National Journal of Physiology, Pharmacy and Pharmacology

RESEARCH ARTICLE

A study of knowledge, attitude, and practice of pharmacovigilance among medical students at a tertiary care teaching hospital in Madhya Pradesh, India

Shashi Marko

Department of Pharmacology, Bundelkhand Medical College, Sagar, Madhya Pradesh, India

Correspondence to: Shashi Marko, E-mail: drshashi0308@gmail.com

Received: May 14, 2019; **Accepted:** Jun 08, 2019

ABSTRACT

Background: The aim of pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use in the society. Targeting the younger doctor for sensitization toward pharmacovigilance is the key to ensure practice of adverse drug reactions (ADR) reporting in clinical practice. **Aims and Objectives:** The objectives of this study are to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance among medical students at Bundelkhand Medical College, Sagar, Madhya Pradesh, a tertiary care teaching hospital. **Material and Methods:** A cross-sectional study will be carried out using a pretested questionnaire. The questionnaire will be designed to assess the KAP regarding pharmacovigilance. The medical students (2nd year, pre-final year, and interns) were included in the study. Only the participants who will give their consent will be included in the study. Result will be calculated by proper statistical analysis. **Results:** The current study was conducted in a Bundelkhand Medical College, Sagar, Madhya Pradesh, which included a total of 228 medical students of which 44% 2nd year, 35% pre-final year students, and 21% interns. Most of them (83.33%) accepted that reporting ADR is necessary, and pharmacovigilance should be taught in detail to health-care professionals. **Conclusions:** This study demonstrated that knowledge of pharmacovigilance among medical students is improving gradually and pharmacovigilance and ADR reporting needs to be made compulsory, have better, interesting ways to learn and understand it, so that the students can practice it with confidence in their clinical practice.

KEY WORDS: Pharmacovigilance; Adverse Drug Reactions; Knowledge; Attitude and Practice

INTRODUCTION

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and represent a substantial economic burden on health-care resources. It has been reported that 2.4%−6.5% of the total admissions in the hospitals are due to adverse reactions, many of which are preventable. The incidence of serious ADRs is 6.7% in India.[1]

Access this article online	
Website: www.njppp.com	Quick Response code
DOI: 10.5455/njppp.2019.9.0620408062019	

The World Health Organization defines pharmacovigilance as "science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems."[2] Many adverse effects of the drug, drug interactions, interactions with food, and other risk factors such as specific toxicities are known years after release of the medicine. Some rare adverse effects (1:100,000) manifest only after the exposure of drug to a large population.[3,4] Such rare adverse effects of the drug can only be known through effective pharmacovigilance.

Pharmacovigilance program (PP) has played a major role in the detection of ADRs and banning of several drugs from the market. However, under-reporting of ADRs is one of the major problems associated with PP.[5] Because of variation in

drug response, individual prescribing habits, drug regulatory system, and availability of drugs, it has been recommended for every country to set up their own PP.[6]

Various methods of detecting an adverse event (AE) include spontaneous reporting, prescription event monitoring, and others.[7] Reporting of AEs from doctors to ADRs database by use of these methods can significantly impact the signal detection of unexpected and rare ADRs.

There is a lack of knowledge and practice of ADR reporting by the doctors.[8,9] Various reasons for under-reporting of AEs by doctors can be lack of time, feeling that a single case report may not be important, concern that reporting will generate extra work, and fear of legal implications.[7,10,11]

The objectives of this study were to assess and evaluate knowledge, attitude, and practice (KAP) of pharmacovigilance among the medical students in a tertiary care hospital.

MATERIAL AND METHODS

Study Design

The present study was conducted at Bundelkhand Medical College, Sagar, Madhya Pradesh. It was questionnaire-based cross-sectional study aimed at assessing the KAP toward ADR reporting. The questionnaire was initially developed accordingly to meet the objectives of the study and after referring to various questionnaires used to assess the KAP toward pharmacovigilance in other various studies performed within and outside India. The questionnaire was standardized and validated by the faculty members of the department of pharmacology.

Ethics Approval

The approval for conducting this study was obtained from the Institutional Ethics Committee of this college.

