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Original Research Article

A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among exam going second year undergraduate medical students in a South Indian teaching hospital

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ABSTRACT

Background: Pharmacovigilance not only helps in the early detection of adverse drug reactions (ADRs) but also facilitates the identification of both, risk factors and the underlying mechanism. To increase the reporting rate, it is essential to improve the knowledge, attitude, and practices (KAP) of healthcare professionals regarding ADR reporting and pharmacovigilance, especially during undergraduate and postgraduate education. The objective of this study was to assess the KAP about pharmacovigilance among exam-going second-year undergraduate medical students.
Methods: A cross-sectional questionnaire-based study was conducted among 150 exam-going second-year undergraduate students from Mysore Medical College and Research Institute, Mysore from April 2022 to June 2022. A validated questionnaire consisting of 22 questions divided into 3 sections; knowledge, attitude, and practice was used. Statistical analysis of data was done using an MS excel spreadsheet.
Results: Out of the 150 participants 133 had good knowledge about ADR and pharmacovigilance. Majority of the students agreed that reporting of ADRs is necessary (95.3%), mandatory (95.3%), and should be included in pharmacology practicals (94.7%). Only 29.3% of the students had witnessed an ADR and none of the participants had ever reported an ADR indicating poor practice among the undergraduate students.
Conclusions: Students had good knowledge and positive attitude towards ADR reporting and pharmacovigilance. Practice regarding pharmacovigilance was found to be poor, indicating the need for training the undergraduate students in ADR reporting by including ADR recognition and reporting as a part of clinical posting curriculum.

Keywords: Pharmacovigilance, CBME curriculum, Practice, Knowledge, Attitude

INTRODUCTION

Drug therapy is an integral part of medical management. It has many beneficial effects, but side effects and adverse drug reactions (ADRs) are its disadvantages. WHO defines ADR as "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function".[1] ADRs are a major health problem for individuals and the public in general; it ranks among the top 10 causes of patient mortality globally.[2] Over 2 million serious cases due to ADRs are seen per year globally. Studies from different parts of the world have reported that the overall prevalence of ADR-related hospitalization varies from 0.2% to 54.5%.[3,4] It is fourth to the sixth leading cause of death in the USA.[5] In a study from South India, it was observed that 3.7% of the total hospitalized patients were suffering from ADR, among which 1.3% were fatal. About 0.7% of hospital admissions were due to ADRs.[6] In India, the highest number of ADRs were reported in the year 2016 (224), while the maximum number of serious ADRs were reported in the year 2017 (105).[7] The incidence of serious ADRs in India is said to be around 6.7%.[8]

Economically, the amount spent to treat and manage these ADRs is remarkable. ADRs are a huge economic burden to society which affects and derails the health care system.[9] On average, the United States spends up to 30 billion US dollars on the management of ADRs. Thus, it becomes important to minimize and prevent harm to patients with the use of these drugs and make sure that the ADRs are detected even before they are manifested clinically. ADRs have become a major public health concern. So, monitoring and prevention of ADRs become vital for ensuring absolute patient safety.

Pharmacovigilance is a process of post-marketing surveillance of drugs that continues throughout the drug lifecycle. It is essential in analyzing and managing the risks associated with drugs that are available for the use of the general population.[10] The results of pharmacovigilance certify the effectiveness and safety of drugs in terms of adverse drug reactions. Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems".[11]

To promote drug safety WHO started the Program for International Drug Monitoring in 1961 and subsequent to that it promoted pharmacovigilance program at the country level in collaboration with the Centre for International Drug Monitoring, Uppsala.

Spontaneous reporting of ADR by health care professionals is the backbone of pharmacovigilance program, but underreporting of ADR is still prevalent and is a cause of concern. Studies have shown that only 6-10% of all ADR cases are reported. Health care professionals have a major role in pharmacovigilance program.[12] ADR reporting does not currently appear to be considered part of routine professional practice by health care professionals. This is essentially due to the absence of a vibrant and active ADR monitoring system and also lack of a reporting culture among health care professionals.

