Original Research Article

A study on Adverse Effects Following Immunization (AEFI) following Covishield Vaccination among Health Care Workers at Tertiary Health Care centre.

Anitha Silvery[1*],Jayasri Helen Gali[2],Vimala Thomas[3],Sara Roohen[4]

[1]Assistant Professor ,Department of Emergency Medicine.Telanagana Institute of Medical Sciences and Research (TIMS).Gachibowli, Hyderabad,India

[2]Professor, Department of Pulmonary medicine, Telanagana Institute of Medical Sciences and Research.Gachibowli, Hyderabad,India

[3]Professor,Department of Preventive and social Medicine, Director, Telanagana Institute of Medical Sciences and Research.Gachibowli, Hyderabad,India

[4] Senior Resident, Preventive and social Medicine, Telanagana Institute of Medical Sciences and Research.Gachibowli, Hyderabad,India

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Abstract

The AstraZeneca's Covisheild vaccine against COVID-19 was rolled out in several parts of the world and approved for emergency authorisation in India from 16th January 2021. Real-time post vaccination experience outside the manufacturers vaccine trial is bizarre and not well documented. Knowledge about adverse events following Covisheild vaccine will educate the people, allay their fears, stigma and lower their hesitancy towards vaccination. The aim of our study is to identify the adverse events following Covisheild vaccination in health care workers (HCW'S) at TIMS. **Methods**: A cross-sectional, observational survey was conducted to study the adverse events following Covisheild immunisation drive among the HCW'S at TIMS from 19th January to 9th March 2021. **Results:** The acceptance of vaccine among the HCW'S was 60 %. The frequency of incidence of AEFI was significantly less following 2nd dose when compared to 1st dose ($p<0.005$). Post-vaccination symptoms were more likely reported in women (57.24%) compared to men (56.10%) ($p> 0.05$). Incidence of AEFI within 30 minutes was significantly higher among females than males ($p=0.027$). AEFI persisted for a longer duration upto 72hrs among females than males and this difference was statistically significant ($p=0.001$). **Conclusion**: Majority of the reported AEFI were, mild, self-limiting, of short duration and none were serious. No hospitalisation was required and nil fatality was observed. This guides the individual to accept the national covid -19 vaccination drive, which is the most crucial step to halt this deadly pandemic. Acceptance and immunisation is crucial to achieve herd immunity to curb this pandemic.

Keywords: Covisheild vaccine, AEFI, health care workers.

Introduction

The covid 19 pandemic had severely impacted health care systems, economic and social progress throughout the world. Strong measures were adopted and some progress was made in containing the spread through better public health interventions, early diagnosis and effective treatment. Scientists across the world have accelerated the process to develop a safe and effective vaccine that will break the chain of transmission to curb this pandemic. As part of the global efforts for rapid development of a safe and effective COVID-19 vaccine, various scientific techniques using different viruses or viral parts were used. The COVID-19 vaccines under use are based on the following techniques: inactivated virus vaccine, viral vector vaccine, nucleic acid vaccine and protein based vaccine.The safety of vaccines is a critical factor in maintaining public trust in national vaccination programs. Vaccines have to meet higher safety standards, since they are administered to healthy subjects. Although vaccines are strictly monitored before authorization, the possibility of adverse events and/or rare adverse events cannot be totally eliminated[1].India has approved two vaccines, made in India –Oxford-Astra Zeneca's 'Covishield' and Bharat Biotech's 'Covaxin' for emergency use authorisation from 16 January 2021.

Covishield is a vector vaccine (weakened version of adenovirus) works by priming the immune system with a SARS-CoV-2 spike protein. It was initially administered in 2 doses 4 weeks apart[2]. Covaxin has been developed by Indian biotechnology company-Bharat Biotech and clinical research body Indian Council of Medical Research (ICMR). Covaxin is an inactivated vaccine.Before a vaccine is licensed, its safety is evaluated in different phases of clinical trials; it subsequently undergoes post-licensure surveillance [3]. Adverse events may occur due to annual changes in vaccine formulations, vaccine administration patterns, environmental factors or genetic factors of the host cannot be totally eliminated. Consequently, annual post-licensure vaccine safety surveillance is fundamental[4].The AEFI'S were classified as minor, severe and serious according to Ministry of Health and Family Welfare (MOHFW). Minor and severe AEFI'S are of minimal medical importance, whereas serious reactions can threaten the person's life

**Correspondence*
Dr.Anitha Silvery
Assistant Professor Department of Emergency Medicine. Telanagana Institute of Medical Sciences and Research (TIMS).Gachibowli, Hyderabad,India
E-mail: anitha.silvery@gmail.com

or functions,thus serious reactions are subject to obligatory reporting[5]. Our aim is to identify the AEFI'S following both the doses of Covisheild among the HCW'S vaccinated at our centre.

