

## To Study the Safety Profile of Vaccines Covishield and Covaxin Administered for Prevention of Sars-Cov-2 in MBBS Students of NSCB Medical College, Jabalpur

Supriya Sharma<sup>1</sup>, Vaibhav Singh Chauhan<sup>2</sup>, Akshata Kalyani<sup>3</sup>, Vimmi Agrawal<sup>4</sup>

<sup>1</sup>Assistant Professor, Department of Pharmacology, NSCB Medical College, Jabalpur (M.P.)

<sup>2</sup>Assistant Professor, Department of Pharmacology, NSCB Medical College, Jabalpur (M.P.)

<sup>3</sup>Assistant Professor, Department of Pharmacology, LN Medical College, Indore (MP)

<sup>4</sup>Assistant Professor, Department of Pharmacology, NSCB Medical College, Jabalpur(M.P.)

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Corresponding author: Dr Vimmi Agrawal

Conflict of interest: Nil

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### Abstract

**Background:** The vaccine hesitancy is not a new phenomenon and was witnessed in previous outbreaks of infectious diseases like measles-mumps-rubella vaccines. In view of above context present study was conducted to study the safety profile of vaccines covishield and covaxin administered for prevention of sars-cov-2.

**Methods:** It was an observational study to assess the safety profile of covishield and covaxin vaccine. The participants were those pursuing MBBS in NSCB Medical College, Jabalpur. The tool used was Google form based questionnaire. Snowballing of invitation was encouraged.

**Results:** Study shows most adverse effect was mild to moderate with pain at injection site being the most common. Paracetamol (NSAID) was the most taken drug.

**Conclusions:** It seems that such mild side effects are acceptable during COVID-19 vaccination as the body will need some time to adopt vaccination dose. Therefore the general people should be aware of these minor side effects which are manageable with some symptomatic treatment like paracetamol and increase the acceptance of the COVID-19 vaccine among the mass population.

**Keywords:** Covishield, Covaxin, AEFI, ADR, Paracetamol (NSAIDS)

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### Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of coronavirus disease 2019 (Covid-19), emerged in China in late 2019 from a zoonotic source. The majority of Covid-19 cases either are asymptomatic or

result in only mild disease [1]. The world was in desperate need of effective vaccines against the Coronavirus Disease 2019 (COVID-19). Vaccines were needed to reduce the morbidity and mortality associated with Covid-19, and

multiple platforms have been involved in the rapid development of vaccine candidates [2].

India began administration of COVID-19 vaccines on 16 January 2021. India initially approved the Oxford–AstraZeneca vaccine (manufactured under license by Serum Institute of India under the trade name Covishield) and Covaxin (a vaccine developed locally by Bharat Biotech) [3].

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 [4].

It was seen that Indian population was hesitant about vaccination for COVID-19 in fear of adverse effect. The vaccine hesitancy is not a new phenomenon and was witnessed in previous outbreaks of infectious diseases like measles-mumps-rubella vaccines. India's healthcare workers were the first to get Covid-19 vaccine when the country begins its immunization drive. In view of above context present study was conducted with the objective to determine the adverse effect following immunization (AEFI) among MBBS students of NSCB Medical college.

### Method

This study was planned as an observational study to assess the safety profile of covishield and covaxin vaccine.

The participants were those pursuing MBBS in NSCB Medical College, Jabalpur.

The tool used was Google form-based questionnaire. Snowballing of invitation was encouraged. The participation was voluntary. Study protocol was approved by the Institutional Ethics Committee and consent obtained from the participants. Data was analyzed using Microsoft Excel software and information obtained were interpreted in context to above aim and objective.

### Inclusion Criteria

1. All MBBS students who have been administered either single or both doses of Covaxin for prevention of SARS-COV-2 virus.
2. All MBBS students who have been administered either single or both doses of Covishield for prevention of SARS-COV-2 virus.

### Exclusion Criteria

1. All students who have been administered no dose of either Covaxin or covishield vaccine.

### Discussion

As we know there is limited study so far on AEFI, in present study there were total 318 (n=318) participants and with male preponderance 54.40 % and female with 45.60 %. Students infected with covid virus before vaccination was 6.29 % (n=20) with major source of infection being Household (45%). [Figure 1]

