

A Cross Sectional Study of Assessment of Knowledge on Pharmacovigilance among Medical Students

Dr.M.Siva Kumar^{1*}, D.Sathish Kumar²

¹ Assistant Professor, Department of Pharmacology, Kurnool Medical College, Kurnool.

² Pharmacovigilance Associate, Department of Pharmacology, Kurnool Medical College, Kurnool.

Corresponding Author: Dr.M.Siva Kumar

Abstract:

Introduction: Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science and activities relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The dark history in 1961 by use of the drug thalidomide in pregnancy causing the birth of thousands of congenitally deformed babies led to the initiation of first organized international efforts to address drug safety issues.

Materials and Methods: This is a study in which a self developed pre-tested questionnaire was designed to assess the knowledge of pharmacovigilance among medical students. Study population consists of 180 students, which include final year medical students and interns. A brief description on the nature of the study and procedure to complete the questionnaire was explained.

The questionnaire which was designed to assess the basic knowledge on pharmacovigilance was distributed among the medical students. Consent form was obtained before starting the study from students.

Results: In this study a total of 180 students were assessed regarding their knowledge about pharmacovigilance, of which 27.7(n=50) were males and 72.2 (n=130) were females. The mean average age of the respondents was 20-23 years. The demographic details of the healthcare professionals are summarized in Table 1.

In this study, 61.7% medical students gave correct response regarding the definition of pharmacovigilance. 64.2% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. 93.3% agreed that ADR reporting is a professional responsibility for them.

Conclusion: In this study, it was showed that majority of the students had knowledge about pharmacovigilance and understand the need for reporting. In spite of that the reporting rate of ADRs by them is very low. Hence, there was huge gap between the ADR experienced and ADR reported by healthcare professional. Here majority of respondents agreed that reporting of ADR is necessary and it should be made an integral part of the clinical activities in order to improve the patient care.

Key Words: Pharmacovigilance, questionnaire, ADR

Date of Submission: 17-05-2019

Date of acceptance: 02-06-2019

I. Introduction

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science and activities relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.¹ The dark history in 1961 by use of the drug thalidomide in pregnancy causing the birth of thousands of congenitally deformed babies led to the initiation of first organized international efforts to address drug safety issues. Further, this episode introduced the adoption of tougher testing, rigorous drug approval and monitoring systems like United States Food and Drug Administration (FDA).² The expansion of scientific knowledge in drug safety is attributable to greater awareness and academic interest in this field. In many medical institutions, particularly in the developed countries, adverse drug reaction (ADR) monitoring is recognized as an essential quality assurance activity.³ Greater integration of pharmacovigilance into clinical practice is still needed. Drug safety should feature in the medical and pharmacy curriculum.³

The underreporting of ADR may be due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting. 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.⁴ 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 (AMC) in Kurnool Medical College also established in 2014 under PvPI. Therefore on this background,

the present questionnaire based study was conducted to assess the knowledge, attitude and practice of spontaneous ADR reporting among future budding doctors; medical students.

II. Materials And Methods

This is a study in which a self developed pre-tested questionnaire was designed to assess the knowledge of pharmacovigilance among medical students. Study population consists of 180 students, which include final year medical students and interns. A brief description on the nature of the study and procedure to complete the questionnaire was explained.

The questionnaire which was designed to assess the basic knowledge on pharmacovigilance was distributed among the medical students. Consent form was obtained before starting the study from students.

Inclusion criteria

Students who are ready to fill the answer for the given questionnaire are included in the study.

Exclusion criteria

Students who are not interested/willing to answer the questionnaire are excluded from the study. Filled up forms are collected back from the students and are analyzed for the results. The statistics was done by using MS Excel for obtaining the results. Final data was expressed as frequency and percentages.

III. Results

In this study a total of 180 students were assessed regarding their knowledge about pharmacovigilance, of which 27.7(n=50) were males and 72.2 (n=130) were females. The mean average age of the respondents was 20-23 years.

The demographic details of the healthcare professionals are summarized in Table 1. In this study, 61.7% medical students gave correct response regarding the definition of pharmacovigilance. 64.2% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. 93.3% agreed that ADR reporting is a professional responsibility for them.

Only 44.6% of students were aware regarding the existence of a Pharmacovigilance Programme in India. 60.8% were aware that the regulatory body responsible for monitoring ADRs in India is Central Drugs Standard Control Organization (CDSCO). 58.4% were aware that International Center for ADR monitoring is located in Sweden (Table 2).

In this study, 76.7% students said they haven't encountered any ADR. And 56.2% students think the likely cause of the ADRs was drug-drug interactions. 50.5% Students were saying that they will report ADRs to ADR monitoring committee of the hospital. Some other practice related questions and the student's response is given below (Table 3).

