Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 04, 2022

ORIGINAL RESEARCH

Knowledge, attitude and practice (KAP)of Pharmacovigilance among MBBS undergraduates

Surbhi Mahajan[1], Aman Sharma[2], Sanjeev Gupta[3], Humera Kouser Qazi[4]

Demonstrator[1], Assistant Professor[2,3], Junior Resident[4]
Department of Pharmacology, GMC Rajouri, Jammu and Kashmir, India

Corresponding author: Dr. Sanjeev Gupta

ABSTRACT:

Aim: To evaluate the Knowledge, attitude and practice (KAP) of Pharmacovigilance among MBBS undergraduates.

Methods: A cross-sectional questionnaire survey was performed at the Department of Pharmacology, GMC Rajouri. This survey involved a total of 100 2nd year MBBS students. The MBBS students were given a total of 20 questions and one day to complete the questionnaire. Ten of the twenty questions were based on knowledge, five on attitude, and five on practice.

Results: 93 percent of students correctly defined pharmacovigilance. 46 percent of students were aware that the most essential function of pharmacovigilance is to determine medication safety. 94 percent of students were aware of India's current national pharmacovigilance programme. Only 23% were aware of the regulatory authority in India responsible for monitoring ADRs, i.e. the central drugs standard control organization. 95 percent know that ADR monitoring centre is present in Institute. Reporting ADR is a professional duty for 47 percent of students. ADR reporting is required according to 97 percent of respondents. Pharmacovigilance should be taught in depth to healthcare workers, according to 94% of respondents. Only 38% of students agreed that every hospital should have a Pharmacovigilance unit. 43 percent of students had read an article about ADR prevention. During their clinical placement, 26% of patients reported ADR. ADR was reported to a pharmacovigilance centre by 23% of people. ADR has formed in 97 percent of cases. 94 percent of employees have received training on how to report ADR.

Conclusion: This study will improve awareness regarding pharmacovigilance among the aspiring doctors so that they can pay more attention towards ADR rebating.

Keywords: KAP, MBBS Undergraduates

Introduction

Pharmacovigilance is the science of collecting, detecting, assessing, monitoring, and preventing adverse effects or any other drug-related problems. The National Pharmacovigilance Program was established in India in 2004 to detect and spontaneously report ADR and to ensure drug safety.[1] It is currently known as the Pharmacovigilance Program of India, and it has been in operation since July 2010 under the auspices of the Central Drug Standard Control Organization. [2]

The All India Institute of Medical Sciences (AIIMS) was created as the National Coordinating Centre (NCC), under which 22 ADR monitoring centres (AMCs) were constructed throughout India to monitor Adverse Drug Reactions (ADR).[3] The National Coordinating Centre was shifted from the All India Institute of Medical Sciences to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.) in order to strengthen the

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 04, 2022

programme and improve execution.[4] The National Coordinating Centre's (NCC-PvPI) committees include the Steering Committee, working group, Quality review panel, Signal review panel, and Core training panel. The occurrence of ADRs imposes a major burden on the country's economy as well as a loss of quality of life. The primary role of health care workers is to immediately and efficiently report adverse drug reactions (ADRs). In terms of genetic and cultural traditions, there is a tremendous disparity in our country's population. As a result, these in formations shape the future of government policies to protect people's well-being. [5-9]

The international database of ADR reports received from various nations is maintained by the Uppsala Monitoring Centre (UMC) in Sweden. India is an active participant in this initiative, with its contribution to the UMC database increased over the period of time, making it the seventh-largest contributor to the UMC drug safety database. [10] Although there has been some progress, much more needs to be done to increase spontaneous reporting. Although spontaneous reporting of ADR by health care providers is the backbone of pharmacovigilance programmes, under reporting of ADR is still frequent and causes worry. According to one study, just 6-10% of all ADR incidents are recorded. A substantial role in the pharmacovigilance programme is played by health care professionals.[11] ADR reporting does not appear to be regarded regular professional practice by health care providers at this time. This is mostly due to the lack of an active and robust ADR monitoring system, as well as a lack of a reporting culture among health care personnel.[12-14] Medical students could play a significant role and bring a paradigm shift in the successful implementation of pharmacovigilance programmes if adequate knowledge and skills are imparted to them during their undergraduate training career, but they currently do not have any significant role due to insufficient training in ADR reporting. [15-16]