Study Population

The target population of this study were the undergraduate students of 2nd year, pre-final year, and interns, who were already exposed and familiar with ADR and pharmacovigilance. The duration of the study was 2 months, from March 2018 to April 2018.

The standardized and validated questionnaire was distributed to all the students of second, pre-final, and interns. The students were explained about the questionnaire and the need for the study. The required instructions for answering the questionnaire was also explained. Willingness to answer the questionnaire was considered as informed consent, with the students signing on top of the questionnaire agreeing to consant to the study. 30 min was given for every participant to complete the questionnaire. Filled up forms are collected back from the students and are analyzed for the results. The statistics was done using MS Excel for obtaining the results. Final data were expressed as frequency and percentages.

RESULTS

In this study, a total of 228 students were assessed regarding their knowledge about pharmacovigilance, of which 100 were 2nd year students, 80 were pre-final year students, and 48 were interns. The distribution of student involvement is depicted in Figure 1.

Analysis of Knowledge

The results of the knowledge-based questions are shown in Table 1. Of the 228 who were included in the study, only 62.52% (52 [52%], 59 [74%], and 27 [56%]) of the responders knew what is pharmacovigilance.

The pre-final students seemed to know the actual definition of an adverse drug reaction than the other two groups. Out of 228 students, 80% 2nd year students, 77.5% pre-final year students, and 54.16% interns were aware of who can report ADRs. Among all the participants 60.52% of the responers (46% second year students, 52.5%% pre-final year students and 56.5% interns) knew about the existance of pharmacovigilance programme of India. About the knowledge of location of WHO-UMC 57.89% responders (58% second year students, 52.5% pre-final year students and 66.66% interns) knew about the location of WHO-UMC.

Analysis of Attitude

Table 2 shows the overall attitude of the undergraduate students toward pharmacovigilance and ADR reporting. 83.33% of the participants totally agreed that ADR reporting is necessary. However, 83% 2nd year students, 77.5% pre-final year students, and 85.41% of the participants supported that reporting of ADRs to be a professional obligation. 67% 2nd year students, 10% pre-final year students, and 47.91%

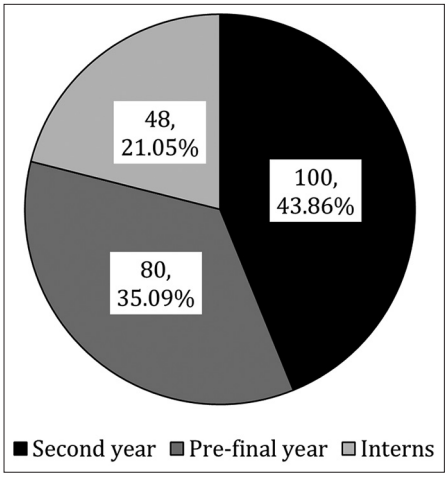

Figure 1: Distribution of student involvement in the study

interns feel that filling of ADR form is complex, and majority 91.66% students thought that pharmacovigilance should be taught to all health-care professional.

Analysis of Practice toward Adverse Drug Reactions (ADR) Reporting

Table 3 shows the practice of 2nd year, pre-final year students, and interns toward ADR reporting. About one-third of the total responders said that they had witnessed an ADR in their clinical postings but only 162 out of 228 had seen an ADR form, and 96.25% pre-final year students had filled ADR form, whereas only 10% 2nd year students and 33.33% interns had filled an ADR form. 80% 2nd year students, 97.5% pre-final year students, and 79.16% interns accepted that they have been trained for how to report ADR.

Table 1: Correct response toward knowledge of pharmacovigilance and ADRs reporting among medical undergraduate students

Question	Second year *n* (%)	Pre-final year *n* (%)	Interns *n* (%)
What is pharmacovigilance?	52 (52)	59 (74)	27 (56)
The most important purpose of pharmacovigilance is	66 (66)	58 (72.5)	29 (60.41)
What is an adverse event?	69 (69)	60 (75)	33 (68.75)
Who can report ADRs	80 (80)	62 (77.5)	26 (54.16)
Do you think ADR reporting is professional responsibility	80 (80)	61 (76.25)	37 (77.08)
Are you aware of pharmacovigilance program of India	46 (46)	65 (81.25)	27 (56.25)
Which regulatory body is responsible for monitoring ADRs?	61 (61)	47 (58.75)	25 (52)
International center for ADR monitoring is located in?	58 (58)	42 (52.5)	32 (66.66)
What type of ADRs should be reported?	83 (83)	55 (68.75)	23 (47.91)
What is a serious adverse event?	63 (63)	67 (83.75)	33 (68.75)

