Research Article

Awareness of pharmacovigilance among medical students

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Abstract

Objective: To assess the awareness of Pharmacovigilance among Medical students. **Materials and Methods:** The study was conducted by Department of Pharmacology of Hassan Institute of Medical Sciences, Hassan among II year medical students after obtaining permission from Institutional Ethical Committee. A questionnaire containing 14 questions with 2 – 5 options were given to each student and they were asked to tick one best suitable option. The questionnaire was based on previous study about Pharmacovigilance and was suitably modified for students. The completed questionnaire was analysed and frequency is expressed as percentage. **Results:** A total of 96 students who were in II MBBS participated in the study. Most of the students had correct understanding regarding Pharmacovigilance and knew the role of Pharmacovigilance in identifying the safety of drugs. 94% of the students were well aware of activities involved in Pharmacovigilance. 50% of the students haven't come across any article about adverse drug reaction (ADR). 81% felt that all unwanted events are not due to medicine alone.73% were aware of drugs banned because of ADR. 92% were aware of the measures to be taken when an ADR is suspected. Majority of the participants agreed that all health care professionals are responsible for reporting ADR and it is a professional obligation. **Conclusion:** The study results revealed that students were aware of Pharmacovigilance, but there was lack of professional obligation towards reporting ADR. Though Pharmacovigilance is being taught as part of Undergraduate curriculum, the students should be involved in more activity based and problem based learning.

Keywords: Adverse drug reaction, Awareness, Pharmacovigilance, Undergraduate students.

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INTRODUCTION

Modern approaches and newer medicines have changed the way in which diseases are treated and prevented. However, inspite of all their benefits, adverse effects due to medicines are common cause of morbidity and mortality[1,2]. Adverse drug reactions (ADR) have a major impact on public health by imposing a considerable economic burden on the society[3]. It is estimated that only 6-10% of all ADRs are reported and underreporting of ADR is a major problem[4]. In the current scenario, the adverse consequences of the drug are detected in the early stage of drug development. However, this process has limitations, even in well designed clinical trials. This is because of many factors such as number of patients studied, duration of treatment, dosage schedule and use of drug in specially selected population. Thus, safety evaluation can only be possible with long term use of drug in clinical practice[5]. As a result of activities related to the detection, monitoring and reporting of adverse events, Pharmacovigilance Programme of India (PvPI) was started[6]. Pharmacovigilance is the science which deals with activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems[7]. Although India is participating in Pharmacovigilance programme, its contribution to Uppsala monitoring database which is responsible for maintaining international database of ADR is very little. The right time to improve the knowledge and awareness about Pharmacovigilance is probably during undergraduate education of the doctors[8].

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Teaching Pharmacovigilance to medical students makes them realise that all drugs can cause ADRs. It emphasises their responsibility to participate in PvPI[9]. This study has been taken to assess the awareness of Pharmacovigilance among medical students.

OBJECTIVE

To assess the awareness of Pharmacovigilance among medical students.

MATERIALS AND METHODS

The study was conducted in Department of Pharmacology of HIMS, Hassan among II year medical students after obtaining permission from Institutional Ethical Committee. A questionnaire containing 14 questions with 2-5 options were given to each student and they were asked to tick or mark one best suitable option. The students were instructed not to reveal their identity in the questionnaire. The questionnaire was based on previous study undertaken about Pharmacovigilance and were suitably modified for students. The completed questionnaire was collected and data was analyzed. Descriptive statistics is used for analysis of data. Frequency is expressed as percentage.

RESULTS

A total of 96 students who were in II MBBS participated in the study. Most of the students had correct understanding regarding Pharmacovigilance and knew the role of Pharmacovigilance in identifying the safety of drugs. 81% of the students felt that all unwanted events are not due to medicine alone. 50% of the students haven't come across any article about Adverse drug reaction (ADR).

