier, majority are related to CNS and CVS problems. People with cardiac diseases were highly susceptible to develop SAE after vaccination followed by hypertension and diabetes mellitus, of both types. According to age factor, pediatrics and geriatrics are susceptible to experience SAEs. Despite the AE and side effects, individuals were highly interested in vaccination which had greatly helped to reduce the infection rate and mortality.

7. Limitations

- Study was conducted in small population.
- Scientific correlations for adverse events were not available.
- Severity of the AE experienced cannot be assessed.
- The batch and product details vaccines of vaccinated people weren't available.

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