

A Cross-Sectional Study on the Extent of Pharmacovigilance Awareness among Fifth Term Medical Students

Manjunath S M^{1,*}, Nagesh Raju G², Someswara GM³

¹Assistant Professor, ²Professor, Department of Pharmacology, ³Associate Professor, Department of Community Medicine, Basaveshwara Medical College & Hospital, Chitradurga – 577502, Karnataka

*Correspondence Author:
E-mail: drsm.manju@gmail.com

ABSTRACT

Background: 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.

Objectives: To assess the awareness of pharmacovigilance among fifth term medical students.

Methods: This was an observational, cross-sectional study based on the questionnaire. The study was conducted on IInd year (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. 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. 48.48% of the students had an idea that all the health care professionals (i.e. doctors, pharmacists, nurses) are responsible for reporting 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% of students thought that, all the types of ADRs (mild, moderate & 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 & 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 & 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 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.

Keywords: Pharmacovigilance, awareness, adverse drug reactions, medical students

INTRODUCTION

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 & surveillance of ADRs will be helpful to reduce the morbidity & 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 & 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 & Hospital, Chitradurga.

OBJECTIVES

To assess the awareness of pharmacovigilance among fifth term medical students

METHODS

This was an observational, cross-sectional study based on the questionnaire. The study was conducted on IIInd 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 analysed.

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.

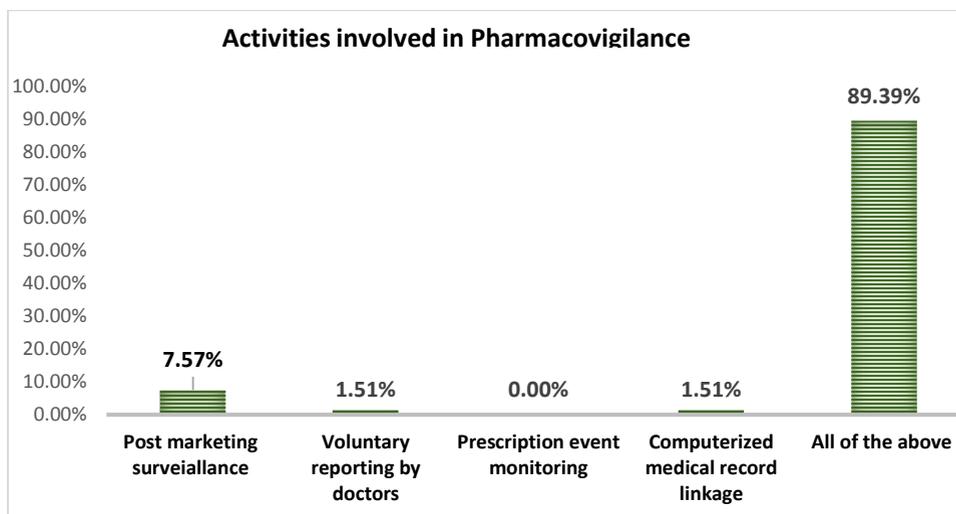


Fig. 1: Activities involved in Pharmacovigilance

89.93% of students were aware of all the activities involved in Pharmacovigilance.

