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Pharmacology Section

Pharmacovigilance: The Extent of Awareness Among the Final Year Students, Interns and Postgraduates in a Government Teaching Hospital

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ABSTRACT

Introduction: Adverse Drug Reactions (ADRs) are encountered commonly in the daily practice. In addition to the obvious morbidity and the mortality which are caused by them, they also cause an economic burden on the health care system. Adverse drug reactions are preventable if the healthcare professional pays close attention to the details of the adverse effects, following a drug administration. An awareness about ADRs can decrease the irrational use of an inappropriate pharmacy. Hence, there is an urgent need to create an awareness among the prescribers (especially junior doctors) about the ADR monitoring.

Objective: The present study was undertaken to assess the awareness, knowledge and the methods of application of pharmacovigilance among the final year MBBS students, interns and post graduates (preclinical, paraclinical and clinical subjects) in a government teaching hospital.

Materials and Methods: A questionnaire which was designed, based on the precedence which was set by previous studies, was standardized and administered to 300 final year students, interns and postgraduates of MMCRI, Mysore. The questionnaire comprised of 25 questions (awareness-5, knowledge-8 and methods of application-12) and each question had only one correct answer. The respondents were graded into 3 categories- poor, unsatisfactory and satisfactory, based on their individual scores. The data was then analyzed by using the contingency coefficient analysis, descriptive statistics and one way ANOVA and the product moment correlation technique was applied for the data analysis by using SPSS for Windows (version 16).

Results: A total of 210 questionnaires were statistically analyzed. It was found that the awareness, knowledge and the methods of application of pharmacovigilance was lesser in the students, as compared to the interns and the postgraduates. The methods of application in the PGs and the interns were considerably higher, probably due to their clinical exposure. It was also observed that higher was the awareness, more was the knowledge and better were the methods of application. They are positively related with a significant correlation coefficient.

Conclusion: The study suggested that it was imperative to include pharmacovigilance in the under graduate training programme, and that the interns and the post graduates should be sensitized to the ADR reporting during their training period. Importance also had to be given to translational pharmacovigilance, to encourage the dissemination of the information which was required, to improve the prescription of the drugs.

Key Words: Pharmacovigilance, Adverse drug reactions, Awareness, Knowledge, Methods of application

INTRODUCTION

Since time immemorial, the use of medicines has been associated with adverse effects. “There are 3 actions of a drug: The one you want, the one you don’t want, and the one you don’t know about”(DJP Barker) [1]. So, it is crucial to monitor both the known and the unknown adverse effects of medicines. This is because the recent epidemiological studies have estimated that adverse drug reactions are the fourth to sixth leading causes of death and that they represent 5% to 10% of the hospital costs [2]. Therefore, in addition to the obvious morbidity and the mortality which are caused by them, ADRs are also an economic burden on our health care system as they prolong the hospital stay and increase the cost of the treatment.

In a country like India, with a large population and vast diversity, it is absolutely necessary to introduce a standard pharmacovigilance programme. Pharmacovigilance is by definition “The science and activities which are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems [3]”. India ranks below 1% in terms of ADR reporting against the world rate of 5% [4].To overcome this problem, the Ministry of Health and Family Welfare, Govt. of India, has initiated the National Pharmacovigilance Programme. The purpose of this programme is to collate the data, analyze it and to use the inferences to recommend informed regulatory interventions, besides communicating the risks to the health care professionals and the public. This programme is coordinated by the National Pharmacovigilance Centre at the Central Drugs Standard Control Organization (CDSCO) in New Delhi. The National Centre is operating under the supervision of the National Pharmacovigilance Advisory Committee, to recommend procedures and guidelines for regulatory interventions. This committee oversees the performance of two zonal, five regional and twenty six peripheral pharmacovigilance centres. The entire network works in coordination to improve the ADR reporting in our country [5].

