Vaccine Safety and Surveillance for Adverse Events Following Immunization (AEFI) for COVID-19 Vaccine in a Tertiary Care Hospital-Kerala

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ABSTRACT

Introduction: The meteoric spread of COVID-19 had facilitated the researchers to develop vaccines. One among the most recommended, Covishield requires further investigations for lighting up the society towards the immunization program. The study has determined the severity and frequency of adverse event following immunization concerning the first and booster dose of the Covishield vaccine. Also, we investigated the relationship between the participant's demographic characteristics with the adverse events encountered due to the two doses. **Materials and Methods:** An observational cross-sectional study was conducted over 6 months among the individuals who were administered with Covishield vaccine registered via Indian government website, COWIN. **Results:** The study constituted of 2470 participants among them the frequency of females who received the vaccine (55.18%; 62.36%) was more significant than the males, so as the adverse events (Female, first dose: 51.41%, Second dose: 64.92%). We observed participants with chronic diseases (39,5%) and had long term medications (15.57%). Those with age greater than 45 years (61.15%) were discerned by the unfavorable episodes of the vaccine compared to the youngsters. First dose predominantly spawn pain at the injection site (40.15%) whereas, fever (34.72%) was the major concern in the second. The causality assessment scale put forward by World Health Organization stated all the reported adverse events following immunization in the first (62.90%) and the second dose (30.28%) was allied to the same category, consistent causal association to immunization. **Conclusion:** The safety surveillance study helped in the investigation wherein the adverse event profile of Covishield vaccine was causal or coincidental. We intend the generated data would reduce the fear and augment the acceptance rate of COVID-19 vaccine among the mass population.

Key words: AEFI, COVID-19, Covishield, Surveillance, COWIN.

INTRODUCTION

The global outbreak of severe acute respiratory syndrome - coronavirus 2 (SARS-CoV-2) is a major public health issue which has erected series of travel restrictions between places to places and lockdown throughout many countries.[1] The infection had affected the healthy adults within the age of 25 to 70 years. The fatality of illness was illustrated by World Health Organization (WHO) and the suspected SARS cases was around 3%, from early studies.[2] As of February 4, 2021, 104 million cases of SARS-CoV-2 have been reported with 57.9 million recoveries and 2.27 million deaths. Nevertheless, 10.8 million have been identified in the Indian subcontinent with 10.5 million recoveries and 155 thousand fatalities. Enhancing the immunity of the people or administration of vaccines can prevent occurrence and

transmission thereby attenuating the ongoing health crisis. Accordingly, numerous researches are carried out to cope up with the demand to safeguard the entire population and have led to an unprecedented number of vaccines clinical trials. The Covishield vaccine developed at Oxford University is a replication deficient chimpanzee adenoviral vector ChAdOx1, enclosed with the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene. There are concerns expressed by our community on the efficacy and safety confined to two vaccines, Covishield and Covaxin, currently available in India. The medical practitioners even though desperate on their arrival agitated on the hurdles they may face in convincing the public with limited evidence. The clinical trial of Covishield, manufactured by Serum Institute, and Covaxin, by Bharat Biotech, revealed relative safety without noteworthy adverse effects.[3] The adverse events following immunization (AEFI) is primarily due to the protective immunogenic nature of the vaccine and not of allergy.[4] The pharmacovigilance authorities have to notify and document any untoward medical occurrence follows the vaccine administration. The ailments imparted are categorized into minor, severe, or profound AEFIs. When minor AEFI are self-limiting and common (pain and swelling at the injection site, fever, irritability, malaise), severe events can lead to disabilities.[5]

A study underwent in the first phase of the Covishield vaccine rollout in Nepal concluded that the first dose of Covishield vaccine caused mild AEFIs that resolved within a few days, except one report of anaphylaxis.[6] Another study in Southern India performed in health care workers reported minor, self- limiting AEFI with the first dose of Covishield to impart no serious AEFIs.[7] However very little published data are available regarding AEFIs after both doses of this vaccine.

