Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 06, 2023

Awareness about adverse drug reaction monitoring among final year medical students in tertiary care teaching hospital: a cross sectional study

Dr. Jarinabanu. Tahashildar[1], Dr. Ravi Shekhar Singh[2], Dr. A.G.Dhavalshankh[3], Dr. M. Ahmed[4]

[1]Assistant Professor, Dept. Of Pharmacology, D.Y. Patil Medical College, Kolhapur, [2]Associate Professor, Dept. Of Pharmacology, Dr.P.D.M medical College, Amaravati, [3]Prof & Head, Dept of Pharmacology, D.Y. Patil Medical College, Kolhapur, [4]Professor, Dept Of Pharmacology, GMC, Doda, Jammu & Kashmir

Corresponding author-Dr. M. Ahmed

Article History: **Received:** 12.04.2023 **Revised:**07.05.2023 **Accepted:** 26.05.2023

ABSTRACT

Background: Adverse drug reaction (ADR) is an unwanted, undesirable effect of a drug that occurs during clinical use. ADRs will occur daily in health care institutions and can unfavorably affect a patient's quality of life, frequently causing considerable morbidity and mortality.

Methods: It was a non-interventional study done among three hundred final year medical students atD.Y. Patil Medical College, Kolhapur & Dr. P.D.M medical College, Amaravati.The study instrument was a predesigned questionnaire was structured by following the precedence, which was set by parallel studies. The participants were given forty-five minutes to answer the questionnaire; the questionnaires were then analyzed by grading the respondents into three categories: poor, unsatisfactory and satisfactory.

Results: This study showed satisfactory results about awareness, knowledge and methods of application of pharmacovigilance among final year medical students 55%, 47%, 54% respectively and positive correlation between awareness, knowledge and methods of application of pharmacovigilance among final year medical students significantly (<0.0001) correlated.

Conclusions: The present study revealed that the final year medical students were satisfactory in awareness and knowledge and methods of application of pharmacovigilance. The correlations told that the higher the awareness, the more was the knowledge and better were the methods of application. Likewise, the knowledge and practices were significantly and positively related to a correlation.

Keywords: Adverse drug reaction, Medical students, Pharmacovigilance

INTRODUCTION

Adverse drug reaction (ADR) is an unwanted, undesirable effect of a drug that occurs during clinical use. ADR seen in healthcare facilities will adversely affect the quality of life of patients.[1]They may cause patients to lose confidence or develop negative emotions towards their physicians. Additionally, ADR may promote self-treatment options, which may lead to an increase in further adverse drug reactions. WHO describes pharmacovigilance (PV) as the science and activities related to the identification, assessment, understanding and prevention of any drug-related problem.[2]PV aims to improve patient safety regarding the use of drugs by providing reliable, balanced information for the evaluation of the drug's risk-benefit profile. In India, just 1% of adverse drug reactions are reported. At the same time, in the rest of the world, the reporting rate is 5%.[3]Awareness-raising among health care staff about PV improves the reporting of adverse drug reactions in our country.[4]Therefore, continuous training on ADR reporting regulations for healthcare professionals is necessary. The previously reported study has found that under-reporting of ADR is related to deficits in the knowledge and attitude among healthcare professionals.[5-7] This study was conducted to evaluate the awareness about ADR monitoring, and methods of application of pharmacovigilance in D.Y. Patil Medical College, Kolhapur &Dr.P.D.M medical College, Amaravati.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 06, 2023

METHODS

The study was a non-interventional study done among the final year medical students at D.Y. Patil Medical College, Kolhapur & Dr.P.D.M medical College, Amaravati. Students who were not willing to participate were excluded from the study.

