REVIEW ARTICLE

The Prevalence of COVID Infection and Adverse Events Following Immunization with COVID-19 Vaccine (Covishield) Among Healthcare Workers and Students of a Dental College in Kerala: A Cross-sectional Study

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Abstract

Background: Any untoward event following immunization without essentially having a cause-and-effect relationship with usage of vaccine is an "Adverse Event Following Immunization (AEFI)." The study aimed at evaluating adverse events experienced by healthcare workers (HCWs) and students of a dental college, following immunization AEFI, with at least one dose of Covishield vaccine developed by Oxford University and AstraZeneca. The association of AEFI across various sex and age groups was also assessed.

Methods: A cross-sectional survey was conducted online among coronavirus disease-2019 (COVID-19)-vaccinated teaching staff, postgraduate students, interns, undergraduate students, and nonteaching staff of a dental college. The common AEFI, post-vaccination activities, and demographic characteristics were collected from respondents using a questionnaire. The effect of host-related factors on 14 specific symptoms of AEFI was also assessed.

Results: After screening, those above 18 years old and received minimum dose of Covishield, 240 participants were included in the study from the dental college. Only 72/240 (30%) participants did not report any AEFI, whereas 11/240 (4.6%) had symptoms of severe intensity. The commonest AEFI reported were moderate weakness (60.8%), pain at the injection site (60.8%), followed by fever (60%), body ache (10.7%), nausea (6.7%), headache (5.8%), chills (5%), and vomiting (1.7%). Females experienced more AEFI than males, particularly gastrointestinal symptoms. The participant's age and number of doses taken affected AEFI. A decrease in self-reported AEFI was associated with increasing age or number of vaccine doses. There is a significant association of AEFI with age of the participants ($p < 0.01$).

Conclusions: In the first 48 hours, AEFI was mostly observed. In the following weeks, the incidence decreased, with no AEFI reported after 15 days following both doses. Adverse events following immunization reported were mild and short-lived. No serious incidents were reported. We have assessed risk factors related to AEFI in participants vaccinated with Covishield. The important factors affecting AEFI are gender, age, and vaccine doses in this study.

Keywords: Adverse events following immunization, Adverse events following vaccination, Coronavirus disease-2019 vaccines.

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Introduction

Coronavirus disease-2019 pandemic has increased morbidity and mortality thus seriously affecting populations and economies.[1,2] Nations are attempting to prevent the spread of COVID-19 with the imposition of measures like vaccination, social distancing, facemasks, quarantine, and lockdowns.[3–5] The disability of physical and psychosocial well-being of people has resulted in economic decline.[6,7] Following vaccination, adverse events will occur occasionally. Vaccinations done under national immunization programs (NIPs) are considered safe and effective.[8] Public trust in vaccine safety increases the benefits of vaccination programs.

The most dominant reason for self-vaccination hesitancy among healthcare professionals is the safety concerns. World Health Organization (WHO) experts and scientists from around the world conduct ongoing monitoring to make sure that vaccines continue to be safe. This helped to understand everyone's role in monitoring and responding to vaccine safety issues and adverse events following COVID-19 vaccination. The unexpected rapid development of the COVID-19 vaccines on novel platforms followed by its rapid distribution on a mass scale poses several challenges in covering vaccine safety.[9] Timely reporting and determination of adverse events following COVID-19 vaccination is the initial step in ensuring the continued safety of the vaccine.[10,11] Surveillance systems need to be ready for identifying and acknowledging AEFI.

