International Journal of Pharmacological Research
ISSN: 2277-3312 (Online)
Journal DOI: https://doi.org/10.7439/ijpr **Original Research Article**

Study on adverse events in Health care workers receiving COVID Vaccine - An Observational study

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Abstract

Background: Vaccines used in vaccination program are considered safe and effective but immunization safety has become as important as the efficacy of vaccination program. The objective of the study was to detect Adverse Events Following Immunization (AEFIs) to inactivated COVID vaccine administered to a Health Care worker in Karnataka.
Methods: The prospective active vaccine safety surveillance study enrolled eligible Health Care workers (HCWs) in the age group 18–60 years receiving vaccination from the immunization centre at HIMS Hospital, Hassan. Study participants were monitored at the site for 30min following vaccination and a telephonic survey was made till 7 days to identify all AEFIs. Causality assessments of the AEFIs were done using a new algorithm developed by the safety and vigilance department of the World Health Organization (WHO).
Results: The incidence of reported AEFIs was 11.4% The most frequently reported AEFI within 1st 30minutes was vomiting [33%] and after 30 minutes was pain at injection site (n=26) with an incidence of 20.4% of vaccine administered, followed by fever (n=25, 19.6% of vaccine), headache (n=21) and giddiness (n=23 of vaccine). Consistent causal association to vaccination was observed in 93.4% of cases.
Conclusions: AEFIs observed among Health Care Workers (HCWs) were non-serious. Hence, inactivated COVID vaccine used in the Vaccine program were found to be safe. Similarly, active multi-centric studies will help to generate more safety data about the inactivated COVID vaccine. Understanding vaccine safety issues among HCWs provide feedback to concerns of vaccine safety, which will enable them to communicate effectively with the public to maintain their confidence/trust in vaccines.
Keywords: Inactivated COVID vaccine, safety active surveillance, adverse events following vaccination, AEFI, causality assessment of AEFIs.

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***Article History:**
Received: 16/08/2021
Revised: 22/09/2021
Accepted: 22/10/2021
DOI: https://doi.org/10.7439/ijpr.v11i10.5679

QR Code

How to cite: Karthik V, Deepak P, Chikkannanavar R, Anusha J, Krishnamoorthy VR, Sahana GN, Nagaral J.V, Raghu N and Manjula MJ. Study on adverse events in Health care workers receiving COVID Vaccine - An Observational study. *International Journal of Pharmacological Research* 2021; 11(10): e5679. Doi:10.7439/ijpr.v11i10.5679 Available from: https://ssjournals.com/index.php/ijpr/article/view/5679

1. Introduction

Severe Acute Respiratory Syndrome Coronavirus- 2 (SARS-CoV-2) is responsible for the global spread of Coronavirus Disease (COVID-19) which is a highly infectious causing mortality and morbidity worldwide. Henceforth, corona virus vaccine is implemented all over the world to prevent the spread of it [1].

Vaccines are urgently needed to contain the ongoing pandemic of SARS CoV-2[2]. Inactivated COVID vaccine is India's first indigenous, cold virion, inactivated vaccine developed by collaboration with Indian Medical Research Council (ICMR) and National Institute of Virology (NIV) for the treatment of highly infectious disease COVID 19. The

vaccine used along with immune stimulants, commonly known as vaccine adjuvants (Al Hydroxiquim-II), to improve the immune response and to produce longer lasting immunity. The Vaccine candidate is produced through the formulation of inactivated virus with Kansas – based vero vax Al Hydroxiquim-II adjuvant [3].

The prime target to developing vaccines is S protein of SARS COV-2 which can interfere with the virus resulting in neutralisation of the infection caused by the virus [4].

Vaccines made to be safe and well-tolerated, although they can cause temporary - local and systemic reactions related to the immunogenicity of the vaccine –this occur within a short time after vaccination, such as change in temperature, headache or sore arm[5].

Hence, the objective of the study was to evaluate incidence and Nature of AEFI among participants receiving inactivated COVID vaccine.

2. Methods

2.1 Study details and criteria

The study was an active surveillance study, carried out over a period of 2 months. The enrolment period was from Jan 16, 2021 to March 16, 2021, and the follow up period was completed on 26 March 2021. Ethical clearance was obtained from the Institutional Ethics Committee of HIMS, Hassan before starting the study. The study was conducted in the vaccination centre, Hassan Institute of Medical Sciences, teaching Hospital, Hassan, India. The study site functions 7days a week and receives vaccine supply through the District Health Office (DHO). Vaccines are administered on all 7days in the week. The study included all HCWs aged 18–60years receiving inactivated COVID vaccine from the vaccination centre, HCWs who have vaccinated with 1st dose of inactivated COVID vaccine or who have completed both the doses and who were willing to give informed consent. HCWs who have not been vaccinated and allergic to 1st dose of vaccine was excluded from the study.

