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Pharmacovigilance - knowledge, attitude and practice among medical students in a teaching hospital of southern India

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ABSTRACT

Background

Drugs although used in the prevention and curing of diseases, are sometimes associated with undesirable adverse drug reactions (ADR). Spontaneous reporting of ADRs has remained the cornerstone and major sources of information of pharmacovigilance and is important in maintaining patient safety. Underreporting of ADRs is a common problem and still remains a major obstacle in the complete success of Pharmacovigilance program.

Aim of the study

To assess knowledge, attitude and practice (KAP) of undergraduate medical students about pharmacovigilance.

Material and Methods

This was a cross sectional, observational, questionnaire based study conducted using a predesigned Knowledge Attitude Practice (KAP) questionnaire among 136 medical students. The completed KAP questionnaire was collected and data analyzed.

Results

Most of the students (97.06%) accepted that reporting ADR is necessary and 56.92% of them for identifying safety of the drug. 85.29% agreed that pharmacovigilance should be taught in detail to health-care professionals. But there was a huge gap between the ADR experienced (36.4 %), and ADR reported (5.88%) by the students. Only 64.71% students have ever seen the ADR reporting form.

Conclusion

Majority of the students had a good knowledge but reasonable attitude and poor practice of pharmacovigilance. There is need for continuous education regarding pharmacovigilance and ADR reporting system among the students who will be the future health-care givers.

Keywords: Adverse Drug Reactions, Medical students, Pharmacovigilance, Knowledge, Attitude, Practice

INTRODUCTION

The safe use of medicine is an important aspect that affects each and every member of society. Reducing the incidence and consequences associated with adverse drug reactions (ADR) is a crucial challenge in drug use. Despite the importance of medicine in the prevention and curing of diseases, its usage is sometimes associated with undesirable adverse reactions and even fatal reactions. [1]

The World Health Organization (WHO) defines an ADR as 'any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose'. [2]

Effective generation of ADR related data helps in practicing evidence-based medicine and thus prevents many adverse drug reactions. Several countries have initiated Pharmacovigilance programmes to monitor the drugs causing ADRs. [3]

According to World Health Organization (WHO) definition, Pharmacovigilance is, "The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems". [3]

The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the adverse drug reaction reports. It has been estimated that only 6-10% of all the ADRs are reported. [4]

Although, India is participating in the program, its contribution to UMC database is very little. The program lacks continuity and suffers from underreporting of ADRs by the health care professionals, the reason for which may be meager funds, lack of trained staff and lack of awareness about detection, communication and spontaneous reporting of ADRs. [5]

Spontaneous reporting of ADRs has remained the cornerstone and major sources of information of pharmacovigilance and is important in maintaining patient safety. Underreporting of ADRs is a common problem and still remains a major obstacle in the complete success of Pharmacovigilance program. Spontaneous reporting of ADRs has played a major role in detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trial phases. This has led to the withdrawal of many drugs in recent past. [6]

The ultimate aim of pharmacovigilance is to ensure safe and rational use of medicines, once they

are released for general use in the society. The most important outcome of pharmacovigilance is the prevention of negative consequences of pharmacotherapy.

Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized. Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programme. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of underreporting. [7]

To make Pharmacovigilance Program a success and improve reporting rate, it is important to improve the knowledge, attitude, and practice (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance and the best time to do so is probably during undergraduate and postgraduate training of the doctors. Therefore, this study was planned to evaluate the baseline knowledge of the undergraduate medical students who are future health care professionals, so as to make reporting of ADRs more vibrant by inculcating culture of reporting and strengthen the Pharmacovigilance Program.

MATERIAL AND METHODS

Present study was a cross-sectional KAP (Knowledge, Attitude and Practices) questionnaire based study. Participants of the study included second year undergraduate medical students of Shridevi Institute of Medical Sciences and Research Hospital, Tumkur. Permission of the Institutional Ethics Committee was obtained before the commencement of the study. Informed consent was obtained from the study participants.

