ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Impact of an Educational Intervention on the Awareness of Pharmacovigilance among Pharmacy and Nursing Students in Puducherry.

S Amarnath*, Arun Sharma, S Jaikumar, S Basalingappa, S Ramaswamy, and M Thulasimani.

Department of Pharmacology, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry- 605 502, India.

ABSTRACT

To assess the awareness of pharmacovigilance among the pharmacy and nursing students and to evaluate the impact of an educational intervention on the same. A survey with self-administered and validated questionnaire containing Basic concepts, Reporting, Documentation and Conclusion (BRDC) was designed and administered to pharmacy students, Dept. of Pharmacy, Mother Theresa Post Graduate and Research Institute of Health Sciences and nursing students of RAAK nursing college, Puducherry. Informed Consent was obtained from the participants and questionnaire containing 15 questions was administered to a total a total of 213 (103 pharmacy and 110 nursing) students participated in the pre and post BRDC survey. Following pre-BRDC survey, an educational intervention in form of an interactive power point lecture was designed for all the participants. The effectiveness was evaluated in a post-BRDC survey. The results were analysed using ANOVA following student's t test. The knowledge of 3rd year students regarding various aspects of pharmacovigilance ranged from 12.84 5 to 25.41%. Similar results were obtained in 4th year pharmacy students. The awareness of pharmacovigilance among nursing students were comparatively better ranging from 16.6 % to 47.6 %, however, the pattern was similar as observed in pharmacy students. Educational intervention programme significantly enhanced the awareness (56.34 % to 74.79%). Comparable results were obtained in 3rd year nursing students. Nursing and pharmacy students from selected population in Puducherry are aware of the various aspects of pharmacovigilance only to some extent. Regular intervention programs like lectures, workshop and continuing medical education (CME'S) are necessary to improve efficacy of pharmacovigilance among them.

Keywords: Pharmacovigilance, pharmacy and nursing students, Awareness, Educational Intervention, Adverse Drug Reaction.

Corresponding author

ISSN: 0975-8585

INTRODUCTION

'*Any drug, no matter how vital its therapeutic actions, has potential to harm'* [1]. The clinical stigma could be ranging from a simple skin rash to a most severe form of fatal anaphylactic reactions. Adverse drug reaction (ADR) is a noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment [2]. The association between ADRs and mortality and morbidity is significantly high [3] and studies suggested that ADRs are the fourth to sixth cause of death [4]. Detection of drugs causing ADRs is a relatively new concept was termed as pharmacovigilance. Pharmacovigilance is concerned with the detection, assessment and prevention of adverse reactions to the drugs. The major source of information to detect an ADR is through spontaneous reporting system but it is associated with relatively low levels of reporting. In comparing the spontaneous reporting rates, India stands less than 1 % when compared with the world wide score of 5 % [5].

The success of pharmacovigilance programme is mainly concerned with the active involvement of health care professionals' (physicians, nurses, pharmacist, and dentists). It's a well known fact that an inadequate awareness about the pharmacovigilance system among the health care professionals is the leading cause of under reporting. The ultimate focus narrows to health care professionals spontaneous reporting of ADRs, for improving the reporting rates.

Pharmacists are easily contacted by the patients, they play a vital role in educating the patient on proper drug intake such as dose, time of administration and precautions, while dispensing the drugs. They are the key players in pharmaceutical industry and drugs control authority in the country. Community pharmacist plays a vital role in ADR reporting [6].

Nursing personnel are the ones who administer drugs to the patients; they constantly supervise the patient and spend most of their time with patients during their health care. They are contacted in most instances for medical assistance and monitoring. Hence, they play an important role in pharmacovigilance.

It is imperative that pharmacists and nurses are expected to have a thorough knowledge about pharmacovigilance. If it is included right from student days they will be able to implement the same effectively when they graduate. The best way to improve the awareness is through educational intervention.

Therefore, this study was conducted to assess the awareness of pharmacovigilance of pharmacy and nursing students. The impact of an educational intervention for improving awareness of pharmacovigilance was evaluated among them at Puducherry.

MATERIALS AND METHODS

Study design: A cross sectional, questionnaire based study.