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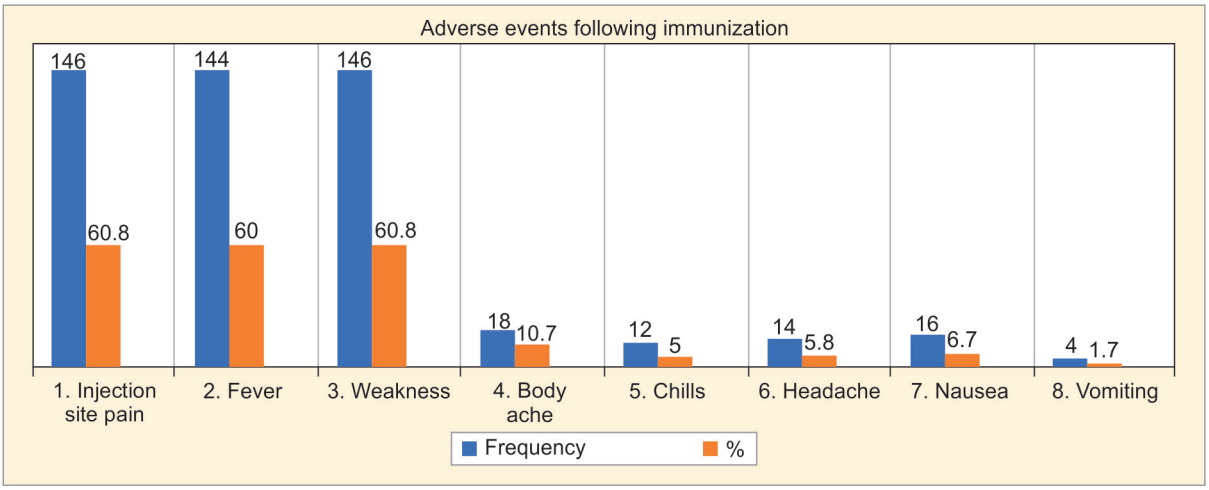

Fig. 1: Frequency distribution of adverse events following immunization

We assessed the AEFI of Covishield in the dental college through an online cross-sectional survey. We assessed how AEFI with Covishield vaccines was influenced by gender, age, vaccine doses, and postvaccination activities. This would help us falsify rumors on AEFI hindering mass immunization programs.[12,13]

Public concerns about vaccine safety can be answered by several research questions like:

- What caused the response?
- Was it related to the vaccine or the way it was administered?
- Are the responses severe?

Aim

To evaluate the adverse events following COVID-19 vaccination among the HCWs and students of a dental college in Kerala.

Methods

After taking clearance from the Institutional Ethics Committee, an anonymous online check using Google forms were circulated among all teaching faculty members, postgraduates, interns, undergraduates, and nonteaching staff of dental college.

In the study, the people who had taken minimum one dose of COVID-19 vaccine and willing to participate were only included. Informed consent was collected from the participants. Data were collected using a prevalidated self-reported questionnaire in the electronic format.[14,15] A questionnaire was prepared on the adverse events following Covishield vaccine. The gender, age, underlying conditions, number of vaccine doses administered,[14] specific symptoms with their initial appearance, and disappearance time after vaccination were included in the questionnaire.[16] Fever, blood pressure changes, body ache, edema, respiratory, and digestive symptoms were the symptoms to be reported.[17,18] Using a self-rating question, the severity of symptoms was also collected. Responses from adults of dental college those above 18 years old and who received minimum dose of Covishield and responded to all necessary questions in the questionnaire appropriately were selected for data analysis. Using universal sampling method, a total of 240 recipients were enrolled.

Statistical Analysis

Microsoft Excel was used to select the participants from the collected response who are adults above 18 years and received minimum one dose of Covishield. Descriptive statistics and hypothesis tests were used to investigate the effects of host-related factors that included gender, age, and number of Covishield vaccine doses on self-reported AEFI. The statistical analysis was done using SPSS software. A counting tool was used to obtain the number of appearances of each symptom. The proportion was calculated by dividing the number of symptoms by the total responses in each group of a factor. The data were analyzed in the form of frequency, percentage, mean, and standard deviation, and to assess the risk factors Chi-square test was used. The hypothesis *z* test was applied for factors having two groups, including gender (males vs females), underlying condition (with vs without), and number of vaccine doses (one vs two).

Results

In our study, 240 individuals, with a mean age of 25.18 + 5.9, participated. All the individuals have taken at least one dose of Covishield vaccine. The study consisted of 196 (81.7%) females and 44 (18.3%) males. A history of at least a family member contacting COVID-19 disease was seen in a total of 114 (47.5%) people. A total of 44 people (18.3%) had a history of COVID-19 disease. A total of 144 people (60%) had anxiety regarding safety issues before taking the vaccine. About 168 of them (70%) had AEFI with COVID-19 vaccine. About 72 people (30%) did not experience any AEFI.