The strength of the study adheres to the adequate sample size and reasonable response rate. But the study constraints in addressing the pregnant, lactating and pediatric population for vaccination. The vaccine safety surveillance would rectify the gaps in the vaccine Pharmacovigilance system.[8] Moreover, the medical practitioners who were desperate to the arrival at such prophylactic measures have expressed difficulties in convincing themselves and the general public. The lack of enough scientific evidence was the major hindrance factor. So, we determined the development, severity and frequency of AEFI associated with the first and second dose of the Covishield vaccine.

MATERIALS AND METHODS

The vaccine, Covishield was manufactured by Astra Zeneca and the immunization drive was initiated throughout India on 16th January 2021. The study was conducted at KIMS Al Shifa Super Specialty Hospital Perinthalmanna, Malappuram district of Kerala, India. An observational cross-sectional study was carried out among the individuals who were administered with the Covishield vaccine registered via the Government website, COWIN. The study was conducted for a period of 6 months from January 2021 to June 2021.

The sample size was calculated by the equation of estimation of prevalence:-

$$n = \frac{z_{1-\frac{\alpha}{2}}^2 p(1-p)}{d^2} = \frac{(1.96)^2(0.50)(1-0.50)}{0.05^2} = 384$$

Where, $Z_{\alpha/2}$ = Normal deviate for two tailed hypothesis (1.96), P= anticipated proportion (0.5), d = Margin of error (0.05). Accordingly, we require 384 samples to yield results confined to the objective with 95% confidence interval.

The inclusion and exclusion criteria were indicated in the protocol submitted to the IEC. All the willing individuals above 18 years of age who registered and administered the Covishield vaccine were included and those who had not administered the second booster dose of the vaccine were excluded from the study. Moreover, participants with muti-morbidities were also recruited. Meanwhile, written informed consent from each enrolled participant were collected and documented.

Thorough literatures search and suggestions from general medicine physicians and adverse drug reaction monitoring center coordinator facilitated us in building up a data collection form (DCF) that served to meet the study objectives. The form retrieved the participant's demographic details, their allergic status, past medical history, and adverse events. The WHO AEFI reporting form is based on the core particulars[8] that include details of the vaccine, event's description, duration, severity, date and time of the beginning and end of the AEFI and its management. The DCF was then validated by a multidisciplinary committee consisting of experts, including a physician, head of the department of pharmacy practice, and a social worker. Upon vaccination, each participants were observed for half an hour for sudden AEFI, while the clinical pharmacist counselled the samples to bolster public and individual support for COVID-19 vaccine.[9]

The participants were then contacted by the clinical pharmacist for three consecutive days following

vaccination, through telephone that facilitated in determine further AEFIs. Consequent AEFI's between the first and second dose were also established, categorized as minor, severe, or serious based on the WHO Classification.[5] The second booster dose of vaccine was given 28 - 60 days after the first dose and similar protocols were maintained to determine AEFI. The telephonic follow-up was also conducted on the 15th day and 30th day following the second dose of vaccination. The AEFIs detected during the observation and 3 days of follow-up were reported to the Drug Safety Associate through Indian Pharmacopoeia Commission to Uppsala Monitoring Centre (UMC). Causality assessment of the AEFIs were done using a new algorithm developed by the safety and vigilance department of the WHO.[10] (Figure 1).

Ethical statement

The study was approved by the Ethical Committee of the institution (IEC), reference number KAS:ADM:IEC:0204:21, and official consent was also granted for performing the study.