Materials and methods

A cross-sectional questionnaire survey was performed at the Department of Pharmacology, GMC Rajouri. This survey involved a total of 100 2nd year MBBS students. The MBBS students were given a total of 20 questions and one day to complete the questionnaire. Ten of the twenty questions were based on knowledge, fiveon attitude, and five on practice. These questions were developed based on previous research for analysing the KAP of ADR reporting. [17,18]

Results

Knowledge

93 percent of students correctly defined pharmacovigilance. 46 percent of students were aware that the most essential function of pharmacovigilance is to determine medication safety. 94 percent of students were aware of India's current national pharmacovigilance programme. Only 23% were aware of the regulatory authority in India responsible for monitoring ADRs, i.e. the central drugs standard control organization. 95 percent know that ADR monitoring centre is present in Institute. (See Table 1).

Table 1: Knowledge based questions.

Questions	Correct (%)	Incorrect (%)
Define Pharmacovigilance.	93	7
The primary goal of Pharmacovigilance is.	46	54
The health care providers responsible for reporting ADR in hospitals are.	50	50
Do you know about India's Pharmacovigilance	94	6

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 04, 2022

programme?		
In India, which regulatory organisation is in charge of overseeing ADRs?	23	77
Where is the International Center of Pharmacovigilance located?	93	7
Which phase of a clinical trial can identify rare adverse events?	28	72
In India, where is the National Pharmacovigilance Center?	87	13
Where to report ADRs?	97	3
Is there any ADR monitoring centre located in your Institute.?	95	5

Attitude

Reporting ADR is a professional duty for 47 percent of students. ADR reporting is required according to 97 percent of respondents. Pharmacovigilance should be taught in depth to healthcare workers, according to 94% of respondents. Only 38% of students agreed that every hospital should have a Pharmacovigilance unit (Table 2).

Practice

43 percent of students had read an article about ADR prevention. During their clinical placement, 26% of patients reported ADR. ADR was reported to a pharmacovigilance centre by 23% of people. ADR has formed in 97 percent of cases. 94 percent of employees have received training on how to report ADR (Table 3).

Table 2: Attitude based questions.

Questions	Correct (%)	Incorrect (%)
Do you believe ADR reporting is a professional need for you?	47	53
Do you believe ADR reporting is required?	97	3
Do you believe that healthcare workers should be trained in depth about pharmacovigilance?	94	6
What are your thoughts on establishing an ADR monitoring centre in every hospital?	38	62
ADR form is complex to fill?	40	60

Table 3: Practice based questions.

Questions	Yes (%)	No (%)
Have you read the article on ADR prevention?	43	57
Have you ever witnessed ADR in patients during your clinical placement?	26	74
Have you ever reported an adverse event to a pharmacovigilance centre?	23	77
Have you seen an ADR form?	97	3
Have you ever received training on how to properly report ADR?	94	6

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 04, 2022

Discussion

Pharmacovigilance is an essential component of comprehensive health care. It aids in the identification and prevention of adverse drug reactions (ADRs) in pharmaceutical goods. The effectiveness of the pharmacovigialnce programme is dependent on the spontaneous reporting of ADR. There have been several research to assess health care practitioners' understanding of pharmacovigilance programmes, but relatively few studies have been conducted among aspiring doctors to assess their knowledge of the same. [13,14]

Table 4 compares knowledge and attitude-based questions from several research. In our survey, 93 percent of students correctly defined pharmacovigilance. This figure was 62.5 percent in a research done by Gupta et al. [20]In our survey, 97 percent of students agreed that reporting ADR is essential. This was comparable to the study done by Gupta et al, where the correct response rate was 96%. Pharmacovigilance should be taught in depth to healthcare workers, according to 94 percent of students in our research. A similar answer was achieved in the study done by Gupta et al, with 92.1 percent. In our survey, 87 percent of participants correctly identified the location of a pharmacovigilance facility in India. In a research done by Meher et al, only 34% of participants correctly identified the location of a pharmacovigilance centre. Table 5 compares practice-based questions with other research. [21,22]

Table 4: Comparison with results of other studies: knowledge and attitude-based questions.[20-22]