Methodology

All the health care workers above 18 years satisfying the eligibility criteria and vaccinated with Covisheild against covid 19 at TIMS, were enrolled in the study after taking the informed consent. Approval was taken from the institutional ethical committee. Of the 816 HCW'S at TIMS 490 willingly received both the doses of the vaccine. Vaccinated beneficiaries were observed for 30 minutes at the place of vaccination for AEFI starting from the time they received the vaccination. Participants were asked to report any AEFI that occurred to them at the earliest and necessary treatment was given. A telephonic enquiry and documentation related to AEFI was done after 24 hrs and 1week after 1st dose of vaccination. After 4 weeks, 2nd dose of vaccine was administered following which AEFI'S were monitored and documented. AEFI'S were categorised into 3 groups, minor, severe and serious AEFI[6].

Table 1:

Minor AEFI	Severe Aefi	Serious AEFI
pain at the injection site	high grade fever(>102)	AEFI cluster*
swelling at injection site	anaphylaxis not requiring hospitalisation (skin rash, abdomial pain, nausea and vomiting)	persistant / significant disability (encephalopathy, seizures) requiring hospitalisation
fever (< 102)		anaphylaxis(shock, sob, laryngeal edema)
irritability		death
malaise		
chills		
giddiness		
headache		
myalgia		
cold		

*cluster of AEFI: Two or more cases of same adverse event related in time, place or the vaccine administered.

Results

Table 2: Distribution of AEFI according to patient characteristics

	Minor AEFI (N %)		Severe AEFI (N %)	
Age (in Years)	**1st dose**	**2ND Dose**	**1st Dose**	**2nd Dose**
21-30(N=282)	154 (54.6%)	40 (14.18%)	16 (5.67%)	2 (0.7%)
31-40(N=150)	80 (53.33%)	28 (18.66%)	8 (5.33%)	3 (0.02%)
41-50 (N=49)	22 (44.89%)	8 (16.32%)	4(8.16%)	1(0.025%)
>50 (N=9)	2 (22.22%)	0	0	0
Total N(%)	258(52.65%)	76(15.51%)	28(5.71%)	6(1.22%)
P Value	0.001		0.001	
Co-morbidities				
Yes N=24 (4.89%)	14 (58.33%)	3 (12.5%)	1 (4.16%)	0
No N=466 (95.1%)	244 (52.36%)	73 (15.66%)	27 (5.79%)	6 (1.28%)
P Value	0.568	0.676	0.738	0.576
Past Covid-19				
Yes N=44 (8.97%)	27 (61.36%)	9 (20.45%)	2 (4.54%)	0
No N=446 (91.02%)	231 (51.79%)	67 (15.02%)	26 (5.82%)	6 (1.34%)
P Value	0.225	0.342	0.726	0.439
Gender				
Male N=221 (45.1%)	115 (52.03%)		9 (4.07%)	
Female N=269 (54.89%)	154 (57.24%)		21 (7.8%)	
P Value	0.249		0.086	

