

Original Research Article

Covishield vaccine experience in a health care setting

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ABSTRACT

Background: SARS-CoV-2 pandemic has affected the whole world and India is one among the most affected countries. Vaccination is the most important tool to halt this pandemic and vaccine hesitancy unfortunately derails vaccination drive. Vaccine hesitancy among people is mainly due to concerns about vaccine safety! This study was done to assess adverse effects of Covishield vaccine among health care workers in a single health care organization.

Methods: All the vaccine recipients were requested to answer a questionnaire with demographic details and various side effects following both the doses of Covishield vaccination.

Results: About 665 employees responded to the questionnaire and the most common adverse reaction following Covishield vaccine was injection site pain, which was reported by 63% of vaccinees after first dose of vaccine.

Conclusions: Covishield vaccine is relatively safe and incidence of major adverse events are rare following vaccination.

Keywords: Covishield, Safety, Health care workers, Adverse effect

INTRODUCTION

We are in the midst of a disastrous pandemic! Coronavirus disease 2019 (COVID-19) illness has affected humankind physically, psychologically, economically and emotionally! While preventive measures like masking, maintaining physical distance and hand hygiene are important, we definitely need more measures to curb this menace. Vaccination is probably the only plausible solution! There has been a lot of vaccine hesitancy among people for various reasons, especially concern regarding adverse effects.¹ There has been information about safety from vaccine trials and other surveys conducted after rolling out vaccination program in India. Its ironical that people are hesitant to take the vaccine when there is a huge shortage of vaccine and it is not freely available for everyone who is willing to take the vaccine! We share our experience with ChAdOx1 nCoV-19 (Covishield) vaccine in our organization hoping it would encourage people to get vaccinated.

METHODS

This descriptive study (survey) was conducted between April 2021 and May 2021 in Yashoda group of hospitals (tertiary level private health care organization with three branches) in Hyderabad, Telangana state, India. Study population included all employees of the hospital. Inclusion criteria included all employees who were aged 18 years or more and had received Covishield vaccine between 22nd January 2021 and first week of March 2021. Exclusion criteria was unwillingness of employees to participate in the study.

Study proforma included demographic details like age, gender, profession; details of comorbidities like diabetes, hypertension, lung disease, cardiac disease and kidney disease; history of drug usage like anticoagulants or antiplatelet agents; history of drug allergy etc. Proforma also included side effects like vaccine associated anxiety, injection site pain, injection site swelling, fever, body

pains, headache, giddiness, vomiting, loss of consciousness, rash, hospitalization, itching and severe allergic reaction.

Proforma was circulated to all employees of the organization and vaccine recipients were requested to answer the questionnaire. Data was collected in physical form. Informed consent was obtained from participants and necessary approvals were obtained from institutional review board of the hospital.

Data was entered in Microsoft excel sheets. Frequency of categorical variables, median and range of continuous variables were calculated using Microsoft excel statistical functions.

RESULTS

About 3000 employees got vaccinated in our organization between January 2021 and first week of March 2021.

Table 1: Demographic details of vaccine recipients.

Age (in years)	Range: 20-63 Median - 42
Sex	Male - 380 (57%)
	Female - 285 (43%)
Profession	Doctors - 208 (31%)
	Nurses - 268 (40%)
	Allied health sciences - 76 (11%)
	Non medical staff - 113 (17%)

Table 2: Clinical characteristics of vaccines.

	Number of vaccinees who responded 'YES'
Diabetes	14 (0.02%)
Hypertension	11 (0.016%)
Cardiac disease	0
Lung disease	1
On antiplatelets	2
On anticoagulants	1
Other Comorbidities	18 (0.03%)
Allergies	Data not available
Both doses taken	589 (0.9%)
History of Covid-19 infection	59 (0.09%)
Tested Antibody level post vaccine after first dose	11 (0.016%)
Tested antibody level after second Dose	7

All of them received Covishield vaccine. 665 people responded to the questionnaire. Vaccine recipients' age ranged between 20 and 63 Years. There were doctors, nurses, allied health science workers and non-medical staff

among the respondents. 589 people took both the vaccines whereas 76 people took only one dose. 47 out of 665 respondents had comorbidities (Table 1).

Table 3: Adverse reactions with Covishield vaccine.

	First Dose Number of vaccinees with response 'YES' (out of 665)	Second Dose Number of vaccinees with response 'YES' (out of 589)
Anxiety -before vaccine	131 (20%)	40 (7%)
Anxiety - post vaccine	96 (14%)	21 (3.5%)
Injection site pain	424 (63%)	207(35%)
Injection site swelling	93 (14%)	39 (6.6%)
fever	277 (42%)	79 (13%)
Body pains	355 (53%)	127 (21%)
Head ache	196 (29%)	72 (12%)
vomiting	25	11
giddiness	87 (13%)	25 (4%)
Loss of consciousness (syncopy)	3	3
hospitalization	4	5
rash	10	3
itching	10	5
Severe allergic reaction	2	3

Most common side effect was injection site pain which was seen in 63% of vaccine recipients (Table 2). Incidence of side effects was less after second dose when compared with first dose. Most of the side effects were minor except a very few moderate to severe adverse reactions. Moderate to severe adverse reactions included 6 episodes of syncopal attacks, severe allergic reactions (5 in total including both doses i.e., less than 0.4%) and 9 people (including both doses) required admission to emergency room and they were discharged within few hours from emergency room.

