

Original Research Article

# A cross-sectional study on the extent of Pharmacovigilance awareness among fifth term medical students


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## Abstract

**Background:** Adverse effects due to medicines are common cause of morbidity and mortality and have a major impact on public health.

**Aim:** To assess the awareness of Pharmacovigilance among fifth term medical students.

**Material and methods:** This was an observational, cross-sectional study based on the questionnaire. The study was conducted on fifth term medical students in the Department of Pharmacology of BMCH, Chitradurga. A questionnaire containing 15 questions with 2-5 options were given to each student and they were asked to mark one best suitable option. We analyzed data of 66 participants. The results were evaluated graphically using Microsoft excel sheet.

**Results:** 89.93% of students were aware of all the activities involved in Pharmacovigilance. 48.48% of the students had an idea that all the health care professionals (i.e. doctors, pharmacists, nurses) are responsible for reporting adverse drug reaction (ADR). 34.84% of students had wrong perception that WHO online database for reporting ADRs was Medsafe and 31.81% thought Vigibase as the WHO online database. 48.48% had the correct understanding that CDSCO is the regulatory body for monitoring ADRs in India. 66.66% students thought that, all the types of ADRs (mild, moderate and severe) irrespective of their severity have to be reported. 61% of students thought that ADR reporting is a Professional obligation. 91% of the students were aware that all the measures (stop the drug, report ADR and treat the condition) have to be taken when an ADR is suspected. Other findings included like, 68% students knew drugs banned because of ADR. Majority of students wrote Thalidomide and Nimesulide as an example for a drug banned because of ADR.

**Conclusion:** The current study revealed that medical students had good awareness about Pharmacovigilance and ADR reporting. Better understanding of subject will help in improving the quality of health care and safety of the patients.

## Key words

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Pharmacovigilance, Awareness, Adverse drug reactions, Medical students, Safety.

## Introduction

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Adverse Drug Reactions are under reported by health care professionals due to lack of awareness. As per World Health Organization, Adverse Drug Reaction (ADR) is any noxious, unintended and undesired effect of the drug which occurs at doses used in humans for the prophylaxis, diagnosis or therapy of a disease or the modification of physiological state [1]. Pharmacovigilance is defined as science and activities related to detection, assessment, understanding and prevention of adverse drug reactions or any drug related problem.

Adverse effects due to medicines are common cause of morbidity and mortality. ADRs have a major impact on public health by imposing a considerable economic burden on the society [2]. It is estimated that only 6-10% of all ADRs are reported and underreporting of ADR is a major problem.

The use of medicines for therapy has been associated with side effects and sometimes harmful adverse drug reactions. Monitoring and surveillance of ADRs will be helpful to reduce the morbidity and mortality among patients. ADRs are associated with large number of hazards leading to increased economic burden both for the individual and also for the community [3].

Pharmacovigilance has constantly grown its importance in the last 15 years as several hospital admissions are due to ADRs [4, 5]. ADRs are responsible for 5% to 20% of hospital admissions [6, 7]. Studies from different settings indicate inadequate knowledge about Pharmacovigilance among healthcare professionals as well as

attitude that are associated with high degree of underreporting [8].

Few studies had been carried out in different countries to assess the knowledge of Pharmacovigilance among the medical students and practitioners. In the U.K., 57% of the medical schools assessed the students' knowledge on the yellow card scheme [9]. In France, a survey which was conducted among medical residents showed that a majority lacked knowledge on Pharmacovigilance [10].

Assessment of awareness of Pharmacovigilance among healthcare professionals is very important due to underreporting of ADRs. As future medical practitioners, medical students need to be well trained on how to recognize, prevent and report ADRs.

The right time to improve the knowledge and awareness about Pharmacovigilance is probably during undergraduate education of the doctors [11]. There is paucity of studies assessing the awareness of Pharmacovigilance among medical students. In view of this, the present study was undertaken to assess the awareness of Pharmacovigilance among fifth term medical students at Basaveshwara Medical College and Hospital, Chitradurga.