Table 1: Demographic details of the healthcare professionals (n=180)

	N=180	Percentage (%)
Gender		
Male	45	27
Female	135	73
Study Population		
Final years	135	75
Interns	45	25
Mean age of students (years)	20-24	

Table 2: Knowledge of pharmacovigilance among medical students

S.No	Questions	Correct response (%)	Incorrect response (%)
1	Define Pharmacovigilance	61	39
2	The most important purpose of pharmacovigilance is	64	36
3	Do you think ADR reporting is professional responsibility?	93	7
4	Which of the healthcare professionals are responsible for reporting ADRs in a hospital	55	45
5	Are you aware of National Pharmacovigilance Programme in India?	46	54
6	In India which regulatory body is responsible for monitoring ADRs?	60	40
7	International center for adverse drug reaction monitoring is located in?	59	42
8	Where is the Regional Pharmacovigilance centre?	77	23

Table 3: Practice related questions and percentage of response

S.No	Questions	Percentage (%)
1	Do you experience adverse drug reactions in your patient during your practice?	Yes (21)
2	Do you ever report any adverse drug reaction (ADR) to the pharmacovigilance center?	Yes (10.3)
3	Have you seen the ADR reporting form?	Yes (13.2)
4	Have you ever been trained on how to report ADR?	Yes (16)

IV. Discussion

Current study was conducted in a medical college which included a total of 180 medical students i.e. 135 (75%) final years, 45 (25%) interns. In many other studies conducted about knowledge and awareness of pharmacovigilance and ADR show lack of knowledge and awareness not only in medical students but also among postgraduates and medical professionals. In study done by Dr. Gupta et al, only 43% are aware of ADR reporting, where as in this study more than 60% of students know regarding pharmacovigilance and ADR reporting.^{5,6}

In recent study done by Zaka Un Nisa⁷, 97% of health professionals can define pharmacovigilance and 34% can define the ADR.¹¹ In another study done by Kutmi M et al⁸, more than 40% MBBS students think ADR reporting is compulsory and when compared to post graduates regarding witnessed ADR, MBBS students witnessed only 20.5%.^{9,10}

According to another study done by S Jeya et al¹¹, second year MBBs students have adequate knowledge and attitude regarding pharmacovigilance compared to residents and even though nurses have good knowledge about pharmacovigilance they do not have adequate knowledge about reporting ADR.⁵

So, compared to other studies in this study most of the students (89.8%) accepted that reporting ADR is necessary and pharmacovigilance should be taught in detail to healthcare professionals.

V. Conclusion

In this study, it was showed that majority of the students had knowledge about pharmacovigilance and understand the need for reporting. In spite of that the reporting rate of ADRs by them is very low. Hence, there was huge gap between the ADR experienced and ADR reported by healthcare professional. Here majority of respondents agreed that reporting of ADR is necessary and it should be made an integral part of the clinical activities in order to improve the patient care.

Our finding strongly suggests that there is a great need to create awareness regarding Pharmacovigilance and to promote the reporting of ADR amongst medical professionals. In conclusion, the results of the present study demonstrate that an educational intervention can increase awareness of pharmacovigilance among the health care professionals and incorporate this gained knowledge of pharmacovigilance into their everyday clinical practice.

References

- [1]. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharm Pract (Granada)* 2011;9:228-35.
- [2]. Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. *Perspect Clin Res.* 2015;6:217-21.
- [3]. Parthiban G, Nileshraj G, Mangaiarkkarasi A, Meher Ali R. A survey on knowledge, attitude and awareness of pharma covigilance among medical students in a teaching hospital, Puducherry. *Indian Journal of Basic and Applied Medical Research.* December 2015;5(1):198-203.
- [4]. Hema NG, Bhuvana KB, Sangeetha. Pharmacovigilance: The extend of awareness among the final year students, interns and postgraduates in a government teaching hospital. *J Clin Diagn Res.* 2012;6(7):1248-53.
- [5]. Datta S, Sengupta S. An evaluation of knowledge, attitude and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. *Perspect Clin Res.* 2015;6(4):200-6.
- [6]. Ganesan S, Vikneswaran G, Reddy KC, Subrahmanyam DK, Adithan C. A Survey on Knowledge, Attitude and Practice of Pharmacovigilance towards Adverse drug reactions reporting among Doctors and Nurses in a Tertiary Care Hospital in South India. *J Young Pharm.* 2016;8(4):471-6.
- [7]. Agarwal R, Daher AM, Ismail MN. Knowledge, practices and attitudes towards adverse drug reaction reporting by private practitioners from Klang valley in Malaysia. *Malays J Med Sci.* 2013;20(2):52-61.
- [8]. Herdeiro MT, Figueiras A, Polónia J, Gestal-Otero J. Physicians' attitudes and adverse drug reaction reporting: a case-control study in Portugal. *Drug Saf.* 2005;28(9):825-33.
- [9]. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, et al. Evaluation of patient reporting of adverse drug reactions to the UK „Yellow Card Scheme“: Literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technol Assess.* 2011;15(20):1-234.
- [10]. Kharkar M, Bowalekar S. Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. *Perspect Clin Res.* 2012 Jul-Sep;3:3:90-4.
- [11]. Nichols V, Thériault-Dubé I, Touzin J, Delisle JF, Lebel D, Bussièrès JF, et al. Risk perception and reasons for noncompliance in pharmacovigilance: a qualitative study conducted in Canada. *Drug Saf.* 2009;32(7):579-90.