Scholars Journal of Applied Medical Sciences (SJAMS)
Abbreviated Key Title: Sch. J. App. Med. Sci.
ISSN 2320-6691 (Online)
ISSN 2347-954X (Print)

A Unit of Scholars Academic and Scientific Society, India
www.saspublishers.com

Pharmacology

Educational Knowledge and Perception of Medical Students towards Practice of Monitoring the Safety of Drugs

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Original Research Article

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Article History
Received: 20.12.2017
Accepted: 25.12.2017
Published: 30.12.2017

DOI:
10.36347/sjams.2017.v05i12.057

Abstract: The purpose of pharmacovigilance is to improve patient safety but under-reporting is the main problem which is due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting. Therefore present questionnaire based study was conducted in medical students for assessing the knowledge, attitude, and practice related to pharmacovigilance. A total of 250 medical students participated in the study. A self-administered pre-validated,semi-structured questionnaire 14-item questionnaire was used to understand student's familiarity with regard to pharmacovigilance. Mean score of completeness of the questionnaire was 19.04 out of 20.During the study it was found that most of the students (80%) were aware of the definition of pharmacovigilance and 85% participants were of the view that ADRs should be reported by only doctors. Only 60% participants know about the location of international ADR monitoring centre and 90% participants know about institutional ADR centre. Whereas 74% opined that only serious ADR with any medicine should be reported and only 20% participants felt that ADR reporting is a professional obligation for doctors. 95% participants were of the view that pharmacovigilance should be taught in detail to healthcare professionals. Out of 81% of those seen ADR, only 20% of them reported it. We conclude that to improve the adverse drug reaction reporting in India, pharmacovigilance should be taught in details during undergraduate. During internship, students should be motivated to fill the case report form and participate in pharmacovigilance program and for students should be awarded to motivate them. It has been advised that medical students should be trained properly on ADR reporting to improve the pharmacovigilance program of the country.
Keywords: Knowledge, Perception, attitude, healthcare, problem.

INTRODUCTION

Pharmacovigilance is not only a science but also actions which include detection, assessment, understanding, and prevention of adverse drug effects or any other drug- related effects. In 1961, thalidomide disaster was the start of establishing the WHO programme for international drug monitoring, WHO promotes pharmacovigilance at the country level in collaboration with monitoring centre at Uppsala [1]. In an effort to strengthen the pharmacovigilance in India, government has initiated Pharmacovigilance programme of India (PvPI). Similarly, the Drug Controller General of India and Indian Council of Medical Research have established ADR monitoring centers in many hospitals in major cities of India[2]. Monitoring is essential for undetected, uncommon and serious ADRs and also for medication safety and understanding of drug risks. Adverse drug reaction reporting is the foundation of any PV system and timely identification and reporting of ADRs to the regional or national drug regulating authorities are critical. For ADR detection spontaneous reporting is common and inexpensive method but under-reporting is a big problem for optimal ADR monitoring [3].The under-reporting of ADR may be due to lack of an adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting[4]. Most ADRs are reported by health professionals and reporting of serious or previously unrecognized ADR is mandatory. [5]. In some European countries like Netherlands and Portugal medical students and pharmacy students can report ADRs [6]. The legal obligation to report ADRs requires health professionals to have the knowledge and skills to recognize and adequately report these reactions. During medical training medical students are taught how to prescribe rationally on the basis of WHO guidelines [7]. Although India is participating in the PV program but its contribution to Uppsala monitoring database of ADR is very little and this is due to less ADR monitoring system and lack of a reporting culture

