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Original Research Article

Study on awareness and perception towards adverse drug reactions among medical and paramedical students in South India

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ABSTRACT

Background: Pharmacovigilance (PV) programme targets the monitoring of safety of drugs. It aims at promoting patient care and improving public health and also helps to assess the risk-benefit profile of medicines. The aim of the study was to assess public knowledge about medicine information, safety, and adverse drug reaction reporting (ADR) in medical and paramedical student community.
Methods: It was a cross-sectional study conducted among medical and paramedical students for the period of six months from November 2021 to April 2022. The questionnaire was adopted from the literature and was validated. Content and face validities were established, and reliability was assessed. In this study a total of 364 participants returned completed questionnaires.
Results: In this study, 364 students completely filled the questionnaire and out of 364 participants, 155 were males (42.58%) and 209 (57.41%) were females. Fourth year students 131 (35.98%) are highly participated in this study and indicated that final year B Pharmacy students having the perceptive knowledge towards ADR. Majority of medical and paramedical students known well about the ADRs.
Conclusions: The results of this study highlighted that although the scores for knowledge of medicines, and tendency to report ADR were better, the score for knowledge regarding medication safety was unsatisfactory. There is a need for a regular training and the re-enforcement for the ADR reporting among the health care personnel both medical and paramedical students.

Keywords: Adverse drug reaction, Medical students, Monitoring, Pharmacovigilance, Reporting systems, Medication safety

INTRODUCTION

Adverse drug reaction (ADR) is an unwanted or a harmful reaction experienced by an individual, after using a drug or drugs, under normal condition, and which is suspected of being related to that drug. Hence ADR may include an exaggerated drug response, an unwanted effect on an organ system, different from that being treated, an allergic or hypersensitivity reaction, an idiosyncratic reaction, or a drug interaction that causes an increased or diminished response. A side effect and a drug allergy are also examples of ADRs.[1]

The WHO programme for international drug monitoring was established in 1962. An international system for monitoring adverse reaction to drugs using information derived from national centers was subsequently initiated under the Drug Monitoring Program. Several approaches have been used to detect ADR.[2] Pharmacovigilance (PV) programme targets the monitoring of safety of drugs. It

aims at promoting patient care and improving public health and also helps to assess the risk-benefit profile of medicines. The monitoring of the effects, contraindications and outright harmful effects of medicines which can result in a high degree of morbidity and in some cases, even mortality, is essential to maximize benefits and minimize the risks.[3]

The success of pharmacovigilance programme depends upon the active involvement of the healthcare professionals such as doctors, nurses, pharmacists. Being the key healthcare professionals, providing information on suspected ADRs is as much moral duty for the healthcare professionals as other aspects of patient care. To transform the pharmacovigilance activity into practices for enhancing safety of patient and more ADR monitoring centre being setup across the country under pharmacovigilance programme of India (PVPI).[4,5]

One of the major challenges that pharmacovigilance programs face worldwide is underreporting. Underreporting of ADRs could be attributed to the knowledge deficit, lack of training or education that health care providers have regarding PV and the safety of medications.

The lack of knowledge of PV and ADRs reporting among HCPs is most likely due to the unavailability of PV as a subject of study in healthcare schools (i.e.; medicine, pharmacy, dentistry, nursing, etc. In fact, a systematic review among medical students investigated the PV and ADR-reporting awareness of healthcare students.

Also, there are many published studies in this area, most of the published studies did not compare healthcare students that need to be educated about pharmacovigilance and ADR reporting as the will encounter in their practice and all need to report the ADRs. The findings of this study can help in identifying educational gap among healthcare students which is essential for the design of educational program which can untimely help in promoting the PV environment and safe practices among future healthcare professionals.[6-8]

The objective of this study was to estimate and compare the knowledge, attitude, and perceptions of pharmacovigilance among students from different healthcare colleges.

METHODS

It was a cross-sectional study and conducted among medical and paramedical students. This study was conducted for period of 6 months from November 2021 to April 2022.

Ethical clearance was obtained from Human Ethics Committee of Valluvanad Hospital, Ottapalam with No: 108/KTN/VND/2021.

Inclusion criteria

The target responders consisted of different medical and paramedical students who willing to participate in this study.

Exclusion criteria

Students who studying in courses other than medical and paramedical. Students who did not give the consent were eliminated from the study.

Sampling strategy and data collection

The study instrument was a pre-designed questionnaire which was structured to obtain information on the knowledge of the ADRs reporting, attitude towards reporting and the factors that in practice could hinder the reporting. Each student was asked to fill a validated structured questionnaire delivered by Google form through social media.