A majority of India’s population prefers government hospitals when they are in need of health care facilities. So, these hospitals can be a good source for generating an ADR database. However, the Herculean task is to foster a culture of reporting among the

clinicians, especially among the junior doctors, as they are more closely associated with the patient care. The present low level of ADR reporting is mostly due to a lack of awareness and training and time constraints [6].

The manner in which a doctor takes the clinical history of a patient can be improved, if he has a sound knowledge of the drug safety issues, with an emphasis on the patient's medication history. It also helps him in understanding the action of the drug better. It thus decreases the irrational use of medicines, adverse drug-drug interactions and inappropriate polypharmacy [7].

Few studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the medical students and practitioners. In the U.K., 57% of the medical schools assessed the students' knowledge on the yellow card scheme [8]. In France, a survey which was conducted among medical residents, showed that a majority lacked knowledge on pharmacovigilance [9]. A study which was conducted in Nigeria revealed an inadequate knowledge on pharmacovigilance among resident doctors [10]. A study which was designed to investigate the awareness of pharmacovigilance among the health care professionals in Jiangsu, China, showed that significant differences existed in the awareness of pharmacovigilance across regions, hospital classes and professions [11]. A study which was conducted at a Nepalese hospital also showed low KAP scores and it suggested the need for educational and managerial interventions [12].

In India, few studies were carried out, which mainly emphasized on the actual process of the ADR reporting. A study which was conducted at 3 different private hospitals in Mysore recommended that several studies of a similar kind, especially in the community setup, needed to be conducted, to know the attitudes of other health care professionals towards the ADR reporting [13]. Hence, the present study was designed with the following objectives:

TO ASSESS

1. a. The awareness on pharmacovigilance .
   b. The knowledge on pharmacovigilance.
   c. The methods of application of pharmacovigilance among the final year students, interns and postgraduates.
2. To compare the results among the three groups.

MATERIALS AND METHODS

Study Design

This was a cross sectional, questionnaire based study.

The Study Setting

This study was conducted at the Mysore Medical College and Research Institute, Mysore (MMCRI). This is one of the oldest government medical colleges in Karnataka which was started in 1924. Today, it is a 1050 bedded tertiary care hospital with an outpatient turnover of about three lakhs, annually.

The Study Population

This was a non-interventional study which was done among the final year MBBS students, interns and the postgraduates who were studying medical, surgical, paraclinical and clinical subjects at MMCRI, Mysore. Those who were not willing to participate and those who did not return the questionnaires in the stipulated time were excluded from the study. However, a prior approval for conducting this study was obtained from the institutional ethics committee of this college.

The Study Instrument

The study instrument was a predesigned questionnaire which 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 the methods of application of pharmacovigilance among the study population.

- The term 'awareness' meant the perception of a situation or a fact.
- 'Knowledge' meant the theoretical or practical understanding of a subject.
- 'Method of application' was the practical application of pharmacovigilance.

  The questionnaire comprised of 25 questions (awareness – 5, knowledge-8 and methods of application-12).

The Study Conduct

The questionnaire was administered to 300 final year MBBS students, interns and postgraduates (from all specialities) who were working at MMCRI, Mysore. The participants were personally briefed about the questionnaire and they were requested to return the duly filled in forms. The participants were given 30 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.

The questionnaires were then evaluated. One point was given to each answered question (max total – 25 points). The awareness level was evaluated, based on the questions, 1 to 5, the knowledge of the respondents was evaluated as per their responses to the questions, 6 to 13 and the methods of application were evaluated, based on the answers to the questions, 14 to 25.

The questionnaires were then analyzed by grading the respondents into 3 categories: poor, unsatisfactory and satisfactory, based on the table which has been given below.

	Score range			
Awareness level	Poor	Unsat	Sat	Max possible score
Awareness	1-2	3	4-5	5.0
Knowledge	1-3	4-6	7-8	8.0
Method of application	1-4	5-8	9-12	12.0

The compiled data was then analyzed by using the following statistical methods – contingency coefficient analysis, descriptive statistics, Chi square test and One way ANOVA and the product moment correlation technique was applied for the data analysis by using SPSS for Windows (version 16).