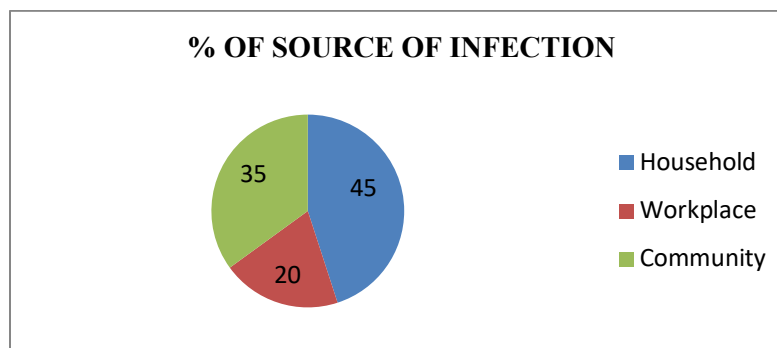
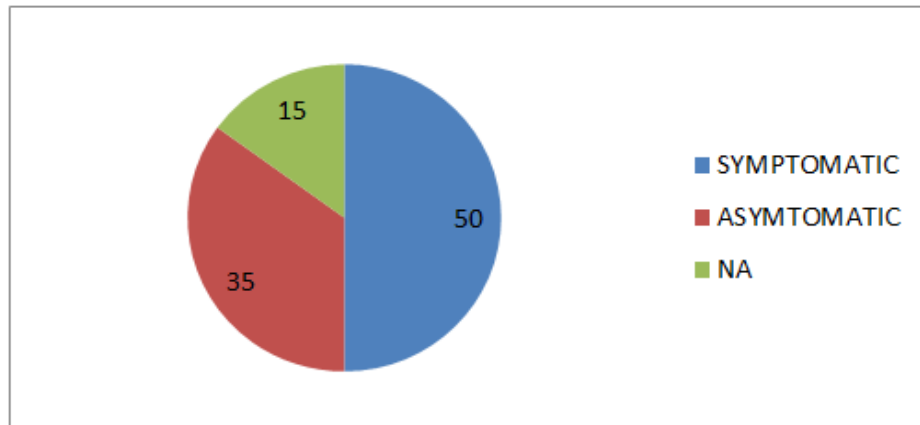
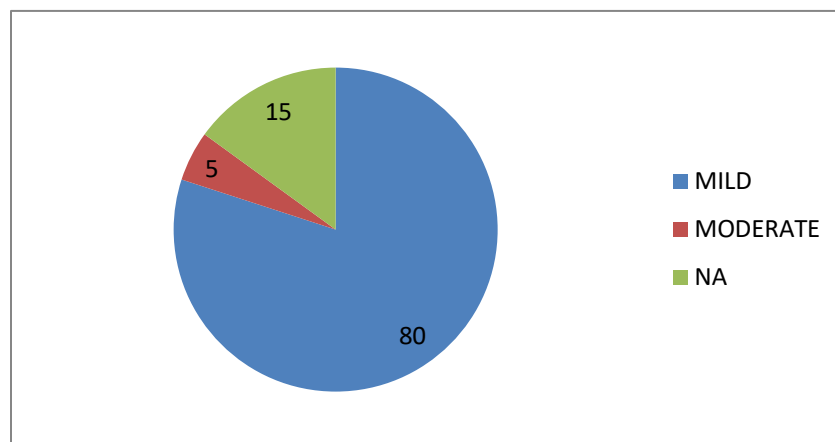


Figure 1: Source of Infection

Among those infected, 50 % were symptomatic (n=10 out of 20) and majority of them had mild type of illness, and they recovered gradually well following Government guidelines for home isolation. [Figure 2, Figure 3]