The study instrument was a predesigned questionnaire was structured by following the precedence, which was set by similar studies. It was validated. The study questionnaire was designed to assess the awareness, knowledge and methods of application of pharmacovigilance among the study population- the questionnaire comprised of 27 questions (awareness-6, knowledge-9 and methods of application-12).The questionnaire was administered to 300 final year medical students at D.Y. Patil Medical College, Kolhapur & Dr.P.D.M medical College, Amaravati. The participants were briefed about the questionnaire, and they were requested to return the duly filled in forms. The participants were given 45 minutes to answer the questionnaire, and they were not allowed to consult anyone during that time. They could maintain anonymity with regards to their names, but they had to write their designations. The questionnaire was designed in such a way that each question had only one correct answer. The answers to the questions were not mutually exclusive. Data collection was carried out for three months from March 2023 to May 2023.

The questionnaires were then analyzed by grading the respondents into three categories: poor, unsatisfactory and satisfactory (Table 1). The questionnaires were then analyzed by classifying the respondents into data from the completed questionnaires are charted categorically in MS Excel sheet, analyzed, and the results are expressed using suitable pictorial representations and percentages.

RESULTS

The questionnaire was administered to 300 final year MBBS students. Data from the completed questionnaires are charted categorically in MS excel sheet, analyzed, and the results are expressed using suitable pictorial representations and percentages. The questionnaire was analyzed by giving 1 for the correct response and 0 for the incorrect one. From this study, the following results were obtained.

Table 1: Grading the respondents into three categories: poor, unsatisfactory and satisfactory.

Response	Poor	Unsatisfactory	Satisfactory
Awareness	1 - 2	3 - 4	5 - 6
Knowledge	1 - 3	4 - 6	7 - 9
Methods of Application	1 - 4	5 - 8	9 - 12

Table 2 shows the final year medical students 13 (13%) are poor, 32 (32%) are unsatisfactory, 55 (55%) are Satisfactory in the awareness of pharmacovigilance. This is because they were educated about detection, assessment, understanding, and prevention of ADR to a certain extent in their syllabus.

Grading	Awareness	Knowledge	Application
Poor	113 (13%)	111 (11%)	109 (9%)
Unsatisfactory	82 (32%)	92 (42%)	87 (37%)
Satisfactory	105 (55%)	97 (47%)	104 (54%)

In the knowledge regarding the existence of various programs, regional centre, the yellow card system, schedule Y, when to report the adverse event in a clinical trial, etc., The final year MBBS students 11 (11%) are poor, 42 (42%) are unsatisfactory, 47 (47%) are satisfactory in the knowledge of pharmacovigilance.

The final year medical students 9 (9%) are poor, 37 (37%) are unsatisfactory, 54 (54%) are Satisfactory in the application of methods of Pharmacovigilance. This is because they use their little Pharmacovigilance knowledge into the form by their clinical exposure, handling drugs, and managing ADRs in the hospital.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 06, 2023

Table 3: Mean and standard deviation, score of awareness, knowledge, application of pharmacovigilance among final year MBBS students.

Grading	Awareness	Knowledge	Application
Poor	1.2±0.4	1.8±0.6	2.2±0.9
Unsatisfactory	3.2±0.5	4.9±0.8	6.2±1.0
Satisfactory	5.3±0.4	8.12±0.8	10.6±0.9

Table 3 shows the final year MBBS students 1.2±0.4 are poor, 3.2±0.5 are unsatisfactory, 5.3±0.4are satisfactory in the awareness of pharmacovigilance. 1.8±0.6 are poor, 4.9±0.8 are unsatisfactory, 8.12±0.8 are satisfactory in the knowledge of pharmacovigilance. 2.2±0.9 are poor, 6.2±1.0 are unsatisfactory, 10.6±0.9 are satisfactory in the application of pharmacovigilance.

Table 4: Correlations of awareness, knowledge and methods of application among final year MBBS students.