Pharmacovigilance not only helps in the early detection of ADRs but also facilitates the identification of both, risk factors and the mechanism underlying the ADR. Although India is participating in the program, its contribution to the Uppsala monitoring database which is responsible for maintaining the international database of ADRs is very little.[13] To improve the reporting rate, it is essential to improve the knowledge, attitude, and practices (KAPs) of healthcare professionals regarding ADR reporting and pharmacovigilance, especially during undergraduate and postgraduate education. Medical students could play a major role in the successful implementation of the Pharmacovigilance program if adequate knowledge and skills are imparted to them during their undergraduate training career, but at present, they do not have any significant role which is due to inadequate training given to them regarding ADR reporting.[14,15]

Pharmacovigilance has been included in the medical undergraduate and postgraduate CBME curriculum in many medical colleges. Very few studies are there to assess the knowledge, attitude, and practice of Pharmacovigilance among undergraduate medical students, and these studies indicate inadequate knowledge about Pharmacovigilance among healthcare professionals. Studies conducted on KAP about pharmacovigilance among undergraduate medical students were found to be effective.[16] However, the results of these studies cannot be applied to medical students in our institute as KAP among the students will differ from institute to institute. Hence, this study has been done to assess KAP of Pharmacovigilance among the exam-going 2nd-year medical students in a tertiary care teaching hospital. The results from this study will be helpful in assessing drawbacks in the current curriculum and planning further course of action.

Objectives

Th objective of the study was to assess the knowledge, attitude, and practices about pharmacovigilance among exam-going second-year undergraduate medical students.

METHODS

Study design

An observational cross-sectional questionnaire-based study was conducted among exam-going second-year undergraduates in the Department of Pharmacology, Mysore Medical College and Research Institute from April 2022 to June 2022 for a period of three months.

Sample selection and study population

The study was conducted among the exam-going second-year medical undergraduates attending the Department of Pharmacology, Mysore Medical College, and Research Institute. The sampling method was purposive sampling and the total sample size was 150. Exam-going second-year undergraduate students consenting to the study were included in the study. Those who were not willing to participate and those who filled the questionnaire incompletely were excluded.

Methodology and data analysis

The study was approved by Institutional Ethics Committee and written informed consent was obtained from all study participants. Data was collected using a self-administered, structured, and pre-tested questionnaire taken from previously conducted similar studies and adapted to fit with the current set-up. A pilot study was conducted on 10 students to validate the questionnaire and changes were made accordingly. Before data collection, students were briefed on the aims and objectives of the study.

The questionnaire used consisted of three parts. The knowledge part had 13 questions and each correct answer counts '1' point while every wrong answer count '0'. An overall score of ≥7 was considered good knowledge (score >50% is considered as good knowledge). The attitude part is composed of 4 questions. The responses were 'agree' or 'disagree' for 3 questions and 1 question with multiple options. The third part (practice part) consisted of 6 questions with different options.

Statistical analysis

Descriptive statistical methods were used and data was analyzed using MS excel spreadsheet and Windows 10 version 20H2. All categorical variables were presented as numbers and percentages.

RESULTS

A total of 150 questionnaires were distributed to be filled by the students, and all 150 were filled and collected, which gave a response rate of 100%. Amongst them, 127 (84.7%) students knew definition of pharmacovigilance, 128 (85.3%) students were able to define ADR, and 124 (82.7%) students about Adverse events. 120 (80%) and 130 (86.7%) students were aware of the location (locality) of the international centre for adverse drug monitoring and the National centre for ADR monitoring. About 122 (81.3%) of them were aware of the national coordinating centre for the pharmacovigilance program in India and 107 (71.3%) responders knew about PvPI.

Out of 150 students 95 (63.3%) responded correctly that the country using Yellow card ADR reporting form was United Kingdom. Almost more than two-thirds (75.3% and 84%) were aware of who can report ADRs and when to report ADRs. Majority of the students 89 (59.3%) were aware of the common scale used to assess the causality of ADR. 55 (36.7%) students opinionated that ADR should be reported for allopathic medicines, 5 (3.3%) for herbal/traditional medicine, 3 (2%) for blood products, 7 (4.7%) for biological and medical devices, and 113 (75.3%) marked all of the above (Figure 1). 118 (78.7%) students were aware of Vigibase, the WHO online database for reporting ADR. Overall, about 133(88.7%) of the total respondents had good knowledge about pharmacovigilance (Table 1).

