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# A STUDY ON ADVERSE EVENTS FOLLOWING IMMUNIZATION RELATED TO COVISHIELD VACCINE WITHIN 28 DAYS AMONG GENERAL POPULATION IN NORTHERN KERALA

Community Medicine

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## ABSTRACT

**Background:** The declaration of COVID-19 as a pandemic was followed by a race for development of a vaccine against it. Covishield was one of the vaccines approved and successfully rolled out in many countries, including India, even before its phase III clinical trials were over. This study was done to determine the pattern of AEFI of Covishield vaccine. **Methods:** ACross-sectional study was conducted at a designated government vaccination site in Kannur District. 100 individuals above 18 years of age who had received both doses of vaccine were selected using simple random sampling. Data collected using a semi-structured questionnaire through phone interviews of the participants was analyzed using descriptive statistical analysis. **Results:** The mean age of the study population was 47.37±11.9 years. 79% and 26% of individuals had experienced some form of AEFI after the 1st and 2nddose of vaccine respectively. The common AEFI reported include fever, local tenderness, malaise and headache.More number of younger participants(<45 yrs) reported AEFI after first dose, with a significant association between AEFI after 1st dose and age. **Conclusion:** Only minor AEFI were reported after each dose, with AEFI reported more commonly after the first dose than the second dose.There was a statistically significant association between the age of the participants and AEFI after 1st dose, with more AEFI being reported by individuals who were <45 years old. No such association was found between age and AEFI after the 2nddose of vaccine. Gender and comorbidity were not found to have any association with the reporting of AEFI.

## KEYWORDS

COVID-19, Covishield, vaccine, AEFI

## INTRODUCTION

The World Health Organization (WHO) declared COVID-19 as a pandemic on March 12, 2020. The virus has affected every country across the world. To halt its spread, herd immunity gained by infection/vaccination needs to be established. The most logical solution is to vaccinate a large proportion of the population.(1) Presently, a few vaccines have been approved and rolled out worldwide on an emergency basis.

On 3 January 2021 India's top drug regulator issued emergency approval for two vaccines for restricted use against COVID-19, although phase III clinical trials for Covishield and Covaxin were still ongoing in India.(2)Along with the rest of the nation, Kerala also successfully rolled out COVID-19 vaccination on 16th January 2021. In the first phase, vaccine was administered to healthcare workers and front-line workers.

In the next phase, from March 1st 2021 onwards, the vaccination campaign was extended to senior citizens (above 60years) and individuals above 45years who satisfied the eligibility criteria. Later eligibility was extended to all individuals >45years of age. From May 1st 2021, everyone above 18years of age became eligible to receive Covid-19 vaccine.(3)

An adverse event following immunization (AEFI) is defined as any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.(4)

This study aims to understand the pattern of AEFI associated with Covishield vaccine among the general population above 18 years of age vaccinated at a tertiary care centre in Northern Kerala, thus intended to add to the currently building up knowledge pool regarding the same.

The primary objective of this study was to determine the pattern of AEFI after the first and second dose of COVISHIELD respectively. The secondary objectives were to compare the patterns between the two doses and to find associations between AEFI and selected socio-demographic characteristics.

## METHODOLOGY:

A Cross-sectional study was done at Government medical college Kannur, a designated vaccination site for COVID-19.Vaccination sessions for the general population in our institution began on March 27th 2021. Our study population consisted of general population above 18 years of age who took both doses of COVISHIELD vaccine. Study was carried out for a six month period.

Sample size was calculated as 100 using the formula $4pq/d^2$, where p= 2.3% and d (absolute precision) was taken as 3% at 95% confidence interval.(5)

### Sampling method:

A list of individuals who had completed the second dose of vaccination between May 1st and September 30th 2021 was obtained.100 individuals were selected from this list by simple random sampling. They were contacted 28 days after their second dose.Whenever an individual could not be contacted, the next individual in the list was included.

### Study materials and tools:

Data was collected using a semi-structured questionnaire over a phone interview of the participant. The questionnaire included socio-demographic variables, co-morbidity, details of AEFI, source of information and apprehension regarding vaccination.

