Section: Pharmacology

Original Research Article

EVALUATION OF ADVERSE DRUG REACTIONS FOLLOWING COVID-19 VACCINATIONS IN A TERTIARY CARE TEACHING HOSPITAL AT DEHRADUN

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Abstract

Background: It is crucial to establish the safety of COVID vaccines since many vaccines were granted emergency approval in order to combat the COVID-19 pandemic which had immobilized the entire world. The study was conducted with the objective of evaluating the various adverse events following COVID-19 vaccine administration in a tertiary care teaching hospital at Dehradun. We aim at evaluation of the adverse drug reactions occurring following the COVID-19 vaccination in a tertiary care center. **Materials and Methods:** The descriptive study was conducted at the ADR Monitoring centre (AMC) of SGRRIM&HS for one year after obtaining approval from the Institutional Ethics Committee. COVID vaccine recipients were actively followed up by contacting them over their registered mobile number for Adverse Event Following Immunization (AEFI) if any, within 24 hours of getting vaccinated. The ADR reports were filled in suspected adverse drug reaction reporting form version 1.4, and Causality assessment was done as per the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. **Result:** 296 AEFIs were reported in 270 recipients of either Covishield or Covaxin within 24 hours of getting administered. 130(48.15%) were males and 140(51.85%) females. The most common age groups reporting AEFIs were 18-35 years with a total of 91(33.7%) recipients and 90(33.3%) in 36-50 years age group. Injection site pain was the most common AEFI in 128(43.24%) recipients followed by fever in 93(31.43%) recipients. 56.3% AEFIs were reported after 1st dose of vaccination in our study. All the AEFIs were non-serious and of probable type according to WHO causality assessment scale. **Conclusion:** Since limited data is available on AEFI for the approved COVID-19 vaccines in India, long term follow up studies are needed to understand the safety of these vaccines in multiple age groups and with comorbid conditions.

INTRODUCTION

The emergence of COVID-19 pandemic had burdened the health professionals globally and led to paralysis of health care systems and worldwide economic crisis.[1] In order to surmount this global pandemic; researchers, healthcare professionals and policymakers around the world were under a huge pressure to deliver adequate preventive and treatment modalities. From the initial stage of COVID-19 infection, scientists were focused on either repurposing the existing drugs or developing vaccines against it.[2] The public health emergency required efforts to test the efficacy and safety of vaccines to combat the COVID-19 pandemic.[3] By January 2021, emergency approval was granted to nine vaccines by regulatory authorities in different parts of the globe.[4]

In India at present twelve vaccines have been granted approval for use that are categorized as 2 protein subunit vaccines which include COVOVAX by Serum Institute of India and Corbevax by Biological

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E Limited, 2 RNA vaccines (Spikevax by Moderna and Gemcovac-19 by Gennova Biopharmaceutical Ltd), 1 DNA vaccine (ZyCoV-D by Zydus Cadila), 6 non replicating viral vector vaccines (Sputnik Light and Sputnik V by Gamaleya, J covden by Johnson & Johnson, Incovacc by Bharat Biotec, Vaxzevria by Oxford/AstraZeneca, Covishield (Oxford/ AstraZeneca formulation) by Serum Institute of India and 1 inactivated vaccine Covaxin by Bharat Biotech.[5]

Billions of doses of vaccine have been administered worldwide.[3] However, some individuals have concerns about receiving COVID-19 vaccination related to vaccine safety and adverse effects 6. COVID-19 vaccine safety implications need to be considered in the novelty of the vaccines developed and used. At present, it is very crucial to establish the safety of the COVID-19 vaccines when emergency approval is being granted to these vaccines without completion of all phases of clinical trials. COO

Hence, the aim of this study was to evaluate the various adverse events following COVID-19 vaccine administration in different age groups at a tertiary care teaching hospital in Dehradun, Uttarakhand.

MATERIALS AND METHODS

This descriptive study was conducted at the ADR Monitoring center (AMC) of SGRRIM&HS for a period of one year from August 2021 to July 2022 after obtaining approval from the Institutional Ethics Committee. As per the guidelines provided to AMC by NCC, PVPI, COVID vaccine recipients were actively followed up by contacting them over their registered mobile number for Adverse Event Following Immunization (AEFI) if any, within 24 hours of getting vaccinated. The recipients had been vaccinated by either 1st dose, 2nd dose or the booster dose of Covishield vaccine or Covaxin. The ADR reports were filled in suspected adverse drug reaction reporting form version 1.4, checked for their completeness and Causality assessment was done as per the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. All these reports were submitted to NCC, PvPI in a timely manner by entering into VigiFlow, a web-based individual case safety report management system, provided by NCC, PvPI to all AMCs.[7]

RESULTS

During the study period, 2700 people were vaccinated with either Covishield or Covaxin in the tertiary care centre of SGRRIM&HS. A total of 270 recipients of Covishield or Covaxin had reported AEFIs within 24 hours of receiving the either vaccine. 233(86.3%) recipients were vaccinated with Covishield vaccine and 37(13.7%) recipients were given Covaxin.

