Adverse reaction following COVISHEILD a covid 19 vaccine-Experience of from a single Centre

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Abstract

The vaccination drive in India is the topmost drive for prevention against COVID-19 vaccination globally. It started from 16th January 2021. In this drive two vaccines have been used. These are Oxford-AstraZeneca's Covishield and Bharat Biotech's Covaxin. This drive has already crossed 600,000 mark in first four days and the government has stated that the drive will be further accelerated in coming days to ensure immunity to the citizens of the country. However, there is a section of the community which is still skeptical to the COVID-19 vaccination. This research work has been conducted to analyze the sentiments in the tweets posted in India regarding these two vaccines. The analysis shows that while a majority of the population is posting with positive sentiments towards these vaccines, there are also negative sentiments associated with them, associated with the emotions such as fear and anger.

Keywords

Covishield, Covaxin, adverse reactions, COVID-19

Introduction

2020 has been a difficult year for all as Covid-19 disease has arisen with unprecedented speed. But a hope against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is only vaccines. However, there is a long series of communicable diseases in which vaccines are only partially effective and we have a series of sensational vaccine defeats. So the evaluation of the safety and efficacy of vaccines that have to use against SARS-CoV-2 virus in different populations is essential because it is an RNA virus, and generally have a high mutation rate (1)(2). India is the second-largest population and one of the major pharmaceutical manufacturing capacities in the world. India has played a central role in the covid-19 vaccination globally. India's drug regulatory authority has given emergency approval of the two vaccines for restricted use against covid-19, on 3 January, however, phase III clinical trials for Covishield and Covaxin was still ongoing in India (3). Covishield, which is being manufactured by the Pune-based Serum Institute of India (SII), the world's largest vaccine manufacturer; and Covaxin, which the Hyderabad-based Bharat Biotech (BB) has developed in conjunction with the Indian Council of Medical Research (4). The mechanism of action of both vaccines are illustrated in figure 1.

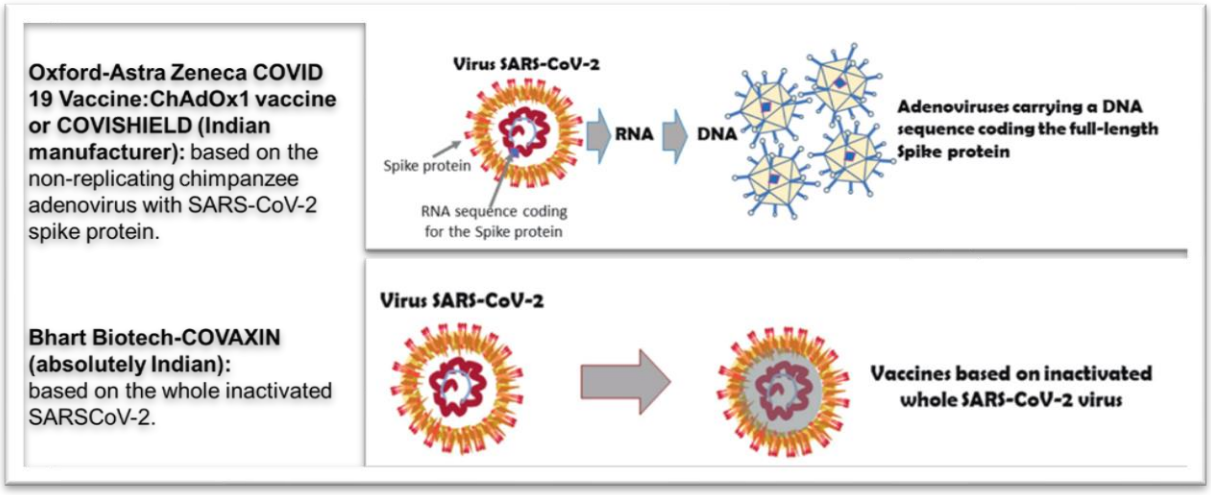


Figure 1. Overview of the Mechanism of Covishield and Covaxin.

There is a big challenge to vaccinate up to 300 million people in the initial stage of COVID-19 in India. The COVID-19 vaccination campaign has been started in India on Jan 16 2021. As of Feb 8, more than 6 million people have been vaccinated in the world's largest vaccination drive. In India, although safety concerns on COVID-19 vaccines were raised. To increase the faith against the safety of COVID-19 vaccine a large number of health workers has undergone vaccination at the initial stages and welcomed the program; dispelled rumors and vaccine's safety through social and electronic media and various other ways (5). However minor Adverse Event Following Immunization (AEFI) has noted in every vaccination center and in some places severe AEFI also globally (6).

AEFI is "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine"(8). Vaccines frequently cause adverse events; however, the vast majority of AEFI are due to the protective immune response induced by the vaccine, and not due to an allergic reaction (7). To access the AEFI whether they are minor or severe in our vaccination center at Pt. JNM Medical College, Raipur Chhattisgarh we have analyse the initial available data. As there are very fewer data available regarding AEFI in Indian populations.

Materials and Methods

All health workers were informed by a short message service (SMS) via COVIN application about their vaccination date before the vaccination. On the day of the vaccination, they waited for their turn to verify their identification card. Frontline health workers were asked to fill a printed form with all demographic details, including any previous Severe Acute Respiratory

Syndrome Coronavirus 2 (SARS-CoV-2) infection and allergies. The vaccine was administered in the deltoid region by the well-trained nurses with the Covishield vaccine.