Study Site: This study was conducted in two different setting one week apart in Dept of Pharmacy, Mother Theresa Post Graduate and Research Institute of Health Sciences and RAAK nursing college, Puducherry.

Study Population and sampling: A total of 103 pharmacy students were enrolled for the study (52 students from III year and 51 students from IV year) total of 110 nursing students were enrolled for the study (54 students from II year and 56 students from III year). An informed consent was obtained from all the participants and those who were not willing to participate were not enrolled in the study

Study Instrument: The study instrument was a self administered and validated questionnaire containing Basic concepts, Reporting, Documentation and Conclusion (BRDC). The questionnaire included of 15 questions.

Study Conduct: The questionnaire was administered to the target population. The participants were personally briefed about the questionnaire and given 30 minutes to answer the questionnaire as a pre BRDC test. They were given an option to maintain anonymity with regard to their names. The pre BRDC test was followed by an educational intervention in form of an interactive power point lecture for 45 minutes duration. Its effectiveness was evaluated by a post-BRDC survey. The results were analyzed using ANOVA followed by student's't' test.

RESULTS

Pharmacy students

3rd year: The pre test analysis among the 3rd year students reveal that an approximate 20%-25% of knowledge of pharmacovigilance on various aspects was found to be present in the test population. However, their knowledge on documentation was limited to 12.84%. These aspects of knowledge BRDC significantly improved ranging between 66.02% to 85.61% on various aspects of pharmacovigilance. It is note worthy that the opinion regarding including pharmacovigilance in curriculum through significantly improved but only to an extent of 45.6%. (Table.1)

Table 1: Analysis of various aspects of pharmacovigilance prior to and after educational intervention among 3rd year pharmacy students.

DESCRIPTION	PRE TEST (%)	POST TEST (%)
AS A WHOLE	20.27 ± 4.6	77.44 ± 1.2**
BASIC CONCEPTS	21.36 ± 5.2	66.02 ± 0.4***
REPORTING	25.41 ± 4.8	85.61 ± 1.2***
DOCUMENTATION	12.84 ± 4.9	85.22 ± 1.1***
CONCLUSION	20.27 ± 4.2	45.60 ± 0.6*

Values represent Mean ± SEM of 52 observations

*P < 0.05, ** P <0.01, ***P < 0.001 were compared with respective pre-test values (ANOVA followed by Student's 't' test)

4th year: A similar results were observed among 4th year students also. However, the pre-test results show a better knowledge on various aspects of pharmacovigilance when compared to 3rd year students and a comparatively lesser impact of educational intervention. (Table.2)

Table 2: Analysis of various aspects of pharmacovigilance prior to and after educational intervention among 4th year pharmacy students.

DESCRIPTION	PRE TEST (%)	POST TEST (%)
AS A WHOLE	24.62 ± 2.62	67.95 ± 1.9**
BASIC CONCEPTS	30.61 ± 4.2	60.13 ± 3.2**
REPORTING	32.56 ± 3.4	75.95 ± 4.2**
DOCUMENTATION	8.55 ± 6.2	76.29 ± 2.1***
CONCLUSION	35.01 ±3.2	46.95 ± 1.9

Values represent Mean ± SEM of 51 observations
*P < 0.05, ** P <0.01, ***P < 0.001 were compared with respective pre-test values (ANOVA followed by Student's 't' test)

When the test population was combined the results revealed that the test population had only 22.42% to 28.95% of the knowledge of pharmacovigilance which was significantly improved by educational intervention 63.1% to 80.83 %. (Table.3)

Table 3: Combined analysis of various aspects of pharmacovigilance prior to and after educational intervention among pharmacy students.

