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RESEARCH ARTICLE

Assessment of knowledge, attitude, and practices of pharmacovigilance and adverse drug reaction reporting among final year medical students - A questionnaire-based study in a tertiary care hospital in Goa

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ABSTRACT

Background: Pharmacovigilance has a significant role in the rational use of medicines by providing information about adverse drug reactions (ADRs). ADRs can lead to significant mortality and morbidity in the health-care industry. Under-reporting of such cases is mainly caused due to inadequate knowledge of pharmacovigilance and ADRs. The effectiveness of pharmacovigilance and ADR monitoring depends on the active participation of all the components of the health-care system; students being the main component. **Aims and Objective:** Purpose of this study was to assess the knowledge, attitude, and practices of pharmacovigilance and ADR reporting among final year medical students in a tertiary care hospital in Goa. **Materials and Methods:** This cross-sectional, observational, and questionnaire-based study was carried out using a predesigned questionnaire. The permission of the Institutional Ethics Committee was taken. The study included distribution of 130 questionnaires to the final year medical students of Goa Medical College. The responses were assessed and analyzed using MS Excel and data were presented as percentages. **Results:** A total of 95 responses from students were obtained out of 130 questionnaires, thus a response rate of 73%. On an average 54.5% of student answered the questions related to knowledge correctly. 67.3% of students had a positive attitude toward pharmacovigilance and ADR reporting. 46.3% felt that not knowing how the reporting works are the main cause of under-reporting. 45.3% students knew what steps were to be taken once an ADR is detected. Only 14.7% of students had seen the ADR reporting form. 38.9% of students had identified ADRs in patients during their clinical postings, and only 6.3% had reported any ADRs. **Conclusion:** The study revealed that there was an inadequate level of knowledge and awareness toward pharmacovigilance and ADR reporting. Efforts are needed to develop a curriculum that includes all aspects of pharmacovigilance in the undergraduate period.

KEY WORDS: Knowledge, Attitude, Pharmacovigilance; Adverse Drug Reactions Reporting; Spontaneous Reporting

INTRODUCTION

All drugs have therapeutic effects and none are absolutely devoid of adverse effects. Prescription of drugs should be judicious and with a satisfactory risk/benefit ratio.[1] Since the advent of drugs, the utilization of medicines has been connected with adverse events.

Drugs prescribed for the disease are often themselves the cause of the serious amount of adverse reactions ranging from mere inconvenience to permanent disability and death. According to DJP Barker, "There are three actions of a drug: The one you want, the one you do not want, and the one you do not know about."[2]

The WHO defines adverse drug reaction (ADR) as, "any noxious, unintended, and undesired effect of a drug, which

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occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."[3] The median incidence of ADRs that leads to hospitalization and ADRs developed during hospitalization is 2.85% and 6.34%, respectively. The fatal ADR incidence is 0.08%, and this is a great cause of concern to the medical profession.[4]

ADRs can result in short- and long-term hospitalization and deaths. ADRs can lead to a considerable economic burden on the health-care system and society, posing a major impact on public health.[5] This is why it is important to monitor and reports the ADRs, to obtain knowledge about the drugs and their effects on the patient so that it facilitates the health services.

Pharmacovigilance is a part of patient care and safety that ensures the efficient use of medicines for the treatment and prevention of ADRs.[6] According to the WHO, Pharmacovigilance is defined as, "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems."[7] Its scope has been broadened to incorporate blood products, medical devices, and vaccines.

The estimated annual cost of drug-related morbidity and mortality resulting from non-optimized medication therapy was $528.4 billion in the US according to a 2018 study.[8] This can be due to superfluous prescription, imprecise diagnosis, cursory application of evidence-based medicines, and outstanding development of new drugs and their unjustified promotion.[9]

In India, a formal ADR monitoring system was started in 1986 with 12 regional centers. In 1997, India became the member of the WHO Programme for International Drug Monitoring managed by the Uppsala Monitoring Centre, Sweden.[10] In July 2010, under Health Ministry, a nation-wide revised ADR monitoring program was launched and named as Pharmacovigilance Programme of India.[11]

Pharmacovigilance program of India aims at improving the ADR monitoring and building an ADR database. The spontaneous reporting system is considered as the backbone of pharmacovigilance.[11]

However, the major hurdle in the complete success of the pharmacovigilance program is underreporting of the ADRs.[12] Such underreported volume of ADR reporting is essentially due to absence of vibrant ADR monitoring system and also inadequacies in reporting culture among health care professionals.[13]

This study was conducted for the assessment of awareness of pharmacovigilance and ADR reporting in medical students in Goa, to gain the perspective of how much impact the undergraduate pharmacovigilance education is making on them, as these students are going to be the future prescribers.

MATERIALS AND METHODS

The approval of Institutional Ethics Committee in Goa Medical College (GMC) was taken, and a questionnaire-based study was conducted in March 2018.