A pre validated KAP Questionnaire was distributed to the students in the classroom by the investigators following a brief explanation on the aims and objectives of the study and voluntary nature of participation. It was also explained to the study participants that data would be used for research purpose with a request for their co-operation was sought. A total of one hundred thirty six questionnaires (136) were distributed among the students.

KAP questionnaire was so designed to assess the student's knowledge of pharmacovigilance, attitude towards pharmacovigilance, but also their practice on

ADR reporting. These questions were based on previous studies done for assessing KAP of ADR reporting. [8, 9, 10] The whole questionnaire had 22 multiple choice questions in total of which ten questions for assessing student's knowledge of pharmacovigilance, five questions for assessing student's attitudes toward pharmacovigilance and seven questions for assessing their practice on ADR reporting. The students have to choose correct response from this list of options. Students were given 30 minutes to complete their task. The filled questionnaire was carefully checked by the investigator for completeness.

Statistical Analysis

All the data were analyzed by entering into Microsoft Excel Sheet on a personal computer. The variables were expressed as counts, percentages and frequencies.

RESULTS

A total of 136 questionnaires were distributed, all of them were returned back and were analyzed, giving a response rate of 100%. The most of the respondents were females, that is, 60.29% compared to 39.71% males.

Assessment of pharmacovigilance related knowledge (Table 1)

While assessing the knowledge of the students on pharmacovigilance, it was found that 69.23% of students gave correct response regarding the definition of pharmacovigilance. According to 56.92% of responders the most important purpose of pharmacovigilance is to identify a safety of the drug. As many as 87.69% of students believed that ADR reporting is a professional obligation for them. Majority of the responders 83.58%, were aware that ADRs can be reported by doctors, nurses and pharmacists. Similarly, 60.61% of students were aware regarding the existence of Pharmacovigilance Programme of India (PvPI). Furthermore, that is, 53.97% responders had the knowledge of location of international ADR monitoring center while 84.38% of students were aware that the regulatory body responsible for monitoring ADRs in India is Indian Pharmacopoeia commission (IPC), Ghaziabad. Only 20% of responders knew about the existence of a Pharmacovigilance center or ADR Monitoring Center (AMC) in their college. Also 55.93% students were aware about the phase of clinical trial in which rare adverse effects commonly found.

Table 1 - Assessment of pharmacovigilance related knowledge

No.	Question	% of correct response
1	Define Pharmacovigilance	69.23
2	The most important purpose of Pharmacovigilance is	56.92
3	Do you think ADR reporting is professional obligation for you?	87.69
4	The healthcare professionals responsible for reporting ADRs in a hospital is/are	83.58
5	Do you know regarding the existence of a Pharmacovigilance Programme of India (PvPI)?	60.61
6	In India which regulatory body is responsible for monitoring ADRs?	84.38
7	Is there any Pharmacovigilance Committee in your Institute?	20.00
8	Where the international centre for adverse drug reaction monitoring is located?	53.97
9	Rare ADRs can be identified in the following phase of a clinical trial	55.93
10	Where is the nearest sub zonal centre for ADR monitoring located?	16.18

Assessment of pharmacovigilance-related attitude (Table 2)

While assessing the pharmacovigilance related attitude of the students, it was found that a total 97.06% of students agreed that reporting of ADR is necessary. Overall, 85.29% of students, were of the view that pharmacovigilance should be taught in

detail to health-care professionals. In continuation with this, only few, that is, 17.91% of students have read articles on prevention of ADRs. Furthermore, only 46.88% of students felt that ADR monitoring center should be established in every hospital. 65.52%, 13.79 %, 12.07%, and 8.62% of responders respectively cited difficult to decide whether ADR

has occurred or not, no remuneration, a single unreported case may not affect ADR database and

lack of time to report ADR to be the possible causes of under reporting of ADRs.