2.2 Study procedure

Eligible HCWs were enrolled into the study after explaining the study procedure to the Healthcare workers and obtaining their written informed consent. All subjects were monitored in the waiting area of the immunization centre at the study site for the occurrence of any unsolicited systemic reactions for 30min following their vaccination. HCWs were provided with a validated patient information leaflet in the local language that had information on vaccination, possible AEFIs and the contact details of the study team. In case of any AEs, HCWs were advised to visit the study site or contact the study team at any time using a toll-free number for 30days following the vaccination. On day 8 following vaccination, a telephonic follow up was conducted with all the enrolled study population irrespective of whether the HCWs contacted the study team or not within the week following vaccination. The study team used a suitably designed case report form to collect the required data from the enrolled study population in case of an AE. The case report form had provision to document demographic details of the HCWs, allergic status, past medical history, and AE details.

The AEFI section of the case report form was developed based on WHO's AEFI core variables, and had provision to collect details of the vaccine, description of AEFI, date and time of start of AEFI, date and time of stop of AEFI, duration of the AEFI, severity, seriousness, details of medical attention sought due to AEFI, management of AEFI, outcome of the developed AEFI, details of the reporter, and a free space for any additional information. If any member of the study population visited the hospital for any reason within the active follow-up period of 7days, the information was collected from the hospital information system using their registration number at the hospital. Any further information required for the causality assessment of the AEFI was ascertained by making another phone call to the study participant wherever necessary.

3. Results

The total number of HCWs enrolled for the active surveillance of AEFI was 2935. Subject received the vaccine were 2058 and of the study included 920 male HCWs and 1138 female HCWs. Of 2058 HCWs, 127 AEFIs were reported from vaccinated subjects (Figure-1).

The incidence of reported AEFIs in our study was 11.4%. The incidence of AEFIs for the age of >18 to 44yrs was 6.9%, and for the ages between 45-60yrs, AEFI incidence was 4.5%. The details are presented in table 1.

Among the study participants with AEFIs, the no. of subject reported AEFIs within 1st 30 minutes was 21 HCWs (16.5%) and within 7 days after the vaccination reported AEFI was 106 (83.4%). (Table 2)

The most frequently reported AEFI within 1st 30 minutes was vomiting [33%], followed by headache [17%] and chills [10%]. Details of the reported AEFIs within 30 minutes are presented in figure 2.

The most commonly reported AEFI after 30 minutes to 7th day was pain at injection site [20.4% (n= 26)] among the HCWs in both 1st and 2nd dose. Second most common symptoms were fever [19.6% (n=25)]. Least common presentation was limb weakness [0.78% (n= 1)]. All HCWs recovered from the AEs. Details of the reported AEFIs after 30 minutes are presented in figure 3.

Figure 1: AEFIs report (vaccinated subjects)

