

Knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a teaching hospital of South Kerala, India

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Received: 24 February 2017

Accepted: 01 March 2017

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ABSTRACT

Background: Prompt reporting and monitoring of adverse drug reactions (ADRs) is necessary to enhance patient safety. This study was conducted to take steps to promote ADR reporting culture in medical students.

Methods: 75 undergraduate Medical students from different batches were given a 20 item structured questionnaire containing 10 questions on Knowledge, 5 questions on Attitude, 4 questions on Practice of Pharmacovigilance and a general question for suggesting the causes of underreporting of ADRs. They were requested to fill up the questionnaire. Each correct response was given a score of 1 and responses were graded. Statistical analysis was done and results expressed in percentage. Using ANOVA and Post hoc analysis, scores of knowledge, attitude and practice were also compared between the batches.

Results: Mean age was 22.01 +/- 1.438 years. 62.7% were females. Mean Knowledge score was significant (6.573 +/- 0.3832). Final year students had better knowledge among the three batches. All students had positive attitude. However, the mean difference in practice scores was statistically significant between all groups. Lack of knowledge regarding where and how to report ADRs, lack of training in ADR reporting, lack of time due to busy schedules and fear of legal issues were suggested as causes of underreporting of ADRs.

Conclusions: Good knowledge, Positive attitude and Poor practice were noticed among undergraduate Medical students towards Pharmacovigilance. Hence students should be familiarised with ADR detection and reporting through Project works and training programmes.

Keywords: Adverse drug reactions, ADR reporting, Knowledge score, Pharmacovigilance

INTRODUCTION

According to World Health Organisation, an Adverse drug reaction (ADR) is defined as 'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.¹ If not adequately managed, ADRs can result in increased patient morbidity and mortality. The concept of Pharmacovigilance was therefore introduced to help in the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems.² Under the Ministry of Health and Family Welfare, the Central

Drugs Standard Control Organisation (CDSCO), New Delhi, has initiated the Pharmacovigilance programme of India (PvPI) for monitoring ADRs and to ensure patient safety.³

PvPI was launched in July 2010 and Indian Pharmacopoeia Commission (IPC) at Ghaziabad was set as the National Coordinating Centre. The Drugs Controller General of India and Indian Council of Medical Research have established many peripheral Pharmacovigilance centres, from where ADRs are reported to IPC, which works in collaboration with the WHO ADR monitoring centre in Uppsala, Sweden. The purpose of PvPI is to collect data, analyse it and use the

inferences to recommend informed regulatory interventions, communicate risks to healthcare professionals and the public, detect medicines of substandard quality and find out errors during prescribing, dispensing and administration of drugs.⁴

Spontaneous reporting of ADRs by health care professionals is the backbone of any Pharmacovigilance program. Unfortunately, under-reporting of ADRs due to various reasons have emerged as a major concern globally.

An awareness of Pharmacovigilance and its importance should be inculcated in the student's right from their undergraduate days. Hence, this study was done to help the faculty to impart knowledge and skills on correct and prompt reporting of ADRs, to understand the need for conducting training programs on Pharmacovigilance and to promote ADR reporting culture in students so as to help them provide rational and safe clinical practice in future, thereby enhancing patient safety.

METHODS

A Cross sectional study was done to assess the Knowledge, Attitude and Practice of Pharmacovigilance among 75 undergraduate Medical students of a Teaching hospital of South Kerala. Stratified random sampling technique was used (strata being an MBBS batch). 25 students each were selected from Final year, Pre final year and third year MBBS batches of the institution. First year and Second year medical students were excluded as they had not completed the class schedules in Pharmacology as per the prescribed curriculum. Institutional Human Ethics Committee approval was obtained prior to the study. Sample size was calculated taking Practice of Pharmacovigilance as 60%, Confidence interval 95% and Relative precision 20% using the formula $n=4pq/d^2$.⁵

A modified, 20 item structured questionnaire, prepared from published studies was used to collect data from students.⁶⁻¹² They were requested to spare half an hour after their classes. After getting their consent, details of the study were explained and the questionnaire was handed over to them. Thirty minutes was given to fill up the questionnaire. They were requested to fill in the response to each item according to the response format in the questionnaire and without disclosing their identity in any form. Anonymity of the participant was maintained throughout and after the study.

"Knowledge of Pharmacovigilance" was assessed by 10 specific questions. Each correct response was given a score of 1. The maximum total score was 10. Responses were graded as follows:

- Score 0 -- Knowledge Nil
- Score 1-4-- Poor Knowledge,
- Score 5-7-- Good Knowledge,

- Score 8-9- Excellent Knowledge,
- Score 10-- Outstanding.

"Attitude towards Pharmacovigilance" was assessed by 5 specific questions and responses were graded as follows:

- Score 0--Attitude nil,
- Score 1-2-- Poor Attitude,
- Score 3 -- Good Attitude
- Score 4 -- Excellent Attitude
- Score 5-- Outstanding

"Practice of Pharmacovigilance" was assessed by 4 specific questions and responses were graded as follows:

- Score 0--Practice Nil.
- Score 1-- Poor Practice
- Score 2--Good Practice
- Score 3--Excellent Practice
- Score 4--Outstanding

Data collected was analysed using SPSS version 18 and results were expressed in percentage. The difference in the scores of knowledge, attitude and practice of Pharmacovigilance was also compared between the batches by ANOVA and Post hoc analysis.

