Original Article

Pattern of Adverse Drug Reactions to Covishield Vaccine among the Faculty of a Tertiary Care Teaching Hospital in Jaipur City

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ABSTRACT

Introduction: This study aims to evaluate the pattern of adverse drug reaction to Covishield vaccine which is being given to faculty doctors at SMS Medical College in Jaipur city.

Methodology: A pre-validated questionnaire was circulated through e-mail to all the faculty members.

Results: A total of 190 participants consented for participation and were enrolled for this study. 119 (62.63%) were male and 71 (37.37%) were female. 48.42% were in the age group of 31-49 years. 86.84% of the enrolled participants had received both the doses of Covishield. Two common adverse effects noted were fatigue and fever. The most common reason for not reporting the adverse effect was a belief that the adverse effect encountered by them is an established adverse effect and not unusual.

Conclusion: The data suggests that Covishield had mild to moderate adverse effects in the study population. Continuing medical education and workshops should be undertaken to educate the health care workers regarding active surveillance.

Keywords: Adverse drug reactions, Covishield, Google forms.

INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*) first emerged in late 2019 in Wuhan (Hubei, China) and briskly turned to global threat affecting 220 countries.[1-4] The devastating impact of this disease worldwide had called forth the need for mitigation policies to contain the pandemic.[5] The Covishield vaccine was approved by the Drugs Controller General of India (DCGI) on 3rd January 2021. This Oxford-AstraZeneca vaccine is manufactured locally by the Serum Institute of India.[6] Common adverse drug reactions (ADRs) to Covishield include pain, swelling, redness, and itching at the injection site, stiffness in the upper arm, weakness in the injection arm, body ache, headache, fever, malaise, weakness, rashes, nausea, and vomiting.[7]

Covishield vaccine is being administered to the faculty doctors of our institution as a part of the vaccination program of Government of India. The results of the current study would highlight the spectrum of adverse effects to this new vaccine and will also help to strengthen the pharmacovigilance program of the Government of India.

METHODS

This retrospective cross-sectional questionnaire based study was conducted among the faculty doctors working in a Government Medical College, Jaipur (Rajasthan) in May, 2021 during the COVID-19 pandemic. Prior to the start of the study, it was approved by the institutional ethics committee of the college. Participation in this study was voluntary and the participants had submitted their informed consents priorly through email. Inclusion criteria were:1) all the faculty doctors working in SMS Medical College and who had received Covishield, and 2) those who gave their consent for participation in the study. Exclusion criteria were: 1) other healthcare workers (nursing staff, technicians), resident doctors, and intern students, 2) those receiving vaccines other than Covishield or no vaccine. A standardized questionnaire using Google form was utilized to collect information about the participants.

The questionnaire included 3 major parts, in sequence: demographic data including age, gender, vaccine data (number of doses received, side effects in terms of duration and severity, and time of onset). Participants were asked to fill the form independently and submit it within a week. The recorded responses were then analyzed.

The automatically generated spreadsheet of the

participants in this study was organized. Microsoft Excel version 2016 (MS Excel 2016) was used for statistical analysis. Descriptive statistics such as frequency, percentage were used for calculation.

RESULTS

A total of 190 participants who consented to participate were enrolled for the final analysis. 119 (62.63%) were male and 71(37.37%) were female (Table 1). The age of most of them was of a range 31-49 years which was about 48.42%. Sixty four (33.7%) study participants suffered from comorbidities including hypertension, diabetes, hyperlipidemia, hypothyroidism, coronary artery disease, and gout in 34, 19, 3, 2, 2 and 4 participants, respectively for which they were taking medications. Two participants were taking antiplatelet drugs, one for coronary artery disease and other for past history of myocardial infarction.

35.78% (N = 68) of the study participants had suffered from COVID-19 infection prior to the vaccination. 86.84% of enrolled participants had received both the doses of Covishield while 13.16% had received only a single dose. A total of 153 (80.52%) out of 190 had obvious adverse effects, ranging mild to moderate in terms of severity, while the rest 19.47% were asymptomatic as depicted in table 1. The duration of moderate adverse effects lasted for 1-7 days in 21.58% of the participants. Eighteen (26.47%) out of 68 participants with the previous history of COVID-19 infection suffered from adverse effects post vaccination, while 54.05% of the participants who suffered from adverse effects had no history of previous COVID-19 infection.

The most common post vaccination symptoms were fatigue (N = 112), fever (N = 108), local pain at injection site (N = 56) and tenderness at injection site (N = 34) and the less likely appeared symptoms were rashes (N = 1), lingual papillitis (N = 1) and lower back pain (N = 4) as shown in table 2. Analgesics and antipyretics were taken by the participants for their adverse effects and one participant had to take topical local anesthetic agent for lingual papillitis. None of the adverse effects required hospitalization. 132 (86.27%) participants didn't even report their adverse drug reactions. Various reasons for not reporting their adverse effects are shown in figure 1.

