Adverse Effects Following Immunization with COVID 19 Vaccine: A Telephonic Survey in NCT of Delhi, India

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ABSTRACT

Introduction: Vaccination against the covid-19 has been developed in India and various countries as the pandemic is on the rise. The present study assessed the reported side-effects following the covid-19 vaccination.

Material and methods: The present study was a cross sectional telephonic survey conducted over a period of 2 months that is for the entire duration of the first phase of COVID 19 vaccinations in India. Informed telephonic consent was obtained from the participants of the study. Majority of the study population consisted of medical, dental, paramedical staff and administrative staff working in eth government hospitals in India.

Results: The most commonly experienced side-effect was pain in the arm injected followed by fever, bodyache and malaise after both the doses. The symptoms such as the headache, pain at the site of injection, chills/ rigors and dizziness/ lightheadedness was significantly more among females and the younger age groups (less than 40 years).

Conclusion: The study population did not report any serious side-effects which were life-threatening or requiring vaccination. They were limited to minor side-effects such as the fever, malaise and bodyache.

Keywords: Covid-19, Bodyache, Dizziness, Fever, Vaccination

INTRODUCTION

Infectious diseases have plagued the world since time immemorial. It was not until the year 1798, that is the discovery of Small Pox vaccine by Edward Jenner, that mankind took a great leap in the prevention of infectious diseases. Since then, numerous vaccines have been developed and are a part of the universal immunization program of the World Health Organization (WHO).[1] A vaccine is an "Immunobiological substance used for active immunization by introducing into the body a live modified, attenuated, or killed inactivated infectious organism or its toxin. The vaccine is capable of stimulating an immune response by the host, who is thus rendered resistant to infection."[2]

The development of the vaccines for controlling the various diseases, has been helpful in reducing the burden and death rate of the infectious diseases. But new infectious agents are coming up due to the human interaction with the zoonotic environment, and these infections have been shown to travel across borders due to globalization. Recent examples of such infections are, SARS CoV-1, MERS, H1N1, Ebola and very recently the COVID -19 Pandemic.[3]

The COVID -19 Pandemic has been touted as the most widespread infectious disease that affected almost all countries of the world in the last 100 years, that since the Spanish flu of 1920. On 30th January 2020 the WHO declared the COVID 19 outbreak to be a 'Public Health Emergency of International Concern; (PHEIC). This declaration came nearly a month after the very first cluster of cases were reported in Wuhan, China on 31st December 2019.[4]

India reported its first COVID case on 30th January 2020 and the first COVID related death was reported on 12th March 2020.[5,6] Approximately 6 months into the Pandemic, in the month of July 2020, India strengthened its resolve to control the Pandemic by accelerating the process of vaccine development and two different COVID 19 vaccines were under development; Bharat Biotech & ICMR collaboration's Covaxin and Astrazeneca-Oxford vaccine manufactured by Serum Institute of India, and developed by Oxford Covisheild.

COVAXIN®, is the India's indigenous COVID-19 vaccine developed by Bharat Biotech along with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). The vaccine was developed using Whole-Virion Inactivated Vero Cell derived platform technology which has the advantage of non-replication and have minimal pathological effects. The dead virus, contained in them does not infect people but has the ability to instruct the immune system for producing the defensive reaction against the infection.[7]

COVAXIN® has a 2-dose vaccination regimen given 28 days apart which has been recently modified to 6-8 weeks. This vaccine does not require sub-zero storage temperatures, no reconstitution requirement, and has ready to use liquid form of multi-dose vials, that are stable at 2-8° C.[7]

The Phase 1 study which included 375 subjects showed excellent safety data without any reactogenicity. Vaccine-induced neutralizing antibody titers were observed with two divergent SARS-CoV-2 strains. The side-effects in all

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reported were 15% among the vaccine recipients.[8] The Phase 2 study, which had 380 participants 12-65 years old showed the tolerable safety outcomes and enhanced humoral and cell-mediated immune responses.[8]

A randomized, double-blind, placebo-controlled, multicentre phase 3 study done among 25,800 subjects showed an 81% interim efficacy in preventing COVID-19 in those without any history of previous infection after the 2nd dose.[7]

COVAXIN® has shown efficacy against UK variant strain as shown by the National Institute of Virology that vaccine-induced antibodies can neutralize UK variant as well as the other heterologous strains.[9] Covaxin was granted DCGI approval for administration in the first phase of Government of India's vaccination program under emergency use guidelines. even before it completed phase III trials. The first dose of Covaxin was administered to healthcare workers on January 16th 2021.