## Material and methods

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This was an observational, cross-sectional study based on the questionnaire. The study was conducted on 2<sup>nd</sup> year (fifth term) medical students in the Department of Pharmacology of BMCH, Chitradurga. Prior permission was obtained from the Institutional Ethics Committee. A questionnaire containing 15 questions with 2-5 options were given to each

student and they were asked to mark one best suitable option (**Annexure - 1**). Students were instructed not to reveal their identity in the questionnaire. Twenty minutes was the time allotted for answering the questionnaire. The questionnaire was based on previous studies undertaken on Pharmacovigilance and it was suitably modified for students. The completed questionnaire was collected and data was analyzed.

Totally 70 students participated in the study, out of which 4 questionnaires were incomplete and eliminated while evaluating results. So, we analysed data of 66 participants. The results were evaluated graphically using Microsoft excel sheet.

## Results

Majority of the students had correct understanding regarding Pharmacovigilance and its role in identifying the safety of drugs.

89.93% of students were aware of all the activities involved in Pharmacovigilance. (**Figure - 1**)

48.48% of the students had an idea that all the health care professionals (i.e. doctors, pharmacists, nurses) are responsible for reporting ADR. (**Figure - 2**)

34.84% of students had wrong perception that WHO online database for reporting ADRs was Medsafe and 31.81% thought Vigibase as the WHO online database. (**Figure - 3**)

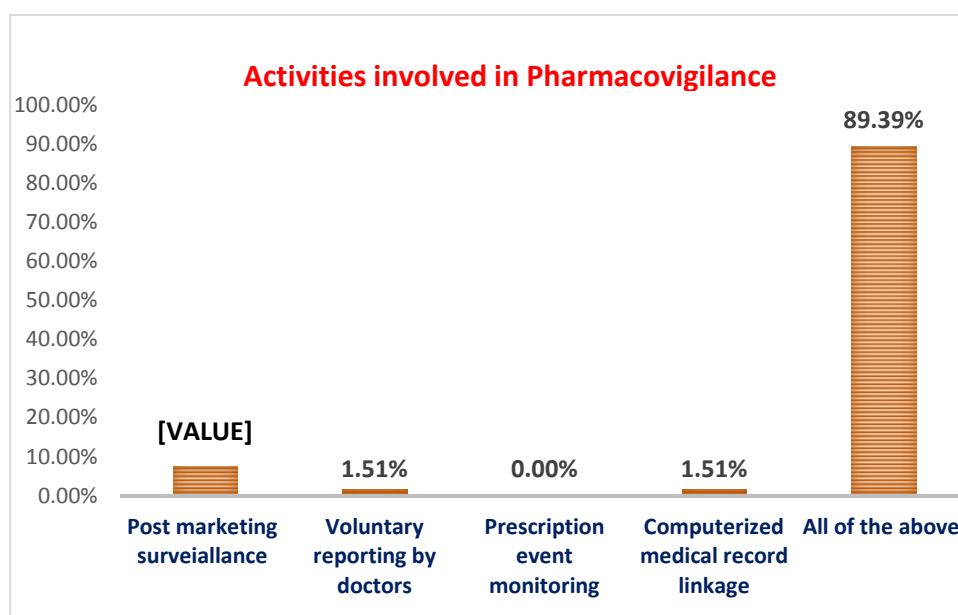
48.48% had the correct understanding that CDSCO is the regulatory body for monitoring ADRs in India. (**Figure - 4**)

66.66% students thought that, all the types of ADRs (mild, moderate and severe) irrespective of their severity have to be reported. (**Figure - 5**)

