Available online at: http://www.iajps.com   *Research Article*

IMPACT OF EDUCATIONAL INTERVENTION ON THE KNOWLEDGE OF PHARMACOVIGILANCE AMONG PHARMACY STUDENTS IN MAHARASHTRA, INDIA.

Gaurav T. Damdar[*1], Rucha M. Mohata[2], Isha S. Pawar[3], Akshay A. Shelke[4]
Doctor of Pharmacy Intern, Government College of Pharmacy, Amravati, Maharashtra, India

Abstract:
Aim: To assess the level of knowledge of Pharmacovigilance among pharmacy students and subsequent change in the knowledge after education intervention.
Methodology: This was across-sectional, interventional and questionnaire based study designed to assess the knowledge of Pharmacovigilance among pharmacy students before and after the educational intervention. The intervention involved four activities: 1) Pre-assessment test 2) 3 interactive sessions, 3) a workshop on filling the Spontaneous ADR reporting form and demonstration on WHO and Naranjo causality assessment scale, 4) post-assessment test. The impact of educational intervention on the knowledge of pharmacovigilance was analyzed using Unpaired Student t test.
Result: Total 202 pharmacy students were participated in the study. In which 92 were male and 110 were females. Out of 202, 83 students were pursuing Pharm D, 65 were pursuing B pharm and 54 were pursuing M pharm. It was found that after the post-assessment test the knowledge was increased up to 75.30% and knowledge gained was about 41.50%.after educational intervention.
Conclusion: The results of the present study shows that an educational intervention can increase awareness about pharmacovigilance among the future health care professionals and can practise this gained knowledge for reporting of spontaneous ADRs to the international database from the perspective of improving global health safety.
Key words: *Pharmacovigilance, educational intervention, ADR, WHO*

Corresponding author:
Mr. Gaurav T. Damdar,
Doctor of Pharmacy Intern,
Government College of Pharmacy,
Amravati, Maharashtra, India
Email: gauravdamdar24@gmail.com
Contact no. 8087151672

QR code

Please cite this article in press as Gaurav T. Damdar et al., ***Impact of Educational Intervention on the Knowledge of Pharmacovigilance among Pharmacy Students in Maharashtra, India.***, *Indo Am. J. P. Sci, 2018; 05(01).*

INTRODUCTION:

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. [1]Pharmacovigilance (PV) was initiated as a consequence of the thalidomide tragedy in the 1960s, for studying adverse drug reactions (ADRs) to medicines after they have been approved for use [2, 3].

Utilization of medicines and occurrence of adverse events are two sides of one coin and cannot be avoided. There are three activities of a medication: ''Desirable, Undesirable and unknown''.Research on drug-related hospitalizations carried out over the past 35 years and has demonstrated that approximately 50% of drug-related patient harms leading to hospitalization are avoidable, that is, they are associated with the way it has been prescribed, dispensed, administered or used and not with the intrinsic properties of the medical product itself.
Thus, the PV activities invariably start with the least resource-demanding method that is, spontaneous reporting of ADRs which are most probably due to unnecessary prescription, inaccurate diagnosis, casual application of evidence-based medicines, irrational use of antibiotics, outstanding development of new drugs and their unjustified promotion.[2]

In the interview for Uppasala Reports in July 2017, Dr. V Kalaiselvan, Chief Scientific Officer, Indian Pharmacopoeia Commission, said that, "*India joined the WHO program for international drug monitoring in 1997. In 2016, 4.2% of all new suspected ADR reports submitted to WHO's global database of individual case safety reports, Vigibase, were sent by India, being the sixth most active reporting country globally that year. He also said that, "in a country like India there are a lot of challenges particularly under-reporting and there is need to educate and raise the awareness about ADR reporting among clinicians and empowerment of pharmacists is required to enhance the ADR reporting*".[4]

The reporting rate of ADRs could be improved with proper and extensive training about PV during the undergraduate and internship periods. There is a great need for introduction of PV in undergraduate and graduate levels in teaching institutions for all health professionals all over the world. Recently, in India it is compulsory for all medical colleges to include PV in the undergraduate curriculum. [2] The present study aims to assess the impact of an educational intervention in pharmacovigilance on the knowledge of pharmacy students.

AIMS AND OBJECTIVES
1. To evaluate knowledge about PV and ADR reporting among pharmacy students.
2. To educate Pharmacy students through interactive sessions and practical workshop.
3. To analyze the impact of educational intervention in the knowledge of PV

METHODOLOGY:
Study design and site:
Thecross-sectional, interventional and questionnaire based study was carried out on Pharmacy students from different Pharmacy institutes of Maharashtra.
The education was provided through "One Day Workshop on Basics of Pharmacovigilance" organized by Doctor of Pharmacy Association Maharashtra under technical support of NCC-PvPI, IPC, Ghaziabad, New Delhi on 25th September 2017.
Study sample: Thestudy involved undergraduate and post-graduate pharmacy students (Pharm D, B. Pharm, M. Pharm). In this study, 202 pharmacy students including 92 males and 110 females were participated.