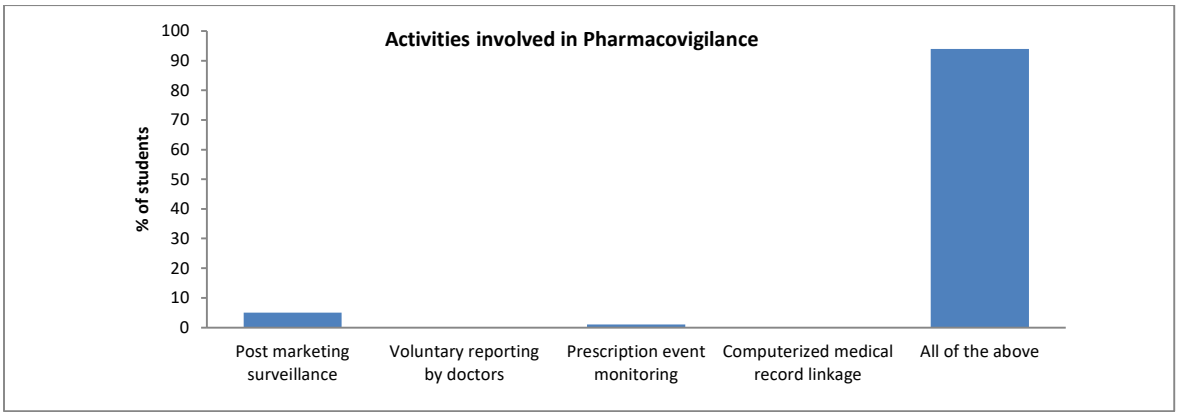

Figure 1: Activities involved in Pharmacovigilance.

94% of the students were well aware of activities involved in Pharmacovigilance.

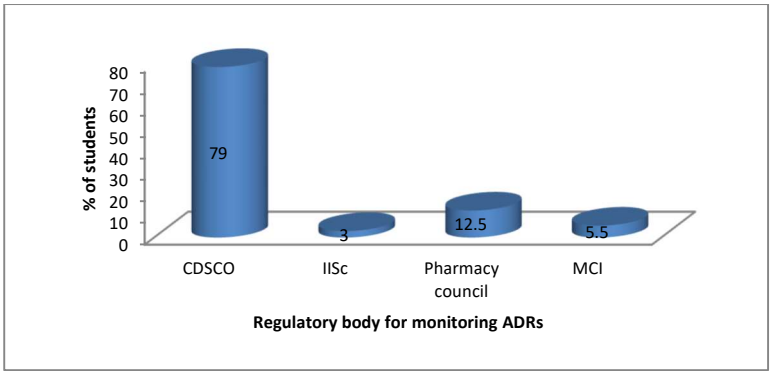

Figure 2: Regulatory body for monitoring ADRs

79% of the students knew that CDSCO is the regulatory body responsible for monitoring of ADRs.

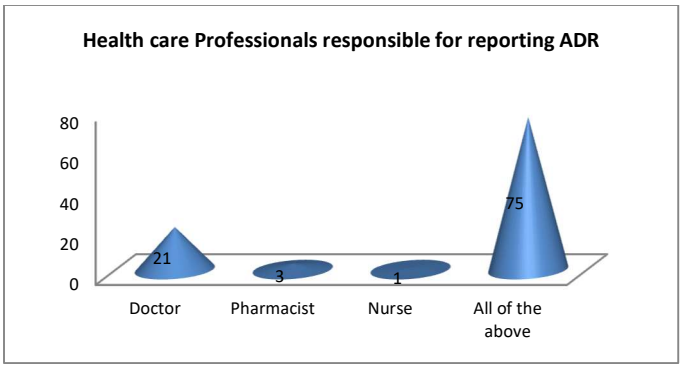

Figure 3: Health care professionals responsible for reporting ADR.

74% of the students had an idea that all the health care professionals (i.e. doctors, pharmacists, nurses) are responsible for reporting ADR.

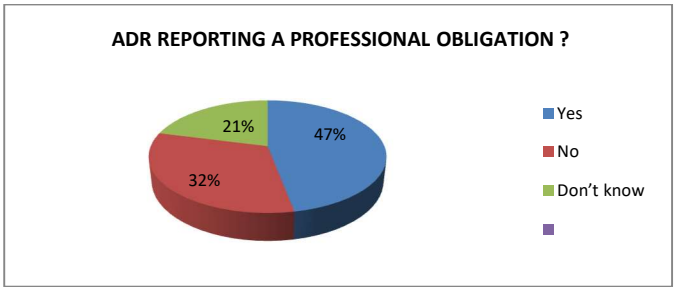

Figure 4: ADR reporting a professional obligation?