130 questionnaires were distributed to the final year medical students and were asked to return the duly filled questionnaires the same day.

A total of 95 students were assessed out of 130 distributed questionnaires.

The questionnaire consisted of 20 questions. It was based on previous studies. It was divided into three sections, i.e., knowledge, attitude, and practice toward pharmacovigilance and ADR reporting.

Data Analysis

The data were collected, and analyzed using MS Excel and results were depicted in the form of percentages.

RESULTS

The questionnaire was given to 130 final year medical students. 95 students filled and returned the questionnaire in the stipulated time frame. Response rate was calculated at 73%.

The questionnaire consisted of a total of 20 questions. Out of which, 13 questions were related to knowledge, four questions were related to attitude, and three questions were related to practice aspects.

Response to Knowledge Related Questions

Figure 1 nearly 78% of students had come across the term pharmacovigilance, 73.7% of students answered the definition of pharmacovigilance correctly and 72.6% were aware of the purpose of pharmacovigilance. 86.3% of students knew the definition of ADRs correctly, but only 18% could identify the types of ADRs.

Nearly 24.2% of students were aware of the most common ADRs and 80% of students correctly identified which ADRs are supposed to be reported. 66.3% of students knew about the regulatory body for pharmacovigilance in India while only 22% knew about the international ADR center location.

Only 46.3% of students had knowledge about the presence of pharmacovigilance center in GMC. 30.5% of students were aware about the National Pharmacovigilance Programme.

65.3% of students could answer correctly about who could report ADRs. It was found that only 45.3% knew what steps should be taken once an ADR is detected.

On an average 54.5% of students correctly answered the questions related to knowledge about pharmacovigilance and ADR reporting [Table 1].

Responses to Attitude Related Questions

There were four attitude related questions. The students had better attitude toward pharmacovigilance and ADR reporting in general. On an average 67.3% student answered positively toward attitude related questions.

97.9% of students agreed that ADR reporting in necessary. 86.3% opined that pharmacovigilance and ADR monitoring should be taught in detail in the medical curriculum. Only 17.9% of students had done extra reading about pharmacovigilance and ADR monitoring.

Students gave their views on what might be the reasons for under-reporting of ADRs; 46.3% students answered that under-reporting is present because there is unawareness about how the reporting procedure works; 23.3% and 20% students thought it is because of busy duty hours or lack of time for follow-up, respectively; 11% students opined that fear of legal consequences might be the reason for under-reporting [Table 2].

Responses to the Practice-related Questions

There were total three practice-related questions. 38.9% of students had ever identified an ADR in a patient, but only 6.3% reported the ADR to their superiors. Only 14.7% of students were aware of ADR form. On an average 19.9% student answered positively about practice-related questions [Table 3].

DISCUSSION

This study was conducted with an aim to explore the knowledge, awareness, and attitude of final year medical students toward pharmacovigilance in a tertiary care hospital in Goa. In this study, the students were assessed because they play a major role in interacting with patients in the clinical departments. They are also an invaluable source for collecting, analyzing and reporting ADRs.

In the present study, overall response rate of 73% was reported. It was 74.7% and 88% in studies conducted in Puducherry and North Maharashtra in medical students and interns, respectively.

Majority of the students were aware of the term pharmacovigilance (78%). 54.5% of final year students answered knowledge related questions correctly; this was >31.1% in the study conducted by Vakade *et al*.[14] in interns. Good knowledge is very important for practicing pharmacovigilance and reducing under-reporting of ADRs.

According to guidelines only health officials (doctors, nurses, and pharmacists) and patients can report the ADRs; 65.3% students gave correct answer. Thus, better training is required to improve the knowledge in the students. Meher *et al*. also found similar results among final year students in their study.[15]

Our study results also depicted a lack of awareness about the international center for ADR reporting (22%) and National Pharmacovigilance Programme (30.5%) which is not surprising as around 82.1% of students had not read any latest literature related to this topic. These results corroborated with the study conducted by Prathiban *et al*. in Puducherry.[16] This is most likely due to more preference given to theoretical knowledge at undergraduate level than the practical knowledge by the students.

It was noticed that 46.3% of students were not aware that GMC is an ADR monitoring center. This could be because at the undergraduate level these topics are not adequately stressed. These observations indicate serious measures have to be taken to educate the undergraduates about these aspects of pharmacovigilance and ADR monitoring.

The overall attitude was appreciable among the students. 97.9% students thought that it was necessary to report ADRs and 86.3% students felt that pharmacovigilance and ADR monitoring should be taught in detail in MBBS curriculum.

In this study, factors that may lead to under-reporting were busy duty hours (23.2%); no knowledge about the reporting procedure (46.3%); no time to follow up the patients (20%); textbooks and other literature already have ADRs (2.11%); fear of legal consequences (11.2%); and lack of remuneration (9.4%%). All these factors may lead to under-reporting.

