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RESEARCH ARTICLE
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EVALUATION OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AFTER 1st DOSE OF COVISHIELD AMONG HEALTH CARE WORKERS.

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Covid -19 pandemic has been one of the most difficult challenges faced by the world .2019 novel coronavirus (2019-nCoV) or severe acute respiratory syndrome (SARS-CoV -2) was the reason behind this pandemic. The outbreak started in Wuhan, a city in the Hubei province of China. (1) There was a high rate of morbidity and mortality worldwide. To control it, precautionary measures like maintaining distance, sanitization, quarantine of symptomatic patients, and use of face masks were used. Treatment was mostly symptomatic. The most important development in COVID-19 was vaccine development. Emergency Use Authorization qualified 2 Indian vaccines- Covishield and Covaxin in India. (2). The vaccination phase began in India on January 16, 2021. It began with involving the healthcare workers, frontline workers, and elderly people as the priority group (3), (4)
Covaxin is an inactivated virus vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) Institute of Virology (5). Whereas, Covishield is a 2-dose version of AstraZeneca vaccine (ChAdOx1/AZD1222,) and was manufactured by the Serum Institute of India. (6) COVISHIELD (ChAdOx1 nCoV-19) is an adenovirus vector-nonreplicating virus vaccine. It carries the recombinant spike protein of SARS-CoV-2. In Phase I/II trials, it showed an acceptable safety profile. During phase III trials, it had an efficacy of 74% in preventing infections. (7)
With the introduction of these vaccines, the risk of ADR/ AEFI has also been introduced. These ADR/AEFI can sometimes be mild/moderate and sometimes serious leading to morbidity and mortality and therefore increasing the health care cost. (8) Various studies have been done since the introduction of COVID-19 vaccines to evaluate their safety and any adverse effects caused by them. This study has been done to evaluate any adverse drug events following the 1st dose of the covishield vaccine among healthcare workers of a tertiary care teaching hospital.

MATERIAL AND METHOD-It is a cross-sectional, prospective study done by the Department of Pharmacology, Santosh Medical College, Ghaziabad. The total duration of the study was 12 months i.e. 16 January 2021 – 15 January 2022; in the first 6 months data collection was done and the rest of the time result was computed and analyzed. People taking 1ST dose Covishield vaccine were chosen

and consent was taken. Those who gave the consent were assessed. After giving 0.5 ml Covishield subcutaneously subjects were allowed 45 mins of rest and any immediate reactions were assessed. After this, AEFI was collected using active surveillance, i.e., participants were contacted telephonically after 24 hours, 48 hours,72 hours, and 7 days for any type of adverse event. Data was collected, tabulated, and analyzed.

RESULT-

A total of 450 participants were included in the study. Out of these 9 were lost during telephonic communication. Out of a total of 441 participants, none showed any immediate reaction i.e. after 48 minutes of vaccine. After 24 hours,407 (92.29%) reported adverse events and 34 (7.71%) showed no symptoms. Out of 407 patients, 215(52.02%) participants had pain at the site of injection, 105 (25.80%) participants had fever,55 (13.51%) had myalgia or arthralgia,15 (3.68%) had headache, 9 (2.2%) had chills and rigor,4 (0.98%)had GIT upset, 3 (0.73%) had cough and only 1 (0.24%) had itching.[Fig. 1] After 48 hours,72 hours, and 7 days, no participant reported any adverse event.

Among all the adverse events, 336(82.56%) were categorized as minor and 71 (17.44%) as moderate. No severe AEFI was reported. [Table 1]

216 (53.07%) patients had local symptoms, and 191 (46.93%) showed systemic symptoms. [Table 2]. Among Local symptoms pain at the injection site is the most common symptom experienced by most of the participants. Among systemic symptoms, fever was the most common symptom followed by arthralgia or myalgia.