RESULTS

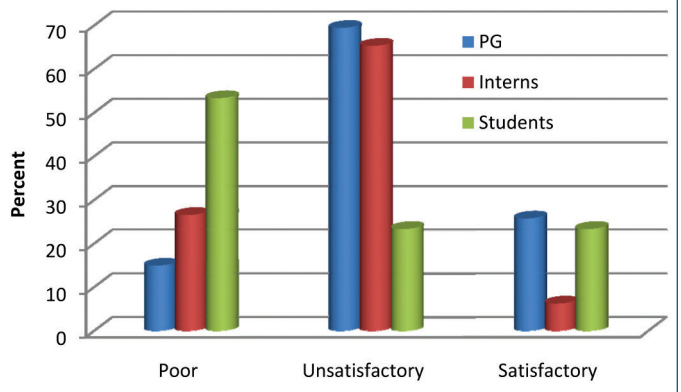
The questionnaire was administered to 300 participants, of whom 132 were post graduates from various departments, 88 were interns and 80 were final year MBBS students. A total of 210 questionnaires were returned, thus giving a response rate of 70% (post graduates -76%, interns -56% and final year students -75%).

Components	Groups	N	Mean	SD	Median	F	P value
Awareness	PGs	101	3.35	1.004	3.0	12.739	.000
	Interns	49	3.06	1.069	3.0		
	Students	60	2.45	1.241	2.0		
	Total	210	3.02	1.151	3.0		
Knowledge	PGs	101	3.46	1.453	3.0	12.340	.000
	Interns	49	3.20	1.620	3.0		
	Students	60	2.30	1.266	2.0		
	Total	210	3.07	1.520	3.00		
Method of application	PGs	101	6.94	2.266	7.0	53.249	.000
	Interns	49	5.65	2.223	6.0		
	Students	60	3.18	2.190	3.0		
	Total	210	5.57	2.737	6.00		

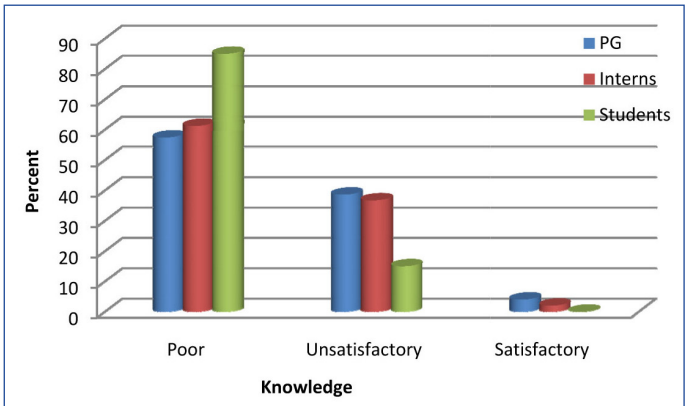
[Table/Fig-1]: Descriptive statistics of Awareness, Knowledge, Methods of application among students, interns and post graduates of MMCRI, Mysore

Variable 1	Variable 2	Correlation coefficient	df	P value
Awareness	Knowledge	.346	208	.000
Awareness	Method	.444	208	.000
Knowledge	Method	.485	208	.000

[Table/Fig-2]: Correlations of awareness, knowledge and methods of application among students, interns and postgraduates



