



USEFULNESS OF TRAINING OF PHARMACOVIGILANCE FOR MEDICAL STUDENTS - A PERSPECTIVE STUDY

Lalit Mohan^{1*}, Ashutosh kumar², Manas Ranjan Mishara³, Anoop Kishore⁴, VeenaNayak⁵

1. Associate, Professor, Dept. of Pharmacology, Narayan Medical College, Jamuhar, Sasaram, India.
2. Assistant Professor, Dept. of Microbiology, Narayan Medical College, Jamuhar, Sasaram, India.
3. Assistant Professor, Dept. of Pharmacology, Narayan Medical College, Jamuhar, Sasaram, India.
4. Lecturer, Dept. of Pharmacology, Manippal College of Pharmaceutical Scinces, Manipal, India.
5. Associate professor, Dept. of Pharmacology, Kasturba Medical College, Manipal, India.

*Corresponding author's E-mail: drlalitjee@rediffmail.com

Accepted on: 29-06-2012; Finalized on: 31-08-2012.

ABSTRACT

Pharmacovigilance, previously more often referred to as adverse drug monitoring or drug surveillance is now regarded as the quality control system of the society regarding the use of medicines. Many new drugs are being introduced in our country. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs. *As we know Pharmacovigilance can only be effective through the active participation of practitioners for consideration this we can effectively train medical students which are future practitioners.* In this study, questionnaire will be distributed to know students opinion on the usefulness of pharmacovigilance training, relevance of in reporting adverse drug reactions. The feedback of the students was positive. The students agreed that the sessions made them aware of the concept of Pharmacovigilance. With regards to the success of the current pharmacovigilance program in India, they had a negative response. The study will be helpful in promoting pharmacovigilance programme to be more success by students in their future career as doctors. In a country like India, where medical students are not taught much about the pharmacovigilance, this study gains attention to medical education planner to add in details of pharmacovigilance in curriculum.

Keywords: Pharmacovigilance, training, medical students.

INTRODUCTION

As the worldwide movement for improvement of patients safety gains momentum subject of drug safety even becomes more important. It is a well-known phenomenon before a product is marketed, experience of its safety and efficacy is limited to its use in clinical trials, that new drugs are marketed widely and are often withdrawn from the market due to the Adverse Drug Reactions (ADRs) which occur once they are used by a larger population than that covered in the clinical trials.¹ The conditions under which patients are studied during the pre-marketing phase do not necessarily reflect the way the medicine will be used in the hospital or in general practice once it is marketed. Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g. pregnant women, children, elderly) and drug interactions are often incomplete or not available. Certain adverse drug reactions may not be detected until a very large number of people have received the medicine. Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the safety of pharmaceutical and related health products. The Who defines pharmacovigilance as "science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems."²

Pharmacovigilance, previously more often referred to as adverse drug monitoring or drug surveillance is now regarded as the quality control system of the society

regarding the use of medicines. Its broader aim is to check if medicines fulfill their intended role in alleviating human suffering and reducing disease related economic loss, with the best acceptable safety in use. The ultimate aim of pharmacovigilance is to attain the safe and rational use of medicines, once they are released for general use in the society. A very important outcome of pharmacovigilance is the prevention of patients being affected unnecessarily by the negative consequences of pharmacotherapy.³

India has more than half a million qualified Doctors and 15,000 hospitals having bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important Clinical trial hub in the world. Many new drugs are being introduced in our country. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs. The national pharmacovigilance programme in India has been restarted as Pharmacovigilance programme for India (PvPI) jointly by CDSCO and Indian Pharmacopeia commission, Ghaziabad. The previous programmes were stopped because of varied reasons, under reporting being one of them. India is a country with a large population, despite which the reporting rate is only 1%. Hence this programme plans to include all the MCI, recognized medical colleges. Under this programme, a department for Pharmacovigilance will be started to implement



pharmacovigilance activities and to improve the rate of reporting the adverse drug reaction (ADRs).⁵

The department of pharmacology, Kasturba Medical College, Manipal established a pharmacovigilance cell in 2010. The main objective of this cell was to collect the ADRs from the hospital and report them. But due to lack of awareness among the prescribers, there was underreporting of ADRs. *As we know Pharmacovigilance can only be effective through the active participation of practitioners for consideration this we can effectively train medical students which are future practitioners.* In this study, questionnaire will be distributed to know students opinion on the usefulness of pharmacovigilance training, relevance of in reporting adverse drug reactions.