Variable 1	Variable 2	Correlation (r)	p value
Awareness	Knowledge	0.818	<0.01
Awareness	Application	0.843	<0.01
Knowledge	Application	0.855	<0.01

**<0.0001 is significance.

Table 4 shows correlations of awareness and knowledge- r value is 0.818 positively correlated and p value <0.0001 is significant. Awareness and application- r value is 0.843 positively correlated and p value <0.0001 is significant. Knowledge and application- r value is 0.855 positively correlated and p value <0.0001 is significant.

DISCUSSION

This study showed satisfactory results about awareness, knowledge and methods of application of pharmacovigilance among final year medical students 55%, 47%, 54% respectively and positive correlation between awareness, knowledge and methods of application of pharmacovigilance among final year MBBS students significantly correlated. Rehanet al[8] conducted a study at Lady Harding Medical College. New Delhi, India and found that the knowledge, attitude and practices of both the undergraduates and the prescribers were comparable, but that they needed further improvement. Desai et al[9] have conducted a study at the civil hospital, Ahmedabad, concluded that under-reporting and a lack of knowledge about the reporting system were evident among the prescribers. Gupta et al[10] conducted at two government teaching hospitals, B. J. Medical College, Pune and Seth G.S. Medical College, Mumbai, also revealed that the awareness on the reporting systems was deficient amongst the resident doctors. Vora et al[11] conducted a cross-sectional, questionnaire-based, multi-centric study which was done on six different medical colleges in Gujarat, India, indicated that the overall knowledge of pharmacovigilance was poor in undergraduate medical students.

CONCLUSION

The present study revealed that the final year medical students are satisfactory in awareness and knowledge and methods of application of pharmacovigilance. However, it was found that they were more skilled in the form which they perform using their meagre knowledge. The correlations revealed that the higher the awareness, the more was the knowledge and better were the methods of application. Likewise, the knowledge and practices were significantly and positively related to a correlation. Therefore, it is a necessity of the hour to implement pharmacovigilance as part of the medical curriculum and also chances of application of knowledge into practice.

Funding: No funding sources
Conflict of interest: None

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 06, 2023

REFERENCES

1. Cobert B. The theory and definitions of drug safety (Pharmacovigilance). In: Cobert's Manual of Drug Safety and Pharmacovigilance, 2nd ed. Sudbury, MA: Jones & Bartlett; 2012: 4-5.
2. World Health Organization. Quality Assurance and Safety of Medicines Team. Safety of medicines: a guide to detecting and reporting adverse drug reactions: why health professionals need to take action. World Health Organization. 2002. Available at: https://apps.who.int/iris/handle/10665/67378. Accessed 9 June 2018.
3. Prakash S. Pharmacovigilance in India. Indian J Pharmacol. 2007;39:123.
4. Lokesh K. Pharmacovigilance/reporting adverse drug reactions: An approach to enhance health surveillance and extending market share by minimizing the chances of drug withdrawals. Int J Pharm Sci. 2015;7(9):1-7.
5. Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitude and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. J Nat SciBiol Med. 2013;4:191- 6.
6. Muraraiah S, Rajarathna K, Sreedhar D, Basavalingu D, Jayanthi CR. A questionnaire study to assess the knowledge, attitude and practice of Pharmacovigilance in a paediatric tertiary care centre. J Chem Pharm Res. 2011;3:416-22.
7. Buchineni M. Attitude and awareness of ADR reporting among clinicians in a tertiary care hospital - a cross-sectional study. Inter JInstitutPharma Life Sci. 2015;5(4):127-30.
8. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: the knowledge, attitude and the practices of the medical students and the prescribers. Natl Med J India. 2002;15(1):24-6.
9. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. PerspectClini Res. 2011;2(4):129.
10. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: knowledge, attitudes and perceptions among the resident doctors. J Pharm Sci Res. 2011;3:1064-69.
11. Vora MB, Paliwal NP, Doshi VG, Barvaliya MJ, Tripathi CB. Knowledge of adverse drug reactions and pharmacovigilance activity among the undergraduate medical students of Gujarat. Inter J PharmaceutSci Res. 2012;3(5):1511.