As shown in Figure 1, 60.8% (146) had injection site pain after COVID-19 vaccination and 39.2% (94) did not have injection site pain. About 60% (144) of them had fever after immunization and 40% (96) did not have fever. About 60.8% (146) people who took the vaccine had weakness after immunization. About 10.7% (18) people experienced body ache following immunization. About 5% (12) of the individuals had chills after vaccination and 46.5% (60) of them did not have any chills after vaccination. About 5.8% (14) of the individuals had headache after vaccination with COVID-19 vaccine. About 6.7% (16) of individuals had nausea after vaccination. Only 1.7% (4) of the individuals had vomiting following vaccination. About 66.7% (160) of the people had taken Paracetamol for the adverse effects and 3.3% (8) did not take it. In 57.5% (138) of the individuals, the symptoms subsided after the intake of Paracetamol. About 4.2% (10) of the individuals took other analgesics along with Paracetamol because their symptoms did not subside with it. Some of them had severe adverse effects. Only 11 individuals had severe adverse events: dizziness and weakness (6, 2.5%), difficulty

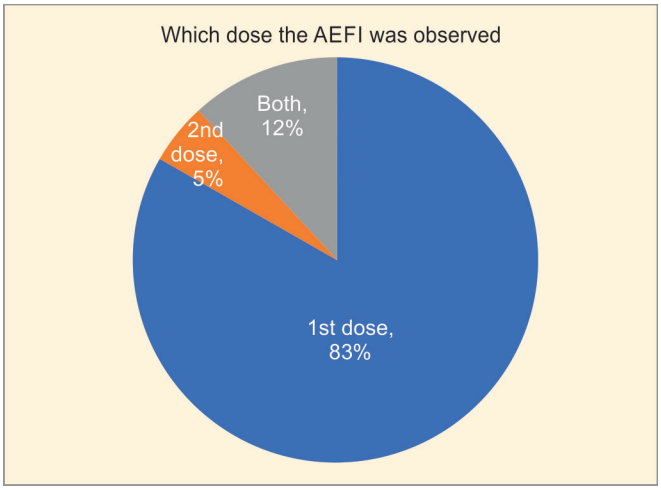

Fig. 2: The dose after which AEFI was observed

in breathing (2, 0.8%), and fast heartbeat (4, 1.7%). About 5% (12) of the individuals were hospitalized for severe AEFI with COVID-19 vaccine. Only 7.5% (18) of the individuals reported these AEFI with COVID-19 vaccine to the nodal officer and 62.5% (150) did not report the adverse effects.

The dose after which AEFI occurred was also included in the study. As shown in Figure 2, 83% of the participants had AEFI after the first dose, 5% had after the second dose, and 12% had AEFI after the first and second doses.

Discussion

The question design options were limited since the survey was conducted using free online Google form. In addition, a questionnaire was released through WhatsApp, hence, the study population was restricted to people who have internet access.[19] To have more respondents to the survey, the number of questions was reduced and simplified, which might have resulted in loss of some intricate information. The reported symptoms may not be fully correct if the participant filled the survey form long after vaccination.[20] Despite these limitations in data collection, this study can bring about significant results in a short time by applying a simple, economical, and contactless method.

As Covishield has been used as the principal vaccine, AEFI data have been updated and reported regularly by government agencies in developed countries and in several scientific publications. These agree with the results of our study that showed that most reported AEFI were fever, body pain, weakness, headache, and pain at the injection site. However, we had higher proportions for these symptoms. Like previous studies, most AEFIs were not severe and resolved within a few days after vaccination. Our results were similar with the majority of AEFI reported being mild and moderate.[8,9]

While other studies showed life-threatening cases that required intensive care treatment and hospital admissions, the incidence of serious events and permanent disability was comparatively lower in our study.[20,21]

In this study, regarding host-related factors, gender, age, and number of vaccine doses showed the most significant effect on self-reported AEFI.[8,9] This agrees with earlier studies. Like other published data, our data observed that AEFI of Covishield was reported more common in females compared with males, in younger adults compared with older ones, and in the first dose compared with the second dose. Females experienced more AEFI than males, particularly gastrointestinal symptoms. Further, clinical studies are necessary to have a better understanding of COVID vaccine.

Conclusion

The new COVID vaccine hesitancy and disinformation among the population on AEFI are hindering mass immunization programs.[20] This study helped to find out public concerns about new COVID vaccine safety, thereby helping in enhancing vaccine uptake and avoiding hesitancy among the population.

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