

A study of assessing knowledge, attitude and practice of pharmacovigilance among medical students of a South Indian teaching hospital

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ABSTRACT

Background: Pharmacovigilance is the science relating to detection, assessment, understanding and prevention of adverse drug reaction. The purpose is to improve patient safety in relation to use of medicines. It is estimated that only 6-10% of adverse drug reactions (ADRs) are reported worldwide. The underreporting of ADR is due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting. Health care professional like physicians, pharmacist and nurses have immense responsibility in reporting ADR. Therefore, the objective of this study was to evaluate the knowledge, attitude and practices (KAP) of undergraduate medical students towards pharmacovigilance.

Methods: A cross-sectional KAP based questionnaires study was carried out in 100 undergraduate students of Konaseema Institute of Medical Sciences, Amalapuram. The response of KAP questionnaires were analyzed in percentage and tabular form.

Results: Nearly 87% participants heard about pharmacovigilance, but only 65% know its need or purpose. 88% people feel that ADR reporting may improve patient safety. Less than half of the students know about Institutional ADR centre. 81% students have seen ADR but only 31% knew about ADR reporting form and surprisingly only 20% have reported ADR. More than 80% feels reporting ADR will increase patient safety.

Conclusions: Participants have good knowledge about Pharmacovigilance but lacks in attitude and practice towards reporting ADR. Greater awareness of pharmacovigilance and incorporation of it in medical curriculum will further strengthen pharmacovigilance activity.

Keywords: Adverse drug reaction (ADR), Drug safety, Knowledge Attitude practice (KAP), Pharmacovigilance

INTRODUCTION

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science and activities relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.¹ The dark history in 1961 by use of the drug thalidomide in pregnancy causing the birth of thousands of congenitally deformed babies led to the initiation of first organized international efforts to

address drug safety issues. Further, this episode introduced the adoption of tougher testing, rigorous drug approval and monitoring systems like United States Food and Drug Administration (FDA).² The expansion of scientific knowledge in drug safety is attributable to greater awareness and academic interest in this field. In many medical institutions, particularly in the developed countries, adverse drug reaction (ADR) monitoring is recognized as an essential quality assurance activity.³ Greater integration of pharmacovigilance into clinical

practice is still needed. Drug safety should feature in the medical and pharmacy curriculum.

Self-medication and the lack of regulatory control measures over the sale of drugs further increase the risk of adverse reactions. The number of drugs in each prescription is highest in developing countries.⁴ Factors such as illiteracy, concomitant use of traditional medicines, and availability of impure and irrational pharmaceutical preparations contribute further to the risk. It is estimated that only 6-10% of ADRs are reported worldwide.⁵ The Pharmacovigilance Programme of India (PvPI) was launched under the Ministry of Health and Family Welfare in July 2010 to safeguard the health of the Indian population by ensuring the safety of the marketed drugs.⁶ Uppsala Monitoring Centre (UMC), located in Uppsala, Sweden, is the field name for the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring. UMC works by collecting, assessing and communicating information from member country's national pharmacovigilance centers in regard to the benefits, harm, effectiveness and risks of drugs.⁷ The main focus and source of data in pharmacovigilance are reports of ICSRs (individual case safety reports) from healthcare providers and patients in member countries of the WHO Programme. A WHO global individual case safety report database (Vigi Base) is maintained and developed on behalf of the WHO by UMC.⁸

The underreporting of ADR may be due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting.⁹ Health professionals are more likely to identify and report important ADRs if they have confidence in their ability to diagnose, manage and prevent such reactions. Pharmacovigilance Programme of India (PvPi) plays a vital role by encouraging the activities of pharmacovigilance in the field of medicine, pharmacy and nursing. The Adverse Drug reaction monitoring center (AMC) in Konaseema Institute of Medical Sciences and Research Foundation was also established in 2016 under PvPI. Therefore on this background, the present questionnaire based study was conducted to assess the knowledge, attitude and practice of spontaneous ADR reporting among future budding doctors; medical students.

METHODS

A cross sectional questionnaire (KAP) based study was conducted among 100 undergraduate medical students after due approval of Institutional Ethical Committee. Willingness to participate and completing the questionnaire was taken as consent for the study.