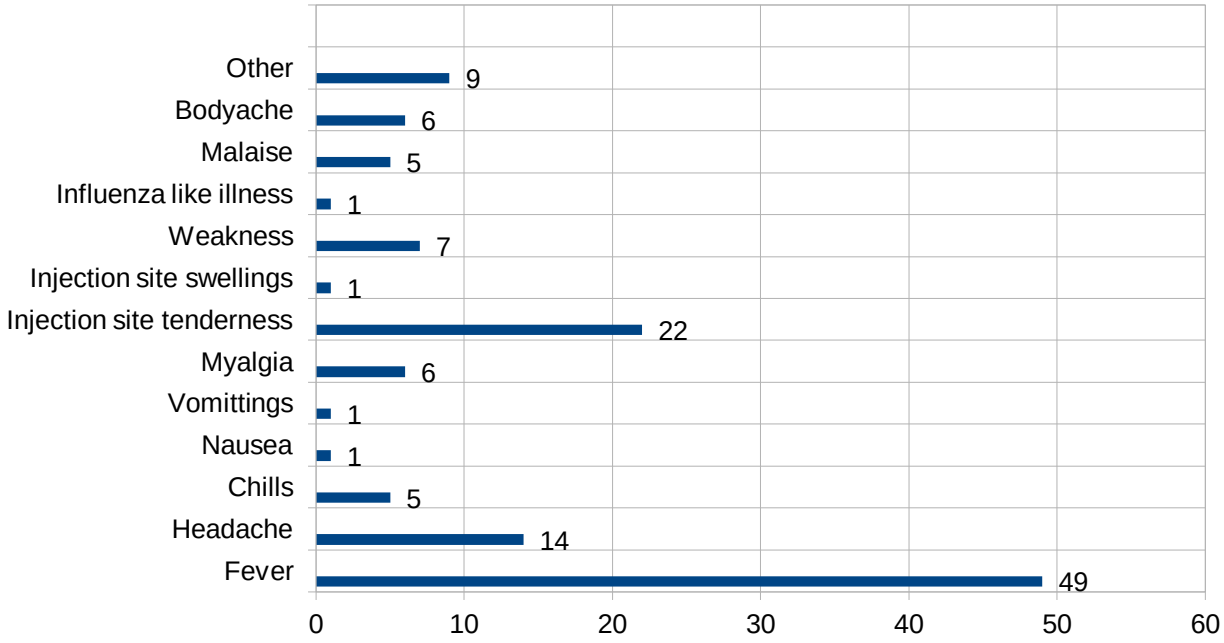
After vaccination, all healthcare beneficiaries were asked to wait for 30 minutes in the observation room to check whether they may experience any type of AEFI.

Results

Some reported within 30 minutes mild AEFI like transient headaches, light-headedness and dizziness. Sometimes tingling in eyes, and increase in blood pressure.

After four hours of vaccination, some health workers complained about irritability in mood, six to 13 hours after vaccines, some complained of myalgia, nausea, tenderness at the injection site and feverish feeling. After 12 hours, fever with chills developed which required paracetamol to resolve.

By the second day of vaccination, fever and headache were resolved, however myalgia and tenderness at the injection site persisted. On the third day, early morning awakening and head heaviness and tenderness at the injection site persisted.



Graph 1: Symptoms and their frequencies

Paracetamol (NSAID) seems to be required with the Oxford vaccine compared to Pfizer or Moderna vaccines to resolve the individuals' common symptoms. Most of the health frontline persons who experience these symptoms posted in social media. As these are common symptoms or side effects observed with viral vaccines, this experience should decrease the fear

of COVID-19 vaccination which appears to cause only a few general side effects observed in some vaccinated individuals in India and Europe. No one developed severe side effects or death in Nepal after the first dose of the Oxford vaccine.

It seems that such mild side effects are acceptable during COVID-19 vaccination as the body will need some time to adopt vaccination dose and to trigger the immune system to induce protective antibodies. Therefore the general people should be aware of these minor side effects which are manageable with some symptomatic treatment like paracetamol to resolve the symptoms timely or such medicine should be taken as prophylaxis to avoid developing the post-vaccination symptoms and increase the acceptance of the COVID-19 vaccine among the mass population while decreasing the psychological fear of any side effect of SARS-CoV-2 vaccination, which would certainly help to counter this pandemic disease through ongoing vaccination program successfully.

The second dose of vaccine as a booster is planned to be administered after 28 days. Though mass vaccination was done in frontline health workers and gave hope to Nepalese society, there is a challenge also. Some of the challenges are vaccine safety and efficacy. Vaccine hesitancy and literacy can be another challenge. An additional challenge is that the new more infectious variants of the coronavirus, first reported in the United Kingdom, have been detected in Nepal, threatening the vaccine rollout strategy [5]. There is a need for long-term monitoring of adverse drug reactions and an urgent need for monitoring by pharmacovigilance centers within a country [6]. Randomised controlled clinical trials are required to confirm the vaccine efficacy in Nepalese populations. Pharmacogenomics study can confirm the dissimilarities in genomic sequence associated with the response of vaccine

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