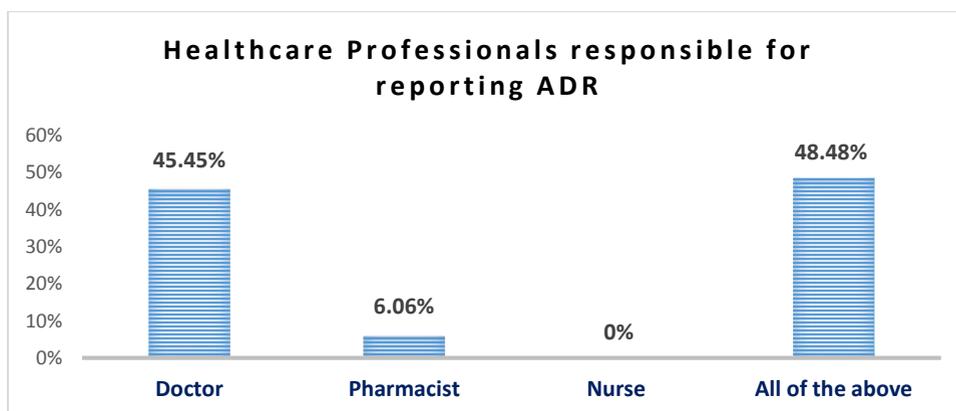


Fig. 2: Healthcare Professionals responsible for reporting ADR

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

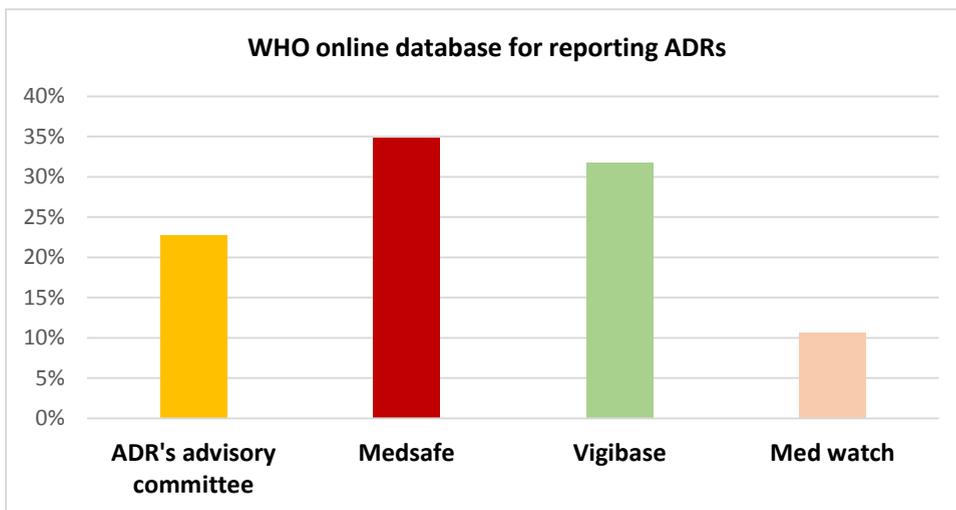


Fig. 3: WHO online database for reporting ADRs

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.

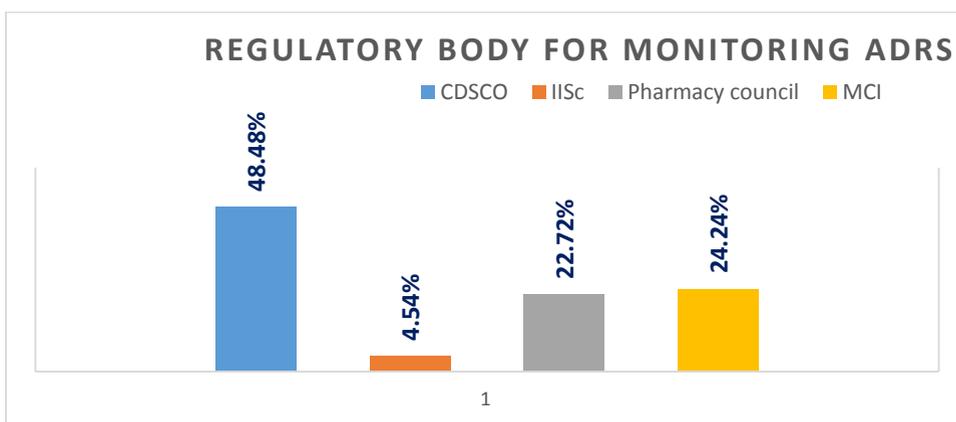


Fig. 4: Regulatory body for monitoring ADRs

48.48% had the correct understanding that CDSCO is the regulatory body for monitoring ADRs in India.