### Statistical Analysis:

Descriptive statistical analysis was done. The association between AEFI and selected variables was analyzed. Results were expressed in frequencies and percentages.

## RESULT:

The study was conducted among 100 individuals who received both doses of the Covishield vaccine.

**Table 1. Age And Gender Wise Distribution Of Study Participants (n=100)**

| Age group (years) | Percentage (%) |
|---|---|
| 25-40 | 21 |

| | |
|---|---|
| 40-55 | 51 |
| ≥55 | 28 |
| Gender | Percentage (%) |
| Male | 51 |
| Female | 49 |

Table 1 shows the age and gender distribution of the study participants. The age of the participants ranged from 26 years to 74 years. The mean age of the study population was found to be 47.37± 11.9 years.

**Table 2. Distribution Of Comorbidities Among The Population**

| COMORBIDITY | PERCENTAGE (%) |
|---|---|
| Diabetes mellitus | 22 |
| Hypertension | 18 |
| Dyslipidemia | 12 |
| Bronchial asthma | 7 |
| CAD | 6 |
| Others | 13 |

*Not mutually exclusive

42% of the study participants reported having comorbidities. Table 2 shows the distribution of the study participants based on the types of comorbidities.

Among the 100 participants who received both doses of vaccine, 79 of them had experienced some form of AEFI after the 1st dose of vaccine. Only 26 people had experienced AEFI after the 2nd dose of vaccine.

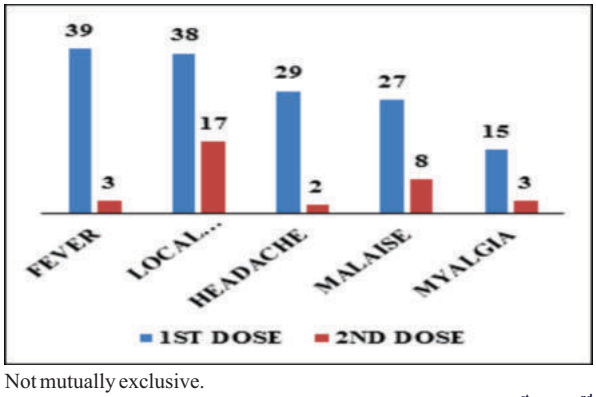


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**Fig 1. Pattern Of Aefi Reported By Participants After 1st and 2nd Dose Of Vaccine**

The most common AEFIs reported after the 1st dose were fever (39), closely followed by local tenderness at the site of injection (38)(Fig. 1). Following the 2nd dose, local tenderness at the injection site was the most common AEFI that has been reported, followed by malaise(Fig.1).

The onset of all AEFI that were reported after 1st dose of vaccination was within 48 hours of receiving the vaccine.Likewise, all the AEFI were reported within 48 hours of taking the 2nd dose vaccine, except one case who had reported local tenderness at the site of the injection, which had started after 72 hours of taking the 2nd dose.Fig.2 & 3 shows the mean duration of the common AEFIs following the first and second doses respectively. None of the participants reported severe or serious AEFI after the 1st and 2nd doses.