ADR: Adverse drug reactions

Table 2: Attitude of medical undergraduate students toward pharmacovigilance and ADRs reporting

Questions	Response	Second year *n* (%)	Pre-final year *n* (%)	Interns *n* (%)
ADR reporting is necessary?	Yes	86 (86)	66 (82.5)	38 (79.16)
	No	14 (14)	14 (17.5)	10 (20.83)
Is ADR reporting a professional obligation?	Yes	83 (83)	62 (77.5)	41 (85.41)
	No	17 (17)	18 (22.5)	7 (14.58)
ADR form is complex to fill?	Yes	67 (67)	8 (10)	23 (47.91)
	No	33 (33)	72 (90)	25 (52.08)
Do you think pharmacovigilance should be taught in detail to health-care professional	Yes	92 (92)	72 (90)	45 (93.75)
	No	8 (8)	8 (10)	3 (6)
ADR reporting will ensure patient safety	Yes	94 (94)	70 (87.5)	46 (95.83)
	No	6 (6)	10 (12)	2 (5)

ADR: Adverse drug reactions

Table 3: Practice of medical undergraduate students toward ADRs reporting

Questions	Response	Second year *n* (%)	Pre-final year *n* (%)	Interns *n* (%)
Do you experience ADRs during your practice?	Yes	24 (24)	22 (27.5)	10 (20.83)
	No	76 (76)	58 (72.5)	38 (79.16)
Have you seen an ADR reporting form?	Yes	55 (55)	76 (95)	31 (64.58)
	No	45 (45)	4 (5)	17 (35.41)
Have you reported an ADR or have you filled an ADR reporting form?	Yes	10 (10)	77 (96.25)	16 (33.33)
	No	90 (90)	3 (3.75)	32 (66.66)
Have you ever been trained on how to report ADR?	Yes	80 (80)	78 (97.5)	38 (79.16)
	No	20 (20)	2 (2.5)	10 (20.83)

ADRs: Adverse drug reactions

DISCUSSION

The current study was conducted in a medical college which included a total of 228 medical students in which 100 2nd year, 80 pre-final year students, and 48 interns. In the present study, more than 60% and 73.68% responder have knowledge about pharmacovigilance and ADR reporting, respectively. Moreover, 60.52% of responders were aware about pharmacovigilance program (PP) of India. Regarding attitude more than 80% have positive attitude toward ADR reporting and more than 90% students thought that pharmacovigilance should be taught to all health-care professional.

In study done by Gupta and Udupa, only 43% are aware of ADR reporting, whereas in this study, more than 60% of students know regarding pharmacovigilance and ADR reporting.[10] Despite having good knowledge and attitude towards pharmacovigilance, the practice of ADR reporting is high only in pre-final year students more than 90% whereas very less in second year students and interns 10% and 33.33% respectively. This was because more emphasis was laid by the department of pharmacology in making them understand the importance of pharmacovigilance by having extra practical demonstrations, case studies, and group tasks related to adverse drug reactions, which has not yet been implemented for the 2nd year students.

The importance of pharmacovigilance leads to the development of international and nationwide PP but only 57.89% knew about the existing WHO monitoring Center. Few of them 60.52% knew about nationwide program. In contrast to this, Gupta and Udupa identified 43% of the participants being were aware of National pharmacovigilance centers in India. In another survey, Oshikoya and Awobusuyi from Nigeria reported that 51.5% of the doctors were aware of the existing national pharmacovigilance center.[8]

In a study done by Kutmi *et al.*, more than 40% MBBS students think that ADR reporting is compulsory, whereas in this study, more than 80% students think that ADR reporting is necessary which is similar to the study done by Gupta and Udupa who identified 89.5% participants, suggesting necessity of ADR reporting.[10,12] According to another study done by Ponmary *et al.*, 2nd year MBBS students have adequate knowledge and attitude regarding pharmacovigilance compared to residents, and even though nurses have good knowledge about pharmacovigilance, they do not have adequate knowledge about reporting ADR.[5] Finding from all the studies including our study implies that there is a significant dearth of ADR reporting practice in spite of a fair attitude toward ADR reporting. Since the doctors are the first tier to come across the patient, they should be motivated to report ADRs.[13]

Limitations of the Study

Use of qualitative research methodology involving face-to-face and in-depth interviews would have been more appropriate. Inclusion of other health-care professional in such studies can give us a better insight into the current state of affairs and suggest appropriate measures.

