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A survey on COVID-19 vaccine complication in India

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Abstract---Objectives- The objective of this survey is to find the various Covid-19 vaccine complication in India and to spread awareness among people about adverse effects and their reporting also to study the rare side effects so to minimize the chances to harmful effects. Methods-Online surveys and questionnaires have been used to collect data from various peoples or subjects. Key findings- Majorly mild adverse effects have been reported, very few severe cases had reported and no rare side effect have been found in this survey. Adverse events those who have been found during the clinal trails had reported no new adverse reported in population of survey involved. Conclusion- The vaccine that have been administered by the population are safer but some precautionary measure must be taken and special attention to be given for elderly person and pregnant ladies and those who are already having any health-related issues while vaccinating them.

Keywords---survey COVID-19, vaccine complication, India.

Introduction

The world has faced an immense outbreak of Severe Acute Respiratory Syndrome Corona Virus-2 (SARS CoV-2) or Corona Virus disease 2019 (Covid-19). This corona virus possesses major threat to humans and animals. During the beginning of the outbreak there were no clue about the treatment of this disease. Precautionary majors were taken like use of face mask, sanitation techniques, symptomatic treatment and prevention was the only choice to avoid Covid-19 infection, sooner or later this outbreak shaped itself to a global outbreak or Pandemic. This affects the world healthcare facilities and put billions of lives on stake not only this millions of lives have lost during this corona pandemic worldwide. Billions of people are affected by this disease.

Researcher and scientists have taken various effort to develop the vaccine against Covid-19 this plays a major role in controlling the Covid surge in the world. The various vaccines authorized for emergency use by FDA are Pfizer-BioNTech, Moderna, Janssen (Johnson Johnson) and many more. The fight against COVID-19 has seen vaccine development move at record speed, with more than 170 different vaccines in trials. But how are they different from each other and how will they protect us against the diseases. There are more vaccine candidates simultaneously in the pipeline for COVID-19 than ever before an infectious disease. All of them are trying to achieve the same thing – immunity to the virus, and some might also be able to stop transmission. They do so by stimulating an immune response to an antigen, a molecule found on the virus. In the case of COVID-19, the antigen is typically the characteristic spike protein found on the surface of the virus, which it normally uses to help it invade human cells. In spite of vaccine advantages there are some serious complication related to it that can cause major health related disadvantages to people.

COVID-19 vaccine drive in India

In India the Covid-19 vaccination was began from 16 January 2021 operating around 3000 centres from inception. The two major vaccines that has been used in India are Covishield and Covaxin which is authorized for emergency use in the country. During the initial day's vaccine been administered to Health workers and frontline workers. In second phase of the vaccination elderly people (45- 60 years) are covered. The government of India widen the vaccination program allowing people above 18 years. A large number of populations have been shielded during this phase. As scientific knowledge evolved and more vaccines became available, the government introduced vaccination for the 15-18 age group in January this year, and for the 12-14 age group in March. The government allows only Corbevax to be administered to those in the 12-14 age group, and only Covaxin to those in the 15-18 age group. The Zydus Cadila DNA vaccine, which has been approved for children aged 12 and above, has not been used in the vaccination drive so far. The adverse events reported during the clinical trial of Covid-19 vaccine trial for Covaxin were headache, Fatigue, Fever, Nausea and Vomiting. The important abnormal laboratory parameters after vaccination included derangements in bilirubin, SGOT, SGPT, Cholesterol C-reactive protein levels. These findings had no support clinical manifestation and for Covishield adverse events were during the phase I clinical trial were mild to moderate local adverse reactions it was more

common during the phase II trials and these are Fatigue, headache is more common and systemic were milder intensity. Serious adverse events reported in the trail study were shoulder injury, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, and right leg paraesthesia were considered to be related to the vaccine.

Currently used COVID-19 in India Covaxin vs covishield

As the results of phase one and two vaccination drive clearly show that both the vaccines are effective enough (against different variants of the COVID-19 virus detected in India so far) and safe. However, both vaccines are different from each other in various factors. Manufactures Both the vaccines are developed by different companies. COVAXIN is developed by Hyderabad-based Company Bharat Biotech International Ltd. in collaboration with the Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV). Whereas COVISHIELD is the vaccine candidate from Pune-based Serum Institute of India, and it is equivalent (but not the same) to vaccine developed by the Oxford University and AstraZeneca (SII, 2021; Bharat Biotech, 2021). Vaccine Type COVAXIN is developed using "Whole-Virion Inactivated Vero Cell-derived platform technology". As the study says the inactivated vaccines do not replicate and are therefore not likely to revert and cause pathological effects. This type of vaccines contains the dead virus and they are incapable of infecting people but still able to instruct the immune system to mount a defensive reaction against an infection. This technology is the well-established, and time-tested platform in the world of vaccine technology (COVAXIN, Bharat Biotech, 2021). COVISHIELD is developed by "Viral Vector Platform Technology" and it's a different technology. Recombinant, replication-deficient chimpanzee adenovirus vector which is carrying the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells. This genetically modified virus is not capable of infecting the beneficiary but can very well instruct the immune system to prepare a mechanism against such viruses.