Design of Questionnaire:
A draft questionnaire was prepared using available data from the literature about ADR reporting among health care professionals. The draft questionnaire was evaluated by five experienced professors and doctors and based upon their responses the questionnaire was modified. The final Knowledge based questionnaire contains 20 questions, to obtain the information regarding demographics of the participants and knowledge regarding pharmacovigilance.

Data collection:
Initially Pre assessment test was administered before educational intervention and briefed to all participants about the purpose of the study and asked to submit the same.The intervention involved three interactive sessions on "Basic concepts and history of PV", "Monitoring and reporting AE/ADR", "Causality Assessment of ADR: a) Naranjo scale b) WHO scale" and workshop on filling the Spontaneous ADR reporting form and demonstration on WHO and Naranjo causality assessment scale by AMC coordinator and PVPI personnel. Along with this, educational material was provided to participants. Then post assessment test of all participants was carried out to assess gain in knowledge.

Statistics Analysis:
The information was recorded and analyzed using Microsoft Excel. The impact of educational

intervention on the knowledge of pharmacovigilance among pharmacy students was analyzed using Unpaired Student t test

RESULTS:
In this cross-sectional, interventional and questionnaire based study a total of 250 Pharmacy students were participated, but only 202 students

completely filled the questionnaires before and after the educational intervention.

Out of 202, 83 students were pursuing Pharm D, 65 were pursuing B Pharm and 54 were pursuing M Pharm. The questions answered by the participants about the knowledge of PV are depicted in the following Table 1.

Table 1: Knowledge of pharmacovigilance and adverse drug reactions reporting before and after educational intervention

Que. No	Questions	Pre-Assessment	Post-Assessment	P value
1	Define Pharmacovigilance?	34.15%	94.05%	<0.0001
2	Define ADR?	41.58%	92.57%	<0.0001
3	The important purpose of Pharmacovigilance is (Most appropriate one) a) To identify safety of drugs* b) To calculate incidence of ADR's c) To identify predisposing factors to ADR's d) To identify unrecognized ADR's	41.08%	69.30%	<0.0001
4	Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market. a) Meta analysis b) Post Marketing Surveillance (PMS) studies*. c) Population studies d) Regression analysis	42.57%	83.66%	<0.0001
5	A serious adverse Event in India should be reported to the Regulatory body within a) One day b) Seven calendar days c) Fourteen calendar days* d) Fifteen Calendar days	26.23%	83.16%	<0.0001
6	The international center for adverse drug reaction monitoring is located in a) Unites States of America b) Australia c) France d) Sweden*	35.64%	74.25%	<0.0001
7	One of the following is a major risk factor for the occurrence of maximum adverse drug reactions a)Arthritis b) Renal failure* c) Visual impairment d) Vacuities	74.25%	98.01%	<0.0001
8	In India which Regulatory body is responsible for monitoring of ADR's? a) Central Drugs Standard Control Organization* b) Indian Institute of sciences c) Pharmacy Council of India d) Medical Council of India	40.59%	81.18%	<0.0001
9	Which one of the following is the 'WHO online database' for reporting ADRs? a) ADR advisory committee b) Medsafe c) Vigibase* d) Med watch	22.77%	76.73%	<0.0001

| 10	Match the ADR reporting systems to the respective countries. 1) Yellow card A) India 2) Green card B) Australia 3) ADR reporting Form C) UK 4) Blue card D) Scotland	36.63%	65.84%	<0.0001
11	Give full form of following: a) CIOMS b) ICSR c) AEFI d) NFI	13.36%	68.81%	<0.0001
12	Rare ADRs can be identified in the following phase of a clinical trial. a) Phase-1 CT b) Phase-2 CT c) Phase-3 CT d) Phase-4 CT*	32.17%	63.86%	<0.0001
13	Thalidomide was indicated for …………..and it was withdrawn due to …………. a) Vertigo, Respiratory distress b) Motion Sickness, Phocomelia* c) Folic Acid deficiency, Neural tube defect d) Eclampsia, Congenital Heart Disease	26.73%	71.78%	<0.0001
14	How many ADR Monitoring Centers (AMC) are there in India? a) 188 b) 211 c) 311 d) 258*	27.22%	73.78%	<0.0001
15	Which of the following is unpredictable type of ADR? a) Augmented b) Bizarre* c) Chronic d) Delayed	26.73%	68.31%	<0.0001
16	Where the National Centre of pharmacovigilance is located? a) New Delhi b) Mumbai c) Kolkata d) Ghaziabad*	32.17%	77.72%	<0.0001
17	Which of the following is the helpline number to report ADR at PVPI? a) 1800-180-2430 b) 1800-180-3024* c) 1800-180-1800 d) 1800-180-1207	26.23%	77.72%	<0.0001
18	According to Will and Brown, how many types of ADRs are classified? a) 5 b) 6 c) 8 d) 9*	30.19%	74.25%	<0.0001
19	Which of the following related ADR can be reported to NCC-PvPI? a) Herbal and traditional medicines b) Vaccines and sera c) Blood and blood products d) All of the above.*	46.53%	74.75%	<0.0001
20	Name banned drug you are aware of due to ADR? (Any two)	14.85%	37.12%	<0.0001