The COVISHEILD™ vaccine developed by Oxford-AstraZeneca collaboration has partnered with the 'Serum Institute of India, Pune' for production of the vaccine which has the active ingredient of recombinant, replication-deficient simian adenovirus that encodes the SARSCoV-2 spike protein with a tissue plasminogen activator (tPA) leader sequence. It is indicated for the active immunisation of the people more than 18 years of age. The use of COVISHIELD™ has been permitted under the emergency situation Drugs Controller General of India. The efficacy of COVISHEILD has been reported to be 71% in trials carried in UK and Brazil. Covisheild is also part of the Nationwide vaccination program in India.[10]

As of March 2021, more than 3 crore people have received at least one dose of COVID 19 vaccine in India. Currently the second phase of vaccination program is underway, which has opened up vaccination facility for those above the age of 60 or those above 45 years of age with comorbidities.[11]

In spite of closely monitored trials some adverse reactions following immunization with either Covaxin or Covisheild are likely to occur. An adverse event following immunization (AEFI) is a medical incident that takes place after immunization, causes concern, and is believed to be caused by immunization.[12] Such adverse reactions have also been reported with the COVID 19 vaccines. The current study was planned to better understand and to establish the prevalence of AEFI after COVID 19 vaccine.

The aim of the present study was to determine the types and prevalence of AEFI after receiving COVID 19 vaccine via a telephonic survey. The study also assessed the variation of side-effects with age and gender.

MATERIAL AND METHODS

The present study is a cross sectional telephonic survey conducted over a period of 2 months that is for the entire duration of the first phase of COVID 19 vaccinations in India. Informed telephonic consent was obtained from the participants of the study.

Census Sampling was done as all health care workers reporting for vaccination at the Vaccination Centre of the government hospitals were included in the study. The information on any adverse reactions following immunization was collected.

A total of 229 individuals were contacted of which the response rate was 66.3% with 152 complete responses. The reasons for non-response were incorrect phone number/ no answer. The prevalence of various adverse effects were determined and any difference in this prevalence between males and females or between different age groups were evaluated.

RESULTS

Majority of the study population consisted of medical, dental, paramedical staff and administrative staff working in eth government hospitals in India. The most commonly experienced side-effect was pain in the arm injected followed by fever, bodyache and malaise after both the doses. The symptoms such as the headache, pain at the site of injection, chills/ rigors and dizziness/ lightheadedness was significantly more among females and the younger age groups (less than 40 years).

Patients with history of asthma reported difficulty in breathing for about a week post-vaccination. None of the participant reported any major side-effects such as the anaphylactic reactions or any severe effects requiring hospitalization.

Demographic variables		Frequency	Percentage
Age	21-30 years	32	21.1%
	31-40 years	75	49.3%
	41-50 years	19	12.5%
	51-60 years	11	7.2%
	More than 60 years	15	9.9%
Gender	Male	59	38.8%
	Female	93	61.2%

Table-1:

Side-effects	After 1st dose		After 2nd dose	
Fever	62	40.8%	58	38.2%
Bodyache	34	22.4%	31	20.4%
Malaise	19	12.5%	15	9.9%
Breathlessness	11	7.2%	9	5.9%
Headache	19	12.5%	12	7.9%
Lightheadedness/ Dizziness	8	5.3%	5	3.3%
Redness/ rashes/ red patches	1	0.7%	4	2.6%
Weakness	2	1.3%	7	4.6%
Pain in the arm injected	105	69.1%	99	65.1%
Weakness in the arm injected	8	5.3%	10	6.6%
Any others	1	0.7%	0	0.0%

Table-2: Showing the occurrence of side-effects

DISCUSSION

In current study, we had minor symptoms such as fever, malaise and bodyache. The intensity of the symptoms showed a gradual decline with age with above 40 years age groups experiencing the fewer symptoms. The findings of the survey

correlated with results from published trials of vaccines. The phase 2/3 trial for Astra-Oxford ChAdOx1 nCoV-19, reported that at least 1 systemic symptom occurred after vaccination with standard dosage by 86%, 77% and 65% subjects among 18–55 years, 56–69 years, and 70 years and older age groups respectively.[13] Though, the placebo injection group also showed comparable symptoms. The phase 3 trial of Pfizer-Biontech vaccine, reported an incidence of headache 42% among vaccination group and 34% among saline placebo.[14] This has been termed the nocebo effect, which results from enhanced anticipation of negative outcomes from an intervention.[15] One of the studies in India by Jayadevan et al[16] also reported the similar findings.

Jayadevan et al[16] reported that women had more chances of developing the post-vaccination symptoms. The onset of symptoms was slightly earlier and the duration slightly longer in this group. This observation was consistent across all age groups. This was consistent with our study as well.

CONCLUSION

The study population did not report any serious side-effects which were life-threatening or requiring medication. They were limited to minor side-effects such as the fever, malaise and bodyache. Higher number of females experienced tiredness and headache following the vaccination. So far, the benefits of the vaccination seem to outweigh the minor side-effects among the study population.

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