

KAP Study Regarding Pharmacovigilance among Medical Students: An Observational Study

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Received: 02-03-2024 / Revised: 15-04-2024 / Accepted: 28-05-2024

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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance among medical students.

Methods: The present study was conducted at Anugrah Narayan Magadh Medical College, Gaya, Bihar, India. It was questionnaire-based cross-sectional study aimed at assessing the KAP toward ADR reporting. In this study, a total of 220 students were assessed regarding their knowledge about pharmacovigilance, of which 100 were 2nd year students, 70 were pre-final year students, and 50 were interns.

Results: The pre-final students seemed to know the actual definition of an adverse drug reaction than the other two groups. Out of 220 students, 81 2nd year students, 60 pre-final year students, and 27 interns were aware of who can report ADRs. Among all the participants 60.52% of the respondents (47 second year students, 62 pre-final year students and 29 interns) knew about the existence of pharmacovigilance programme of India. The overall attitude of the undergraduate students toward pharmacovigilance and ADR reporting 185 participants totally agreed that ADR reporting is necessary. However, 93 2nd year students, 62 pre-final year students, and 46 participants supported that reporting of ADRs to be a professional obligation. About one-third of the total responders said that they had witnessed an ADR in their clinical postings but only 150 out of 220 had seen an ADR form, and 66 pre-final year students had filled ADR form, whereas only 12 2nd year students and 18 interns had filled an ADR form.

Conclusion: The present study concluded 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.

Keywords: Pharmacovigilance; Adverse Drug Reactions; Knowledge; Attitude and Practice

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Introduction

Adverse drug reactions (ADRs) are global problems and affects majority both children and adults causing both morbidity and mortality [1-4] and also a major impact on public health. [5] The success of a pharmacovigilance program depends upon the active involvement of the healthcare professionals such as doctors, pharmacist, nurses. [6,7] Being the key healthcare professionals, providing information on suspected ADRs is as much a moral duty for the DOCTOR as other aspects of patient care. [8] Spontaneous ADR reporting is important to monitor known and unknown adverse effects of medicines. [9]

Furthermore, spontaneous reporting of ADRs has played a most important role in the detection of serious and unusual ADRs during marketing of the

drug in actual practicing in the market. This has led to the withdrawal of many drugs in the past such as rofecoxib, cisapride, terfenadine, etc. [7] To transform the pharmacovigilance activity into practices for enhancing the safety of patient and more ADR monitoring center are being set up across the country under pharmacovigilance program of India (PvPI). [10] It can also help to prevent the occurrence of new medicine tragedies and can improve the safety profile of pharmaceutical products. [11] ADR reporting does not currently appear to be considered a part of routine professional practice by health care professional. [12]

The PvPI was launched with a broad objective in patient safety for more than one billion people of India. In July, 2010, the Central Drug Standard

Control organization, New Delhi has initiated a nationwide pharmacovigilance program under aegis of Ministry of health and Family welfare, Government of India with All India Institute of Medical Sciences (AIIMS), New Delhi as a National Coordinating Center (NCC) to monitor ADR. [13] The (UMC, WHO), Sweden is maintaining the international database of ADR reports received ADRs report data from several national pharmacovigilance centers of different countries. However, still, it is estimated that only 6–10% of all ADRs are reported in all over the world. Although, India is one of participating in national pharmacovigilance program, but its contribution to UMC database is very little. Now a days, participation is increased but not up to mark. This program is essential due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care professional in India. [14]

The aim of the present study was to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance among medical students.

Materials and Methods

The present study was conducted at Department of Pharmacology, Anugrah Narayan Magadh Medical College, Gaya, Bihar, India for six months. It was questionnaire-based cross-sectional study aimed at assessing the KAP toward ADR reporting. In this study, a total of 220 students were assessed regarding their knowledge about pharmacovigilance, of which 100 were 2nd year

students, 70 were pre-final year students, and 50 were interns.