Statistical analysis

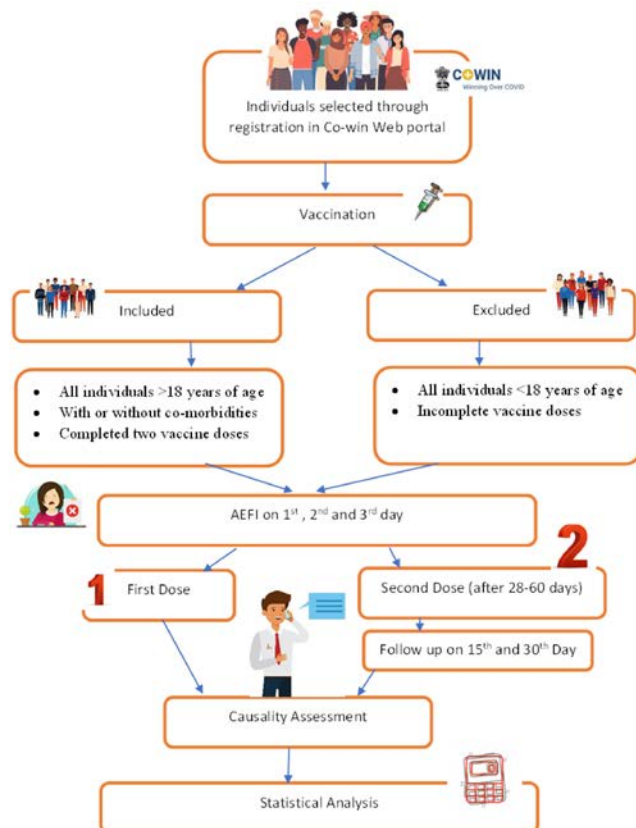All the data collected during the study period were statistically analyzed for formulating the result by using the statistical package for social science [SPSS] 26.0 for the windows version. The collected information was summarized and the variables such as age, gender, commonly seen AEFIs after first and second dose, past history and concomitant illness, the association between the presence of concurrent disease and development of AEFI, history of drug intake in AEFI population were tabulated. The inferential statistics such as chi square test, likelihood ratio test was employed to find the association between the variables. The significance of each result was inferred from the $p < 0.05$.

RESULTS

We had retrieved data of 2470 participants enrolled into the study. The gender characteristics inferred greater frequency of females who received the first dose ($n=932$, 55.18%) and second dose ($n=487$, 62.36%) of vaccine compared to males ($n=757$, 44.82%; $n=294$, 37.64%). Moreover, The AEFIs were also higher in females after first and second dose ($n=347$, 51.41%; $n=211$, 64.92%) than in males ($n=328$, 48.59%; $n=114$, 35.08%) (Figure 2). The chi-square test showed no association between gender and development of AEFIs ($p > 0.05$). According to the guidelines for vaccination, two age category groups of below 45 years and above 45 years were designated which included front line workers in hospital or health care services and common public. The study subjects above 45 years received a greater number of the first dose ($n=1083$, 70.14%) than below 45 years ($n=461$, 29.86%), while, the number of subjects who received the second dose were higher in below 45 years ($n=445$, 65.63%) group compared to those above 45 years ($n=233$, 34.37%). The AEFIs occurred predominately in those above 45 years ($n=576$, 61.15%) than below 45 years ($n=366$, 38.85%). Chi-square test stated no association between participants' age and development of AEFI ($p>0.05$).