Type of study

It was a cross-sectional, KAP questionnaire based study. About 100 undergraduate medical students were included

in this study. A questionnaire consisting of 14 questions was prepared with reference from previous studies on pharmacovigilance with minor modifications.¹⁰⁻¹⁴

After explaining the study purpose, questionnaire was distributed to all the participants with 30 minutes time allotted to fill it. The KAP questionnaire was analyzed question wise and their percentage value was calculated. The knowledge based questions assessed, knowledge regarding various aspects of pharmacovigilance such as a location of local and national ADR monitoring centers, purpose, type of ADRs to be reported, who can report and how ADR reporting done. The attitude based-questions assessed the view of the participants regarding the impact of ADR, current system of Pharmacovigilance, obligation towards ADR reporting. The practice based-questions determined practice concerning reading articles, and reporting ADR.

RESULTS

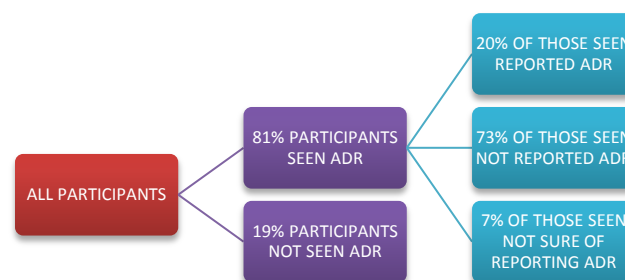


Figure 1: Attitude and practice of participants towards ADR reporting.

Figure 1 shows attitude towards reporting ADR. Out of 81% of those seen ADR, only 20% of them reported it.

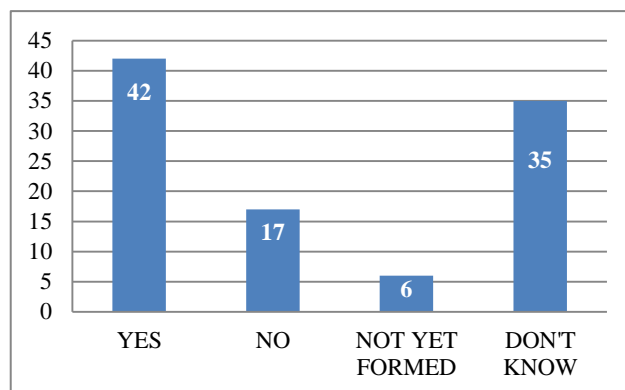


Figure 2: Knowledge of Institutional ADR monitoring centre.

Figure 2 shows only 42% participants know about institutional ADR centre.

Figure 3 shows only 45% of the participants feels reporting ADR is professional obligation. However majority of the participants (80%) felt need of pharmacovigilance to be taught in great detail to health care professional.

Out of all the participants, nearly 87% heard about pharmacovigilance, but only 65% know its need or purpose. The results are summarized as shown in Table 1.

Table 1: KAP questionnaire based study results.

Sr. no	Question	Correct/positive Response (%)	Incorrect response (%)	Not responded
1.	Science of pharmacovigilance deals with	87	13	Nil
2.	Need and purpose of pharmacovigilance	65	35	Nil
3.	Name the regulatory body of ADR in India	51	47	2
4.	Where the International ADR monitoring centre is located?	50	47	3
5.	Is there any Pharmacovigilance committee/ADR centre in your institution?	42	56	2
6.	Health care professionals responsible for reporting ADR are	47	52	1
7.	Do you think reporting an ADR is professional obligation for Doctors?	45	47	8
8.	Should pharmacovigilance be taught in detail to health care professionals?	80	18	2
9.	Did you read any case report or article on ADR?	6	18	76
10.	Did you see an ADR reporting form?	31	69	Nil
11.	Have you ever seen ADR during clinical postings?	81	19	Nil
12.	If yes, have you ever reported ADR?	20	73	7
13.	Do you think reporting ADR will increase patient safety?	88	3	9
14.	Name of "WHO online data base" available for reporting ADR?	11	78	11