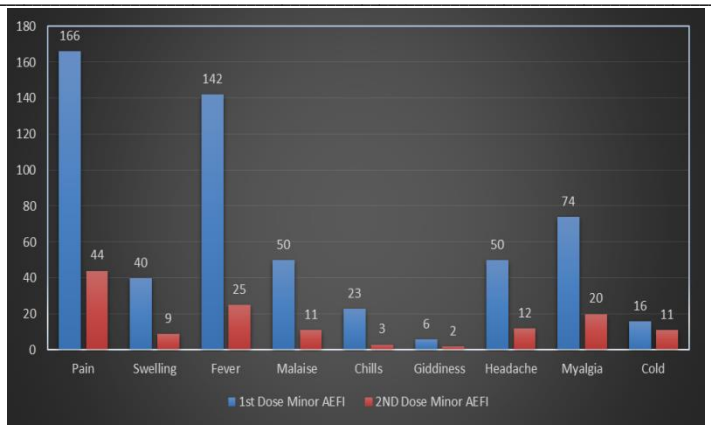

Fig 1: Frequency of minor AEFI

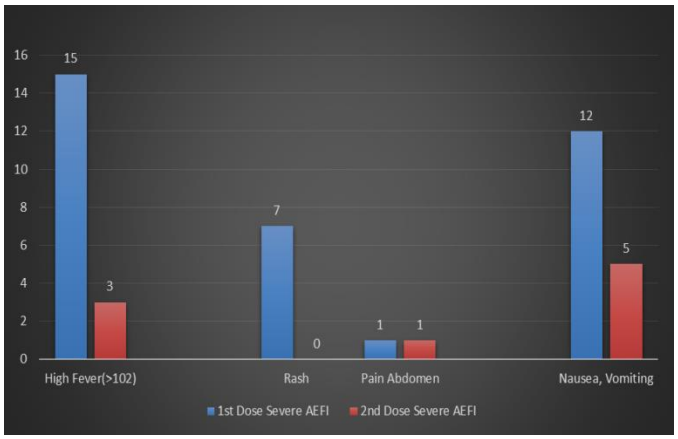

Fig 2: Frequency of severe AEFI

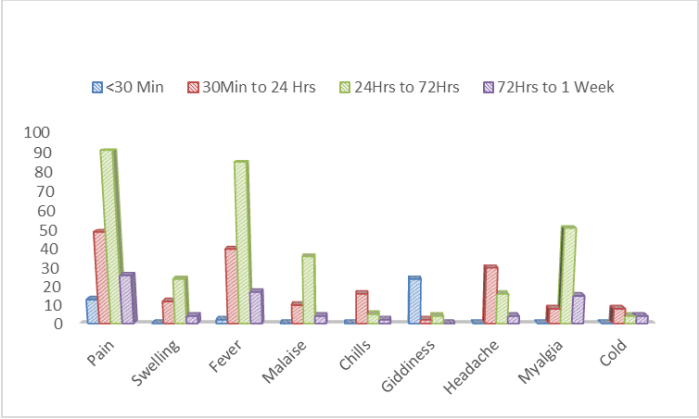

Fig 3: Time line of minor AEFI after 1st dose

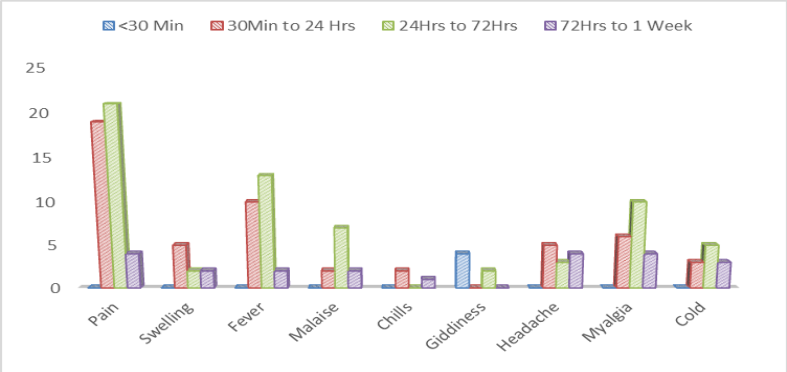

Fig 4: Time line of minor AEFI after 2nd dose

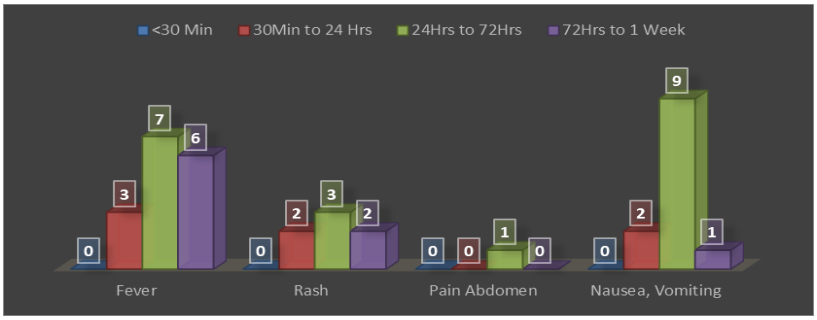

Fig 5: Time line of severe AEFI after 1st dose

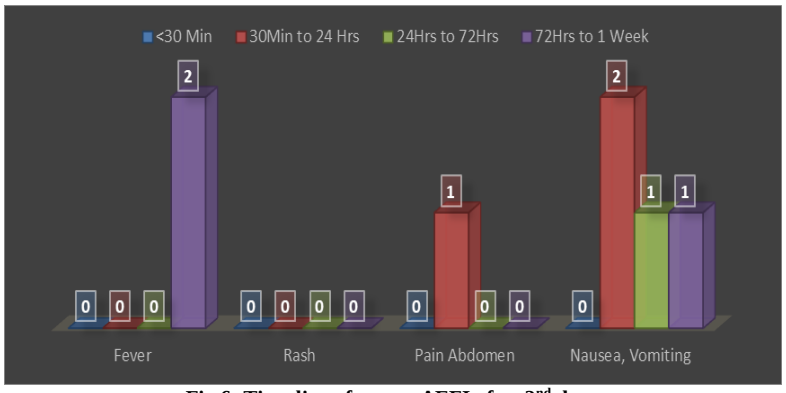

Fig 6: Time line of severe AEFI after 2nd dose

Table 3: AEFI time line distribution according to age

		Less than 30 mints	30 mints to 24 hrs	24 hrs to 72 hrs	72hrs to 1 week
Minor AEFI duration in 1ST dose					
Age	21-30	25	76	95	20
	31-40	11	38	50	07
	41-50	3	11	13	04
	more50	0	1	1	00
Total		39	126	159	31
P-value		0.706	0.679	0.407	0.528
Severe AEFI duration in 1ST dose					
Age	21-30	00	5	08	03
	31-40	00	2	03	03
	41-50	00	0	03	02
	more50	00	0	00	00
Total			7	14	08
P-value			0.780	0.477	0.528

Minor AEFI duration in second dose					
Age	21-30	3	19	21	5
	31-40	1	9	16	8
	41-50	0	6	2	1
	more50	0	0	0	0
Total		4	34	39	14
P-value		0.866	0.387	0.336	0.180
Severe AEFI duration in second dose					
Age	21-30	00	01	1	0
	31-40	00	01	0	2
	41-50	00	00	0	0
	more50	00	00	0	0
Total		00	02	01	2
P-value			0.808	0.864	0.602

Table 4: AEFI time line distribution based on gender

		Less than 30 mints	30 mints to 24 hrs	24 hrs to 72 hrs	72 hrs-1week
Minor AEFI duration in 1st dose					
Gender	Male	11	55	62	09
	Female	28	71	97	22
Total		39	126	159	31
P-value		0.027	0.704	0.060	0.308
Severe AEFI duration in 1st dose					
Gender	Male	00	4	03	02
	Female	00	3	11	06
Total		00	7	14	08
P-value			0.519	0.195	0.368
Minor AEFI duration in 2nd dose					
Gender	Male	1	10	5	3
	Female	3	24	34	11
Total		4	34	39	14
P-value		0.417	0.05	0.001	0.07
Severe AEFI duration in 2nddose					