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.

Study Population

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

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 consent to the study. 30 min was given for every participant to complete the questionnaire. Filled up forms are collected 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

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

Question	Second year <i>n</i>	Pre-final year <i>n</i>	Interns <i>n</i>
What is pharmacovigilance?	54	55	26
The most important purpose of pharmacovigilance is	67	56	28
What is an adverse event?	70	58	34
Who can report ADRs	81	60	27
Do you think ADR reporting is professional responsibility	81	59	38
Are you aware of pharmacovigilance program of India	47	62	29
Which regulatory body is responsible for monitoring ADRs?	62	45	27
International center for ADR monitoring is located in?	59	39	34
What type of ADRs should be reported?	84	52	24
What is a serious adverse event?	65	66	34

The pre-final students seemed to know the actual definition of an adverse drug reaction than the other two groups. Out of 220 students, 81 2nd year students, 60 pre-final year students, and 27 interns were aware of who can report ADRs. Among all the participants 60.52% of the respondents (47 second year students, 62 pre-final year students and 29 interns) knew about the existence of pharmacovigilance programme of India.

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

Questions	Response	Second year <i>n</i>	Pre-final year <i>n</i>	Interns <i>n</i>
ADR reporting is necessary?	Yes	85	60	40
	No	15	10	10
Is ADR reporting a professional obligation?	Yes	84	55	42
	No	16	15	8
ADR form is complex to fill?	Yes	68	7	24
	No	32	63	26
Do you think pharmacovigilance should be taught in detail to health-care professional	Yes	93	62	46
	No	7	8	4
ADR reporting will ensure patient safety	Yes	95	62	47
	No	5	8	3

The overall attitude of the undergraduate students toward pharmacovigilance and ADR reporting 185 participants totally agreed that ADR reporting is necessary. However, 93 2nd year students, 62 pre- final year students, and 46 participants supported that reporting of ADRs to be a professional obligation.

Table 3: Practice of medical undergraduate students toward ADRs reporting

Questions	Response	Second year <i>n</i>	Pre-final year <i>n</i>	Interns <i>n</i>
Do you experience ADRs during your practice?	Yes	25	18	12
	No	75	52	38
Have you seen an ADR reporting form?	Yes	55	63	32
	No	45	7	18
Have you reported an ADR or have you filled an ADR reporting form?	Yes	12	66	18
	No	88	4	32
Have you ever been trained on how to report ADR?	Yes	82	67	40
	No	18	3	10

About one-third of the total responders said that they had witnessed an ADR in their clinical postings but only 150 out of 220 had seen an ADR form, and 66 pre-final year students had filled ADR form, whereas only 12 2nd year students and 18 interns had filled an ADR form.

Discussion

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. [15]

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.” [16] 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. [17,18] Such

rare adverse effects of the drug can only be known through effective pharmacovigilance. The pre-final students seemed to know the actual definition of an adverse drug reaction than the other two groups. Out of 220 students, 81 2nd year students, 60 pre-final year students, and 27 interns were aware of who can report ADRs. Among all the participants 60.52% of the respondents (47 second year students, 62 pre-final year students and 29 interns) knew about the existence of pharmacovigilance programme of India. 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 whereas very less in second year students and interns 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 overall attitude of the undergraduate students toward pharmacovigilance and ADR reporting 185 participants totally agreed that ADR reporting is necessary. However, 93 2nd year students, 62 pre-final year students, and 46 participants supported that reporting of ADRs to be a professional obligation. About one-third of the total responders said that they had witnessed an ADR in their clinical postings but only 150 out of 220 had seen an ADR form, and 66 pre-final year students had filled ADR form, whereas only 12 2nd year students and 18 interns had filled an ADR form. 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 Kulmi who identified 89.5% participants, suggesting necessity of ADR reporting. [19,20] 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. [21] 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. [22]

Conclusion

The present study concluded 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.

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