DESCRIPTION	PRE TEST (%)	POST TEST (%)
AS A WHOLE	22.42 ± 5.1	72.74 ± 1.2**
BASIC CONCEPTS	25.94 ± 4.2	63.10 ± 0.9***
REPORTING	28.95 ± 3.9	80.83 ± 1.1***
DOCUMENTATION	10.72 ± 3.6	80.83 ± 2.1***
CONCLUSION	28.71 ± 3.2	45.90 ± 0.9*

Values represent Mean ± SEM of 103 observations
*P < 0.05, ** P <0.01, ***P < 0.001 were compared with respective pre-test values (ANOVA followed by Student's 't' test)

Nursing students

2nd year: Based on the analysis of the data of pre-test it was observed the nursing students had a better knowledge of pharmacovigilance ranging from 32.83% to 47.6%. However, similar to pharmacy students they had only 16.66% of the knowledge on documentation. In contrast to pharmacy students their knowledge on conclusion is better, represented by 47.6%. All the aspects of pharmacovigilance were significantly improved by educational intervention, however, to a lesser extent when compared with pharmacy students. (Table.4)

Table 4: Analysis of various aspects of pharmacovigilance prior to and after educational intervention among 2nd year nursing students.

DESCRIPTION	PRE TEST (%)	POST TEST (%)
AS A WHOLE	32.83 ± 4.1	64.76 ± 1.2***
BASIC CONCEPTS	40.63 ± 4.7	66.87 ± 2.1*
REPORTING	38.32 ± 2.9	74.79 ± 1.1***
DOCUMENTATION	16.66 ± 3.9	58.67 ± 1.4***
CONCLUSION	47.60 ± 1.1	56.34 ± 1.4**

Values represent Mean ± SEM of 54 observations
*P < 0.05, ** P <0.01, ***P < 0.001 were compared with respective pre-test values (ANOVA followed by Student's 't' test)

3rd year: The results of the analysis of the 3rd year nursing students were almost comparable with that obtained with 2nd year students. The educational intervention significantly improved their knowledge, however, comparatively lesser on the basic aspects.(Table.5)

Table 5: Analysis of various aspects of pharmacovigilance prior to and after educational intervention among 3rd year nursing students.

DESCRIPTION	PRE TEST (%)	POST TEST (%)
AS A WHOLE	32.60 ± 5.1	66.09 ± 0.9**
BASIC CONCEPTS	38.69 ± 3.9	52.38 ± 0.4**
REPORTING	39.90 ± 2.6	75.15 ± 0.9**
DOCUMENTATION	16.15 ± 3.5	70.04 ± 1.4***
CONCLUSION	44.38 ± 2.1	59.18 ± 1.4 *

Values represent Mean ± SEM of 56 observations
*P < 0.05, ** P <0.01, ***P < 0.001 were compared with respective pre-test values (ANOVA followed by Student's 't' test)

Data, when analyzed after pooling of 2nd and 3rd year values, showed results without any significant difference when compared individually.(Table.6)

Table 6: Combined analysis of various aspects of pharmacovigilance prior to and after educational intervention among nursing students.

.

DESCRIPTION	PRE TEST (%)	POST TEST (%)
AS A WHOLE	32.71 ± 3.1	65.44 ± 1.2***
BASIC CONCEPTS	38.63 ± 2.5	59.49 ± 1.6**
REPORTING	39.13 ± 3.9	74.98 ± 0.9***
DOCUMENTATION	16.40 ± 4.2	64. 46 ± 2.1***
CONCLUSION	45.97 ± 3.9	57. 79 ± 2.4*

Values represent Mean ± SEM of 110 observations
*P < 0.05, ** P <0.01, ***P < 0.001 were compared with respective pre-test values (ANOVA followed by Student's 't' test)

DISCUSSION

Spontaneous reporting of ADR shall improve the efficacy of pharmacovigilance. Reporting can be done by health care professionals like physicians, nursing personal and

pharmacists. As indicated earlier a sound knowledge about pharmacovigilance only facilitates reporting. If such knowledge is important beginning from student's days, reporting will be very effective when they become eligible to do so.

The finding of the present study reveals that the nursing students of selected population have a better knowledge of various aspects of pharmacovigilance such as basic concepts, reporting, conclusion and pharmacovigilance as a whole. They lack awareness regarding documentation. Similar results are indicative among the pharmacy students. The significant enhancement on these aspects of pharmacovigilance by educational intervention strongly suggests the inclusion of such regular programs in the course work of nursing and pharmacy students.