Table 2 shows the overall attitude and practice of the undergraduate students towards pharmacovigilance and ADR reporting. The majority of the participants 143 (95.3%) agreed that ADR reporting is necessary and they think reporting ADR should be made mandatory. 142 (94.7%) participants agreed when asked about including ADR reporting in pharmacology practicals. 83 (55%) students felt that the main challenges in implementing PvPI was lack of trained personal followed inadequate communication 78 (52%), the reporting culture 69 (46%) and politics 58 (38.7%).

Out of 150 participants, 141 (94%) have seen an ADR reporting form. 44 (29.3%) responders said that they had witnessed an ADR in their clinical postings and none of the participants had ever reported an ADR. 68 (45.3%) students reported that they had never read any articles regarding ADR. Most of the students 97 (64.7%) found difficulty in reporting ADRs. The most common difficulty in reporting ADR was non-availability of ADR forms 37 (38.1%) followed by doctor-patient communication 35 (36%), poor patient cooperation 12 (12.4%), lack of time 9 (9.3%), and 4 (4.1%) students gave other reasons (Figure 2). About 121 (80.7%) students suggested immediate stoppage of the drug in case of occurrence of serious adverse drug reactions (Figure 3).

Table 1: Knowledge of the study participants toward pharmacovigilance (N=150).

S. no.	Knowledge item questions		Responses (%)
1.	What is pharmacovigilance?	Correct	127 (84.7)
		Incorrect	23 (15.3)
2.	Define ADR?	Correct	128 (85.3)
		Incorrect	22 (14.7)
3.	What is an adverse event?	Correct	124 (82.7)
		Incorrect	26 (17.3)
4.	The International centre for adverse drug monitoring is located at	Correct	120 (80)
		Incorrect	30 (20)
5.	In India, the pharmacovigilance programme is coordinated by	Correct	122 (81.3)
		Incorrect	28 (18.7)
6.	What does PvPI stand for?	Yes	107 (71.3)
		No	43 (28.7)
7.	Which country uses yellow card ADR reporting form?	Correct	95 (63.3)
		Incorrect	55 (36.7)
8.	Who can report ADRs?	Doctors	46 (30.7)
		Nurses	20 (13.3)
		Pharmacists	24 (16)
		Dentists	26 (17.3)

Continued.

S. no.	Knowledge item questions		Responses (%)
		All of the above	113(75.3)
9.	Which scale is commonly used to assess the causality of ADR	Correct	89 (59.3)
		Incorrect	61 (40.7)
10.	ADR with which of the following should be reported?	Allopathic medicines	55 (36.7)
		Herbal/traditional medicine	5 (3.3)
		Blood products	3 (2)
		Biological and medical devices	7 (4.7)
		All of the above	92 (61.3)
11.	The National centre for ADR monitoring is located at	Correct	130 (86.7)
		Incorrect	20 (23.3)
12.	When to report ADR	Common side effects like nausea, urticaria, skin allergies etc.	9 (6)
		Hospitalization	19 (12.7)
		Disabilities	18 (12)
		Death	15 (10)
		All of the above	126 (84)
13.	Which of the following is the WHO online database available for reporting on ADR?	Correct	118 (78.7)
		Incorrect	32 (21.3)

Table 2: Attitude and practice of the study participants towards pharmacovigilance (N=150).