CONCLUSIONS

In this study, it was showed that majority of the students had knowledge about pharmacovigilance and understand the need for reporting. In spite of that the reporting rate of ADRs by them is very low. Hence, there was huge gap between the ADR experienced and ADR reported by health-care professional. Here, majority of respondents agreed that reporting of ADR is necessary and it should be made an integral part of the clinical activities to improve the patient care.

So finally, from the study, we can conclude that the overall knowledge and attitude are definitely better among the undergraduate students. The practice of pharmacovigilance and ADR reporting has to improve, and it can be done so by including pharmacovigilance throughout the entire course of medical curriculum and incorporating better, efficient and interesting methods to teach, sensitize, and practice pharmacovigilance.

ACKNOWLEDGMENT

The author is grateful to the study participants who voluntarily took part in the study. Author wishes to acknowledge the support provided by the department and college, for encouraging research.

REFERENCES

1. Goyal M, Bansal M, Yadav S, Grover V. Assessment to assess the attitude, knowledge and practices of medical professionals about adverse drug reactions and their reporting in a teaching hospital. Ind J clin Pract 2013;24:281-4.
2. World Health Organization. The importance of Pharmacovigilance. Geneva: World Health Organization; 2002.
3. WHO policy Perspectives on Medicines, Pharmacovigilance: Ensuring the Safe use of Medicines, Geneva: World Health Organization; 2004. Available from: http://www.apps.who.int/medicinedocs/pdf/s6164e/s6164e. [Last accessed on 2019 Apr 08].
4. Oberg KC. Adverse drug reactions. Am J Pharm Edu 1999;63:199-204.
5. Ponmary SJ, Sivaraman M, Aruna T, Subhasree V. Knowledge and awareness of pharmacovigilance among various medical fraternities. Asian J Pharm Toxicol 2015;3:45-8.
6. World Health Organization. Safety of Medicine: A Guide to Detecting and Reporting Adverse Drug Reactions. Geneva: World Health Organization; 2002.
7. British Medical Association. Reporting Adverse Drug Reactions: A Guide for Healthcare Professionals; 2006. Available from: http://www.isoponline.org/wp-content/uploads/2015/01/BMAreport.pdf. [Last accessed on 2016 Sep 26].

8. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reactions reporting in a teaching hospital in Lagos, Nigeria BMC Clinical Pharmacology.2009;9:14.
9. Bello SO, Umar MT. Knowledge and attitudes of physicians relating to reporting of adverse drug reactions in sokoto, North-Western Nigeria. Ann Afr Med 2011;10:13-8.
10. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors. J Pharm Sci Res 2011;3:1064-9.
11. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, *et al.* Awareness and attitudes of healthcare professionals in Wuhan, china to the reporting of adverse drug reactions. Chin Med J (Engl) 2004;117:856-61.
12. Kulmi M, Reddy P, Dhakre S, Shinde M, Goyal C. Knowledge, attitude and practices of pharmacovigilance among the postgraduate and undergraduate medical students in a tertiary care hospital in Central India. Int J Basic Cli Pharm 2017;6:1127-32.
13. Katekhaye VM, Kadhe NG, John J, Pawar SR. Knowledge, attitude and practice of pharmacovigilance among medical professionals at a tertiary care hospital in Mumbai, Maharastra, India. Int J Res Med Sci 2017;5:156-61.

How to cite this article: Marko S. A study of knowledge, attitude, and practice of pharmacovigilance among medical students at a tertiary care teaching hospital in Madhya Pradesh, India. Natl J Physiol Pharm Pharmacol 2019;9(9):851-855.

Source of Support: Nil, **Conflict of Interest:** None declared.