Figure 1: The workflow of the COVID19 vaccine study.
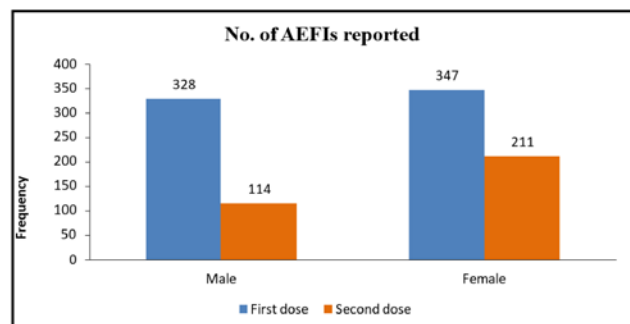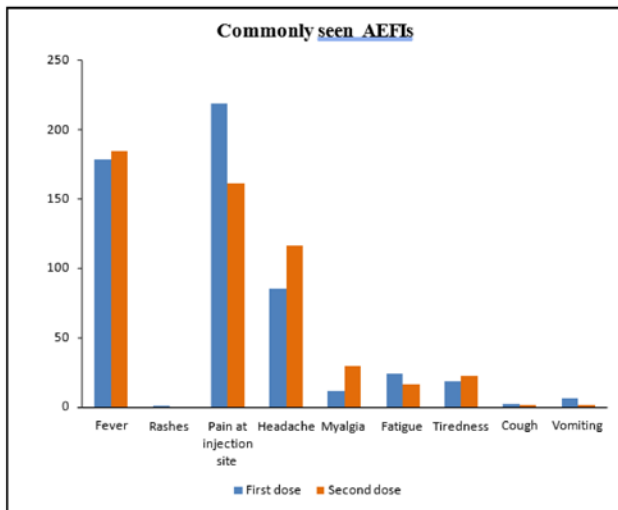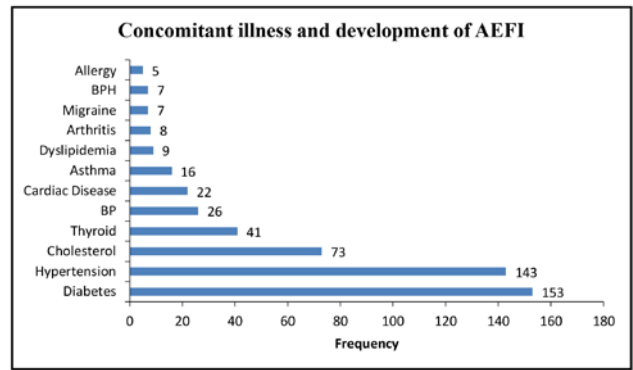

Figure 2: Number of AEFIs reported in males and females in first and second dose of the COVID19 vaccine.

Recurrently appearing AEFIs after the first and the second dose were reviewed together. The results showed that there was a higher incidence of pain at the injection site (*n*=218, 40.15%) followed by fever (*n*=178, 32.78%), and headache (*n*=85, 15.65%), reported as AEFIs following the first dose. However, fever (*n*=184, 34.72%) followed by pain at the injection site (*n*=161, 30.38%) and headache (*n*=116, 21.89%) was profound after the second dose. There were very few rashes (*n*=1, 0.18%) because of the first dose and cough (*n*=1, 0.19%) and vomiting (*n*=1, 0.19%) due to the second (Figure 3). We identified 39.49% (*n*=667) and 13.44% (*n*=105) with concomitant illness during the first and second dose, while, 60.51% (*n*=1022) and 86.56% (*n*=676), did not appear with any co-morbidities. The prevalence was evident in the case of Hypertension (*n*=306, 28.20%) followed by Diabetes Mellitus (*n*=341, 31.43%), Dyslipidemia (*n*=141, 13%) and Cardiac diseases (*n*=57, 5.25%) with lower incidence of Chronic Kidney Disease (*n*=1, 0.09%) and Stroke (*n*=1, 0.09%) (Figure 4). However, Likelihood Ratio showed co-morbidities did not have any relation with the reported AEFIs (*p*= 0.074). Additionally, we retrieved the drug consumption of our subjects interpret the drug interactions and their consecutive association with the AEFIs. The study had 15.57% and 19.46% with ongoing drug consumption, even before the first and second vaccine doses of vaccine, while 84.43% (*n*=1426) and 80.54% (*n*=629) lacked adequate medication history.

All the reported AEFI in the first(*n*=675; 62.90%) and the second dose (*n*=325; 30.28%) belonged to the same category; Consistent causal association to immunization (A). Among the subcategories of A, the reports of