Earlier studies concluded on these lines on different parts of globe revealed the following. A study conducted on pharmacy students in Malaysian public universities suggested that lack of in-depth understanding of facts about ADR reporting [7]. A similar study from Nigerian university suggested that the poor knowledge on ADR reporting mandate a fast update on curriculum containing pharmacovigilance [8]. Another study conducted in India among pharmacy students concluded with a similar results stating deficiency of knowledge regarding ADR reporting and pharmacovigilance [9]. A Hong Kong based survey of pharmacists suggested that they were unaware of ADR reporting system [10].

Two studies done in, Iran stated that nurses have a poor knowledge and practice of ADR reporting [11, 12]. Another study done in Sweden among nurses stated that more than half of study population were aware of their role in reporting but only few had actively reported and which mandate for further training for the nurses [13]. A study conducted in Iran among pharmacist and nurses together about knowledge, attitude and practice concluded that most of the health care professional are poor with the basic understanding of the ADR system and pharmacovigilance and suggested for regular workshops on the same [14]. A Nepal based survey conducted among the health care professionals in a teaching hospital suggested that there is a limited knowledge towards ADRs and pharmacovigilance [15].

The analysis of the data of the present study revealed that, the nursing and pharmacy students of Puducherry possess a significant knowledge on various aspects of pharmacovigilance, however, was deficient in some areas. Improving awareness of pharmacovigilance through the power point lecture as done in this study and by conducting continuing medical education programs, workshops is strongly suggested. Such training shall make the pharmacovigilance more effective.

CONCLUSION

Incorporation of knowledge on pharmacovigilance from student days is likely to yield better reporting and thus safety of drugs

ISSN: 0975-8585

ACKNOWLEDGEMENTS

We wish to thank all the students who participated in the survey. Special thanks to Dr.R.Murali (Dean), Dr.K.Girija (Head, Dept of pharmaceutical Chemistry), Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry and The Principal, RAAK Nursing College, Puducherry for permitting to conduct this study.

REFERENCES

[1] Nies AS. Principle of therapeutics - ADR and Drug Toxicity. In: Hardman JG, Limbird LE, eds. Goodman & Gilman's The Pharmacological basis of therapeutics.10th ed. New York, NY: McGraw-Hill; 2001:45-66.
[2] Requirements for adverse reaction reporting. Geneva, Switzerland: World Health Organization.1975.
[3] Lazarou J, Pomeranz BH, Corey PN. JAMA1998;279(15):1200-1205.
[4] Srinivasan R, Ramya G. Int J Res Pharm Chem 2011; 1(3):606-11.
[5] The National Pharmacovigilance Protocol, Ministry of Health and Family Welfare, Govt of India. http://www.panaceabiotec.com/medicalzone/National%20Pharmacovigilance%20Protocol.pdf (Last accessed on 01-02-2014).
[6] Mes K, den Berg L TW. d. J-v Van Grootheest A C. Int J Pharm Pract 2002; 10: 267–272.
[7] Elkalmi R, Hassali MA, Ibrahim MI, Widodo RT, Efan QM, Hadi MA. American J Pharm Edu 2011; 75(5)
[8] Showande JS, Oyelola FT. Int J Med Updates 2013; 8(1):24-30.
[9] Sharma S, Sharma J, Aggarwal T. Asian J Pharm Clin Res 2012; 5(3).
[10] Lee KK, Chan TY, Ranymond K, Critchley JA. Ann Pharmacother 1994; 28(12):1400-1403.
[11] Hanafi S, Torkamandi H, Hayatshahi A, Gholami K, Javadi M. Iran J Nurs Midwifery Res. 2012; 17(1): 21-25.
[12] Hajebi G, Mortazavi SA, Salamzadeh J, Zian A. Iranian J Pharm Res 2010; 9 (2): 199-206.
[13] Ekman E, Petersson G, Tagerud S, Backstrom M. Drug, Healthcare and Patient Safety. 2012; 4: 61-66.
[14] Salehifar E, Ala SH, Gholami KHA. J Mazandaran University Medical Sci 2007; 16(56): 125-115.
[15] Palaian S, Ibrahim MI, Mishra P. Pharmacy Practice (Internet) 2011; 9(4): 228-235.