S. no.	Statements		Responses (%)
1.	Do you think reporting ADR is necessary?	Agree	143 (95.3)
		Disagree	7 (4.7)
2.	Do you think reporting ADR should be made mandatory?	Agree	143 (95.3)
		Disagree	7 (4.7)
3.	Should ADR reporting to be included under pharmacology practical?	Agree	142 (94.7)
		Disagree	8 (5.3)
4.	Which of the following are challenges for implementing PvPI	Political	58 (38.7)
		Lack of trained personal	83 (55.3)
		The reporting culture	69 (46)
		Inadequate communication	78 (52)
5.	Have you ever witnessed an ADR?	Yes	44 (29.3)
		No	106 (70.7)
6.	Have you seen an ADR reporting form?	Yes	141 (94)
		No	9 (6)
7.	Have you ever reported an ADR?	Yes	-
		No	150 (100)
	If yes, where?	At your institute	-
		An ADR reporting centre	-
		Concerned pharma company	-
		Others	-
8.	Have you ever read any article regarding ADR?	Yes	82 (54.7)
		No	68 (45.3)
9.	Do you find any difficulty in reporting ADRs?	Yes	97 (64.7)
		No	53 (35.3)
	If yes, what difficulties	Non availability of ADR form	37 (38.1)
		Patient cooperation	12 (12.4)
		Do not have time	9 (9.3)
		Doctor-patient communication	35 (36)
		Any other	4 (4.1)

Continued.

S. no.	Statements		Responses (%)
10.	Upon occurrence of serious ADR, what needs to be done with the suspected drug?	Dose reduced	15 (10)
		Stopped immediately	121 (80.7)
		Dose tapered and stopped	28 (18.7)
		Don't know	7 (4.7)

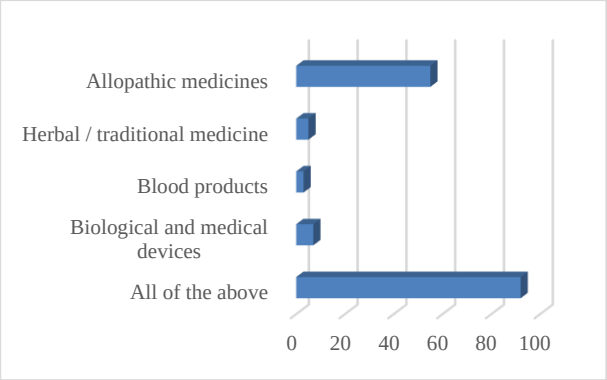

Figure 1: Medications that require ADR reporting.

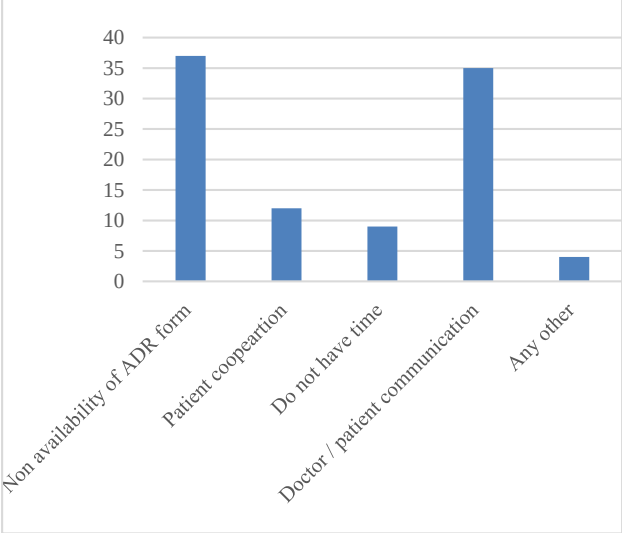

Figure 2: Difficulty in reporting ADRs.

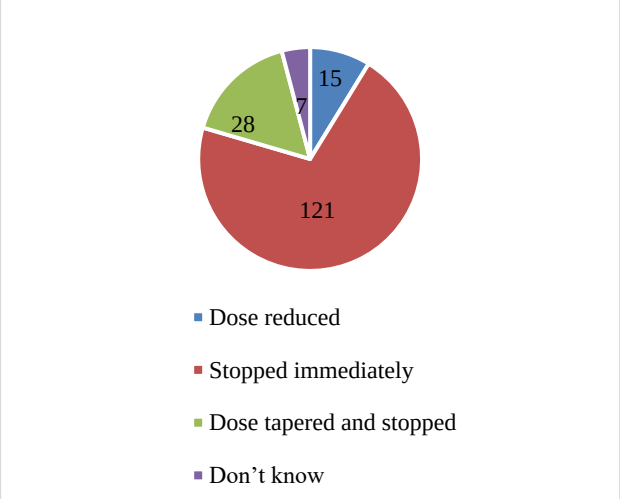

Figure 3: Responses to serious ADRs.