Table 2 - Assessment of pharmacovigilance-related attitude

No.	Question	% of correct response
1	Do you think reporting of adverse drug reaction is necessary?	97.06
2	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	85.29
3	Have you anytime read any article on prevention of adverse drug reactions?	17.91
4	What is your opinion about establishing ADR monitoring centre in every hospital?	46.88
5	Which of the following factor discourage you from reporting ADRs?	
	(a) Difficult to decide whether ADR has occurred or not	65.52
	(b) No remuneration	13.79
	(c) A single unreported case may not affect ADR database	12.07
	(d) Lack of time to report ADR	8.62

Assessment of pharmacovigilance-related practice (Table 3)

On assessing the pharmacovigilance-related practice, it was found that only 36.4 % of students have experienced ADRs in patient during their hospital visit in clinical postings. Very few of them, that is, 5.88% have ever involved in reporting ADR to pharmacovigilance center. Furthermore, it was

observed that 64.71% of students have seen the ADR reporting form and 80.6% of students know that filled ADR form submitted to pharmacovigilance centre is the method of reporting ADR. In accordance with this, it was found that only 57.58% of students have been trained on reporting on ADR. In addition, only 28.36% of students agreed that there is a Pharmacovigilance Committee in their Institution.

Table 3 - Assessment of pharmacovigilance-related practice

No.	Question	% of correct response
1	Have you ever experienced adverse drug reactions in your patient during your hospital visits?	36.4
2	Have you ever involved in reporting of ADR to the Pharmacovigilance centre?	5.88
3	Have you ever seen the ADR reporting form?	64.71
4	Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	57.58
5	Is there any Pharmacovigilance Committee in your Institute?	28.36
6	Methods commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs	52.46

DISCUSSION

ADR reporting is an integral part of pharmacovigilance and is important for patient care. Underreporting of ADR is a major threat to the success of pharmacovigilance program.

The ultimate aim of pharmacovigilance is to ensure safe and rational use of medicine. The most important outcome of pharmacovigilance is the prevention of patients being affected unnecessarily by the negative consequences of pharmacotherapy. [11, 12]

The present study evaluated the baseline Knowledge of all second year undergraduate medical students who are studying in M.B.B.S, regarding ADR reporting and Pharmacovigilance.

This study is one of the few studies done among undergraduate medical students regarding KAP of pharmacovigilance. Generally, the knowledge of ADRs and Pharmacovigilance among the medical students were found to be moderate.

In our study, nearly 69.23% participants knew correctly about the definition of pharmacovigilance, but only 56.92% knew 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. [13]

In the present study, almost more than half of the participants knew that Indian Pharmacopoeia commission (IPC) Ghaziabad is the nodal body of pharmacovigilance in India (84.38%) and UMC, Sweden is International ADR monitoring centre (53.97%), which indicates good 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. [14]

In this present study, 83.58% students knew 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. [15]

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In our study, 87.69% of participants think that ADR reporting is a professional obligation which is comparable to other studies. [16, 17]

In the present study, 56.92% of respondents feel that ADR reporting may improve patient safety. 36.4 % of students have also seen ADR but surprisingly only 5.88% people are involved in reporting ADR. We can clearly see that practices for reporting are lacking which is also an observation by various other studies. [18, 19]

The main focus of the pharmacovigilance is to promote the safe and the rational use of medicines. It has played a major role in detection of ADRs but previous studies suggest that under-reporting of ADRs is one of the major problems associated with pharmacovigilance program. [20]

Major reason for under reporting is lack of knowledge and skill about pharmacovigilance program, which was reflected in our study, and is consistent with the findings of other studies. [21]

This was indicating that continuing sensitization is required regarding ADR reporting and pharmacovigilance. It can be done by educational interventions like incorporation of pharmacovigilance related activities in the undergraduate practicals, continuous medical education (CME), and workshop on pharmacovigilance. [22]

CONCLUSION

This study showed that the undergraduate medical students had a good knowledge but reasonable attitude and poor practice towards pharmacovigilance. The findings of the study suggest a huge scope for improving the awareness and knowledge about pharmacovigilance among the students who will be the backbone of health care delivery in future. For this, pharmacovigilance related activities should be included in the medical teaching curriculum and also there is a need for continuous medical education programmes (CME) regarding pharmacovigilance and ADR reporting system among students who will be the future health-care givers.

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