A survey among undergraduate pharmacy students in Nigeria on ADR reporting and other pharmacovigilance activities showed lack of knowledge in the respective fields which were attributed to the absence of pharmacovigilance in their curricula; ultimately lack of knowledge may lead to under-reporting.[17]

The health-care professionals have to be actively involved in the pharmacovigilance program as the economic and social burden due to ADRs is on the rise. Although many reasons can be attributed to the underreporting of ADRs, the main reason is the lack of adequate knowledge and awareness about pharmacovigilance among the health-care professionals as explained by Hema *et al*.[18] Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market after approval. Few examples

Table 1: Response to questions related to knowledge of pharmacovigilance

Q. No	Questions	Correct responses *n* (%)
2	What is the definition of pharmacovigilance?	70 (73.7)
3	What is the purpose of pharmacovigilance?	69 (72.6)
4	What is the definition of ADR?	82 (86.3)
5	What are the types of ADR?	18 (18.9)
6	Which is the most common ADR?	23 (24.2)
7	Which ADRs should be reported?	76 (80)
8	Where is international ADR center located?	21 (22.1)
9	What is the regulatory body for monitoring ADRs in India?	63 (66.3)
10	Is there pharmacovigilance center in GMC?	44 (46.3)
11	Knowledge about national PV program	29 (30.5)
12	Who can report ADRs?	62 (65.3)
13	What steps to be taken once an ADR is detected?	43 (45.3)

ADR: Adverse drug reaction, GMC: Goa Medical College

Table 2: Positive response to questions related to attitude toward pharmacovigilance

Q. No	Questions	Correct responses *n* (%)
1	Is it necessary to report ADRs?	93 (97.9)
2	Should PV and ADR monitoring be taught in detail in MBBS curriculum?	82 (86.3)
3	Have you read any article related to PV or ADR monitoring?	17 (17.9)
4	What are the reasons for underreporting?	
	Busy duty hours	22 (23.2)
	Do not know how the reporting procedure works	44 (46.3)
	No time to follow-up patients	19 (20)
	Textbooks and other literature already have ADRs mentioned	2 (2.11)
	Fear of legal consequences	11 (11.6)
	Non-remuneration	9 (9.47)

ADR: Adverse drug reaction

Table 3: Positive response to questions related to practices of pharmacovigilance

Q. No	Questions	Correct responses *n* (%)
1	Have you ever come across an ADR form?	14 (14.7)
2	Have you ever identified an ADR in a patient during the clinics?	37 (38.9)
3	Have you ever reported any ADR?	6 (6.32)

ADR: Adverse drug reaction

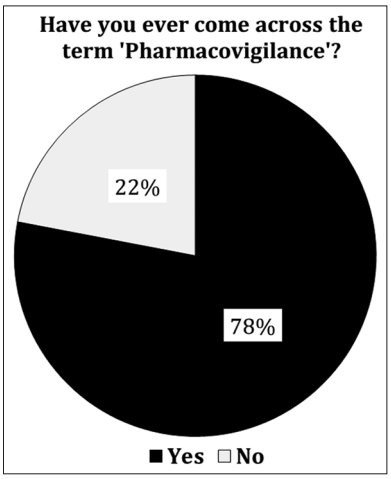

Figure 1: Response to question 1 regarding the knowing the term "pharmacovigilance"

are benoxaprofen, cerivastatin, cisapride, domperidone (injectable), valdecoxib, and sibutramine.[19]

Pharmacovigilance and ADR reporting are an integral part of the health services. Spontaneous reporting is an important method for reporting ADRs and identifying new ADRs.

The topic of the ADRs is covered in most of the pharmacology textbooks. However, the students are not adequately trained to apply this knowledge in practice. The results of the present study indicate that knowledge and positive attitude exerts a strong influence on ADR reporting. Incorporating

the teaching programs related to pharmacovigilance and ADRs for medical professionals during their undergraduate period might provide a solution to strengthen ADR reporting in India. Continued Medical Education programmes and other training programs can help in sensitizing them. The students can be posted in the pharmacovigilance centers. Even organizing regular quiz programs for both the staff and the students can foster a better means of creating awareness about pharmacovigilance.

Limitations

Questionnaire-based studies are liable to bias. Furthermore, this study had a small sample size.

CONCLUSION

This study showed that students had better attitude, but limited knowledge and poor practice toward pharmacovigilance and ADR reporting. Although pharmacovigilance is being taught to some extent in theory, the knowledge on the practical aspect is lacking.

Revision of present academic curriculum is necessary to include the application of pharmacovigilance in medical practice. The result of this study is just the tip of an iceberg. Awareness about pharmacovigilance and ADRs should be a priority.

This is going to reflect on the future practice and decreased irrational use of drugs.

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