Figure 4: Concomitant illness and development of AEFIs in our study population.
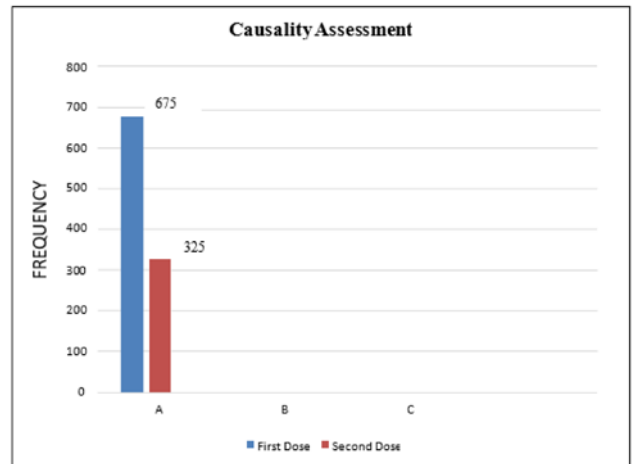
Figure 5: Causality Assessment of the reported AEFIs related to the COVID19 vaccine in our study population.

Consistent causal association to immunization (A), Adverse reaction due to errors on administration of vaccine (B), inconsistent causal association to immunization (C)

AEFI cases were solely under the subcategory; Vaccine-product related (A1). Nevertheless, 6.80% (*n*=73) of the population did not attend the AEFI follow-up calls (Figure 5).

DISCUSSION

The observational cross-sectional study on surveillance for adverse events following immunization (AEFI) of COVID-19 Vaccine comprised of 2470 participants. The severity and frequency of the AEFI associated with the first dose and booster dose of the Covishield vaccine and its interdependence with subject's demographics were studied. The gender characteristics of our population were estimated and it showed that the female participants received both the first and the booster dose at an increased rate than the male group. Similar pattern was observed in terms of AEFIs, wherein females had dominating prevalence after the

Figure 3: Recurrently appearing AEFI after first dose and second dose of the COVID19 vaccine.

both the doses. The results suggest that the association between gender characteristics and the development of AEFI was statistically insignificant. This was contradictory to the study conducted by Garcia- Rivera E, Szenk M, Suratekar R *et al*., which proposed higher cases of nausea and vomiting in women classified as adverse event related to the COVID-19 vaccine. This was justified by the enhanced reactogenicity in females. [11] Moreover, our study implies no gender association with the reported AEFIs.

COVID-19 had more number of male populations to be affected with the infection and the severity being lower in females which was quantified by lesser hospitalization and death.[12] However, the fear of being infected was observed to be greater in women.[13] This have led to an increase in vaccine utilization among the female compared to male. Women exhibited greater immnune response with vaccine administration.[14] Moreover, increased age, polypharmacy, renal and liver disease and female gender are more sensitive towards adverse events. The reasons behind the incidence of AEFIs in women are not clear, however, the pharmacokinetics, immunological and hormonal changes can impart the differences.

According to the guidelines for vaccination, two age categories were designated, which were participants greater than 45 years and less than 45 years. The study results revealed that the subjects above 45 years (age) received higher number of first doses while the subjects who completed their booster dose were those below 45 years (age). AEFI development was also at an escalated rate among above 45 years (age) than those below. The study notified that the association between age and development of AEFI was statistically insignificant. This was contrary to Jeon M, Kim J, Oh C, Lee J *et al*.'s observations, which urges that the incidence and severity of local and systemic AEFIs were significantly higher in the younger health care workers group below 35 years (age) than in the older.[15] The geriatrics, especially those living with co-morbidities are highly prone to COVID-19. This escorted the health officials to promote the elderly towards immunization and was evident from the increase number of participants in age greater than 45 years in our study.[16] Additionally, we identified participants with high prevalence of hypertension, diabetes mellitus and dyslipidemia.

The AEFIs that appeared recurrently after the first and the second dose were reviewed together. There happened to be higher incidence of pain at the injection site followed by fever and headache after the first dose. Whereas, fever followed by pain at the injection site and headache dominated in the later dose. Meager count for

rashes in the first dose and cough and vomiting in the second dose were documented. The adverse events such as coagulopathies, myocarditis pointed out by center for disease control and prevention, was not observed in our center.[17] Meanwhile, all the minor events encountered were self-limiting and cured with home remedies and Over-the-Counter medications. The AEFIs observed in our participants were similar to the results posted by Minji J, Jehun Kim, Chi Eun Oh, Jin-Young Lee, where the majority had tenderness (63.7%) and pain (54.2%) at the injection site, headache (52.6%), and fatigue (53.1%) with varying severity and the events resolved within few days.