MATERIALS AND METHODS

The Pharmacovigilance training workshop was conducted for the second year (4th semester) undergraduate medical students at Kasturba Medical College, Manipal, during the month of January 2010. One month prior to the training workshop, the students were intimated and only those interested were asked to enroll. A total of 56 students enrolled themselves for the training programme. It was conducted in the medical education department, where the students were divided into 8 groups and each group comprised of 3-4 members of both genders. The training programme was divided into three sessions each of half an hour duration. The first session focused on the need for pharmacovigilance and reporting of adverse drug reactions. The definition, types of ADR's and the severity assessment was covered in the second session. The third session dealt with the reporting of ADRs, filling an ADR-CDSCO form and causality assessment with emphasis on Naranjo's algorithm.⁵ At the end of the third session the students were given the following two cases and were asked to fill the CDSCO form, assess the causality as well as severity assessment on the basis of Hartwig scale.⁶

The students will be asked to complete a questionnaire, which consists of two parts. The first part will collect demographic and other relevant information about the student respondents. The sex and nationality of the respondents will be noted. The questionnaire to be used in the study is shown in the Appendix. The second part of the questionnaire consists of feedback regarding student's view of training session of pharmacology. The students will be asked to score each individual statement using the following key: 1- strongly disagrees with the statement, 2- disagree, 3- neutral, 4- agree and 5- strongly agree with the statement. The students are instructed to use whole numbers only. Students will be informed that their participation in the study is voluntary. The questionnaire will be based on mainly review of literature and discussion with faculty members of pharmacology department, KMC, Manipal.⁷ The data was analyzed using SPSS 11.5 version. The median total scores and median with interquartile range of individual statements were calculated.

RESULTS

Altogether, Fifty six students were present and all of them participated in the study. The demographical characteristics of the students are listed in (table 1). The median scores of the individual statements are listed in (table 2). The maximum possible score was 100.

Table 1: Demographic characteristics of the students

| Characteristics | | Number | Percentage |
|-----------------|------------|--------|------------|
| Sex | Male | 28 | 54.9 |
| | Female | 23 | 45.1 |
| Nationality | Indian | 45 | 28.24 |
| | Non Indian | 6 | 11.76 |

Table 2: Median scores of individual statements

| S. No. | Median score (Inter quartile range) |
|--------|-------------------------------------|
| 1 | 5(5-5) |
| 2 | 5(5-5) |
| 3 | 4(4-5) |
| 4 | 3(3-4) |
| 5 | 2(2-2) |
| 6 | 3(3-3) |
| 7 | 5(5-5) |
| 8 | 4(4-5) |
| 9 | 5(5-5) |
| 10 | 4(4-5) |
| 11 | 5(5-5) |
| 12 | 5(5-5) |
| 13 | 4(4-5) |
| 14 | 5(5-5) |
| 15 | 4(4-5) |
| 16 | 4(4-5) |
| 17 | 4(4-5) |
| 18 | 5(5-5) |
| 19 | 3(3-3) |
| 20 | 5(5-5) |

DISCUSSION

Medical doctors along with other healthcare professionals should be aware of the importance of reporting and should report adverse drug reactions (ADRs) as part of their professional responsibility. Doctors should be knowledgeable about the ADR reporting systems in their region and country. Developed countries have incorporated the teaching of pharmacovigilance into medical and pharmacy curricula.^{8,9} However, in developing countries most medical colleges do not teach pharmacovigilance. ADRs are only covered as a topic in the theory course.

To the best of our knowledge, the present study is to introduce activity based learning of pharmacovigilance to medical students in South Asia. Pharmacovigilance is an important area of practice for doctors. We hope our experience will be of interest to researchers and teachers from South Asia and other developing regions. Moreover by implementing this programme into medical colleges, the medical students who are the future practitioners will be aware of the methodology to report the adverse drug reactions. This could be one of the methods to improve



the rate of reporting adverse drug reactions in our country.¹⁰

The students enthusiastically participated in this training programme. The filling up of CDSCO forms though a difficult task was made an easy one by group discussion. Naranjo's algorithm was designed by Naranjo *et al.*,⁵ to assess the causality. Hartwigscale⁶ categorizes ADRs into seven levels as per their severity. Severity of ADR is categorized as mild, moderate or severe. When an ADR does not require an antidote, therapy or prolongation of hospitalization it is categorized to be of mild severity. When a change in therapy, specific treatment or an increase in hospitalization by at least one day is required it is of moderate severity. Severe ADR includes all potentially life threatening reactions causing permanent damage or requiring intensive medical care. Lethal reactions are those which may lead to death of the patient. In both the cases severity was assessed according to Hartwig scale.

The feedback of the students was positive. The students agreed that the sessions made them aware of the concept of Pharmacovigilance. With regards to the success of the current Pharmacovigilance program in

India, they had a negative response. This response suggests the students' concern regarding the program. One of the most striking findings was that the students wanted Pharmacovigilance to be incorporated in their curriculum. We got similar responses of feedback on training programme of Pharmacovigilance study done by subhish.¹¹

The Pharmacovigilance centre was established in the department in the year 2010. But the rate of reporting ADR was very less. In view of this, we planned to educate the undergraduates about pharmacovigilance. This workshop proved step wise learning of pharmacovigilance programme and very beneficial as the ADR reporting improved thereafter.¹² We also plan to conduct such workshops for the postgraduates in various disciplines. We hope that our experience will be of interest to researchers and teaches of various medical colleges. Our study had a few limitations. It was a preliminary study and included only 56 medical students. Moreover, only one batch of students was included in the training program. We also did not evaluate the improvement of knowledge of the students regarding pharmacovigilance, following the training program.