Methodology

Stimulated reporting and online survey method are used.

Study design

An online survey was conducted on 138 people from various states across the country who had taken covid vaccine.

Study duration

This study was carried out for a period of one month from March 2022 to April 2022.

Study procedure

Data is collected from people who has administered the Covid vaccine, they were given list of questionnaires that consists demographic data, Date of vaccine administered, Type of vaccine administered and their Adverse events observed and other information were taken. Patient consent had also taken and their identity is been kept secret.

Result

The data collected from survey is summarized below

Table.1.

VARIABLE SUBJECTS (%)	
AGE GROUP	SUBJECTS
15-18	1
18-44	130
45-60	6
>60	1

Table.2

GENDER	
MALE	63(45.7%)
FEMALE	75(54.3%)

Table.3

VACCINE ADMINISTRED	
COVISHIELD	121(87.7%)
COVAXIN	• 12.3%)

Adverse event report

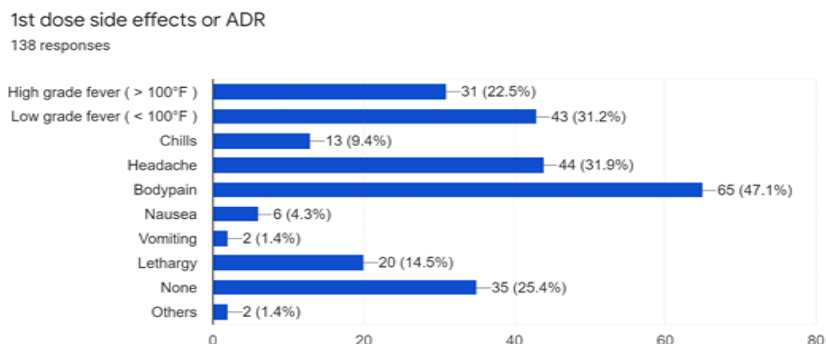


Figure.1.

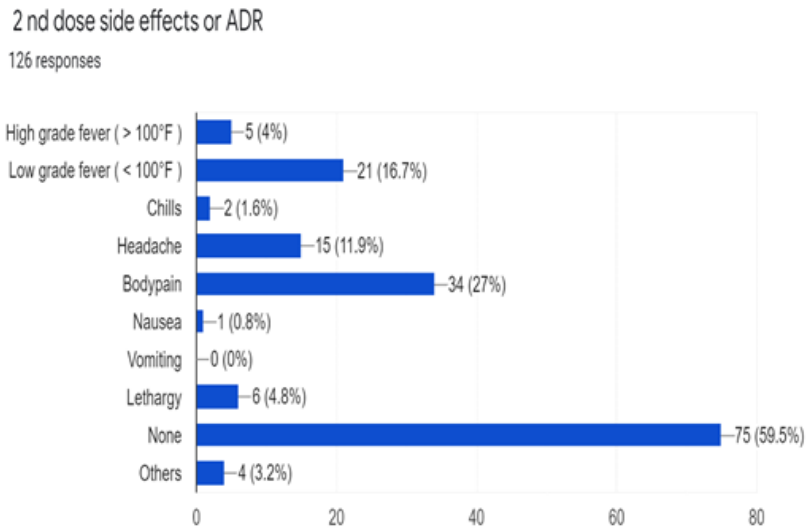


Figure.2.

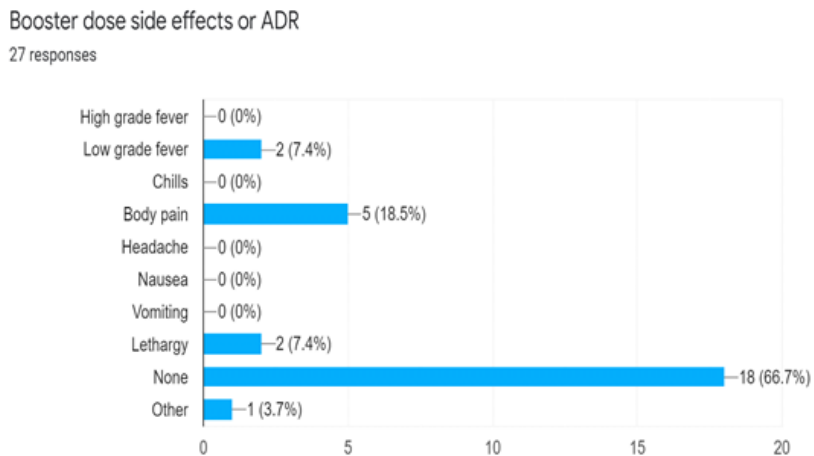


Figure.3.