The current study aimed for asafety surveillance that detects and rapidly investigate AEFIs to determine if the temporal relationship is causal or coincidental.[18] All the subjects enrolled in the study were assessed for their medication history or concomitant illnesses. Among the 2470 subjects, half of the participants did not suffer from any comorbidities. While others dominated with Hypertension followed by Diabetes Mellitus and Dyslipidemia, and there were few participants with kidney disease and Stroke. Hence, 15.57% of our participants during the first dose of vaccination and 19.46% on second dose were on long term medications. The study depicted the concomitant illness or drug consumption and development of AEFI was statistically insignificant ($p= 0.074$) which was homogeneous with the study performed by Parthasarathi Gurumurthy, Mandyam Dhati Ravi *et al*.[19] Thus, the AEFIs reported in our population were vaccine related and independent of the subject demographics.

The causality Assessment for adverse events of Covishield vaccine was developed by the safety and vigilance department of the WHO. There are 4 different categories and subcategories under AEFI case report form section of WHO Manual, they are

A. Consistent causal association to immunization

A1) Vaccine - product relatedA2) Vaccine - quality related

A3) Immunization error related reaction A4) Immunization anxiety related reaction

B. Indeterminate

B1) Consistent temporal relationship but insignificant evidence for causality

B2) Conflicting trends of consistency and inconsistency with causality

C. Inconsistent causal association to immunization

– Underlying or emerging condition(s) in the vaccine

– Condition caused by exposure to the external factors

All the reported AEFIs in the first and the second dose belonged to the same category; Consistent causal association to immunization (A). Among the subcategories of A, the cases were solely under the subcategory; Vaccine-product related (A1). These results were parallel to the study conducted by Juny Sebastian, Madhan Ramesh *et al.* concerning the expanded program of immunization (EPI) among the children, with its incidence of 93.4%.[20] In contrast, fewer AEFIs were classified as inconsistent causal association to immunization (C) in our study due to the lack of evidences. Since the Covishield vaccine related adverse reactions are known, the causal association is accepted even where the events could have happened by coincidence.

Causality assessment assisted in proving an association between the event and the immunization. All the reported AEFIs were mild-to-moderate in severity. Such mild side effects associated with the Covishield vaccine are acceptable as the body requires time to adapt to vaccination dose and triggers immune response using protective antibodies. The major strength of our study is that it adheres to the adequate sample size and reasonable response rate. However, few facets that had curtailment the study were, single center and exclusion of pregnant and lactating women, so the results cannot be generalizable. There may be possibility of bias due to unnoticed variables. The current surveillance system can be further strengthened to improve the rate of pure reporting of AEFI. This would be facilitated by implementation of mobile or web based self-reporting system adjacent to the available pharmacovigilance portal. The health officials can review the events and suggest management strategies in timely manner, would be an effective method to reduce the fatal responses occurring to the vaccinated individuals.

CONCLUSION

A coordinated and harmonized safety surveillance approach to vaccine safety monitoring will generate data needed to support timely decision-making, thus, increasing the acceptance of the COVID-19 vaccine among the mass population while decreasing their psychological fear. This active surveillance system helps to counteract the pandemic through successful participation in the worldwide vaccination program. Though the arrival of vaccination had provided a ray of hope to the world, there were many challenges faced in their success path, including addressing the bizarre thoughts of people concerned with their medical conditions and hesitancy in getting vaccinated. The study participants experienced only mild to moderate, self-limiting AEFI after the two doses of Covishield. The hospital reported no serious AEFI following the vaccination. Covishield has a good safety profile, and the general population should be aware of these minor AEFIs that are self-manageable with symptomatic treatment such as Over-the-counter Analgesics (Paracetamol/Acetaminophen) that resolve the symptoms quickly manner.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

AEFI: Adverse events following immunization; **DCF:** Data collection form; **COVID19:** coronavirus disease; **WHO:** World Health Organization; **UMC:** Uppsala Monitoring Centre.