among healthcare workers to drug- related problems [8]. Greater integration of pharmacovigilance into clinical practice is still needed and drug safety should be included in medical curriculum. It is important for health-care professionals to know how to report and where to report an ADR. The active participation of health-care professionals in the pharmacovigilance program can improve the ADR reporting [9]. It has been emphasized that there is a positive correlation between the training of Pharmacovigilance and reporting ADR by health-care professionals [10]. Factors like the unawareness about the method to decide the causal relationship between the ADR can only be removed by regular training [11]. The significance of adverse event monitoring and reporting can be increased through academic interference. This will ultimately help in improving the efficiency of pharmacovigilance program in India. It is recommended that hospital management, pharmaceutical companies, drug regulatory agencies should pay a significant contribution toward educating doctors on ADR monitoring and reporting. Along with this; few more suggestions were advised by previous researches. These include: Inclusion of pharmacovigilance in the undergraduate curriculum for health-care professionals [12], Perseverance of pharmacovigilance center [13], establishing a network of doctors for ADR reporting, [14] easy accessibility to ADR reporting forms[15], Promotion of patient self-reporting [16], and regular E-mail update on the safety of drugs [17], 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 was also established in SMS Medical College, Jaipur. Therefore on this background, the present questionnaire- based study was conducted to assess the knowledge, attitude, and practice of spontaneous ADR reporting among future doctors.

MATERIALS AND METHODS

A cross-sectional, a questionnaire based study was conducted among medical students of SMS Medical College, Jaipur. Study was approved from institutional ethics committee. A total of 250 medical students participated in the study. Willingness to participate and completing the questionnaire was taken as consent for the study. A self-administered 14-item questionnaire was used to understand student's familiarity with regard to PV and whether they were undertaking any ADR reporting practices, and to explore the obligation towards ADR reporting. The questionnaire consisted of questions included in previous national and international studies that examined the KAP of medical students. After explaining the study purpose, questionnaire was distributed to all the participants. The participants were personally briefed about the study questionnaire and were requested to record the time taken to complete it. The identity of the participants was not revealed The KAP questionnaires were evaluated for their completeness, and completeness scores were assigned as pre-decided (maximum score: 20). One point was given to each answered question (14 points) and the remaining six points were allotted for suggestions given (4 points), and two points was allotted for completing the concluding information. 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. 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

The questionnaire was administered to 300 medical students. A total of 250 questionnaires were returned, giving a response rate of 83%. The average time taken to complete the questionnaire was 5 minutes and the mean score of completeness of the questionnaire was 19.04 out of 20. 55% participants were within the age group of 21-23 years (Table-1). Of the participants, 70% were males and 30% females as shown in Table- 1.

Table-1: Demographic characteristics of the participants (n = 250)

Gender:	Percentage
Male	70%
Female	30%
Age(years)	
18-20	45
21-23	55

Assessment of pharmacovigilance- related Knowledge

While assessing the pharmacovigilance related attitude of students, it was found that most of the students (80%) were aware of the definition of pharmacovigilance. Overall, 85% participants were of the view that ADRs should be reported by only doctors. In continuation with this, 60% participants know about the location of international ADR monitoring centre and 90% participants know about institutional ADR centre shown in Table-2.

Table-2: Assessment of Pharmacovigilance-related Knowledge (n=250)

Participant's Knowledge	No. of respondents (%)
Definition of Pharmacovigilance	
- Detection, assessment, understanding & preventing adverse effects	200(80%)
- Science detecting the type & incidence of ADRs.	35(14%)
-The process of improving the safety of drugs	15 (6%)
-The science of monitoring ADRs occurring in a Hospital	0
-Do not know	0
Healthcare professionals responsible for reporting	
-Doctor	212(85%)
-Pharmacist	0
-Nurses	0
-All of the above	38(15%)
Regulatory body of ADR in India	
-Central Drugs Standard Control Organization	175 (70%)
-Indian Council of Medical Research	0
-Indian Clinical Research Institute	75 (30%)
Location of International ADR monitoring centre	
-New Delhi	50(20%)
- Bombay	37(15%)
- Ghaziabad	150(60%)
- Bangalore	13(5%)
Awareness about Pharmacovigilance committee/ADR centre in the institute	
-Yes	225(90%)
-No	12 (5%)
Knowledge about vigiflow	
-Yes	100(40%)
-No	150(60%)