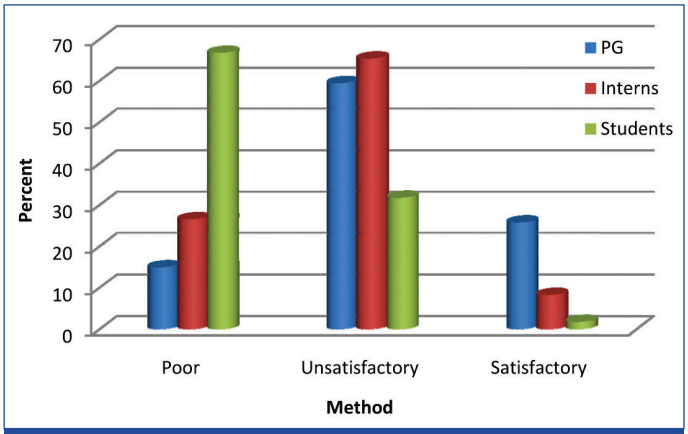
[Table/Fig-3]: Awareness scores of students, interns and postgraduates



[Table/Fig-4]: Knowledge scores of students, interns and post graduates

The descriptive statistics indicated that the mean awareness and the knowledge scores of the students were lower than those of the interns and the post graduates. The mean scores of the methods of application were considerably higher among the post graduates and the interns as compared to those among the students.

The correlations revealed that the level of awareness among the respondents was significantly related to the knowledge and the



[Table/Fig-5]: Methods of application scores of students, interns and postgraduates

methods of application of pharmacovigilance, linearly and positively with correlation coefficients of 0.346 and 0.444, with significance levels of 0.001 and 0.001 respectively. In other words, the higher the awareness, more was the knowledge and better were the methods of application. Likewise, the knowledge and the methods were significantly and positively related to a correlation coefficient of 0.485 and a significance level of 0.001.

DISCUSSION

The innumerable social and economic consequences of adverse drug reactions cultivate a need to actively involve health care professionals in the pharmacovigilance programme.

The main aims of pharmacovigilance are the early detection of the adverse reactions and interactions, monitoring the frequency of the adverse reactions, identification of the risk factors for the adverse reactions and dissemmation of the information which is required to improve the prescription of drugs. So, the main prerequisite of pharmacovigilance is the reporting of suspected adverse drug reactions [14]. A proper coordination amidst the health care professionals and the medical institutions is the most required for a successful pharmacovigilance programme .

Many factors are associated with the adverse drug reaction under reporting among the healthcare professionals. But basically, in order to improve the reporting rate, it is important to properly educate the healthcare professionals regarding ADR reporting/ pharmacovigilance. The most appropriate time to do so, is during the undergraduate and the postgraduate training of the doctors. This study endeavoured to evaluate the extent of the awareness,

knowledge and the methods of application of pharmavovigilance of the final year MBBS students, interns and postgraduates of a government teaching hospital.

Some Indian studies which were conducted at the Lady Harding Medical College. New Delhi, showed that the knowledge, attitude and the practices of both the undergraduates and the prescribers were comparable, but that they needed further improvement [15]. A similar study which was conducted at the Civil hospital, Ahmedabad, concluded that under reporting and a lack of knowledge about the reporting system were clearly evident among the prescribers [16]. A study which was 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 very low amongst the resident doctors [17].

A cross sectional, questionnaire based, multi-centric study which was done on six different medical colleges in Gujarat indicated that the overall knowledge of pharmacovigilance was poor in undergraduate medical students [18]. A study which was conducted at a paediatric tertiary care centre in Bangalore suggested that educational interventions and the improvement of the facilities would help in enhancing the reporting rate [19]. A study which was conducted in Malaysian Public Universities on pharmacy students, suggested that a customized comprehensive curriculum which was related to pharmacovigilance should be designed and implemented in the pharmacy schools [20].

In this study, we assessed the awareness, knowledge and the methods of application of pharmacovigilance among 3 different groups of respondents. This is because students, interns and post graduates can play a major role in interacting with patients in the clinical departments. They are also an invaluable source for collecting, analyzing and reporting ADRs.

The mean awareness score of the students (2.45) was lower than that of the interns (3.06) and the post graduates (3.35). Many (74%) were unaware that pharmacovigilance, in addition to drug related problems, included blood related products, herbal products, medical devices and vaccines.