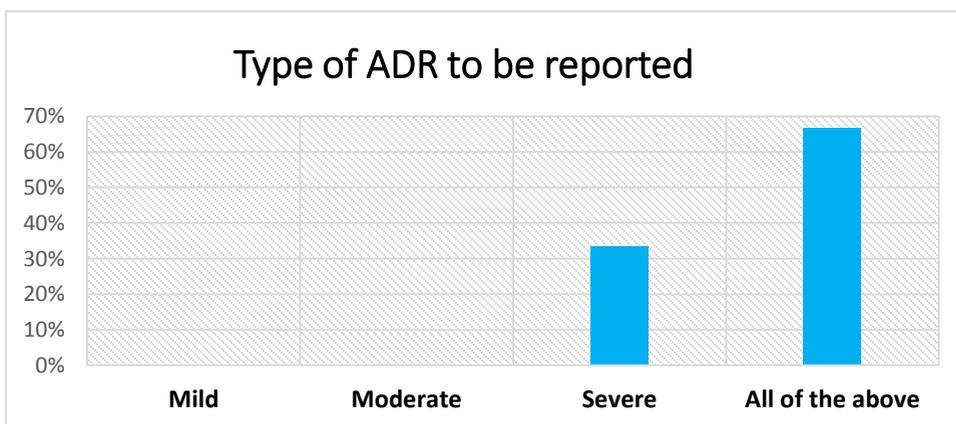


Fig. 5: Type of ADR to be reported

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

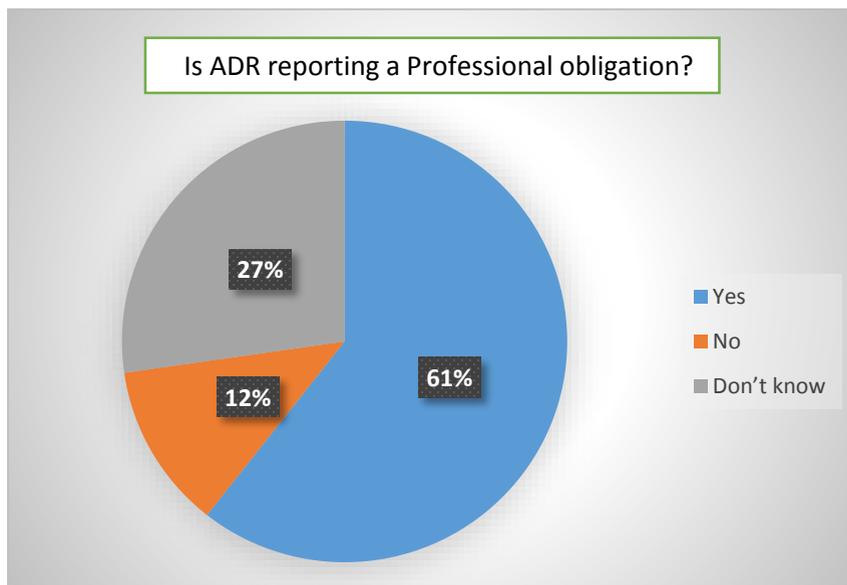


Fig. 6: Is ADR reporting a Professional obligation?

61% of students thought that ADR reporting is a Professional obligation.