Discussion

In this survey 138 people from various states across the India have participated and reported the adverse events from the COVID-19 vaccine. Out of the 138 participants or subjects all of them are administered the first shot of vaccine but only 123 participants are administered with First and second dose of the vaccines while 14 people had taken the booster dose along with first and second doses.

Majority of the participants have administered with Covishield i.e., 121 whereas only 17 people had taken Covaxin shots. In this survey a major portion of participants are between 18-44 age group while only one subject is 16 years old and one is more than 60 year, thus severity of adverse effect that are reported in this survey majorly comes from people between 18-44 years. The percentage of male and female are 54.3% and 45.7% respectively.

The data of adverse effect which are reported are based on cumulative adverse effect of both of the vaccines (Covaxin & Covishield) during the first, second and booster doses therefore data which shown above in the figure.1. It was found that most common adverse event reported during the first dose of the vaccines are

- Body pain (47.1%)
- Headache (31.9%)
- Low grade fever (31.2%)
- High grade fever (22.5%)
- Lethargy (14.5%)
- Chills (9.4%)
- Nausea (4.3%)
- Vomiting (1.4%)

Although 35 (25.4%) subjects do not notice any adverse event during the first dose of the vaccination and other adverse effects reported were severe leg pain after vaccination and blockage of nostrils. Data suggests that all the above adverse reactions are mentioned during clinical trial of vaccine and no serious adverse events have been reported during the first dose of the both vaccines. The observation from the figure.2. suggests that larger population have no adverse reactions during the second dose but the common adverse events that delineate are given below listed below-

- Body pain (27%)
- Low grade fever (16.7%)
- Headache (11.9%)
- Lethargy (4.8%)
- High grade fever (3.2%)
- Chills (1.6%)
- Nausea (1%)

However, one person mentioned severe swelling all over the body and also had high grade fever after the second dose of Covishield vaccine, he anguished with allergic reaction and is now been treated with medication. The time interval between first dose and second dose of the Covishield is 4 to 8 weeks but doses interval varies from 4-28 weeks i.e., 1 to 7 months this could be due the availability of people and vaccines from state to state. Huge number of subjects had vaccinated in between 4-12 weeks (1-3 months) whereas for Covaxin the dosing interval between one and second dose is 4 weeks but people are vaccinated at an interval of 12 weeks. In the similar manner for booster doses 14 people are fully vaccinated with all the doses that has recommended, most of them have not experienced any adverse effect though few have reported the adverse events which are stated below

- Body pain
- Low grade fever
- Lethargy
- Pain at site of injection

The trend of adverse events from first dose to second is slightly different but the very common adverse events are body pain, low grade fever and lethargy, so to treat such adverse reactions physician have advised to take medication such as painkiller like paracetamol. The figure.4. shows that people who had taken medication after vaccination.

Conclusion

During the clinical trial the adverse reactions were Headache, Fatigue, Fever, Nausea, vomiting, diarrhea, Pain in legs and arms though some rare side effect are blood clotting and thrombocytopenia for Covishield and for Covaxin are fever. Swelling, redness in the similar way in the online survey the participants also witnessed with same adverse events body pain, fever (low grade and high grade), fatigue or lethargy, nausea, vomiting and also pain at the site of injection. The majority of the population had non serious adverse events i.e., body pain during first, second and booster doses however half of the population haven't observed any symptoms during the second dose and third dose. 1 out of 138 participants faced a severe adverse event from Covishield vaccine after his second dose, the participant had high grade fever and swelling, his condition worsens and he consulted to physician the other side effect are nostril blockage and severe leg pain also have been reported in this survey, these complication already mention during the vaccine trials therefore precaution must be taken during the vaccination, patient history from any disease should be considered and there is no need to worry about major the complication related to these two vaccines namely Covishield and Covaxin there is no as such serious AEFI been reported so far. Vaccine is an important measure to combat from this deadly Covid disease but also adverse effect should not avoid its reporting must be done.

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