

Original article

A survey on knowledge, attitude and awareness of pharma covigilance among medical students in a teaching hospital, Puducherry

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Abstract

Introduction: Adverse drug reactions (ADR) represent major concern on the health care system which causes morbidity and mortality. Under reporting of ADR in India could be due to inadequacies in knowledge and awareness about Pharmacovigilance (PV) and ADR reporting among the health care providers. This study was aimed at suggesting possible ways for improving ADR reporting.

Methods: A cross sectional questionnaire (24 questions) based study suitable for assessing the basic knowledge, attitude and awareness of Pharmacovigilance was designed and distributed among 415 undergraduate medical students (Final year part 1& 2) and Interns of Sri Manakula Vinayagar Medical College and hospital, Puducherry. Data were analysed using Epi info software 7.0 and the values were expressed in descriptive statistics.

Observation and results: Among 81% of the respondents who were aware of the term Pharmacovigilance, only 53% had better knowledge regarding PV. 33% of the students were aware of various government ADR Centres in India. Common reasons observed in the study for failure in implementing PV in India were lack of awareness (42%) and lack of enough research on ADRs (23%). 80% of students felt that there is a need for intensive training about PV in the undergraduate curriculum.

Conclusion: An alarmingly inadequate level of knowledge and awareness towards PV was observed in this study. Efforts are needed to develop a curriculum that incorporates all important aspects of PV in the undergraduate and internship training periods.

Keywords: Pharmacovigilance, Knowledge, Awareness, Attitude

Introduction:

Since the advent of drugs, the utilization of medicines has been connected with adverse events. There are only three activities of a medication: “The one you want, the one you don’t want and the one you don’t know about”.¹ Adverse drug reactions (ADR) are described as “a response to a medicament which is noxious and unforeseen and which happens at dosages ordinarily utilized for the diagnosis, prophylaxis or treatment of a disease or for the alteration of p-hysiological function”.² ADRs inflict a considerable economic burden on the healthcare system and society, thereby posing a major impact on

public health.³ The World Health Organization (WHO) defined the term Pharmacovigilance (PV) as “The pharmacological science and activities relating to the detection, assessment, understanding and prevention of the adverse effects, or any other drug related problems”.⁴ In the recent past, its worries have been broad-ened to incorporate herbal, traditional and complementary medicines, blood products, medical devices and vaccine-s.⁵ Studies conducted all through the world showed that ADRs produce significant reduction in the quality of life, increase hospitalization, lengthen hospital stay and increase mortality. The switching from prescription

only medicines to over the counter drugs have increased the risk of general public to ADRs, which are reported sporadically.⁶ The cost of drug related morbidity and mortality exceeded 177.4 million dollars as on 2000, of which about 70 % were expenses for hospital admissions.⁷ This is due to superfluous prescription, imprecise diagnosis, cursory application of evidence based medicines, outstanding development of new drugs and their unjustified promotion.⁸

The international database of ADRs, maintained by the Uppsala monitoring center, Sweden, reported about 4.7 million cases from several national centers of 96 member countries. However, only 6-10% of all ADRs are likely re-reported.⁹ Such underreported volume of ADR reporting 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 Adverse Drug Reactions could be improved with proper and extensive training about Pharmacovigilance during the undergraduate and internship periods.

Aim and objectives:

This study is a step, directed to evaluate the baseline knowledge, awareness and attitude of the undergraduate students and Interns of Sri Manakula Vinayagar Medical College and Hospital, Puducherry towards Pharmacovigilance.

Materials and methods:

This was a questionnaire based survey conducted among undergraduate students (Final year Part-1 and Part -2) and interns of Sri Manakula Vinayagar Medical College, Puducherry during the year 2014. After obtaining approval from the Institutional Ethics Committee and informed written consent from the participants, the study was commenced. A

predesigned questionnaire (24 questions: knowledge – 8, Attitude- 8, Awareness -8) which was structured by ensueing the preexisting studies was used in order to assess the knowledge, awareness and attitude of Pharmacovigilance amidst the study population. The questionnaire was distributed among 415 study subjects and they were explained clearly about the nature and purpose of the study. Proper instructions with reference to filling up of questionnaires were provided. The participants were given 30 minutes to complete the questionnaire.

Statistical analysis:

Data was entered and analyzed using Epi_info software program (version 7.0) and results were expressed in descriptive statistics.