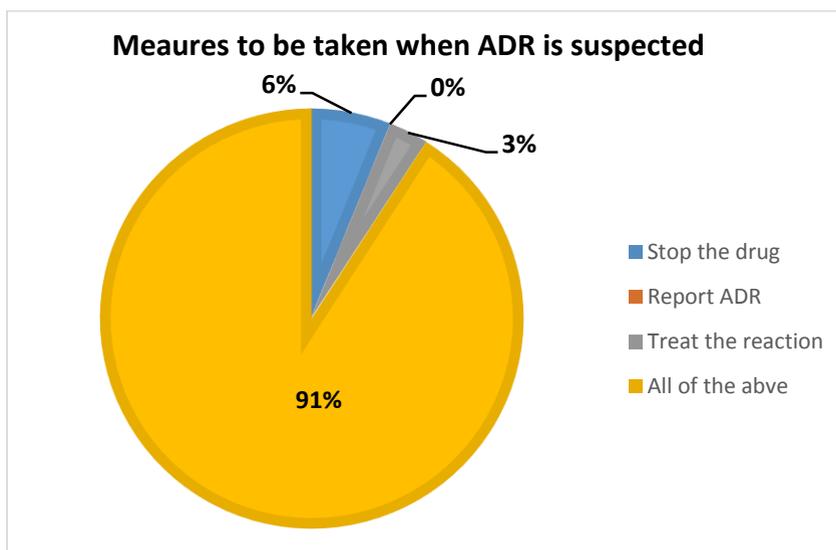


Fig. 7: Measures to be taken when ADR is suspected

91% of the students were aware that all the measures (stop the drug, report ADR & 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 & Nimesulide as an example for a drug banned because of ADR.

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 opinion⁶ 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 has 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.

Acknowledgement: Nil

Declarations:

Funding – No funding sources

Conflict of interest – None declared

Ethics approval – The study was approved by Institutional Ethics Committee

REFERENCES:

1. The world health organization: A safety of medicines a guide to detecting and reporting adverse drug reactions, Geneva, 2002.
2. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria: BMC Clin Pharmacol 2009;9:14.

3. Ayani I, Aguirre C, Gutierrez G, Madariaga A, Rodríguez Sasiain JM, Martínez-Bengoechea MJ. A cost-analysis of suspected adverse drug reactions in a hospital emergency ward. *Pharmacoepidemiol Drug Saf.* 1999;8:529-34.
4. Von Laue NC, Schwappach DL, Koeck CM. The epidemiology of preventable adverse drug events: A review of literature. *Wien KlinWochenschr* 2003;115(12):407-15.
5. Wu WK, Pantaleo N *et al.* Evaluation of outpatient drug reactions leading to hospitalization. *American journal of Health System Pharmacy* 2003;60(3):253-9.
6. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta analysis of prospective studies. *Journal of the American Medical Association* 1998;279(15):1200-05.
7. Pirmohamed M, James S, Meakin S, *et al.* Adverse drug reactions as cause of admission to hospital: Prospective analysis of 18,820 patients. *British Medical Journal* 2004;329(7456):15-19.
8. Figueiras A, Tato F, Fontainas J, Gestal-Oterro JJ *et al.* Influence of physicians' attitudes on reporting adverse drug events: A case control study. *Medical Care* 1999;37(8):809-14.
9. Cox AR, Marriott JF, Wilson KA, Ferner RE. Adverse drug reaction teaching in UK undergraduate medical and pharmacy programmes. *J. Clin Pharm Ther* 2004;29(1):31-35.
10. Graille V, Lapeyre-Mestre M, Mon Tadric JL. Drug vigilance: An opinion survey which was conducted among the residents of a university hospital. *Therapie* 1994;49(5):451-54.
11. Gupta P, Udupa A. Adverse drug reaction reporting and Pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors: *J Pharma Sci Res* 2011;3:1064-9.
12. Rehan HS, Ravinder KS, Deepti C. Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital: *Indian Journal of Pharmacology* 2012;44(6):699-703.
13. Deepak P, Jayashree V Nagara. Awareness of Pharmacovigilance among medical students. *International Journal of Recent Trends in Science and Technology* 2014;13(2):262-65.
14. Radhakrishnan R, Sudha V, Danturulu MV. An educational intervention to assess knowledge attitude practice of Pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital: *International Journal of PharmTech Research* 2011;3(2):678-92.