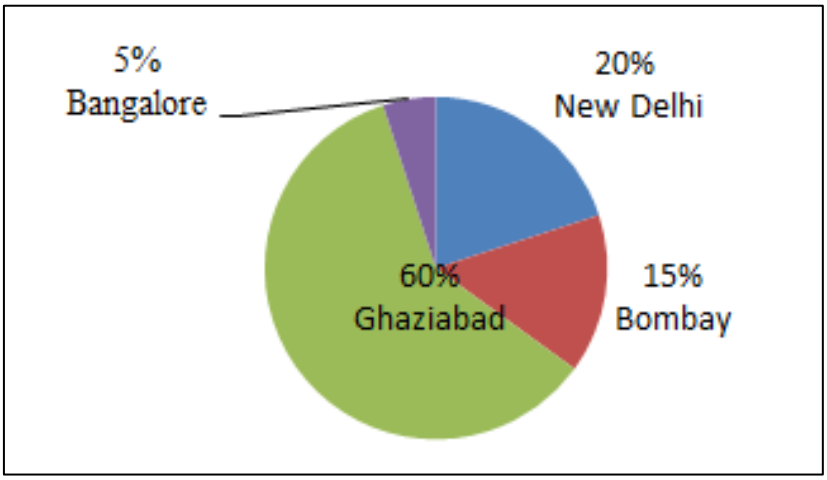

Fig-1: Knowledge of participants about location of International ADR monitoring centre

Whereas 74% opined that only serious ADR with any medicine should be reported. Furthermore, only 20% participants felt that ADR reporting is a professional obligation for doctors. Overall, 95% participants were of the view that pharmacovigilance should be taught in detail to healthcare professionals shown in Table-3.

Out of 81% of those seen ADR, only 20% of them reported it. Furthermore, total 65% read article on pharmacovigilance as shown in Table-4.

Table-3: Assessment of Pharmacovigilance-related attitude (n=250)

Participant's attitude	No. of respondents (%)
ADRs should be reported by	
-All serious ADRs	185(74%)
-ADRs to herbal and non-allopathic drugs	0
-ADRs to new drugs	25(10%)
-ADRs to vaccines	0
-Unknown ADRs to old drugs	40(16%)
Did you see an ADR reporting form?	
-Yes	112(45%)
-No	138(55%)
Do you think reporting ADR will increase patient safety?	237(95%)
-Yes	13(5%)
-No	
Do you think reporting an ADR is a professional obligation for doctors?	
-Yes	50(20%)
-No	200(80%)
Should pharmacovigilance be taught in detail to health care professionals?	
-Yes	237(95%)
-No	13(5%)

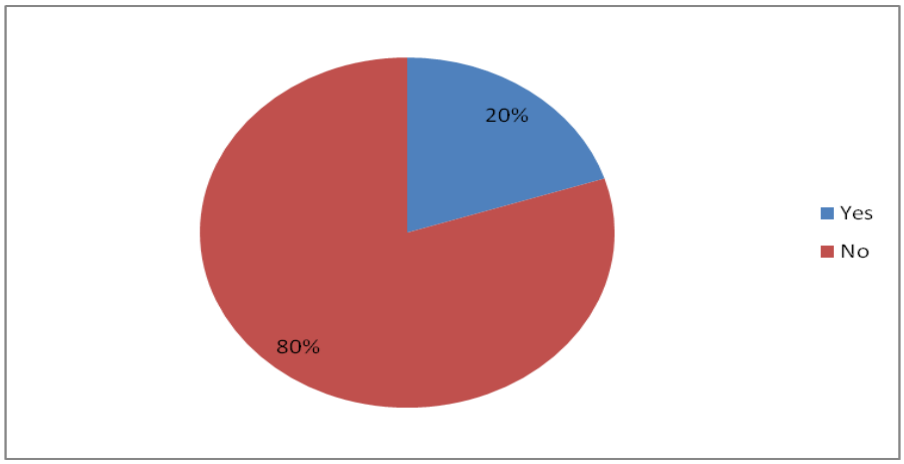

Fig-2: Is ADR reporting professional obligation for doctors?