DISCUSSION

As of 11th June 2021, 17.4 crore confirmed cases of COVID-19 and 37.6 lakh deaths were reported and 215.6 crore vaccine doses were administered worldwide.¹ At the same time, 2.9 crore confirmed cases and 3.6 lakh deaths were reported in India and 24.6 crore vaccine doses were administered.² At this time, only Covishield and inactivated SARS-CoV-2 vaccine, BBV152 (Covaxin) were available widely and Gam-COVID-Vac (Sputnik V) was about to be made available.^{3,4} Efficacy of ChAdOx1 nCoV-19 vaccine was found to be 70.4% in interim analysis of phase 3 trial conducted in Brazil, South Africa

and the UK.⁵ Questions were raised about efficacy of Covishield vaccine against newer variants of SARS-CoV-2 infection and especially delta variant which dominated during second wave in India.⁶⁻⁸ This aspect of vaccine efficacy can potentially increase vaccine hesitancy among people. Many people were hesitant about taking vaccine due to safety concerns. Minor adverse reactions are very common with ChAdOx1 nCoV-19 vaccine.⁹ Injection site pain was the commonest adverse reaction reported in 77% in volunteers who were given prophylactic paracetamol and in 83% of volunteers who did not receive prophylactic paracetamol in phase 2 trial of ChAdOx1 nCoV-19 vaccine.⁹ In our study also, injection site pain was the most common adverse reaction reported (63% after first dose and 35% after second dose). 42% of vaccinees in our study developed fever after first dose where as 51% volunteers felt feverish in phase 2 trial of ChAdox1nCov-19 vaccine.⁹ Myalgia was experienced by 53% of vaccinees in our study as compared to 60% of volunteers (without prophylactic paracetamol) in phase 2 trial of ChAdox1nCov-19 vaccine.⁹ In the same published study, 68% of vaccinees reported headache whereas only 29% of vaccinees reported headache in our study.⁹ Vaccine associated adverse reactions were less after second dose compared to first dose and same was noted in phase 2 trial of ChAdox1nCov-19 vaccine.⁹ People were very anxious about vaccination when vaccination drive was initiated among front line workers in January 2021 in India. Even among health care personnel, about 20% people reported significant anxiety before first dose of vaccination in our study. In a study done in Delhi, in the two weeks after immunization with Covishield vaccine, none of the 1638 evaluated participants reported any serious adverse events (i.e., require hospitalization or emergency room visit).¹⁰

Major thrombotic events were reported with ChAdOx1 nCoV-19 vaccine in European countries. In Norway and Denmark, 59 venous thromboembolic events were observed in the vaccinated cohort compared with 30 expected based on the incidence rates in the general population.¹¹ 11 excess events were reported per 100 000 vaccinations. 11 cases of thrombotic thrombocytopenic purpura (TTP) were reported in Germany and Austria following ChAdOx1 nCoV-19 vaccine.¹² These events occurred 5 to 20 days after receiving vaccination. Bilateral superior ophthalmic vein thrombosis, ischaemic stroke, and immune thrombocytopenia was reported in a vaccine recipient after ChAdOx1 nCoV-19 vaccination.¹³ After reviewing these adverse events, European Medicines Agency(EMA) stated that benefits of ChAdOx1 nCoV-19 vaccine outweigh risks.¹⁴⁻¹⁶ However in India, there have not been any published case reports of TTP or thrombotic events attributable to Covishield vaccine! There were no thrombotic events reported in our study also.

Its ironical that many people are not able to get vaccinated due to vaccine shortage and at the same time, there are many people who are avoiding vaccination because of undue concerns about vaccine safety and efficacy. Though our analysis included only 1254 doses of Covishield

vaccine, nearly 6000 doses were administered among health care personnel in our organization between January 2021 and first week of March 2021. The fact that there were no vaccine related fatalities or life-threatening adverse event reports should be encouraging people to shed vaccine hesitancy and come forward for vaccination. Limitations of study this were limited response from vaccinees (only a proportion of vaccine recipients responded) and small sample size considering rarity of severe adverse events associated with the vaccine.

CONCLUSION

Minor adverse reactions were common with Covishield vaccine, commonest side effect being injection site pain. Major adverse effects were very rare. This study involved health care workers and results of this study hopefully will help mitigate vaccine hesitancy among people.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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