Author Contributions

Conceptualization, Dilip Chandrasekhar, Mohammed Salim Karattuthodi, Linu Mohan Panakkal; methodology, Dilip Chandrasekhar, Mohammed Salim Karattuthodi, Linu Mohan Panakkal, Angel Mary William, Anjana A, Annmaria Benny, Aqila Karuppam, Beneta Sarah Sam, Shinu Cholamugath, Jaffer Chalil Parambil, Aneesh Puthiyedath Joy; investigation, Angel Mary William, Anjana A, Annmaria Benny, Aqila Karuppam, Beneta Sarah Sam; resources, Dilip Chandrasekhar, Mohammed Salim Karattuthodi, Linu Mohan Panakkal, Angel Mary William, Anjana A, Annmaria Benny, Aqila Karuppam, Beneta Sarah Sam, Shinu Cholamugath; writing—original draft preparation, Dilip Chandrasekhar, Mohammed Salim Karattuthodi, Linu Mohan Panakkal, Angel Mary William, Anjana A, Annmaria Benny, Aqila Karuppam, Beneta Sarah Sam, Shinu Cholamugath, Jaffer Chalil Parambil, Aneesh Puthiyedath Joy; supervision, Dilip Chandrasekhar, Mohammed Salim Karattuthodi, Linu Mohan Panakkal.

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SUMMARY

The meteoric spread of COVID-19 had facilitated the researchers to develop vaccines. The study has determined the severity and frequency of adverse event following immunization concerning the first and booster dose of the Covishield vaccine.: An observational cross-sectional study was conducted over 6 months among the individuals who were administered with Covishield vaccine registered via Indian government website, Co-win. Also we investigated the relationship between the participant's demographic characteristics with the adverse events encountered due to the two doses. The study constituted of 2470 participants among them the frequency of females who received the vaccine (55.18%; 62.36%) was more significant than the males, so as the adverse events (Female, first dose: 51.41%, Second dose: 64.92%). We observed participants with chronic diseases (39,5%) and had long term medications (15.57%). Those with age greater than 45 years (61.15%) were discerned by the unfavorable episodes of the vaccine compared to the youngsters. The causality assessment scale put forward by World Health Organization stated all the reported adverse events following immunization in the first (62.90%) and the second dose (30.28%) was allied to the same category, consistent causal association to immunization. The safety surveillance study helped in the investigation wherein the adverse event profile of Covishield vaccine was causal or coincidental. We intend the generated data would reduce the fear and augment the acceptance rate of COVID-19 vaccine among the mass population.

PICTORIAL ABSTRACT
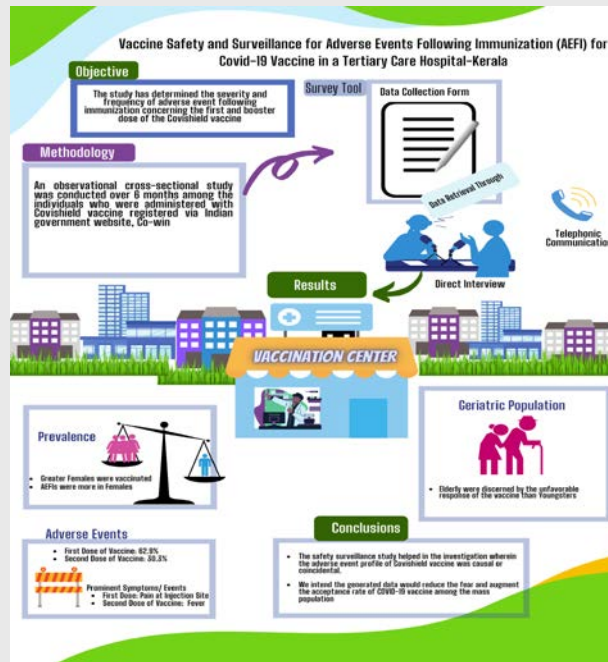
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