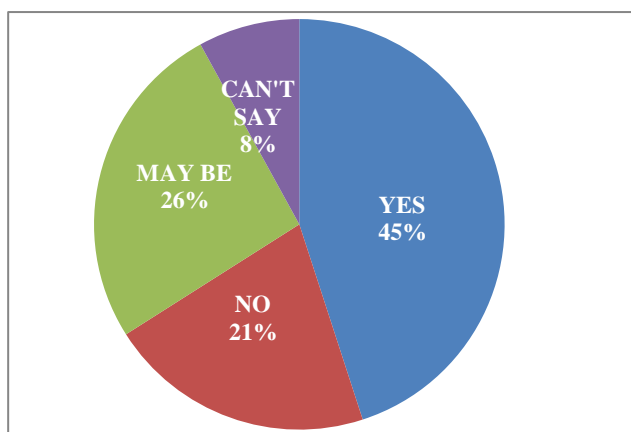


Figure 3: Is ADR reporting professional obligation for doctors?

DISCUSSION

The present study is a questionnaire-based study to assess the knowledge, attitude and practice of pharmacovigilance towards ADR reporting among doctors in a tertiary care teaching hospital. A spontaneous reporting system of ADRs is fundamental to drug safety surveillance but under-reporting is a well recognized issue. Numerous studies are done to assess the KAP of

health care professionals towards pharmacovigilance, but a very few studies have been done among the undergraduate or postgraduate doctors to evaluate their knowledge.^{10,15,16} This study is one of the few studies done among 100 undergraduate medical students regarding KAP of pharmacovigilance. In our study, nearly 87% participants heard about pharmacovigilance, but only 65% know its need or purpose. Similar study in undergraduate medical students by Meher, et al recently reported that 33% of final, 41% of prefinal and 22% of second year students know the definition of pharmacovigilance.¹⁷ In Parthiban et al study it was concluded that 81% were aware of the term Pharmacovigilance, but among the participants who were aware, only 53% had a better knowledge about Pharmacovigilance and ADR reporting.¹⁸

In the present study, almost only half of the participants knew that Indian Pharmacopeia commission (IPC) Ghaziabad is the nodal body of pharmacovigilance in India (51%) and UMC, Sweden is International ADR monitoring centre (50%), which indicates lack of awareness. Parthiban et al also reported lack of awareness about the International centre for ADR reporting (23%) while only 17.4% of the students have the awareness regarding National Pharmacovigilance programmes.¹⁸ In this present study, 47% students know that Doctors, nurses and Pharmacist can report ADR as per the

guidelines. Sound knowledge but poor awareness about ADR monitoring centers and reporting has also been observed among the undergraduate students and interns in various studies.^{18,19}

In our study, only 45% participants think that ADR reporting is a professional obligation which is less as compared to other studies.^{12,20,21} This is the attitude component which needs to be modified for improving the underreporting of ADR. Good knowledge and attitude remove the misconceptions, obstacles and potential barriers to the activities that we would like to implement thus initiating the practices for reporting. In the present study, 88% people feel that ADR reporting may improve patient safety. 81% students have also seen ADR but surprisingly only 20% people have reported ADR. We can clearly see that practices for reporting are lacking which is also an observation by various other studies.²¹⁻²³

Causes of underreporting are indifference to reporting, lack of interest in registration and lack of time for too many activities in the clinical routine.²⁴ This underreporting can be overcome by making easy access to registration forms, simplifying documents, toll free number assistance, financial incentives, creating more ADR centre, facilitating communication between registrars and pharmacovigilance centers would improve the notification rates of problems related to medication.²⁵⁻²⁷ Studies evaluating the attitudes of nursing staff found that the lack of knowledge in completing the notification form, and the lack of time to report ADRs are the main causes of underreporting in this class.^{28,29} Therefore, strategies must be developed to improve the acquaintance of these professionals to the pharmacovigilance service. There is a need for training and educational activities like CMEs for increasing the awareness about reporting of ADRs. Importance on adverse event reporting should be emphasized while teaching undergraduate and post graduate students.

CONCLUSION

Poor reporting of ADR from countries including India is essentially due to absence of vibrant ADR monitoring system and also inadequacies in reporting culture among health care professionals. The reporting rate of ADR could be improved with proper and extensive training about Pharmacovigilance in health care professionals. We conclude that further large scale awareness of pharmacovigilance is required among medical students for better understanding of ADR and its reporting. Special emphasis of pharmacovigilance in medical curriculum and its incorporation in medical internship is required to bring more awareness about rational usage of drugs; thereby minimising the adverse drug events or other drug related problems.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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