Gender	Male	00	1	0	0
	Female	00	1	1	2
Total		00	2	1	2
P-value			0.361	0.364	0.438

Discussion

Fear of unknown is the root cause for vaccine hesitancy. By clearly describing the AEFI'S, our study will be reassuring to the persons fearful of the novel covid 19 vaccines. Out of the 816 HCW'S, acceptance towards Covisheild vaccine was only 60% (N=490) at TIMS. This clearly shows that the acceptance of vaccine would be much less than 60% in the general population, who will have limited knowledge when compared to HCW'S. Vaccination safety has become as important as the efficacy of vaccines. Expectations from vaccinations are much higher, and problems arising from the vaccines are less acceptable to the general public[7,8]. In our study, 61% of the vaccinated HCW'S reported at least one AEFI following both the doses of Covisheild. It is a common belief that an injection-site reaction to a vaccine is a predictive sign of a desirable vaccine response ('no pain, no gain' concept). However limited data is available to either support or disprove this concept[9].In our study 191 HCW'S developed no AEFI after the vaccination. The incidence of AEFI in our study was 61.02% (n=299) and all the events were reported within 1week of vaccination. 286 (58.36%) persons developed AEFI following 1st dose, of which 258 (52.65%) had minor AEFI while 28 (5.7%) persons had severe AEFI. Of the 28 persons, 24 of them had both minor and severe AEFI'S after 1st dose. 82 (16.73%) HCW'S had AEFI'S after 2nd dose, 76 persons (15.5%) had minor, of which 11 had minor AEFI only after 2nd dose. Severe AEFI'S after 2nd dose were seen in 6 persons of which, 2 persons had only after 2nd dose. These finding in our study correlated with the results from published trials on vaccine, and all were self-limiting.[10]

