Original Research Article

A study on adverse effect following immunization COVID-19 vaccination Covishield among MBBS student s of a tertiary care institution in a rural area of Chhattisgarh, India

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ABSTRACT

Background: India has granted emergency use authorization to two COVID-19 vaccines, Pune based Serum Institute of India's Covishield and Hyderabad- based Bharat Biotech International Ltd.'s Covaxin, for the vaccination drive. Once a vaccine is in use, it must be continuously monitored to make sure it continues to be safe. These data will add on in policy making and also help vaccine to be safely tracked throughout its use. In view of above background present study has been conducted to determine adverse effect following immunization.

Methods: A cross sectional observational study was conducted among 400 MBBS students of a rural medical college in Chhattisgarh, India from January 2021 to March 2021. Approval was taken from institutional ethical committee and written informed consent was obtained from participants. A semi-open questionnaire was used to estimate the adverse effect following Covishield administration. Data was processed, analysed using SPSS software and information was obtained.

Results: Study shows most common adverse effect was pain at injection site (86%), followed by fever (76%). Female received more (69%) treatment compared to male (31%). Almost 100% of subject experienced adverse effect following immunization (AEFI) following first dose administration whereas about 20% only experienced adverse effect following administration of second dose.

Conclusions: Pain at injection site was most common adverse effect followed by fever. Adverse effect was four times more with first dose compared to second dose. Female received more treatment compared to male. Majority had fever and pain for 1-2 days only. Thus, it was concluded that vaccine have no serious side effect.

Keywords: AEFI, Covishield, Fever, Pain, Treatment received

INTRODUCTION

India has granted emergency use authorization to two COVID-19 vaccines ,Pune based Serum Institute of India's Covishield and Hyderabad- based Bharat Biotech International Ltd.'s Covaxin, for the vaccination drive.¹ India has vaccinated the highest number of persons on the first day under its COVID-19 vaccination programme, the

world's largest such exercise. This is much higher than many other countries including the US, the UK and France.¹ Tracking of vaccinated person is ongoing to lookout safety and efficacy.² In view of above context present study was conducted with the objective to determine the adverse effect following immunization (AEFI) among study subject. It will help to policy maker to conclude based on the observation.

METHODS

A cross sectional observational study was carried out on total of 400 MBBS Students of Chandulal Chandrakar Memorial Medical College at district Durg, Chhattisgarh, India, during January 2021 to March 2021 using semi-open questionnaire. Sample size was obtained using formula $4pq/L^2$. Where p was taken as 50% and $q = 100 - p$, L (allowable error) = 10% of p. Study protocol was approved by the institutional ethics committee and written informed consent obtained from the participants.

Exclusion criteria

Those who were not willing to participate in study were excluded from study.

Data was analysed using SPSS software and information obtained were interpreted in context to above aim and objective.

RESULTS

In present study sex ratio was 1.08 (Table 1). Study shows most common adverse effect was pain at injection site (86%), followed by fever (76%), joint ache (40%), Headache (30%), chills (22%), tachycardia (10%), motor weakness (6%) and 4% of people experienced numbness, 4% urticaria, 4% rashes respectively, and others 4% including congested eyes and fatigue (many subject experienced more than one adverse effect) (Figure 1). Among the entire participant 32% received treatment; female received more (69%) compare to male (31%) (Table 2).

Table 1: Gender distribution of study population.

Gender	Number	Percentage
Male	192	48
Female	208	52
Total	400	100

Table 2: Gender wise distribution of treatment received for AEFI.

Gender	Number	Percentage
Female	88	69
Male	40	31
Total	128	100

Table 3: Dose based distribution of AEFI.

Dose	Number	Percentage
First dose	400	100
second dose	80	20
Total	480	100

*Same person (n=80) experienced adverse effect following administration of second dose

Figure 1: Bar diagram showing distribution of adverse effect following Covishield administration.

(Same subject experienced more than one adverse effect).