P< 0.0001 (comparisons between the Pre- Assessment and Post- Assessment responses).
Response to all 20 questions of knowledge based questionnaire shows p value of <0.0001 on unpaired student t test and are highly significant.

Table 2: Knowledge of pharmacy students towards Pharmacovigilance before & after educational intervention.

Sr. no.	Educational Qualification	Pre-assessment score	Post-assessment score
1.	Pharm D	34.05%	77.40%
2.	B. Pharm	31.5%	73.80%
3.	M. Pharm	36.20%	73.80%
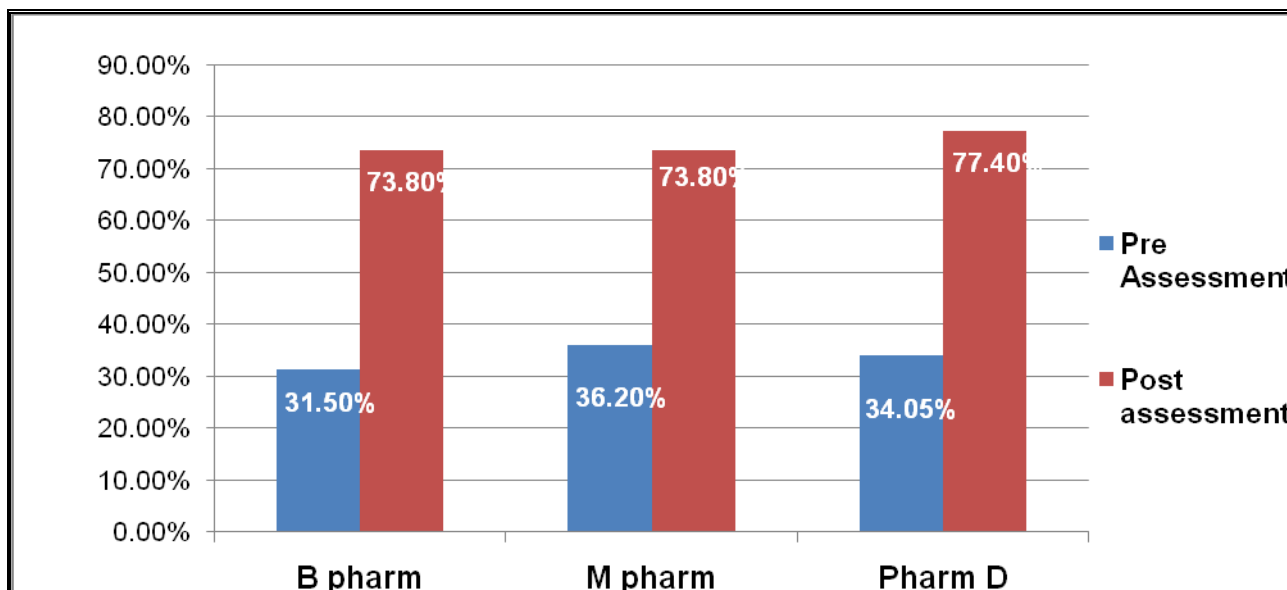
Fig.1 Knowledge of pharmacy students towards Pharmacovigilance before & after educational intervention.
In study it was found that the knowledge gained by both male and female participants was approximately equal as shown in figure 2
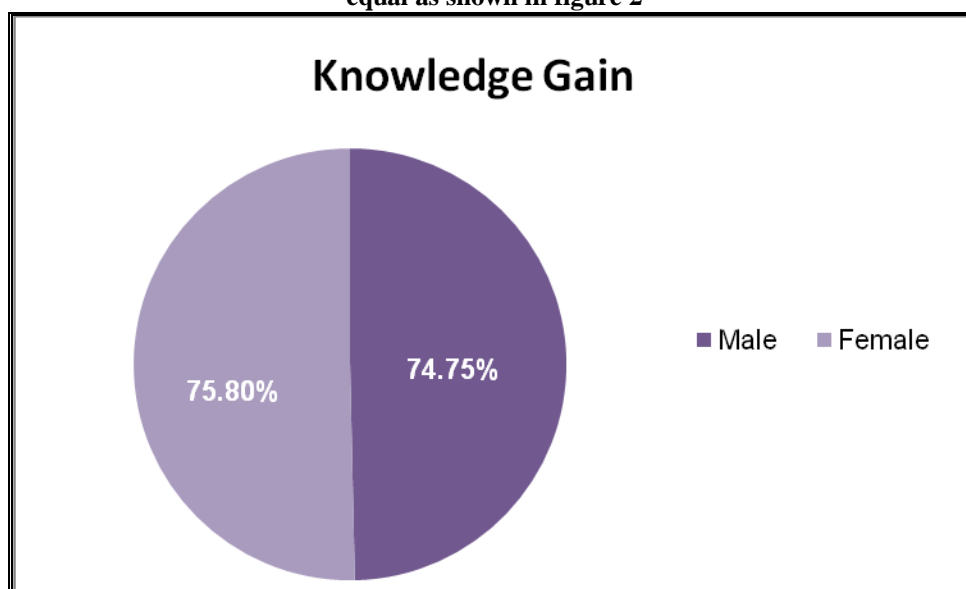
Fig. 2 Gain in knowledge following education intervention

