e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(4); 436-441

Original Research Article

To Evaluate the Attitude, Knowledge and Practice Regarding Pharmacovigilance in Undergraduate Students & Postgraduate Residents at a Tertiary Healthcare Centre – A Questionnaire Based Study

Kumar Sneha[1], Amruta Pingale[2], Dikkar Vaishnavi[3]

[1]Junior Resident 2, Department of Pharmacology and Therapeutics, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik-422003, India

[2]Assistant Professor, Department of Anaesthesia, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik-422003, India

[3]Final Year MBBS, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik-422003, India

Received: 03-02-2022 / Revised: 25-02-2022 / Accepted: 28-03-2022
Corresponding author: Amruta Pingale
Conflict of interest: Nil

Abstract

Introduction: Spontaneous reporting of Adverse Drug Reaction is a method of monitoring the safety of drugs and is the basic strategy for the post marketing surveillance of the drugs . Despite its importance there is a very little reporting of ADRs by the healthcare professionals[1] The present study evaluates the knowledge, attitude, practice about ADR reporting in undergraduate & postgraduate students at a tertiary care centre.

Materials and methods: A questionnaire based cross sectional study containing 20 questions to assess knowledge, attitude and practice regarding Pharmacovigilance and ADR reporting was circulated to Undergraduates and Postgraduates in a tertiary care hospital . Students who were willing to participate and gave their consent were included in the study.

Result: A total of 141 students participated in the study. Of which 78% of students gave correct response regarding the definition of Pharmacovigilance . 80.9% were aware of National Pharmacovigilance program of India (PvPI) . 98.6% agreed that both doctors and patients are benefitted by ADR reporting . 63.8% have seen an Adverse drug reaction before but, only 28.4% had played the role of reporting an Adverse drug reaction because of under sensitisation about Pharmacovigilance and ADR reporting among undergraduates . 63.1% could recall when asked about the training in Adverse drug reaction reporting . 98.6% agreed that workspace environment should encourage ADR reporting .

Conclusion: This study demonstrated that knowledge and attitude towards Pharmacovigilance and ADR reporting is increasing among Undergraduate Medical students and Postgraduate Residents but practice towards the same is still deficient.

Keywords: Pharmacovigilance, ADR reporting, Undergraduate, Postgraduate

Introduction

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as, "a response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. [1]

Adverse drug reactions have been reported as a significant cause of morbidity and mortality across all age groups, with appreciable number of hospital admissions, as well as substantial financial burden on the society and the healthcare systems . Spontaneous ADR reporting system is a global phenomenon, and the cornerstone of pharmacovigilance activities . Healthcare professionals in any capacity therefore play a crucial role in pharmacovigilance system, and as such they require considerable knowledge and expertise in the field of medication safety, especially for early recognition, detection, management and reporting of ADRs . However, studies have indicated that a large proportion of ADRs are not reported by healthcare professionals, especially in developing countries due to a number of factors including lack of awareness and knowledge of pharmacovigilance and ADR reporting . It is estimated that only 6–10% of all ADRs are reported. Thus, underreporting has been a major obstacle to spontaneous reporting of ADRs, and this poses a great challenge to pharmacovigilance activities as well as negatively impact public health. Healthcare professionals are therefore expected to consider ADR reporting as their professional obligation, since an effective system of ADR reporting is important to improve patient care and safety and in turn improving overall health. Similarly, patients play a vital role in spontaneous reporting system, as only the patient really feels the adverse effect of the drug . The success or failure of any spontaneous reporting system depends on the active involvement of reporters. Thus, direct patient participation in ADR reporting will increase efficiency of the pharmacovigilance system, as well as bridge the gap of underreporting on the part of healthcare professionals. [2]

In order to improve the reporting rate, it is important to improve the Knowledge, Attitude and the Practices (KAP) of the healthcare professionals with regards to the ADR reporting and the pharmacovigilance. [3] Our study was a step which was taken in that direction and it endeavoured at evaluating the baseline KAP of the Undergraduate students and Postgraduate Residents at a teaching hospital, regarding the ADR monitoring and pharmacovigilance.

Materials and methods

1) Study design: Questionnaire based cross sectional study

2) Site of study: Department of Pharmacology of a tertiary care hospital

3) Study participants: Undergraduates Medical students and Postgraduate Residents of all years.

Exclusion criteria:

- First year Undergraduate medical students
- Students who are not willing to participate

4) Data collection instruments: Questionnaire containing 20 questions about Pharmacovigilance and ADR monitoring were circulated on a Google form to students after they give their consent and Institutional Ethics Approval.