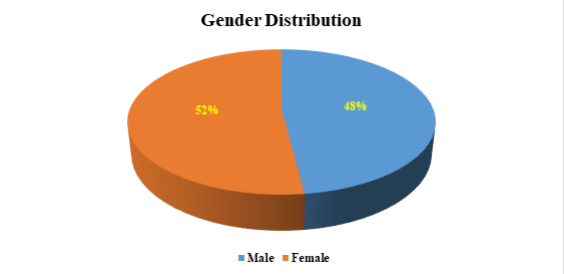

Figure 1: Gender Distribution of vaccine recipients

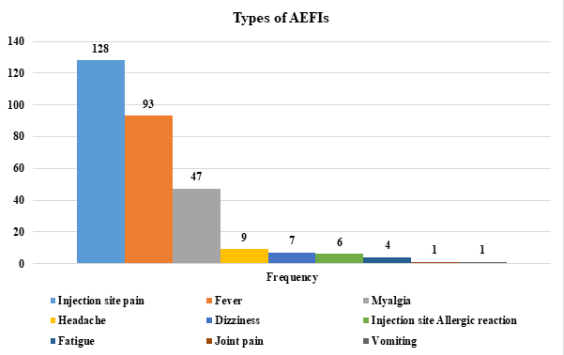

Figure 2: Types of AEFIs

Table 1: Age -wise distribution

Age	Number(%age)
<18 years	47(17.4%)
18-35 years	91(33.7%)
36-50 years	90(33.3%)
51-65 years	27(10%)
>65years	15(5.6%)

The ADR reports were analyzed and evaluated at the ADR monitoring centre of SGRRIM&HS. Out of 270 recipients, 130(48.15%) were males and 140(51.85%) females. The age group of recipients was divided in the following categories; <18 year (since the vaccines were approved only in 12 and above age group at the time of study) which included 47(17.4%) recipients, 18-35 years with 91(33.7%) recipients, 90(33.3%) in 36-50 years, 27(10%) in 51-65 year age group and 15(5.6%) in >65 year age group. 152(56.3%) people reported the AEFIs with 1st dose followed by 92(34.1%) with 2nd dose and 26(9.6%) with booster dose of the vaccine. A total of 296 AEFIs were reported in 270 people vaccinated with either Covishield or Covaxin. 128(43.24%) Injection site pain was the most common AEFI; followed by 93(31.43%) fever; 47(15.9%) myalgia; 9(3.04%) headache; 7(2.42%) dizziness; 6(2.02%) injection site allergic reaction; 4(1.35%)fatigue; 1(0.34%) joint pain and vomiting each. Recovery was

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seen in 150 (55.6%) recipients and 120(44.6%) had not recovered at the time of reporting. Medical intervention was done in 154(57%) recipients and 116(43%) did not require any medical treatment. All the reported events were of non-serious type. Causality assessment done as per WHO-UMC scale showed that all the reported events were probably related to vaccination. All the events were reported with reasonable time duration, and unlikely attributable to any other diseases.

DISCUSSION

This is a descriptive study of reported AEFI submitted by AMC of the institute to National Co-ordinating Centre, PvPI, India. A total of 296 AEFI reported from 270 vaccine recipients of either Covishield or Covaxin. Out of 270 recipients, 130(48.15%) were males and 140(51.85%) females [Figure 1]. This indicates that more AEFIs are reported in females. This was similar to another study by Konda et al. in which more AEFI were reported by females as compared to males.[8] Clinical trials conducted in the United Kingdom, Brazil and South Africa which studied the safety and efficacy of Covishield vaccine also showed more female participants.[9] On the other hand, in a study by Polack et al., male predominance was observed as compared to females.[10] Further research must be done to assess the cause for the gender variation in reporting AEFIs. In our study 33.7% of AEFIs were reported in 18-35 year age group followed by 33.3% in 36-50 year age group and 17.4% in <18 year age group. 10% AEFIs were reported in 51-65 year age group and only 5.6% AEFIs were reported in >65 year old elderly people [Table 2]. Other studies have also shown that AEFIs were more frequently reported in ≤ 50 year age group than in >65 year elderly people.[10,11] However the reason for this is not known and more studies are needed to confirm the findings of our study.

Amongst 296 AEFIs reported, 43.24%, 31.43% and 15.9% were injection site pain, fever and myalgia respectively [Figure 2]. A study by Polack et al also showed that injection site pain was the most commonly reported AEFI. In another study, fever was the most frequently reported AEFI 8. In our study 56.3% AEFIs were reported after 1st dose of vaccination. Similar observations of more number of AEFI after first dose were noted from clinical trials.[9,11] A study by Konda et al also showed that majority AEFIs were observed after the first dose. But as per a study by Ella et al., there was no correlation between the dose of vaccine and the number of adverse events reported.[12] In contrast, data from clinical trials involving mRNA based vaccines showed that more AEFI were reported following second dose compared to that reported after first dose.[13,14]

All the AEFIs were non-serious and were of probable type according to WHO UMC causality assessment scale. This was similar to the study by Konda et al.[8] The study had few limitations. All the AEFIs were reported within 24 hours as the recipients were contacted telephonically after getting vaccinated. Any AEFI which occurred beyond the follow up period of AMC personnel might have been missed from being reported. Since the vaccinated recipients were contacted only via telephonic conversation, there is a possibility that few AEFIs may not have been reported. The data on comorbid conditions and any previous medication history was also not obtained and so the exact correlation of AEFI with disease or drugs could not be established.

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We are grateful to all the recipients of COVID-19 vaccines who promptly reported AEFIs.

CONCLUSION

In our study, we conclude that most commonly reported AEFIs were pain at injection site, fever and myalgia. All the AEFIs were non-serious. More AEFIs were reported after the first dose of vaccination and in <51 year age group. Since limited data is available on AEFI for the approved COVID-19 vaccines in India, long term follow up studies are needed to understand the safety of these vaccines in multiple age groups and with comorbid conditions.

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