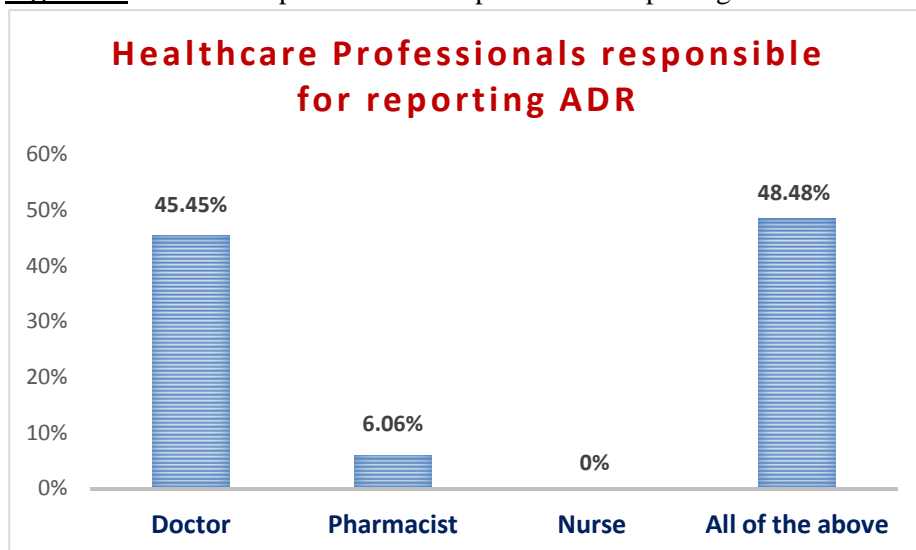
61% of students thought that ADR reporting is a Professional obligation. (**Figure - 6**) 91% of the students were aware that all the measures (stop the drug, report ADR and treat the condition) have to be taken when an ADR is suspected. (**Figure - 7**)

Other findings include - 68% students knew drugs banned because of ADR. Majority of students wrote Thalidomide and Nimesulide as an example for a drug banned because of ADR.

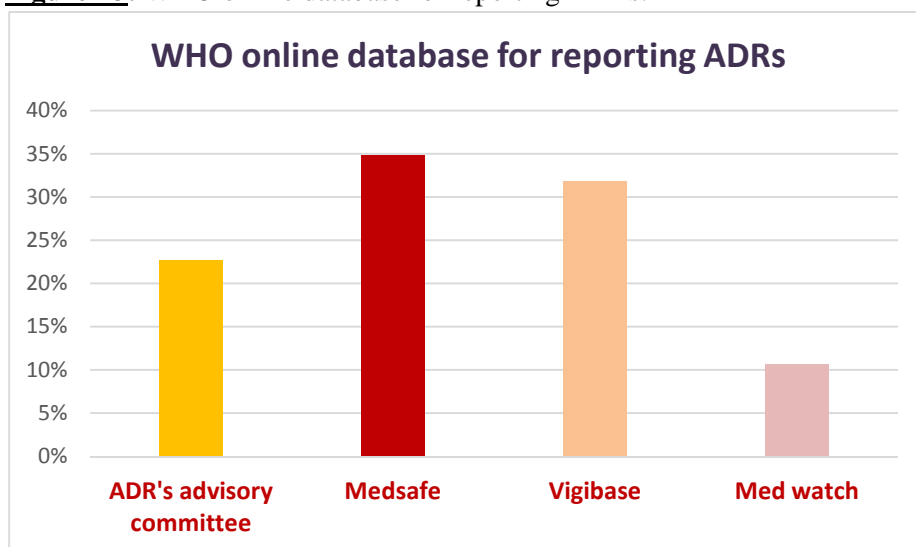
**Figure - 1:** Activities involved in Pharmacovigilance.