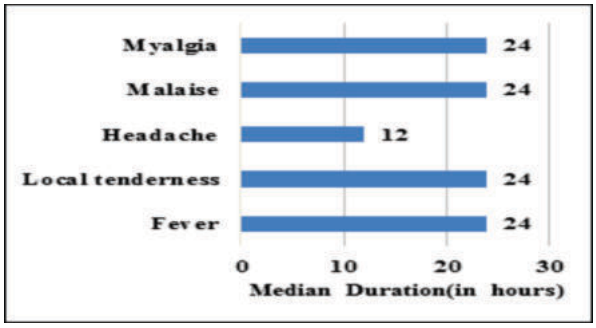


**Fig 2: Median Duration Of The Common Aefi After 1st Dose**

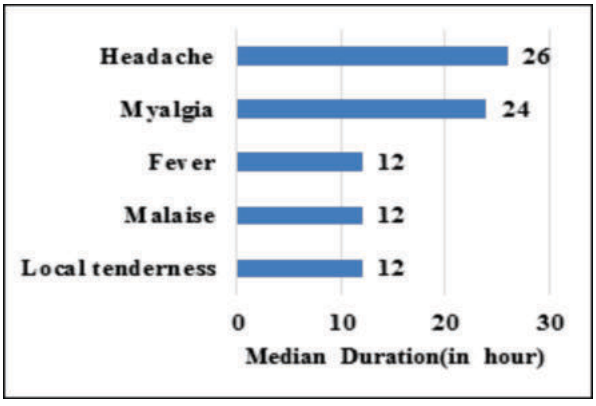


**Fig 3: Median Duration Of The Common Aefi After 2nd Dose**

None of the participants required hospitalization for their AEFI after the1st and 2nd dose vaccine.

**Table 3: Association Between Aefi After Each Dose And Selected Socio-demographic Characteristics**

| AEFI following 1st dose | | | | |
|---|---|---|---|---|
| Age (yrs) | Noted AEFI (%) | No AEFI noted (%) | OR (CI) | P-value* |
| <45 | 51(89.5) | 6(10.5) | 4.55 (1.59-13.05) | 0.005 |
| ≥45 | 28(65.1) | 15(34.9) | | |
| Gender | | | | |
| Male | 38(74.5) | 13(24.5) | 0.57 (0.21- 1.53) | 0.26 |
| Female | 41(83.7) | 8(16.3) | | |
| AEFI following 2nddose | | | | |
| Age (yrs) | Noted AEFI (%) | No AEFI noted (%) | OR (CI) | P-value* |
| <45 | 18(31.6) | 39(68.4) | 2.02 (0.78 - 5.22) | 2.14 |
| ≥45 | 8(18.6) | 35(81.4) | | |
| Gender | | | | |
| Male | 11(21.6) | 40(78.4) | 0.62 (0.25 - 1.54) | 1.06 |
| Female | 15(30.6) | 34(69.4) | | |

*significant at $p < 0.05$

Table 3 shows, after receiving first dose, 51(89.5%) of the participants who were less than 45 years old reported AEFI while only 28(65.1%) of those above or equal to 45 years reported. This difference was found to be statistically significant [$\chi 2=8.7651$ at $p < 0.05$]. Participants less than 45 years had 4.55 times more risk of AEFI than participants. Gender, however, did not have any significant association with the reporting of AEFI.

Age and gender did not have a significant association with the incidence of AEFI after the 2nd dose.

**Table 4: Association Between Aefi After Each Dose And Comorbidities**

| Co-morbidity | Noted AEFI (%) | No AEFI noted (%) | OR (CI) | P-value* |
|---|---|---|---|---|
| FOLLOWING FIRST DOSE | | | | |
| Present | 32(76.2) | 10(23.8) | 0.75 (0.28-1.97) | 0.34 |
| Absent | 47(81.1) | 11(18.9) | | |
| Co-morbidity | Noted AEFI (%) | No AEFI noted (%) | OR (CI) | P-value* |
| FOLLOWING SECOND DOSE | | | | |
| Present | 12(28.6) | 30(71.4) | 1.26 (0.51-3.09) | 0.25 |
| Absent | 14(24.1) | 44(75.9) | | |

*significant at $p < 0.05$

A total of 32(76.2%) of participants with comorbidities reported AEFI after receiving first dose while 47(81.1%) of those without comorbidities reported the same (Table 4).

This difference is not statistically significant. 12(28.6%) of participants with comorbidities reported AEFI after receiving second dose while 14(24.1%) of those without comorbidities reported the same. This difference is not statistically significant.