Sample size calculation

Sample size was calculated using an online calculator. The target population was identified as student population of medical and paramedical courses.

Structure of questionnaire

Questionnaire was adopted from the available literatures and was further developed and validated. The final version consisted of closed ended questions covering the demographic information such as sex, age, course of study, year of study, type of college, place of studying. The questionnaire had two sessions, (1) knowledge about ADR and PV; and (2) perception about ADR. There were 22 questions in total; 8 related to knowledge, 4 related to perception and 8 related to attitude, 1 question was asked to determine the reasons for under-reporting. The study participants were given informed consent before starting the survey.

Data analysis

The data observed were entered in Microsoft excel spreadsheet and were analysed.

RESULTS

In this cross sectional study, a questionnaire designed in Google form was distributed through social media; around 364 students completely filled the questionnaire and were selected for analysis. Out of 364 participants, 155 were males (42.58%) and 209 (57.41%) were females. This showed that women participated more actively when compared to men (Figure 1).

Figure 2 showed that distribution of study subjects based on their course and which noted higher responses from B

Pharmacy graduates 146 (40.10%) than any other paramedical courses. From medical courses which shows only 54 responses (14.83%).

Figure 3 exhibited that, fourth year students 131 (35.98%) are highly participated in this study and followed by third year and second year students.

This study showed that, Students have basic knowledge and awareness about ADR, Table 1 and Figure 4 indicated that final year B Pharm students having the perceptive knowledge towards ADR. Majority of medical and paramedical students known well about the ADRs.

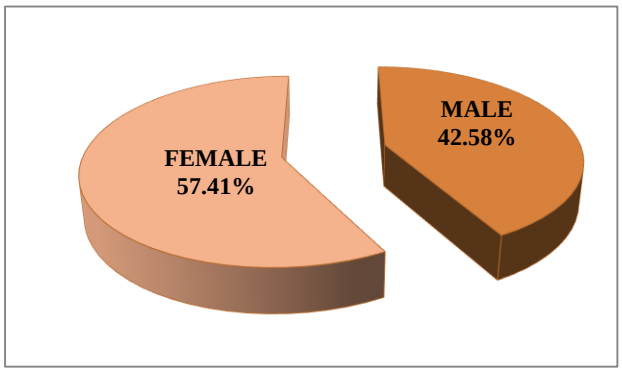

Figure 1: Gender wise distribution of participants.

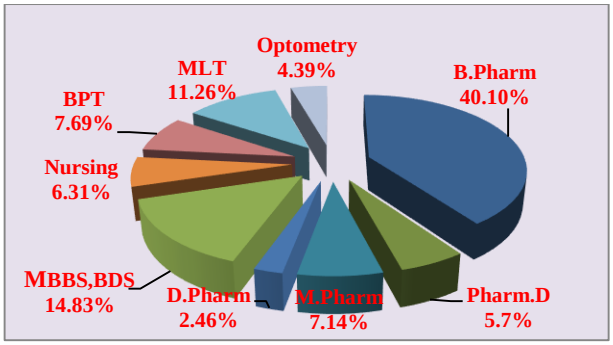

Figure 2: Distribution study subjects based on course of study.

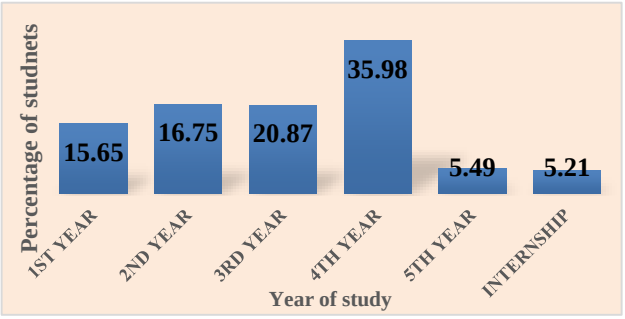

Figure 3: Distribution of participants based on year of study.

Table 1: Awareness about adverse drug reaction among students.