APPENDIX

Usefulness of training of Pharmacovigilance activities for medical students - a perspective study.

Participation depends on your willingness. No personal information should be written on the paper (name, registration number). Please answer legibly and write the appropriate no. in boxes wherever required.

Sex: M/ F

Nationality:

Medium of instruction at school: English/ Regional

Government selected/ self financing

For the following statements score using the following key: 1- strongly disagree, 2- disagree, 3-neutral, 4-agree, 5-strongly agree

1. The session made me aware me concept of pharmacovigilance
2. Pharmacovigilance is very much essential for developing country like India
3. Adverse drug reactions are one of the major causes of death in world.
4. Herbal drugs reaction also carry equal risk of causing adverse drug reaction as that of modern medicine
5. Pharmacovigilance programme in India is successful.
6. The adr reporting form should be single page.
7. Pharmacovigilance should be mandatory in India.
8. Pharmacovigilance should be incorporated in curriculum of MBBS.
9. The pharmaceutical industry should report adverse drug reactions.
10. The session may useful for my job.
11. Hospital drug and therapeutic committee should be a part of the pharmacovigilance programme
12. Causality assessment is important step in pharmacovigilance.
13. Severity assessment is not important step in pharmacovigilance.
14. A good numbers of adverse drug reactions can be prevented if appropriate measures are taken.
15. Patients should not be allowed to report adverse drug reactions.
16. Dosages adjustment is important strategy to prevent the occurrence of adverse drug reactions.
17. The session was informative and interesting.
18. The facilitators performed role effectively
19. I would like to pursue career in pharmacovigilance.
20. I would welcome similar session in futures.



CONCLUSION

The study was successful in evaluating the students' feedback on the educational sessions about pharmacovigilance. Overall, students liked the session and were interested in having similar sessions in the future. The ultimate aim is to expand this exercise further and transfer the skills to undergraduate medical students. The study will be helpful in promoting pharmacovigilance programme to be more success by students in their future career as doctors. In a country like India, where medical students are not taught much about the pharmacovigilance, this study gains attention to medical education planner to add in details of pharmacovigilance in curriculum

Acknowledgements: The authors acknowledge all the students who participated in the study spending their valuable time.

REFERENCES

1. Olsson S. Pharmacovigilance training with focus on India. *Indian J Pharmacol* 40 (Suppl 1): 2008; 528-30.
2. Lee A, Thomas SHL. Adverse drug reactions In Walker R and Edward C. *Clinical pharmacy and therapeutics*. 3rd edition Churchill Livingstone 2003; 33-46.
3. Olsson S. The need for pharmacovigilance. In: Gupta SK. *Pharmacology and therapeutics in the new millennium* Narosa publishing house, New Delhi., 2001; 502-508.
4. [http:// cdsco.nic.in/pharmacovigilance_intro.htm](http://cdsco.nic.in/pharmacovigilance_intro.htm)
5. Naranjo CA, Busto U, Sellers EM. A method for estimating the probability of adverse drug reactions. *ClinPharmacolTher* 30: 1981;239- 45.
6. Hartwig SC, Siegel J, Schneider P J. Preventability and severity assessment in reporting adverse drug reactions. *Am J Hosp Pharm* 49: 1992; 2229- 32.
7. Subish P, Mohamed IzhamMi, et al; Education sessions for pharmacy students on pharmacovigilance: a preliminary study *JCDR* ; 4:2010: 2427-32.
8. A.R. Cox, J.F. Marriott, K.A. Wilson and R.E. Ferner, Adverse drug reaction teaching in UK undergraduate medical and pharmacy programmes, *Clin. Pharm. Ther.* 29: 2004; 31–35.
9. Shankar PR, Subish P. Designing a spontaneous adverse drug reaction reporting form: an exercise for medical students. *Int J Risk Saf Med.* 18:2006; 115–119.
10. Ravishanker P, Subish P, Mishra P, Dubey AK. Teaching Pharmacovigilance to medical students and doctors. *Indian Journal of Pharmacology* 38(5):2006; 316-319 .
11. Subish P, Mohamed IzhamMi. Education sessions for pharmacy students on pharmacovigilance: a preliminary study *JCDR*; 4: 2010: 2427-32.
12. Nayak V, Mohan L, Chogtu B, Bairy KL. Pharmacovigilance: workshop for undergraduate medical students. *IJHSR* 2(1): 2012: 153-156.