The mean knowledge score of the students (2.30), was lower than that of the interns (3.20) and the post graudates (3.46). A vast majority (89.5%) were ignorant of the number of centers under the national pharmacovigilance programme. Several (80.5%) did not know when the National Pharmacovigilance Programme had officially commenced. A considerable number were ignorant about the schedule Y (75%) and archiving (81%).

In the methods of application of pharmacovigilance, the post-graduates had a considerably higher mean score of 6.94 as compared to the interns, with a mean score of 5.65 and the students had a much lower score of 3.18.This difference can be attributed to the greater clinical exposure of the former two. However, a majority (53.3%) were not aware that even nurses and pharmacists could report adverse drug reactions. A large number (69.5%) did not know the various methodologies which were employed to assess the causality of the adverse effects (the WHO Assessment Scale, the Naranjo Scale, the European ABO System, etc). A considerable number (59%) were not sure when a de-challenge was not applicable in case of the adverse drug reactions.

The above observations indicated that serious measures had to be taken to educate the junior doctors about these aspects of pharmacovigilance. Numerous studies have revealed that many physicians were unaware of the pharmacovigilance programmes and the ADR reporting systems which existed in the country.

These studies also attempted to identify the possible measures that could enhance the involvement of physicians in the pharmacovigilance programme. These measures included, creating an awareness about pharmacovigilance, implementing ADR reporting as an integral part of the undergraduate, internship and post graduate training, providing active manpower to collect the ADR reports from busy clinicians, provision of the feedback to the reporting healthcare professionals and the involvement of nurses and paramedical staff in reporting the ADRs.

To facilitate the activity of pharmacovigilance, a culture of learning about it should start early in the professional training of the health care students. This enables the medical students to realize that all medicines can cause adverse drug reactions. In addition, their responsibility of participating in the National Pharmacovigilance Programme is emphasized. Consequently, the rational use of medicines, the adverse drug-drug interactions and the inappropriate polypharmacy have been considerably to be reduced in the clinical practice.

An outline of the adverse drug reactions is covered in most of the pharmacology text books. However, the students are not adequately trained to apply this knowledge in practice. The theoretical knowledge on pharmacovigilance, the National Pharmacovigilance Programme and its centres and ADR monitoring should be included in the syllabus. The actual practical knowledge can be gained by visiting a pharmacovigilance centre and by observing its functioning.

Both the interns and the post graduates are invaluable sources for collecting, analyzing and reporting ADRs. They play a major role by interacting with the patients and their peers in the clinical departments. They should be familiarized with the ADR reporting and the methods for assessing the causality and the severity of ADRs. Continued Medical Education programmes and other training programmes can help in sensitizing them. The interns can be posted to the pharmacovigilance centres. Suitable measures have to be taken to alert them to prevent ADRs.

In addition, every institution should conduct monthly meetings to monitor ADRs. All the departments should compulsorily participate in such meetings and provide an active feedback. Incentives should be given to promote the reports on ADRs. Even organizing regular quiz programmes for both the staff and the students can foster a better means of creating an awareness about pharamacovigilance. Importance should be given to translational pharmacovigilance to encourage the dissemination of the information which is required to improve the prescriptions of drugs.

CONCLUSION

Today, the need for an efficient pharmacovigilance system has been realized more than ever, to ensure the safe use of medicines. Pharmacovigilance is being taught to some extent in theory, but the knowledge on the practical approach is lacking. The present academic curriculum should be revised to include the application of pharmacovigilance in the medical practice. A culture of learning about pharmacovigilance should start early in the professional training of doctors. The medical students who are aware of pharmacovigilance are sure to realize that all medicines can cause ADRs. Moreover, they, by participating in the National

Pharmacovigilance Programme, can detect the adverse effects which result from the drug use in the population. This will definitely decrease the irrational use of medicines and emphasis should be made on the ADR detection and reporting.