S. no.	Knowledge related questions	Response (%)	
		Correct	Incorrect
1.	Do you know about adverse drug reactions?	76.43836	23.56164
2.	Do you know which age group can be harmed from adverse drug reactions?	71.50685	28.49315
3.	Which category of drugs experience adverse drug reactions?	65.47945	34.52055
4.	Do you think that adverse drug reaction is harmful?	60.54795	39.45205
5.	Do you know who is responsible for reporting adverse drug reactions in hospital?	52.32877	47.67123
6.	When should adverse drug reaction be reported?	68.76712	31.23288
7.	Do you know adverse drug reaction reporting is necessary?	63.83562	36.16438
8.	Do you know which of the following scale used to assess causality of adverse drug reaction?	71.23288	28.76712

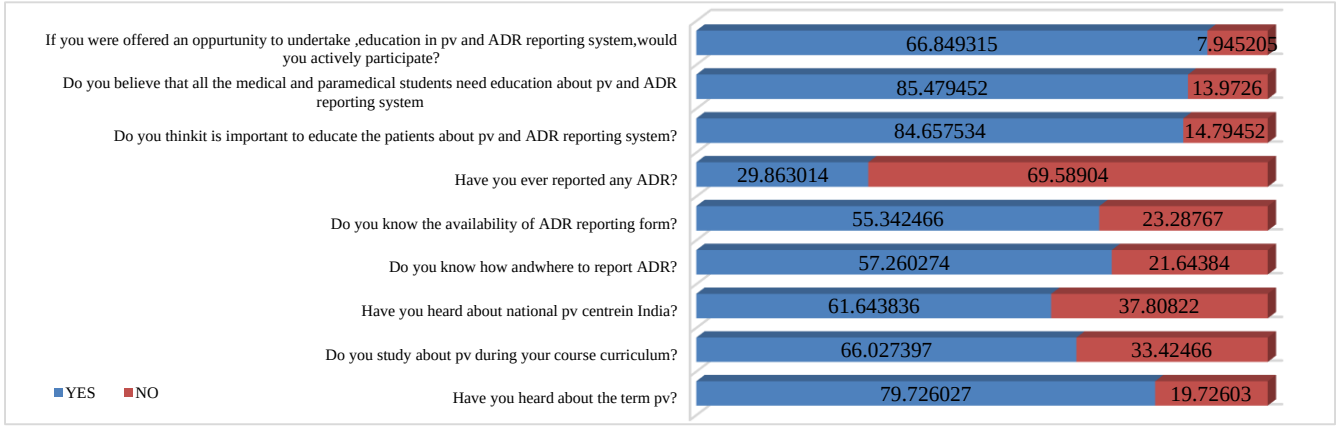

Figure 4: Attitude and perception related questions in ADR and PV among medical and paramedical students.

DISCUSSION

In this study, the attitude of the student groups towards seeking of medicine knowledge and ADR reporting was positive. The same report was obtained by a study conducted by Islam et al and the report shown that there was overpriced awareness about medicine information, safety, and ADR reporting.[5]

ADR reporting is an activity that may take some time to become fully accepted as a role for the pharmacist and integrated into their daily routines. According to Alamo et al, they conducted a study on health care professionals' knowledge, attitude, and practise towards adverse drug reaction reporting and associated factors at selected public hospitals. Education and training, which appear to have a significant influence on ADR reporting, should be continued and reinforced in order to improve ADR reporting by pharmacists. Both medical and paramedical students should be aware of and monitor the ADR to ensure drug safety as a prior role.[8,9] Periodic trainings should be held by pharmacy authorities to update reporting knowledge, like ADR reporting form availability, reporting centres, modes, and benefits of reporting, etc, and must be made mandatory to all community health care professionals. Adisa et al conducted a study on the awareness, knowledge, attitude, and practise of adverse drug reaction reporting among health workers and patients in selected primary healthcare centers.[10] The authorities must create awareness among all the health care professionals by providing adequate training and improving quality education programmes among students. Pharmacists must be encouraged and constantly motivated so that ADR reporting becomes a voluntary responsibility.

Drug safety can be achieved and maintained with a positive attitude towards PV, which is an essential role of a pharmacist. Scholarships and other encouraging perks should be given to those who report ADRs among the medical and paramedical student communities to keep them motivated and focused. Increased vigilance on the use of medications through more education and awareness classes should be provided by doctors, pharmacists, and nurses, as well as patient reporting of ADRs. This may become more rapid and advanced with the use of new software and the internet. Cooperation and health care teamwork are needed for better health care aspects.[11,12]

As per study results, HCPs observe ADRs during their clinical practice, but the reporting of those ADRs is very much limited to the concerned authorities, whether the pharmaceutical industry or a government department. Furthermore, the study reveals the reasons that could be looked into for the betterment of the reporting of ADRs.[13] As has been mentioned, physicians are not very cooperative to report ADRs, so to increase reporting, many countries allow pharmacists working in hospitals and the community, nurses, and even patients to report ADRs. Medical practitioners are the primary component of the ADR reporting system, but every healthcare professional that has knowledge, attitudes, and perceptions about ADRs can play a part in reporting ADRs.[14,15]

Main limitation of this study included the duration, it was conducted a period for six months and the data collection method also affects this study. The data was collected in online plate form and we could not have much control over the study participants.