- Only students willing to participate in study was asked to fill the online form.
- The data collected was assessed by percentage frequency-based calculation

Result:

Knowledge:

89.4% Medical students gave correct response regarding definition of ADR.93.6% were aware about who all can

report ADR. 75.2% were aware that CDSCO [Central Drugs Standard Control Organization] is the regulatory body responsible for ADR reporting. 78% were aware about the definition of Pharmacovigilance.80.9% were aware about Pharmacovigilance Programme of India.51.1% could recall about National Pharmacovigilance centre for ADR which is in Ghaziabad.46.1% could recall about the scale for causality assessment.73% were aware about international ADR reporting centre that is in Sweden [Table 1]

Table 1: Knowledge related question and percentage of correct and incorrect response

Knowledge related questions	Correct	Incorrect
Define Adverse Drug Reaction	89.4%	13.6%
Who can report Adverse Drug Reaction?	93.6%	6.4%
In India which regulatory body is responsible for monitoring Adverse Drug Reactions?	75.2%	24.8%
What is Pharmacovigilance?	78%	22%
What does PvPI stand for?	80.9%	19.1%
Where is National Pharmacovigilance centre in India located?	51.1%	48.9%
What is the common scale used for causality assessment?	46.1%	53.9%
Where is the international centre for Adverse Drug Reaction is located?	73%	27%
Is it necessary to report only serious Adverse Drug Reaction ?	70.9%	29.1%
Are you aware of VIGIBASE online database for reporting Adverse Drug Reaction?	76.6%	23.4%

Attitude:

All undergraduate and postgraduate students agreed that ADR reporting is necessary. 98.6% agreed that both patients and Doctors are benefitted from reporting ADR. 82.3% feel that reporting of ADR is a medical obligation. 95.7% believes that ADR can be prevented with proper knowledge of drug interaction. 98.6% were of the view that workspace environment should encourage ADR reporting. 87.2% answered rightly for the case scenario in table 2 that even a mild ADR should also be reported.[Table 2].

Table 2: Attitude related questions and percentage of correct and incorrect response

Attitude related questions	Correct	Incorrect
Adverse Drug Reaction reporting is an important activity to improve safety of medicines?	100%	-
Are the Doctors and Patients benefitted from reporting Adverse Drug Reaction ?	98.6%	1.4%
According to you is the reporting of Adverse Drug Reaction, a Medical obligation?	82.3%	17.7%
Adverse Drug Reactions can be prevented by proper knowledge about the drug interactions?	95.7%	4.3%
Are you of the opinion that workspace environment should encourage reporting an Adverse Drug Reaction?	98.6%	1.4%

Case scenario : A 57 year/M patient who is a known case of chronic renal disease was admitted to your hospital with severe anaemia . Blood transfusion was advised. During the transfusion, patient developed chills, rigor and fever. Transfusion was stopped at once and the patient was managed with antipyretics, antihistamines, and steroid . What will you do in this case?	87.2%	12.8%

Practice:

Among the participants, 63.8% have seen ADRs in patients before and 63.1% could recall their training in ADR reporting. 31.9% have done causality assessment of ADR . only 28.4% have reported ADR before because of under sensitisation about Pharmacovigilance and ADR reporting among undergraduates. [Table 3].

Table 3: Practice-related questions and percentage of response

Practice-related questions and percentage of response			
Have you seen an Adverse Drug Reaction form before?	Have you been trained in Adverse Drug Reaction reporting ?	Have you done causality assessment of Adverse Drug Reaction ?	Have you ever played any role in reporting Adverse Drug Reaction from your institution?
63.8% (yes)	63.1% (yes)	31.9% (yes)	28.4% (yes)

Discussion:

The major finding in our study is that both Undergraduates and Postgraduates feel that ADR reporting is necessary and Pharmacovigilance should be taught in detail. There is a major underreporting of ADR and there is a huge gap between whether they have seen or experienced ADR [63.8%] and reporting of the same[28.4%] by the students and the reason for the same could be because of under sensitisation about Pharmacovigilance and ADR reporting among undergraduates and confusion in determining that whether ADR has occurred or not. To encourage and promote ADR reporting from undergraduates, ADR ambassadors have been appointed during their second year MBBS course and they will further encourage their fellow undergraduate students and even patients and their relatives during their regular postings in various departments.