The correlation between the age and the post vaccination adverse events suggests that the vaccine reactogenicity declined with advancing age. Vaccine reactogenecity is associated with elevation of inflammatory cytokines, but is not a reliable sign of immune response[11].Similar trend was observed in our study, where incidence of minor adverse events declined with age, this was possibly due to higher tolerance to pain and illness symptoms gained with life experience and/or the waning of innate immune defence mechanisms[12]. However, limitation in our study is that majority of the vaccinated persons belonged to the age group between 21 -40 years {n=432, (88.16%)}

There was a higher incidence of AEFI'S among females than males in our study, possibly related to genetic or hormonal differences.[13]

Primary prevention remains the mainstay for mitigating the risks associated with COVID-19 in patients with co-morbidities. A significant step in primary prevention is timely vaccination. When stratified according to co morbidities, out of 24 HCW'S who had co-morbidities, 18 HCW's have experienced AEFI after both the doses of Covisheild. However, majority of the reported AEFI were minor (1st dose-N=14 and 2nd dose – N=3) and self limiting. Only 1 person developed severe AEFI towards 1st dose and none following the 2nd dose. The incidence of AEFI did not differ significantly between the HCW'S with and without co-morbidities. Diabetes mellitus (DM) was the most common co-morbidity seen 9 persons (37.5%) in our study. The novel coronavirus disease (COVID-19) tends to portend a poor prognosis in patients with DM. With clinical data supporting a robust neutralizing antibody response in COVID-19 patients with

DM, vaccination in individuals with DM is justified[14] Limitation in our study is that majority of the vaccinated persons were between21-40 years, hence incidence of co-morbidities was low.HCW'S with the past history of covid were observed for the pattern of AEFI and compared with those without past covid history. Majority of the AEFI'S were minor (dose 1-61.36%, dose 2 - 20.45%) and severe events after both the doses were, dose 1- 4.48%, dose 2- 0.89%. However, p value was non-significant (p> 0.005).

Among the AEFI, pain was the most common symptom reported after both the doses (1st dose -N=166, 2nd dose - N=44), followed by fever (1st dose -N=142, 2nd dose-N=25) and myalgia (dose1-N=74, dose 2- N=20). After 1st dose a combination of all the 3 common symptoms (pain, fever and myalgia) was seen in 22 (7.8%) HCW's, however none of the HCW'S had a combination of these 3 symptoms after 2nd dose. Least common AEFI was giddiness reported after both doses (dose 1-N=6, dose 2-N=2). Pain was the most common symptom observed during the whole follow up period upto 1 week, followed by fever.Among severe AEFI, the most common reported symptom was high grade fever after the first dose (n=15), and nausea and vomiting after the second dose (n=5). The least common symptom was abdominal pain after the first dose (N=1), and rash was seen in none after the second dose.

Majority of the AEFI events were observed during the 24-72 hr period and least events were reported during the 72hr - 1 week period. Females had experienced early (within 30 minutes) and longer duration (upto 72 hrs) of symptoms after both the doses when compared to males and was statistically significant (p=0.027 & p=0.001 respectively).

The limitations in our study, was that the sample size was less and majority of the HCW'S vaccinated belonged to younger age group (21-40 years, 88.16%). Thus there is a need to conduct further studies with larger sample size for all the age groups from the general population and for various other covid 19 vaccines.

Conclusion

54.89% of healthcare professionals who completed both the doses of vaccination reported minor AEFI'S and most of them lasted for less than 72 hrs. 6.12% of HCW'S had severe AEFI, no serious events were reported. There was a significant decrease in incidence of AEFI after second dose when compared to first dose (p < 0.005). Symptoms were more common among younger individuals (3rd & 4th decade). AEFI'S were more likely reported by females than males but, the difference was not statistically significant. However, females had experienced early (within 30 minutes) and longer duration (upto 72 hrs) of symptoms after both the doses when compared to males and was statistically significant (p=0.057 & p=0.001 respectively). Injection site pain, low grade fever and myalgia were the most commonly reported minor AEFI following both the doses of Covisheild. High grade fever, nausea and vomiting were the most frequent severe AEFI'S. Majority of the AEFI events were observed during the 24-72 hr period and least events were reported during the 72hr - 1 week period. There was no significant difference in the incidence of AEFI among the participants with and without comorbidities (p> 0.05). Elderly HCW'S (>40years) had lesser incidence of AEFI after both the doses of Covisheild when compared to younger group (21-40years).(p= 0.336).

Conflict of Interest: Nil
Source of support:Nil

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