CONCLUSION

One of the major challenges that PV programs face worldwide is underreporting. Underreporting of ADRs could be attributed to the knowledge deficit, lack of training or education that health care providers have regarding PV and the safety of medications. The lack of knowledge of PV and ADRs reporting among health care professionals is most likely due to the unavailability of PV as a subject of study in healthcare schools i. e.; medicine, pharmacy, dentistry, nursing, etc. In fact, a systematic review among medical students investigated the PV and ADR-reporting awareness of healthcare students. Also, there are many published studies in this area, most of the published studies did not compare healthcare students that need to be educated about PV and ADR reporting as the will encounter in their practice and all need to report the ADRs. The findings of this study can help in identifying educational gap among healthcare students which is essential for the design of educational program which can untimely help in promoting the PV environment and safe practices among future healthcare professionals. The success of PV programme depends upon the active involvement of the healthcare professionals such as doctors, nurses, pharmacists. Being the key healthcare professionals, providing information on suspected ADRs is as much moral duty for the healthcare professionals as other aspects of patient care. To transform the PV activity into practices for enhancing safety of patient and more ADR monitoring centre being setup across the country under PVPI. Encouragement to student's community is needed therefore; various social media platforms could be used to provide awareness. In addition, communicating with HCPs to educate patients about the NPC and ADR reporting process during patient counselling could be very helpful in increasing ADR reporting.

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REFERENCES

1. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause

of admission to hospital: prospective analysis of 18 820 patients. BMJ. 2004;329(7456):15-9.
2. Lihite RJ, Lahkar M. An update on the Pharmacovigilance Programme of India. Front Pharmacol. 2015;6:194.
3. Ganesan S, Sandhiya S, Reddy KC, Subrahmanyam DK, Adithan C. The Impact of the Educational Intervention on Knowledge, Attitude, and Practice of Pharmacovigilance toward Adverse Drug Reactions Reporting among Health-care Professionals in a Tertiary Care Hospital in South India. J Nat Sci Biol Med. 2017;8(2):203-9.
4. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. J Pharmacol Pharmacother. 2013;4(1):S73-7.
5. Zheng R, Tao L, Kwong JSW, Zhong C, Li C, Chen S, et al. Risk factors associated with the severity of adverse drug reactions by Xiyanping injection: A propensity score-matched analysis. J Ethnopharmacol. 2020;250:112424.
6. Kongkaew C, Noyce PR, Ashcroft DM. Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. Ann Pharmacother. 2008;42(7):1017-25.
7. Munasinghe TM, Singer DR. Costs and prevention of adverse drug reactions. Eur J Intern Med. 2001;12(5):403-5.
8. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: a challenge for pharmacovigilance in India. Indian J Pharmacol. 2015;47(1):65-71.
9. Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2009;32(1):19-31.
10. Stergiopoulos S, Brown CA, Felix T, Grampp G, Getz KA. A Survey of Adverse Event Reporting Practices Among US Healthcare Professionals. Drug Saf. 2016;39(11):1117-27.
11. Hardeep, Bajaj JK, Rakesh K. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. J Clin Diagn Res. 2013;7(1):97-9.
12. Conforti A, Costantini D, Zanetti F, Moretti U, Grezzana M, Leone R. Adverse drug reactions in older patients: an Italian observational prospective hospital study. Drug Healthc Patient Saf. 2012;4:75-80.
13. Alhawassi TM, Abuelizz HA, Almetwazi M, Mahmoud MA, Alghamdi A, Alruthia YS, et al. Advancing pharmaceuticals and patient safety in Saudi Arabia: A 2030 vision initiative. Saudi Pharm J. 2018;26(1):71-4.
14. Dukes MN. The importance of adverse reactions in drug regulation. Drug Saf. 1990;5(1):3-6.
15. Reumerman M, Tichelaar J, Piersma B, Richir MC, Agtmael MA. Urgent need to modernize pharmacovigilance education in healthcare curricula: review of the literature. Eur J Clin Pharmacol. 2018;74(10):1235-48.

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