DISCUSSION:

In the present study average score of participants in Pre-assessment was found to be 33.80% and it was increased up to 75.30% after educational intervention. Hence the knowledge gained was about 41.50%. Evidently, the documented results of question on define Pharmacovigilance (Pre score 31.15%) and ADR (Pre Score 41.58%) was increased up to 94.05% and 92.57% (P value <0.0001)respectively after the educational intervention, which strongly suggested pharmacists are in need of information regarding the Pharmacovigilance

Program of India (PVPI).The Question about the information of the location of International and National Centre for ADR monitoring, shows there was an increased positive response rate of 35.64% before to 74.25% and 32.17% to 77.72% (P value <0.0001) respectively after the educational intervention program.

In our study, more than half of the study participants were unaware of the 'WHO online database', 'Basic concept and terms of PV', 'regulatory authority of PVPI', 'Helpline number for ADR reporting', 'Number of ADR monitoring Centers (AMCs) in

India' ,'timeframe for reporting of serious adverse events'. Hence there is a great need to create promotion and awareness on ADR reporting among pharmacy students [7].

In our study the impact of educational intervention was found to be significant, these results were consistent with the Dr. Y. P. Reddy et al.[5] and Dr. Nitin Kothari et al.[6]. They also revealed that educational interventions can raise the knowledge and awareness about pharmacovigilance in the most significant manner.

Feedback following the program showed that pharmacy students who attended the educational intervention sessions on Pharmacovigilance and ADR reporting were much satisfied, and considered it more effective and valuable. This educational interventional study increased the knowledge and awareness in participants about Pharmacovigilance, monitoring and reporting ADRs.

CONCLUSION:

The results of the present study shows that an educational intervention can increase awareness about pharmacovigilance among the future health care professionals and can practise this gained knowledge for reporting of spontaneous ADRs to the international database from the perspective of improving global health safety.

REFERENCES:

1.The importance of pharmacovigilance. WHO, Geneva; 2002. Available from: http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf

2.Sten Olsson, Shanthi N Pal & Alex Dodoo. Pharmacovigilance in resource-limited countries. Expert Rev. Clin. Pharmacol. 2015, 8:4, 449-460.

3.Rogie Royce Carandang, Karen Cao, Nikki Beatrice Jose, Frances Diana Almonte, Ron Michael Tinio. Knowledge and Attitudes on Adverse Drug Reaction Reporting of SelectedHospital-based Health Practitioners in Manila, Philippines. Sch. Acad. J. Pharm., September 2015; 4(6):301-307.

4.Uppsala reports – covering the world of pharmacovigilance. July 2017;76, page no 8-9

5.V. Lokesh Reddy, S.K. Javeed Pasha, Dr. MohanrajRathinavelu, Dr. Y. Padmanabha Reddy. Assessment of Knowledge, Attitude and Perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India. IOSR-JPBS. (Mar-Apr. 2014). 9:2, 34-43.

6.Nitin Kothari, Nazima Mirza, Neeraj Agrawal, Mahesh Choudary, MeenuPichholiya, Somnath M. Matule, Bharat Kumar Goyal. An Evaluation of Knowledge and Perception of Pharmacy Students toward Pharmacovigilance and Adverse Drug Event Reporting. Asian Journal of Pharmaceutics. Oct-Dec 2015, 9 (4), 262.

7.Rana Abu Farha, MervatAlsous, EmanElayeh and Dima Hattab.A Cross-Sectional Study on Knowledge and Perceptions of Pharmacovigilance among Pharmacy Students of Selected Tertiary Institutions in Jordan. Tropical Journal of Pharmaceutical Research October 2015; 14(10): 1899-1905.