Results:

Among the 415 undergraduate students (Final year Part-1, Part-2 and Interns) participated in our study, 310 questionnaire was returned with the response rate of 74.7%. 81% (n=250) were aware and 19% (n=60) were unaware of the term Pharmacovigilance (Figure 2). Among the participants who were aware of the term Pharmacovigilance, only 53% (n=134) had a better knowledge about Pharmacovigilance and ADR reporting. With respect to the awareness about centers for Pharmacovigilance and ADR reporting only 23.5% (n=73) gave correct response referring to international center for ADR monitoring, 17.4% (n=54) provided appropriate response about National Pharmacovigilance programme, 61% (n=189) furnished precise response about ADR monitoring organization in India. Only 57% (n=177) responded correctly with reference to the existence of national coordinating center for Pharmacovigilance (Table 2). With reference to the question “who can report ADR?” 47% (n=146) expressed both health care and non-health care professionals can report, 43% (n=133) conveyed only health care professionals are

entitled for ADR reporting (Table 2). An alarming 36% (n=112) revealed concerns that ADR reporting shatters our professional image. With respect to the common cause for failure in implementing Pharmacovigilance, 42% expressed lack of awareness as the fundamental reason for the failure (Figure 1).

90.3% (n=280) opined that elaborate Pharmacovigilance teaching for health care professionals would be beneficial and 84% (n=260) suggested that appropriate training in Pharmacovigilance should be added in the curriculum (Figure 3).

Table 1: Questions assessing Knowledge about Pharmacovigilance.

S. No	Questions	% answered correctly
1.	Term 'Pharmacovigilance'	80%
2.	Definition of Pharmacovigilance	80%
3.	Pharmacovigilance deals with	52%
4.	Phase of clinical trial associated with Pharmacovigilance	27%
5.	Pharmacovigilance unit in medical college mandatory?	88%
6.	Aim of Pharmacovigilance	83%
7.	Knowledge about ADRs	48%
8.	System of medicines involved in ADR reporting	29%

Table 2: Questions assessing Awareness about Pharmacovigilance.

S. No	Questions	% answered correctly
1.	International Centre for ADR monitoring	24%
2.	Establishment of National Pharmacovigilance Programme ADR monitoring organisation in India	25%
3.	National co-ordinating Centre for Pharmacovigilance	61%
4.	Who will get benefitted for reporting ADR?	57%
5.	Pharmacovigilance is the responsibility of?	69%
6.	Who can report?	57%
7.	Most commonly seen ADRs like headache, fever and vomiting has to be reported?	43%