Around 47% of the students thought that ADR reporting is a professional obligation.

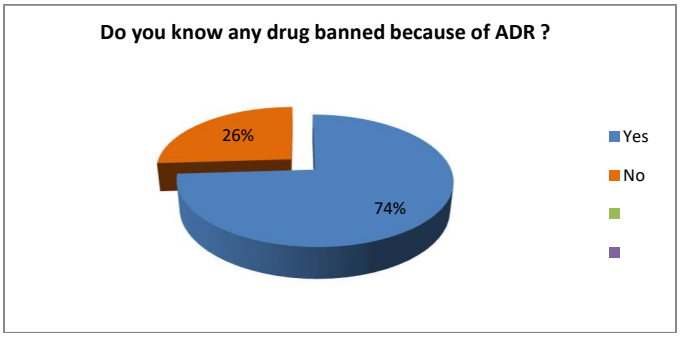

Figure 5: Do you know any drug banned because of ADR?

74% of the students knew the drugs banned because of ADR. The students were asked to give an example for a drug banned because of ADR. Majority of the students wrote Pioglitazone (40%) and Thalidomide (30%) as an example for drug banned because of ADR.

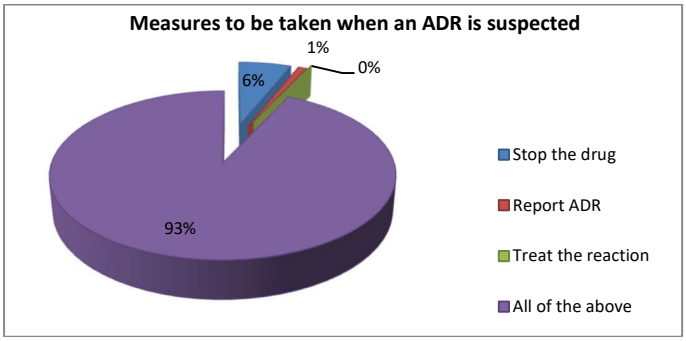

Figure 6: Measures to be taken when an ADR is suspected

93% of the students were aware of the measures that have to be taken when an ADR is suspected.

DISCUSSION

In addition to the obvious morbidity and mortality, ADRs are also an economic burden on the health care system. Hence their early detection and prevention is necessary. In the present study, 94% of the students were aware of activities involved in Pharmacovigilance compared to 26% in a study done by Rehan *et al*[6]. In our study, 79% of the respondents were aware of the regulatory body responsible for monitoring ADRs compared to 84% in a study done by Radhakrishnan *et.al*[10]. Regarding reporting of ADRs based on severity, in our study 84% of the students had an opinion that all ADRs should be reported irrespective of the severity whereas in a study done by Rehan *et al*., around 65% students had the similar opinion[6]. In a study done by Khan *et al* 66% respondents (doctors) considered ADR reporting to be professional obligation whereas in our study 47% respondents (students) thought that ADR reporting is a professional obligation[7]. This difference might be because of increased awareness among doctors compared to undergraduate students. In our study, 93% respondents (students) were aware of the measures that has to be taken when an ADR is suspected whereas in a study by Sonali et.al, 37% of the respondents (resident doctors) had awareness about measures to be taken when an adverse drug reaction is suspected[11]. Results pertaining to knowledge of the students in this study were encouraging. Majority of the students were aware of the term Pharmacovigilance, its activities and regulatory body monitoring ADR's. This might be the result of inclusion of causality assessment of ADR in our practical syllabus. Although there was varied response among students regarding professional obligation for ADR reporting, they should be encouraged to report all the types of reaction irrespective of severity. Educational intervention has been found to improve the attitude towards Pharmacovigilance.

CONCLUSION

The study results revealed that students are aware of Pharmacovigilance, but there was lack of professional obligation towards reporting ADR. Though Pharmacovigilance is being taught as part of Undergraduate curriculum, the students should be involved in more activity based and problem based learning.

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