Almost 100% of subject experienced AEFI following first dose administration whereas about 20% only experienced adverse effect following administration of second dose (Table 3). Here we observed 42% of people had fever for 1-2 days, 32% for 0-1 days, 18% for 2-3 days and rest 8% for 3-4 days (Figure 2). Concerned to pain at local injection site persisted following immunization, study observe that, 47% people experienced pain for 2-3 days, 40% 0-1 days, 9% 4-5 days and 2% for 8-9 days respectively (Figure 3).

Figure 2: Distribution of subject with no of days they experienced fever.

Figure 3: Distribution of subject with pain persisting (in days) at site of injection.

DISCUSSION

As we know there is limited study so far on AEFI, in present study sex ratio was 1.08 (Table 1). Study shows most common adverse effect was pain at injection site (86%), followed by fever (76%), joint ache (40%), Headache (30%), chills (22%), tachycardia (10%), motor weakness (6%) and 4% of people experienced numbness, 4% urticaria, 4% rashes respectively, and others 4% including congested eyes and fatigue (Figure 1). Among the entire participant 32% received treatment; female received more (69%) compare to male (31%) (Table 2). In a similar study, adverse effect was seen in 75.5% of the women and 45% of the men. The most common ones were pain at the injection site (76.1%) followed by body ache (46.8%), headache (30.3%), and fever (22%). The respondent also complained of stiffness in the arm (11.5%), swelling in the arm (16.5%), and GI symptoms and vomiting (4.1%). But there was no case of serious adverse event following immunization.³ This observation is almost similar to present study except fever which was second most common side effect (about 76%) whereas in this study it was only 22%. In present study, 100% of subject experienced adverse effect following immunization (AEFI) following first dose administration whereas about 20% only experienced adverse effect following administration of second dose (Table 3). Here we observed 42% of people had fever for 1-2 days, 32% for 0-1 days, 18% for 2-3 days and rest 8% for 3-4 days (Figure 2). Concerned to pain at local injection site persisted following immunisation, study observe that, 47% people experienced pain for 2-3 days, 40% 0-1 days, 9% 4-5 days and 2% for 8-9 days respectively (Figure 3). In a similar study, after four hours of vaccination, some health workers complained about irritability in mood, six 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. Paracetamol (NSAID) seems to be required with the Oxford vaccine compared to Pfizer or Moderna vaccines to resolve the individuals' common symptoms.⁴ In another study it was observed that, fever, fatigue, body ache and nausea were some of the most common adverse effect whereas soreness at the site of vaccination, lethargy/malaise are other common symptoms experienced by few individuals post their vaccination. While the post vaccination side effects may linger on for a day or two, experts believe it is highly manageable at home.⁵ In another study, it was noted that over 53.1 per cent did not encounter any side effects. While 20.4 per cent had tenderness, pain and warmth, 18.9 per cent had chills and felt feverish, including a small group who complained of swelling, lump and redness at the injection site.⁶ This study is dissimilar to present study where 100% subject experienced adverse effect although none

was serious to get hospitalised. India has reported 234 adverse events following immunisation (AEFIs), including 71 deaths, for both the vaccines as per Dr N K Arora, an advisor to the national AEFI committee.⁶ There is a need for long-term monitoring of adverse drug reactions and an urgent need for monitoring by pharmacovigilance centres within a country. The central government decided to conduct a deeper review of post-vaccination side-effects from the Oxford-AstraZeneca corona virus vaccine news agency AFP reported. The news came after several countries had suspended rollout of AstraZeneca shot over blood clot fears. However, no cases of blood clots have been reported so far in the country, AFP said. Denmark, Norway and Iceland paused use of Oxford-AstraZeneca corona virus vaccine as a precaution after isolated reports of recipients developing blood clots.⁷

As the study was conducted on MBBS students who attended institution physically, less number of participants were available for study.

CONCLUSION

Majority had minor adverse effect and maximum shows adverse effect following first dose of administration. About 3:1 ratio F:M observed concerning treatment received for adverse effect.

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Conflict of interest: None declared

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

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