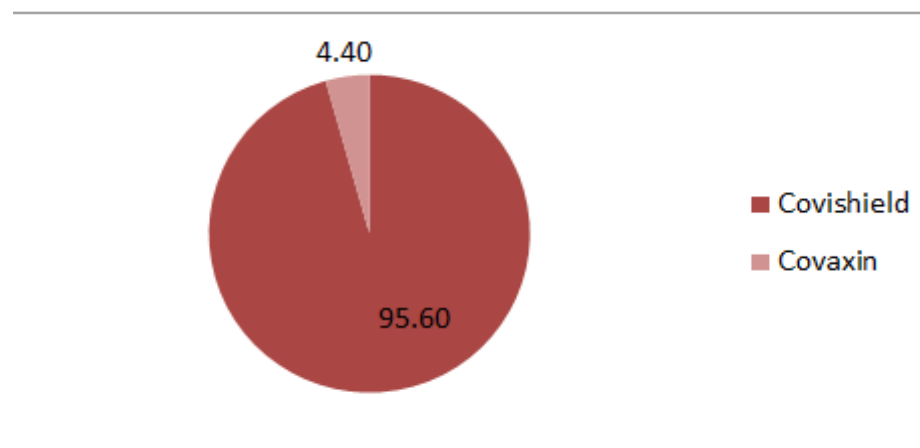


**Figure 2: Percentage of Type of Illness**



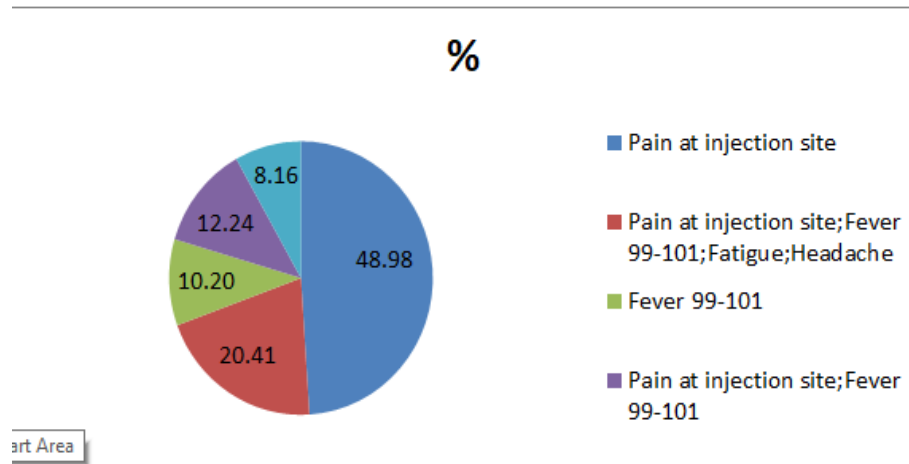
**Figure 3: Percentage of Severity of Illness**

Out of 318 participants, 304 received Covishield as their first dose while 14 received Covaxin as their first dose, this might be due to our center received covishield vaccines first than covaxin. Figure 4



**Figure 3: Percentage of Covishield and Covaxin Received**

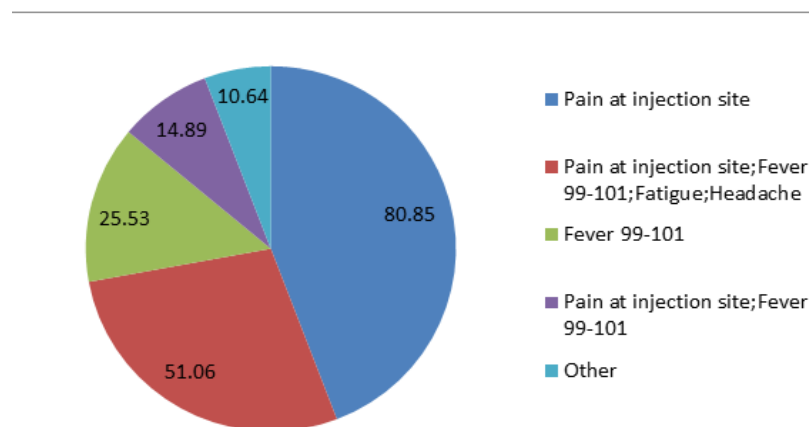
Out of 318 participants, 147 had reported adverse effect following immunization and most common reported ADR were Pain at injection site, Fever 99 to 101, Fever with chills, Fatigue, Headache. [Figure 5]



**Figure 4: Percentage of Different ADR Reported**

Severities of reported ADR were mild to moderate and 75 % patient taken Tablet Paracetamol for symptomatic relief and they all recovered gradually well. While the post vaccination side effects may linger on for a day or two, experts believe it is highly manageable at home [5].

Both the vaccines were injected intramuscularly with a minimum gap of 4 weeks during early immunization drive. Following second dose of vaccination, 86 participants reported ADR. Majority of reported ADR were Pain at injection site, Fever 99 to 101, Fever with chills, Fatigue, Headache. Pain at injection site being the most common reported ADR. [Figure 6]



**Figure 5: Percentage of Reported ADR Following 2nd Dose of Vaccine**

Paracetamol (NSAID) was the most taken drug to resolve the individuals' common symptoms. As these are common symptoms or side effects observed with 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. No serious side effect or death was reported in participants who received Covid Vaccine.

### Limitation

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. Pain at the site of injection was the most common reported ADR. 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 develop their own protective antibodies. Therefore the general people should be aware of these minor side effects which are manageable with some symptomatic treatment like paracetamol and increase the acceptance of the COVID-19 vaccine among the mass population, which would certainly help to overcome this pandemic disease and making vaccination programme successful.

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