Questions	Our study (%)	Gupta et al[20](%)	Meher et al[22] (%)	Pimpalkhute et al[21] (%)
Define pharmacovigilance	93	62.4	41	67.85
In India, where is the National Pharmacovigilance Center?	87	-	34	-
Where is the International Center of Pharmacovigilance located?	93	75.2	-	38.4
The health care providers responsible for reporting ADR in hospitals are.	50	-	40	-
Do you believe ADR reporting is a professional need for you?	47	69.3	23	35.2
Do you believe ADR reporting is required?	97	97	59	-
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	96	92.1	-	-

Table 5: Comparison with results of other studies: practice-based questions.[20,23,24]

Questions	Our study (%)	Gupta et al[20] (%)	Muraraiah et al[23] (%)	Desai et al[24] (%)
Which phase of a clinical trial can identify rare adverse events?	28	64.4	85	60
Have you ever reported an adverse event to a pharmacovigilance centre?	23	22.8	15	12.4
Have you ever received training on how to properly report ADR?	94	53.5	-	-

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 04, 2022

Conclusion

This study will improve awareness regarding pharmacovigilance among the aspiring doctors so that they can pay more attention towards ADR rebating.

References

1. Adithan C. National pharmacovigilance programme. Indian J Pharmacol 2005;37:34.
2. Pharmacovigilance programme of India 2010. CDSCO, Ministry of Health and Family Welfare, Government of India; 2010, Nov. Available from: http://www.cdsco.nic.in/pharmacovigilance. [Last accessed on 2013 Dec 20].
3. World Health Organization. The Importance of Pharmacovigilance–Safety Monitoring of Medicinal Products. Geneva: World Health Organization; 2002.
4. Pharmacovigilance Program of India (PvPI) [homepage on the internet] .The start of the programme. Updated on Jan 30, 2017. Available from: http://www.ipc.gov.in/PvPI/ pv_home. html.
5. Pharmacovigilance Program of India Annual Performance Report 2015-2016.Available from: http://www.ipc.gov.in/PvPI/pub.html.
6. Jayanthi CR, Renuka M, Panchaksharimath P. An observational Study to analyze the Adverse drug Reactions among the Elderly at A Tertiary Care Hospital. Biomedical and Pharmacology Journal.2017;10(1):345-52.
7. Lazarou J, Pomeranz B, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA.1998; 279: 1200–1205.
8. Hazell L, Shakir SA. Under-reporting of adverse drug reactions. Drug Safety.2006; 29(5):385-96
9. 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.
10. Smith CC, Bennett PM, Pearce HM, Harrison PI, Reynolds DJ, Aronson JK, *et al.* Adverse drug reactions in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. Br J Clin Pharmacol 1996;42:423-9.
11. Shirodkar SN. India become seventh largest contributor to WHO-UMC's drug safety data base. Available from: http://www. pharmabiz.com. [Last accessed on 2014 Apr 13].
12. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: A systematic review. Drug Saf 2009;32:19-31.
13. Gupta P, Udupa A. Adverse drug reporting and pharmacovigilance: Knowledge, attitude and perception among resident doctors. J Pharm Sci Res 2011;3:1064-6.
14. 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. Perspect Clin Res 2011;2:129-36.
15. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Natl Med J India 2002;15:24-6.
16. Vora MB, Paliwal NP, Doshi VG, Barvaliya MJ, Tripathi CB. Knowledge of adverse drug reactions and pharmacovigilance activity among the undergraduate students of Gujarat. Int J Pharm Sci Res 2012;3:1511-5
17. Upadhyaya P, Seth V, Moghe VV, Sharma M, Ahmed M. Knowledge of adverse drug reaction reporting in first year postgraduate doctors in a medical college. Ther Clin Risk Manage. 2012;8:307-12.

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 04, 2022

18. Remesh A. Identifying the reasons for under reporting of ADR: A cross sectional survey. Res J Pharm Biol Chem Sci. 2012;3:1379–86.
19. 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 Sci Biol Med. 2013;4:191– 6.
20. Gupta SK, Nayak SP. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India:An observational study.J Per Cli Research 2015;6(1):45– 52.
21. Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. Indian J Med Sci. 2012;66:55–61
22. Meher BR, 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. K Per Cli Res. 2015;6(4):217-21.
23. 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.
24. 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. Perspect Clin Res. 2011;2:12