Table-4: Assessment of pharmacovigilance-related practices (n=250)

Questions	No. of respondents (%)
Have you ever seen ADR during clinical posting?	
-Yes	202(81%)
-No	48(19%)
If yes, have you ever reported ADR?	
-Yes	50(20%)
-No	200(80%)
Did you read any case report or article on ADRs?	
-Yes	88(35%)
-No	162(65%)

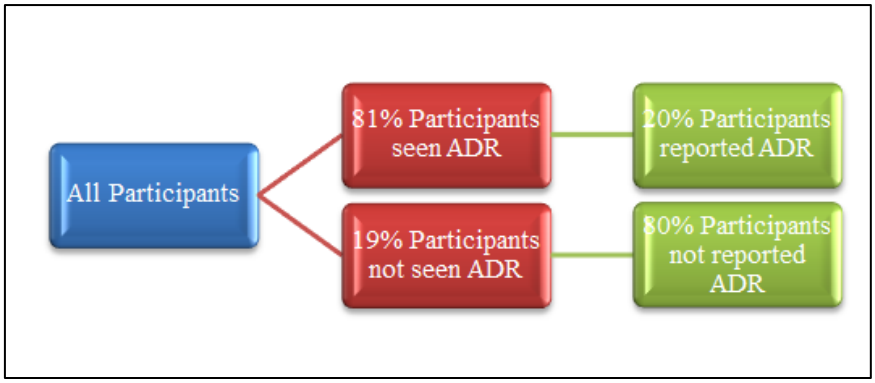

Fig-3: Attitude and practice of participants towards ADR reporting

DISCUSSIONS

The current study was a questionnaire-based study to assess the knowledge, attitude, and practice of pharmacovigilance towards ADR reporting among medical students in SMS Medical College, Jaipur. Many studies are done to assess the KAP of healthcare professionals towards pharmacovigilance, but a very few studies have been done among the undergraduate medical students to evaluate their knowledge [18-20]. The current study included a total of 250 medical students. The response rate reported in this study was highest (90%) than that reported in other studies [8]. In our study, nearly 100% participants heard about pharmacovigilance, but only 80% know its definition and need or purpose. A similar study in undergraduate medical students by Parthiban *et al*. reported that 81% were aware of the term Pharmacovigilance, but among the participants who were aware, only 63% had a better knowledge about Pharmacovigilance and ADR reporting [21]. In this present study, 85% students know that only doctors can report ADR and only 15% students know that, doctors, nurses and pharmacist can report ADR as per guidelines. Therefore poor awareness about ADR reporting has been observed during this study and similar results were reported by Parthiban et al among undergraduate students [21]. Majority of students (70%) knows the regulatory body of ADR in India and 60% know the location of international ADR monitoring centre. In this study 90% students are aware about institutional ADR centre but only 40% know about vigiflow. These findings were also observed in a study conducted by Gupta P [8]. The responses to the knowledge-based questions in this study indicate an average degree of knowledge regarding diverse aspects of pharmacovigilance. Majority of the respondents (74%) were of the opinion that ADR reporting has to be done for all serious ADRs, which is similar to the findings reported by Gupta and Udupa [8]. Hence from this study it is clear that students are aware about the fact that ADRs due to any medicine from any system of health care have to be reported. In the present study, 95% students feel that ADR reporting may improve patient safety. In our study, only 20% students think that ADR reporting is a professional obligation which is less as compared to other studies [22, 23]. It is an indication of a positive attitude toward the need to report, but a relative lack of commitment to do so. Most of the students (95%) accepted that reporting ADR is necessary, and pharmacovigilance should be taught in detail to health-care professionals. These findings are in correlation with findings of a study conducted by Gupta *et al.* [8] 81% students have seen ADR but surprisingly only 19%

Students have reported ADR. We can clearly see that practices for reporting are lacking which is also an observation by a study conducted by Agarwal R *et al*. [24]. During the study, students have also given some suggestion for improving adverse drug reaction reporting like training and educational activities for pharmacovigilance. Students also suggested that case report form should be simple and short for easy understanding and to motivate patients also for reporting.

CONCLUSION

During the study, we conclude that to improve the adverse drug reaction reporting in India, pharmacovigilance should be taught in details during undergraduate. During internship, students should be motivated to fill the case report form and participate in pharmacovigilance program and for students should be awarded to motivate them. It has been advised that medical students should be trained properly on ADR reporting to improve the pharmacovigilance program of the country.

ACKNOWLEDGEMENT

Authors would like to thank all medical students of the college for participating in the study.

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