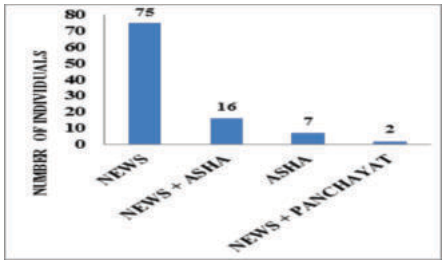


**Fig 4: Source Of Information Regarding Vaccine (n=100)**

Fig. 4 shows that News was the major source of information regarding the vaccine among the study population.

A total of 28(28%) participants reported that they were apprehensive of taking the first dose of vaccine. None of them were apprehensive before taking the second dose.Of the 28 participants who were apprehensive,23(82.1%) gave reason that they feared severe side effects after taking the vaccine while 5(17.9%) said they were worried regarding the worsening of their pre-existing comorbidities.

**Table 5: Association Between Apprehension Before The First Dose And Reporting Aefi**

| Apprehensive before 1st dose | AEFI noted | No AEFI noted | OR (CI) | p-value* |
|---|---|---|---|---|
| Yes | 24 (85.7) | 4 (14.3) | 1.85 (0.56 – 6.09) | 0.31 |
| No | 55 (76.4) | 17 (23.6) | | |

*significant at $p < 0.05$

No significant difference in reporting of AEFI after 1st dose was seen between participants who were apprehensive regarding taking vaccine before the 1st dose and those who weren't (Table 5).

## DISCUSSION:

Our study was conducted among 100 individuals who received both doses of Covishield vaccine.

In our study, the mean age of the study population was 47.37± 11.9 years, with age ranging between 26 – 74 years. In a study which was conducted among healthcare workers of Government owned medical colleges in Kerala, the mean age of the participants was 30 ± 11.3years ranging between 18- 68 years, which is slightly lower compared to ours. In the same study, the proportion of females was found to be higher (71%) than in our study, where it was 49%.(6)

In the above mentioned study, it was found that 63.3% respondents & 24.3% of participants reported AEFI after the first and second dose respectively. This was similar to our study where 79% of respondents reported AEFI after the 1st dose and 26% after the 2nd dose.(6)

In our study, the most common AEFI reported after 1st dose of vaccine was fever (39%) and local tenderness (38%). This was similar to a study conducted in Nepal, where the common AEFI reported were pain at the injection site (55%) and fever (37.1%).(7)

In the majority of participants of our study (83%), the AEFI reported after 1st dose vaccine lasted for ≤24 hours. This was in contrast to the study conducted in Nepal, where the majority of people had resolution of AEFI symptoms beyond 24 hours.(7)

In our study, we did not find any significant association between gender and AEFI. However, in a study conducted by Remlabeevi A et al, a significant association was observed between gender and occurrence of AEFI, with females having higher incidence of AEFI after 1st dose of vaccine.(6)

Preexisting comorbidities did not have a significant association with the incidence of AEFI after 1st and 2nd dose vaccines. A similar finding was obtained in the study conducted among healthcare workers of government owned medical colleges in Kerala.(6)

It was observed in our study that after obtaining the 1st dose of vaccine 89.5% of the participants who were less than 45 years old reported AEFI, while only 65.1% of those above 45 years had reported incidence of AEFI. This was in contrast to the results obtained from a prospective observational study, where a significant association between age and AEFI was found, with the incidence of AEFI being higher in the older age group (>50 years).(8)

News was the major source of information regarding the vaccine among the study population. Also, 28% of participants reported being apprehensive prior to receiving the first dose of vaccine, the main reason being fear of side effects.

## CONCLUSION:

In our study, only minor AEFI were reported after each dose, with AEFI reported more commonly after the first dose than the second dose.There was a statistically significant association between the age of the participants and AEFI after 1st dose, with more AEFI being reported by individuals who were <45 years old. No such association was found between age and AEFI after the 2nddose of vaccine. Gender and comorbidities were not found to have any association with reporting of AEFI.

The main limitation of this study was that data was collected after 28 days of 2nd dose vaccine, certain minor AEFI might have been forgotten by participants, thus causing recall bias. The study can be further extended to include a larger population and participants can be followed up for longer duration, so as to understand the long term and remote AEFI.

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