DISCUSSION

Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market. The ultimate aim of pharmacovigilance is to ensure patient safety and rational use of medicines, once a new medicine is released for general use in society. The most important outcome of pharmacovigilance is the prevention of patients being affected by unnecessary negative consequences of pharmacotherapy.[17] However, under-reporting of ADRs is one of the major problems associated with pharmacovigilance programs.[18,19] One of the better means of overcoming under-reporting is to increase the KAP of the healthcare professional regarding ADR monitoring and pharmacovigilance programs.

Pharmacovigilance has been included in the medical undergraduate CBME curriculum. The present study was undertaken to determine the knowledge, attitude and practice of Pharmacovigilance among exam going second year medical students to study the impact of pharmacology teaching among them.

In this study 84.7% students correctly defined Pharmacovigilance which corroborates with similar study by Dhananjay et al (87) and 85.3% students defined ADR which is slightly higher than study by Meher et al (80).[20,21]

In our study, 86.7% and 80% students had good knowledge about the National and International centers for ADR monitoring respectively, which is higher compared to other studies by Dhananjay et al (51% and 50) and Parthiban et al (17% and 23) that reported lack of awareness among students.[20,22]

It is necessary to create awareness among health-care professionals that ADR with drugs from any system of healthcare should be reported because many patients have the habit of taking medicines from different systems of healthcare such as Ayurvedic, Homeopathy, Unani etc., and no medicines are free from ADRs. In the present study, only 61.3% of the participants opined that ADR from any system of healthcare should be reported. The results obtained are similar to that of the study done by Kalikar et al.[23] In contrast to the study by Bhagavathula et al in which 55.6% of students were not aware about PvPI programme, in the present study 71.3% of the students knew about the PvPI programme.[24] 75.3% of responders had knowledge of who can report the ADR. In another study results had shown slightly higher knowledge regarding reporting of ADR.[23] Knowledge regarding who can report an ADR is important as the involvement of paramedical staff in spontaneous reporting of ADRs is essential and will help

in improving the reporting rates, since they are in close contact with the patients for a longer duration than doctors.

In the present study, percentage of students who agreed that the reporting of ADRs is necessary, mandatory and should be included in the pharmacology practical were 95.3%, 95.3% and 94.7%respectively. Other studies by Meher et al and Upadhyaya et al showed good attitude for ADR reporting among medical students.[21,25] During practical lecture, the students were shown an ADR reporting form. Majority of the students were aware of the ADR reporting form. Only 6% of the students responded No when asked if they had seen an ADR reporting form previously. In the present study, 64.7% of students found difficulties in reporting ADRs due to reasons such as non-availability of forms (38.1), lack of time (9.3), poor doctor-patient communication (36) and poor patient co-operation (12.4). In another study, lack of easy access to ADR reporting forms (49.2) was the major factor that discouraged reporting.[26]

On assessing practice, it was found that only 29.3% of them had witnessed an ADR in their clinical postings and none of the participants had ever reported an ADR. Many studies reported poor practice in ADR reporting.[14,19,27] In our study, similar results were found.

CONCLUSION

The findings of the study suggests that students had good knowledge and showed better attitude towards ADRs reporting and pharmacovigilance, but poor practice regarding Pharmacovigilance. Results from the present study suggest that the inclusion of pharmacovigilance in the medical undergraduate CBME curriculum benefits the students by improving their knowledge and attitude towards ADR reporting. Practice regarding pharmacovigilance was found to be inadequate in the study, suggesting that steps have to be taken to improve the ADR reporting practice of the students by including ADR recognition and reporting as a part of clinical postings.

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