DISCUSSION

Covishield vaccine is a recently approved vaccine for emergency use authorization in India, however, similar to other vaccines, it is not without adverse effects. In the present study, out of 190 participants, 153 (80.52%) were symptomatic and 37 (19.47%) were asymptomatic. Few

Table 1: Demographic details of the study participants

Variables	Frequency	Percentage
Sex		
Male	119	62.63%
Female	71	37.37%
Age (in years)		
<30	26	13.68%
31-49	92	48.42%
50-69	72	37.89%
Doses of vaccination received		
One	25	13.16%
Two	165	86.84%
Past history of COVID-19 infection		
Encountered COVID-19 before vaccination	68	35.78%
Not Encountered COVID-19 infection till date	122	64.21%
Adverse effects post vaccination		
Yes	153	80.53%
No	37	19.47%
Severity of symptoms		
Mild	129	78.42%
Moderate	24	21.58%

Table 2: Various adverse effects encountered post-vaccination

Adverse effects	Frequency of ADRs (After first dose)	Frequency ADRs (After second dose)	Total participants experiencing adverse effects	Percentage
Fatigue	78	34	112	58.95%
Fever	56	52	108	56.84%
Pain at injection site/injection arm	22	34	56	29.47%
Tenderness at injection site/injection arm	19	15	34	17.89%
Rashes	1	–	1	0.52%
Lingual Papillitis	–	1	1	0.52%
Lower back pain	2	2	4	2.1%

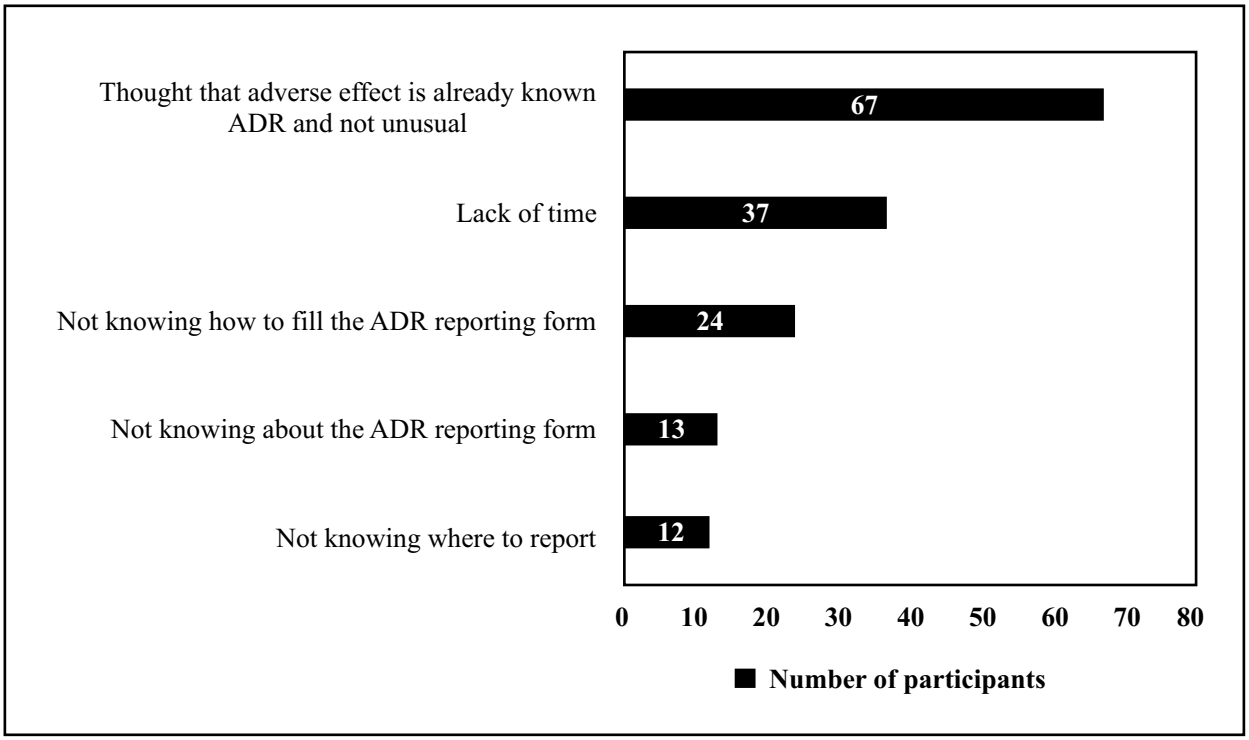

Figure 1: Various reasons for not reporting the adverse effects post-vaccination.

most common symptoms noted in our study were: fatigue (58.94%), fever (56.84%), local pain (29.47%) and tenderness at injection site (17.89%). These results are similar to previous international studies from Iran and Wuhan in China which reported fever (46%), fatigue (44%) and headache (39%) as few common adverse effects in vaccinated individuals.[8,9] Post-vaccination adverse effects occurred in 26.47% of the patients with a previous history of COVID-19 infection. At present, there are no studies on correlation of past COVID-19 infection and adverse effects following COVID-19 vaccination.

Only one participant (0.52%) in the present study suffered from post-vaccination allergic reaction unlike in another study where the reported rate of allergic reaction was a little higher (1.7%).[10] The possible reason could be ethnic difference between the study population in this study which was conducted in UK. Regarding severity of adverse effects, most symptoms were mild (78.4%) to moderate (21.6%) and no severe side effects were noted. This finding is similar to study conducted in Wuhan which stated most symptoms as mild to moderate in severity.[9]

There is a need to develop new ADR reporting forms highlighting the type of COVID vaccine, distributor details, and details of the professional, administering the vaccine, history of COVID-19 diagnosis, COVID-19 symptoms at the time of vaccination. This could be used by various health care professionals trained in its use to provide COVID vaccine specific side effects.[11]

86.27% of the participants did not report their adverse effects. The reasons for not reporting the adverse effect have been studied previously like inadequate risk perception about newly marketed drugs, fear, lack of clarity of information on ADR form as few important reasons for under reporting of the adverse effects.[12] Similarly, in the present study majority of the participants believed that their adverse effects are not unusual to be reported. These findings suggest the need for training of our health care workers on reporting of adverse effects following immunization. Only then the active surveillance will be at par along with the mass vaccination program of the Government of India.

CONCLUSION

Fatigue, fever, local pain, and tenderness at injection site are the most commonly reported side effects of Covishield. The adverse drug reactions reported in the present study were mild to moderate in severity. Training of health care professionals regarding adverse drug reaction reporting is the need of hour.

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