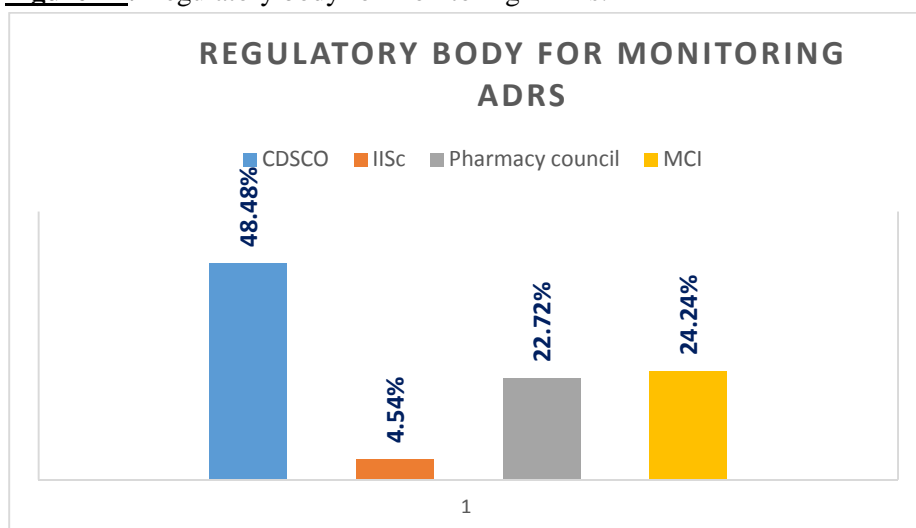
**Figure - 2:** Healthcare professionals responsible for reporting ADR.



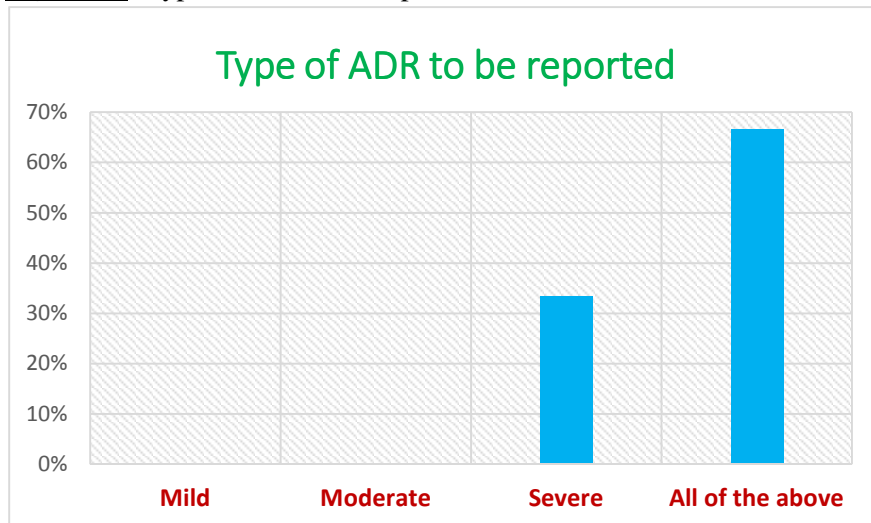
**Figure - 3:** WHO online database for reporting ADRs.



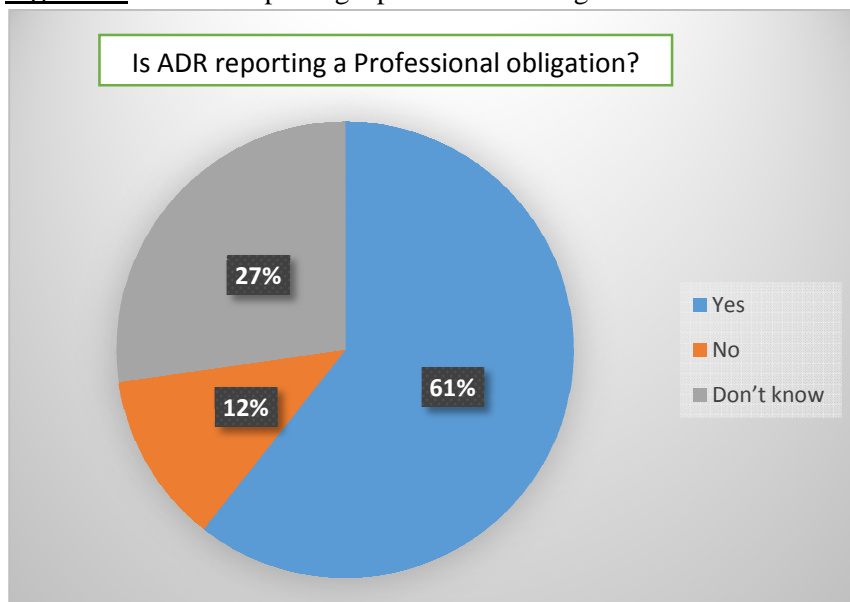
**Figure - 4:** Regulatory body for monitoring ADRs.