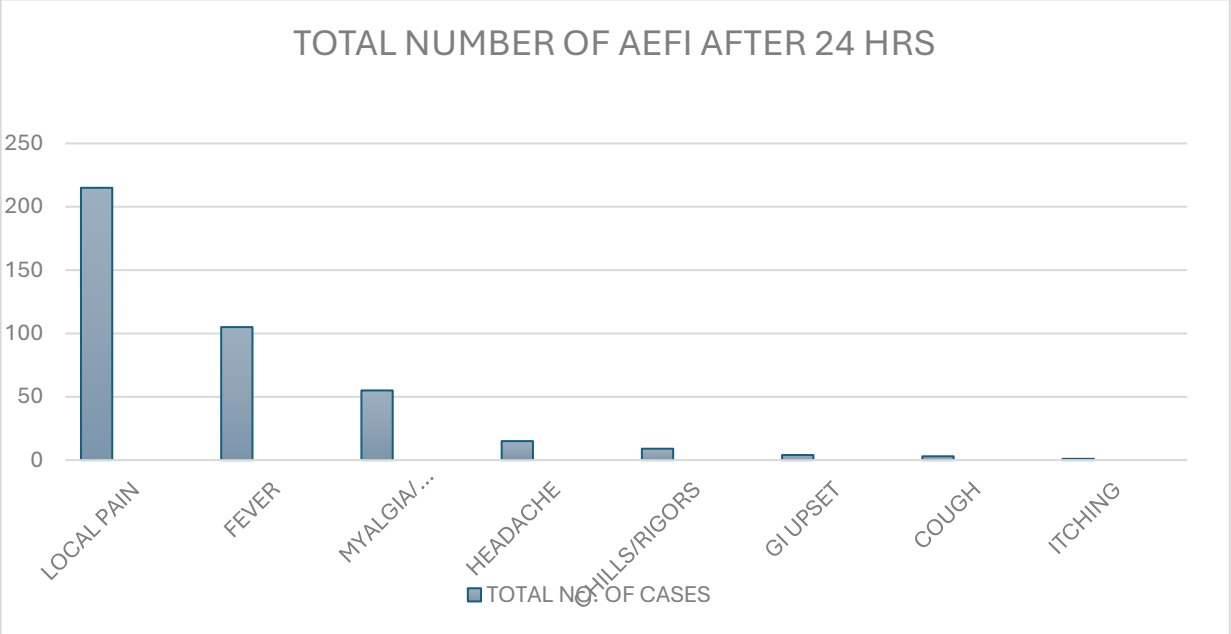

FIGURE 1. AEFI after 24 hrs. of vaccine

TABLE 1: Severity of AEFI

S.NO	SEVERITY	TOTAL NO. OASEES
1	MILD	336
2	MODERATE	71
3	SEVERE	0

TABLE 2: AEFI Profile

S.NO.	SYMPTOMS	TOTAL NO. OF CASES	PERCENTAGE
1	LOCAL SYMPTOMS (TOTAL)	216	53.07%
	LOCAL PAIN	215	52.82%
	ITCHING	1	0.24%
2	SYSTEMIC SYMPTOMS(TOTAL)	191	46.93%
	FEVER	105	25.80%
	ARTHRALGIA/ MYALGIA	55	13.51%
	HEADACHE	15	3.68%
	CHILLS AND RIGOR	9	2.2%
	GIT UPSET	4	0.98%
	COUGH	3	0.73%

DISCUSSION

In our study, none of the 441 participants showed any immediate AEFI whereas in a study by Kaur, it was observed in 0.9% of participants [9]. After 24 hrs, out of 441, 407 (92.29%) participants reported AEFI. Out of this,215 (48.75%) had local pain, and 105 (23.8%) had a fever.55 (12%) had myalgia or arthralgia, 15 (3.4%) had headaches and 9 (1%) reported chills and rigors. GIT Upset, Cough, and Itching constituted 4 (0.98%), 3 (0.73%), and 1 (o.24%). It was similar to the study by Sathyapalan et al, where the most common symptom was local pain followed by fever [10]. Also, in a study by Sahya S Dev et al, [11] local pain was the most common cause followed by myalgia. This is opposite to various studies, [12][13], [14], [15], [16] in which, fever was the most common AEFI.

In our study, most AEFIs, are mild i.e. 82.55% which is similar to a study done at BHU University [9]. There were no serious aefi reported in our study. This is in contrast to some studies where severe aefi were also reported. [9], [15].

Local symptoms were more reported as compared to systemic symptoms similar to Sathyapalan et al [10]. In contrast to certain studies, [9], [14], [15] in which systemic symptoms were more reported. Among systemic, fever is the most common symptom [9], [10], [12], [14], [15]. Among local symptoms, local pain is the most common symptom. [10].

LIMITATIONS:

There are certain limitations to our study. This study was done on a small group of people, so the result cannot be applied to a larger population. It was done on healthcare workers, therefore reporting bias is possible. Only active surveillance was used, so it could be possible that a few cases might be lost due to no passive surveillance. AEFI were recorded for only 7 days, and no long-term AEFI were recorded. No demographic data or any co-morbid situation already present in the participant was asked, therefore gender distribution and the effect of any co-morbid situation on AEFI are unknown.

CONCLUSION.

Our study was done to assess the AEFI post-Covishield vaccine. It was seen that no AEFI were reported immediately in 45 minutes. After 24 hrs local pain was the most common AEFI followed by fever. The majority of AEFIs are mild and no serious AEFIs were reported. Local symptoms are more common than systemic symptoms. Among local symptoms, local pain, and systemic symptoms, fever was the most common .so, it can be said that the vaccine was well tolerated and safe.

CONFLICT OF INTEREST- No conflict of interest.

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