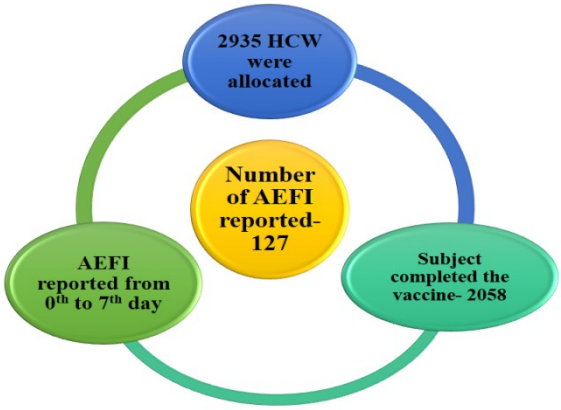

Figure 2: Details of the reported AEFIs within 30 minutes

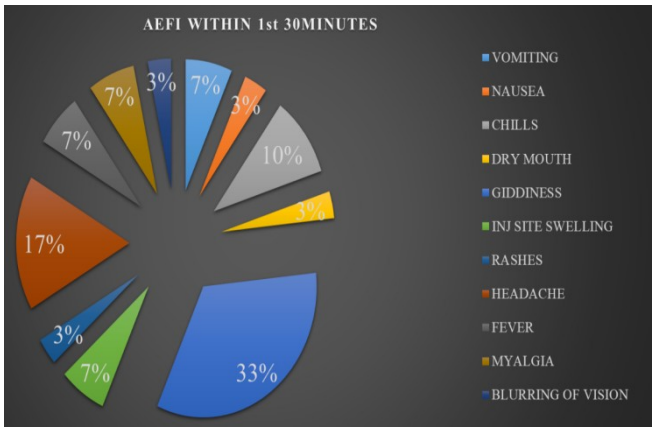

Figure 3: Details of the reported AEFIs after 30 minutes

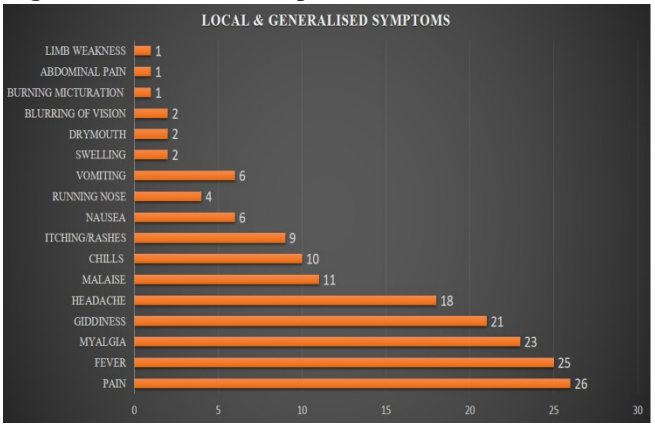

Table 1: Incidence of reported AEFIs in study

Demographic Data of AEFI Population			
Age	**Vaccinated**	**AEFI**	**Percentage**
>18 to 44 years	1372	96	6.9 %
45- 60 years	686	31	4.5 %
Sex			
Male	920	46	5.0 %
Female	1138	81	7.1 %
No. of Vaccine			
1st Dose	2058	108	5.2%
2nd Dose	2017	19	0.9 %

Table 2: Incidence of sudden & delayed onset AEFI

Onset of reaction	No. of subject reporting AEFI
<30 min	21
Within 7 days	106

3.1 Causality assessment of AEFI

The criteria for selecting cases for causality assessment using WHO's causality assessment algorithm are as follows: serious events; occurrence of events above the expected rate or of unusual severity; signals; AEFIs caused by immunization errors; significant events of unexplained cause occurring within 30days of immunization; events causing significant community concern. We tried to assess the causality of all the reported events using the algorithm irrespective of the above-mentioned criteria; 93.4% of the reported AEFIs had consistent causal association to Vaccination and 0.9% of the events had indeterminate causal relationship with vaccines.

Events were assessed as indeterminate, as the temporal relationship was consistent but there was insufficient definitive evidence for the vaccines causing the event. The majority of AEFIs were minor or severe but not serious in severity, but 9 reactions were serious in nature and the affected HCWs were hospitalized. There was no death following vaccination and during the causality assessment. There was no need for any medical attention in 97.0% of cases and all HCWs recovered from AEFI within 1–2days of occurrence. Remaining doses of vaccines were discontinued for the serious AEFIs.

4. Discussion

The overall incidence of AEFI in our study was found to be 11.4% among the vaccinated beneficiaries. Further, we observed that the incidence of AEFIs were relatively high among females being 7.1% when compared to males 5.0%. Among the study participants with AEFIs, the no. of subject reported AEFIs within 1st 30 minutes was 21 HCWs (16.5%) and within 7 days after the vaccination reported AEFI was about 106 (83.4%).

The most frequently reported AEFI within 1st 30 minutes was vomiting [33%], followed by headache [17%] and chills [10%] which might be probably due to anxiety induced.

The most commonly reported AEFI after 30 minutes to 7th day was pain at injection site [20.4% (n= 26)] among the HCWs in both 1st and 2nd dose – which may probably be due to the presence of adjuvant Al Hydroxiquim-II. Second most common symptoms was fever [19.6% (n=25)]- may be due to immunogenic response produced by inactivated vaccine.

Least common presentation was limb weakness [0.78% (n= 1)] which might be due to inappropriate injection technique. The training and experience of HCWs involved in immunization programs are important in preventing immunization error-related reactions, as reflected in this study. All HCWs recovered from the AEs.

5. Limitation

Since, the study was single centric and had a smaller sample size we could not assess AEs in the larger population. The number of reported AEFI; may not match with the actual AEFI data which was collected from HCWs through telephonic follow up.

6. Conclusion

AEFIs observed among Health Care Workers were non-serious. Hence, inactivated COVID vaccine used in the Vaccine program were found to be safe. Similarly, active multi-centric studies will help to generate more safety data about the inactivated COVID vaccine.

Understanding vaccine safety issues among HCWs provide feedback to concerns of vaccine safety, which will enable them to communicate effectively with the public to maintain their confidence/trust in vaccines

Acknowledgements

The author would like to thank his guide Dr. Deepak P for his supervision and reviewing the manuscript; also, very grateful to my colleagues Dr. Sahana GN, Dr. Jayashree VN and Dr. Priyanka Anbazhagan for their help in writing the manuscript. This observational study did not receive any specific grant from funding agencies in public, commercial, or not-for-profit sectors.

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