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APPENDIX-1
Pharmacovigilance Questionnaire

Tick the correct answer Students/Interns/PGs

Awareness

1. Are you aware of the term of pharmacovigilance?
   Yes /No

2. Is it mandatory to have pharmacovigilance unit in the medical college?
   Yes/No

3. What is pharmacovigilance?
   a. Adverse drug reaction (ADR) monitoring
   b. Therapeutic drug monitoring
   c. Vigilance over the pharma company for drug production
   d. All

4. Pharmacovigilance includes
   a. Drug related problems
   b. Blood related products
   c. Herbal products
   d. Medical devices and vaccines
   e. All

5. Aim of the pharmacovigilance is to assess
   a. Safety over efficacy
   b. Efficacy over safety

Knowledge

6. Under the National Pharmacovigilance Programme, all are true except
   a. 26 Peripheral Pharmacovigilance Centres (PPC)
   b. 4 Regional Pharmacovigilance Centres (RPC)
   c. 2 Zonal Pharmacovigilance Centres (ZPC)
   d. None

7. National pharmacovigilance programme (NPP) was officially inaugurated at New Delhi in the year
   a. 2002
   b. 2004
   c. 2006
   d. 2008

8. AIIMS New Delhi is a
   a. Peripheral Pharmacovigilance Centre
   b. Regional Pharmacovigilance Centre
   c. Zonal Pharmacovigilance Centre
   d. National Pharmacovigilance Centre

9. Pharmacovigilance in clinical research is the responsibility of
   a Sponsorers
   b. Investigator
   c. Ethical committee
   d. All

10. Schedule Y was developed in
    a. 1968
    b. 1978
    c. 1988
    d. 1998

11. Archiving is to be done for a period of
    a. 2 yrs
    b. 3 yrs
    c. 4 yrs
    d. 5 yrs

12. Is audit of pharmacovigilance mandatory
Yes / No

Methods Of Application

13. Co-ordinator's eligibility at ZPC should be
    a. A Pharmacologist preferably not below the rank of an assistant professor
    b. A Pharmacologist preferably not below the rank of an associate professor
    c. A Pharmacologist not below the rank of professor
    d. Any of the above

14. Most common type of ADR?
    a. Type A
    b. Type B
    c. Type C
    d. Type D

15. Which of the following defines serious adverse event?
    a. Life threatening
    b. Disability
    c. Death
    d. Hospitalization

16. ADR reporting can be done by
    a. Doctors
    b. Nurses
    c. Pharmacists
    d. All

17. ADR reporting done for all except
    a. New drugs
    b. Old drugs
    c. Any reaction or even minor reaction of new drug
    d. Any reaction or even minor reaction of old drug

18. ADR report submission follows which order
    a. Peripheral pharmacovigilance centre (PPC) → Regional pharmacovigilance centre (RPC) → Zonal Pharmacovigilance Centre (ZPC)
    b. RPC → PPC → ZPC
    c. ZPC → RPC → PPC
    d. Any order

19. Methodologies employed to assess causality of adverse effect is/are
    a. WHO assessment scale
    b. Naranjo's scale
    c. Europeon ABO system
    d. All

20. ADR forms are called
    a. Yellow card
    b. Red card
    c. Green card
    d. Pink card

21. Elements which are mandatory to record
    a. Identifiable patient details
    b. Identifiable reporter details
    c. Suspected medicinal products
    d. All

22. Dechallenge is not applicable when the
    a. Drug is one dose treatment
    b. Reaction had occurred after drug was discontinued
    c. Lack of efficacy
    d. All

23. Is ADR synonymous to adverse event?
Yes /No

24. The commonly seen ADRs like headache, fever, vomiting has to be reported
Yes / No

25. Non Medical people can report ADR to a near by medical person
Yes / No
If yes by what means of communication
    a. Orally
    b. Telephone
    c. E mail
    d. All

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