After comparing the result with other similar studies in India, it is observed that knowledge and attitude towards Pharmacovigilance is slowly increasing as many health professionals believe that it is necessary to report ADR and they all are of the view that there should be more sensitization regarding Pharmacovigilance and ADR reporting in their workspace but the actual practice of ADR reporting is still deficient among health professionals.

The adverse effect reporting rate in our study [28.4%] is similar to the study by Gupta SK et al [4] - 23.8%, Khan SA et al [5] – 19.1% and Pimpalkhute SA et al [6] - 25%.

Our study state that adverse event monitoring and reporting can be significantly increased through academic interference and factors like unawareness regarding the method to determine causal relationship between ADR can be only removed by regular training for the same.

Regular training on ADR reporting for Postgraduates and especially Undergraduates to increase sensitisation on ADR reporting. Easy accessibility of ADR form are the measures taken by our institute to encouraged and promote ADR reporting.

Table 4: Comparison with results of the published studies from India

Comparison with results of the published studies from India (knowledge-related questions)				
Definition of Pharmacovigilance	**Our result – 78%**	**Gupta SK et al [4] -62.4%**	**Pimpalkhute SA[6] - 64.2&**	**Bajaj JK et al [7] - 77%**
PvPI program	**80.9%**	**75.2%**	**52.3%**	**59%**

Table 5: Comparison with results of the published studies from India

Comparison with results of the published studies from India (attitude-related questions)				
ADR reporting obligation	**Our result-83.2%**	**Gupta SK et al [5] -69.3%**	**Rajesh R et al [8] -89.4%**	**Remesh A [9-11] – 80%**
ADR Reporting necessary	**100%**	**97%**	**91.8%**	**89%**
Teaching and encouragement of ADR reporting	**98.6%**	**92.1%**	**94.1%**	**76%**

Table 6: Comparison with results of the published studies from India

Comparison with results of the published studies from India (practice-related questions)				
Seen ADR	**Our result-63.8%**	**Gupta SK et al [4] -64.4%**	**Khan SA et al [5] – NA**	**Pimpalkhute SA [6] - 67.8%**
Reported ADR	**28.4%**	**23.8%**	**19.1%**	**25%**
Trained on how to report ADR	**63.1%**	**53.5%**	**25%**	**NA**

Limitations of the study:

The major limitation of this study was small study population and some other factors such as accuracy to recall and personal bias could also have affected the results in some ways.

Conclusion:

In conclusion , our study showed that majority of students [undergraduates and postgraduates] had good knowledge and attitude regarding pharmacovigilance and ADR Reporting but reporting rate of the ADR by them is low. There was also a gap between ADR experienced and ADR reported by the students.

Our study also showed that undergraduate and postgraduate students have started to understand the importance of pharmacovigilance and ADR reporting because majority of the participants agreed that ADR and pharmacovigilance should be taught in their workspace environment and both patients and doctors are benefitted from ADR reporting.

For all medicines, there is a trade-off between its benefit and its potential for harm. By ensuring that medicines of good quality, safety and efficacy are used rationally, the harm can be minimized. Such practices regarding sensitization of ADR reporting can be of potential benefit for safer use of drugs in the long term.

References:

1. Hussain R, Hassali MA, Hashmi F, Akram T. Exploring healthcare professionals' knowledge, attitude, and practices towards pharmacovigilance: a cross-sectional survey. Journal of pharmaceutical policy and practice. 2021 Dec;14(1):1-3.
2. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. BMC health services research. 2019 Dec;19(1):1-4.
3. Hardeep 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. Journal of clinical and diagnostic research: JCDR. 2013 Jan;7(1):97.
4. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. Perspectives in clinical research. 2015 Jan;6(1):45.
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 Sci Biol Med 2013;4:191-6
6. 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
7. Hardeep, Bajaj JK, Kumar R. 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;7:97-9
8. Rajesh R, Vidyasagar S, Varma DM. An educational intervention to assess knowledge attitude practice of pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital. Int J Pharm Tech Res 2011;3:678-92
9. Remesh A. Identifying the reasons for under reporting of ADR: A cross sectional survey. Res J Pharm Biol Chem Sci 2012;3:1379-86
10. Augustine A, Rajesh M, Parimala K. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among medical interns in a tertiary care hospital, Kanchipuram. Drug Invention Today. 2019 Jan 15;12(1).
11. Hays, P. . (2022). Evidence Basis for Pharmacogenetic Testing in Psychiatry. Journal of Medical Research and Health Sciences, 5(3), 1838–1859.