Figure 1: Common cause of failure in implementing Pharmacovigilance in India

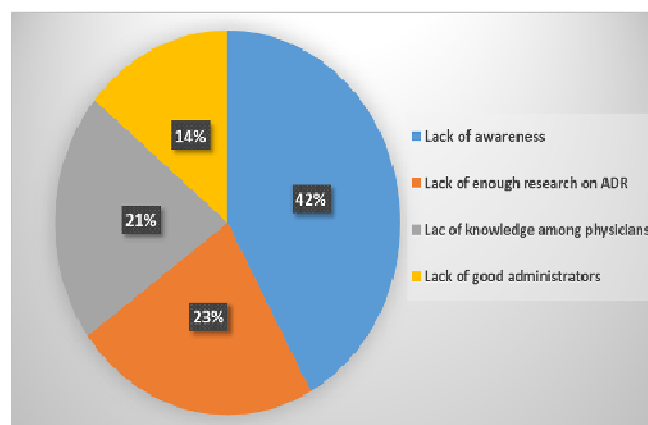


Figure 2: Percentage aware of the term Pharmacovigilance

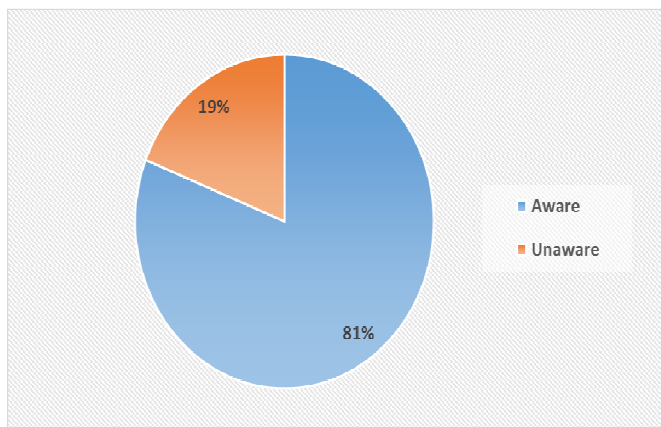


Figure 3: Need for Pharmacovigilance teaching and training

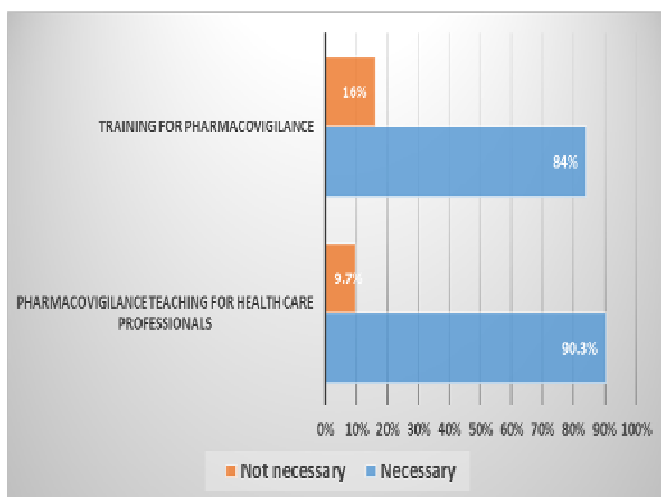
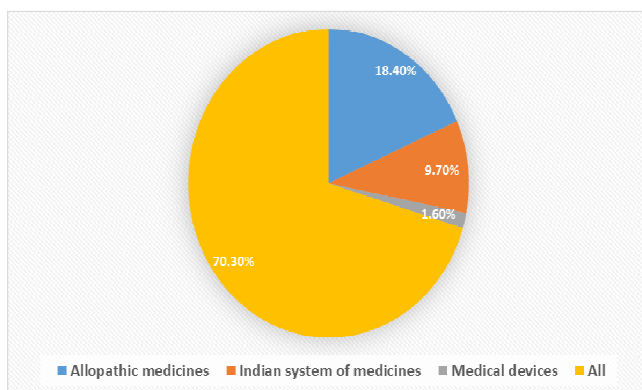


Figure 4: Knowledge about ADR reporting



Abbreviation's used:

ADR – Adverse drug reaction, CRRI – Compulsory Rotatory Residential Internship, PV – Pharmacovigilance, WHO – World health organization

Discussion:

The health care professionals need to be actively involved in the Pharmacovigilance programme as the economic and social burden due to adverse drug reactions is on the rise. Though many reasons can be attributed to underreporting of adverse drug reactions, the main reason is the lack of proper knowledge and awareness about Pharmacovigilance among the health care professionals as explained by Hema NG et al.¹⁰ Study conducted in New Delhi showed that the students and prescribers needed further improvement in their knowledge, attitude and practices.¹¹ A similar study conducted in Pune also explored the lack of awareness on reporting systems among the resident doctors. This study was conducted with aim to explore the knowledge, awareness and attitude of undergraduate students and interns towards Pharmacovigilance in a teaching hospital, Puducherry.

Our study showed an overall response rate of 74.7%. Most students were aware of the term 'Pharmacovigilance' (81%). Among those students, 53% had a knowledge score of more than 70%. This goes in par with the study results of Praveen S et al.¹² Only health care professionals (Doctors, Dentist, Nurses and Pharmacist) can report ADR as per the guidelines. But, 47% of the students have responded that both healthcare and non-health care professionals can report ADR. Thus, a better training is necessary for the students to improve their knowledge regarding ADR reporting and Pharmacovigilance. Hema NG et al found an unsatisfactory and poor awareness among the undergraduate students and interns.¹⁰ Our study results also depicted a lack of awareness about the International centre for ADR reporting (23%). Only 17.4% of the students have the awareness regarding National Pharmacovigilance programmes which is

not surprising as around 81.9% of students had not attended any CME, conference or Seminars regarding Pharmacovigilance and ADR reporting. The overall attitude towards ADR reporting and Pharmacovigilance was acceptable, but the lack of knowledge and awareness was found to be the most common cause of failure in successful implementation of the Pharmacovigilance programme in India which goes in accordance with the study results of Praveen S et al.¹² Yet, 36% of the students think that reporting ADR's shatters our professional image, which might pose a greater threat to the community in the future. Their interest and attitude in learning about Pharmacovigilance and ADR reporting was appreciable as 90.3% conveyed that elaborated Pharmacovigilance teaching for health care professionals was the need of the hour and 84% (n=260) desired appropriate training in Pharmacovigilance to be added in the curriculum. A study conducted in six different medical colleges in Gujarat showed that the overall knowledge of Pharmacovigilance was poor in undergraduate medical students.¹³ A study done in Pharmacy students of Malaysian Public Universities suggested a customized Pharmacovigilance curriculum to be designed and implemented in pharmacy schools.¹⁴

A better training about Pharmacovigilance in undergraduate curriculum might help to solve this emergent problem of underreporting of ADR's. A regular simulated environment and workshop on Pharmacovigilance should be conducted for the students and periodic evaluation of their responses should be done. An educational visit to the Pharmacovigilance centres to observe the academism will help to improvise the need for ADR reporting.

Conclusion:

Our study suggested that though the attitude towards Pharmacovigilance and the eager to learn about ADR reporting was appreciable among the medical students, there lies an insufficient knowledge and awareness about Pharmacovigilance. Many reasons can be put forwarded for underreporting of ADRs. Widening the teaching programmes for medical

professionals during their undergraduate period might provide a solution to strengthen ADR reporting in India. The results of this study is just the tip of iceberg with reference to the knowledge, awareness and attitude of students towards Pharmacovigilance. Many studies from different institutions of different geographical areas need to be done to improvise the need for ADR reporting in the near future.

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