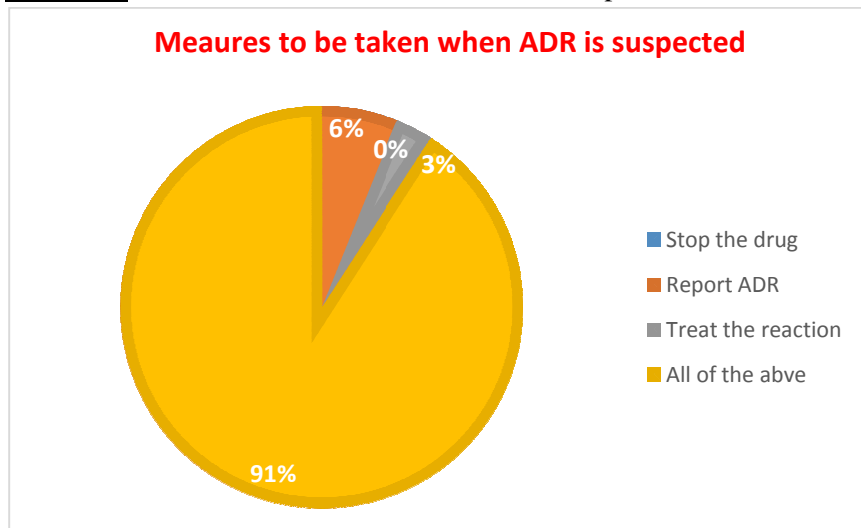
**Figure - 5:** Type of ADR to be reported.



**Figure - 6:** Is ADR reporting a professional obligation?



**Figure - 7:** Measures to be taken when ADR is suspected.



## **Discussion**

Adverse effects due to medicines are common cause of morbidity and mortality. ADRs have a major impact on public health by imposing a considerable economic burden on the society [2]. It is estimated that only 6-10% of all ADRs are reported and underreporting of ADR is a major problem. The aim of Pharmacovigilance Programme of India (PvPI) is to ensure rational therapy by encouraging the adverse drug reaction reporting.

In our present study, 89.39% of the students were aware of activities involved in Pharmacovigilance compared to 26% in a study done by Rehan, et al. [12] and 94% reported by Deepak, et al. [13]. In our study, 48.48% of participants were aware of the regulatory body responsible for monitoring ADRs which was low when compared to 84% reported by Radhakrishnan, et al. [14] and 79% reported by Deepak P, et al. [13].

Regarding reporting of ADRs based on severity, in our study 66.66% of students had an opinion that all ADRs should be reported irrespective of the severity, whereas in a study done by Rehan, et al. [12] around 65% students had the similar opinion and 84% in a study by Deepak, et al. [13].

In our study 61% students thought that ADR reporting is a professional obligation. In another study by Deepak, et al. [13] only 47% of students thought that ADR reporting is a professional obligation. The reason for this difference could not be ascertained. In our study, 91% of students were aware of the measures that have to be taken when an ADR is suspected, and similar was the result in a study by Deepak, et.al. [13], who reported 93% of the students had awareness about measures to be taken when an adverse drug reaction is suspected.

The overall results of this study was encouraging, considering the fact that most of the students were aware of the term

Pharmacovigilance, its activities, measures to be taken when ADR is suspected, type of ADR to be reported, regulatory body monitoring ADR's, the healthcare professionals responsible for reporting ADRs. This encouraging results may be because, we have included Pharmacovigilance problem based learning as a part of Practical curriculum and it reflects the students' understanding on the subject. But, still there were some grey areas considering that most of students got it wrong when responding to the WHO online database for reporting ADRs.

## **Conclusion**

The current study revealed that medical students had good awareness about Pharmacovigilance and ADR reporting. Better understanding of the subject on Pharmacovigilance in these undergraduates would help them as future doctors in improving the quality of health care, as well as safety of the patients.

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