RESULTS

A total of 75 questionnaires were analysed. The response rate was 100%. The mean age of the study population was 22.01 +/- 1.438 years. 37.3% were males and 62.7% were females. 92% of the students had heard the term "Pharmacovigilance" and 81.3% knew the correct definition. 84% were aware of a National programme for Pharmacovigilance. Only 58.7% knew that the International ADR monitoring centre is located at Sweden and CDSCO is the regulatory authority for PvPI. 89.3% knew which the serious adverse events were but only 21.3% were sure of when to report them. 50.7% students were of the opinion that only doctors could report ADRs and 24% thought that not only doctors but also nurses, pharmacists and dentists could report ADRs. 70.7% agreed that all ADRs should be reported; however, 8% felt that only serious and rare adverse effects have to be reported. Only 76% were aware of the existence of a Pharmacovigilance committee in their institution. 93.3% students agreed that it was their duty to report ADRs. All of them wanted ADR reporting to be made mandatory as part of hospital policy and wanted training on Pharmacovigilance. Only 18.7% knew that ADRs could be reported without confirming that it is related to a particular drug. 14.7% wanted ADR reporting forms to be kept in wards for easy access and reporting. 52% students admitted that they had seen an ADR reporting form and 22.7% agreed that they have read articles on prevention of ADRs. 68% agreed that they have come across ADRs during their clinical postings but it was reported by only 28% students (Table 1).

Table1: Percentage distribution of knowledge, attitude and practice of pharmacovigilance among undergraduate medical students.

Sr. No	Questions	Frequency (%)
		n = 75 (100)
1	Heard of the term "Pharmacovigilance"	69 (92)
2	Knows the correct definition of Pharmacovigilance	61 (81.3)
3	Aware of a National programme for Pharmacovigilance in India	63 (84)
4	Knows where the international centre for Pharmacovigilance is located	44 (58.7)
5	Aware of the regulatory authority for ADR monitoring in India	44 (58.7)
6	Aware of what a "Serious adverse drug reaction" is.	67 (89.3)
7	Knows within what time a "Serious adverse event" (excluding death) has to be reported to the regulatory authorities	16 (21.3)
8	Knows who can report an Adverse drug reaction	18 (24)
9	Knows which Adverse drug reactions have to be reported.	53 (70.7)
10	Aware of the existence of a Pharmacovigilance committee in their institution	57 (76)
11	Thinks it is their duty to report Adverse drug reactions	70 (93.3)
12	Feels that ADR reporting should be made mandatory as part of hospital policy	75 (100)
13	Feels that a training on ADR reporting should be given to all health care professionals	75 (100)
14	Thinks that it is necessary to confirm that an ADR is related to a particular drug before reporting it	14 (18.7)
15	Feels that ADR reporting forms should be kept in all wards and OP for easy access and reporting	39 (52)
16	Seen an Adverse drug reaction reporting form	71 (94.7)
17	Read articles on prevention of Adverse drug reactions	17 (22.7)
18	Seen Adverse drug reactions during Clinical postings	51 (68)
19	Reported ADRs to the ADR monitoring centres	21 (28)

Table 2 shows the grades of Knowledge, Attitude and Practice scores of the medical students regarding Pharmacovigilance.

Table 2: Grading of knowledge, attitude and practice of pharmacovigilance among undergraduate medical students.

Grade	Knowledge n (%)	Attitude n (%)	Practice n (%)
Nil	0 (0)	0 (0)	14 (18.7)
Poor	5 (6.7)	0 (0)	21 (28)
Good	47 (62.7)	8 (10.7)	17 (22.7)
Excellent	22 (29.3)	54 (72)	19 (25.3)
Outstanding	1 (.3)	13 (17.3)	4 (5.3)
Total	75 (100)	75 (100)	75 (100)

Knowledge was poor in 6.7% students. There was a strong positive attitude in all the students. But the Practice of Pharmacovigilance was inadequate in 46.7% students.

The Overall Mean score for Knowledge among the students was 6.5733 ± 1.39665 with a p value of 0.042. Final year students had the highest level of knowledge regarding Pharmacovigilance, the Mean \pm SD being 7.12 ± 1.33292 . There was a statistically significant difference between the knowledge scores of final year and

third year medical students with a p value of 0.015. The overall Mean score for attitude was 4.0667 ± 0.52847 with a p value of 0.266. Attitude towards Pharmacovigilance was however, better among the Pre final year students.

The overall Mean score for practice was 1.7067 ± 1.19428 with a p value less than 0.001. Post hoc analysis showed a significant difference between all groups with maximum difference between final year and third year medical students for Practice of Pharmacovigilance (Table 3).

According to 68% students, lack of knowledge regarding where and how to report ADRs was one of the major causes of underreporting. Lack of training in ADR reporting and lack of time due to busy schedules were other important reasons. Along with these reasons, a few opined that it could also be due to fear of legal issues.

DISCUSSION

Availability of multiple numbers of brands for drugs, lack of medication safety practices and failures in the regulatory environment of drug use often account for considerable development of adverse drug reactions. In 2012, a meta-analysis showed that 52% of ADR-related emergency hospitalizations and 45% of ADRs in inpatients were preventable.^{13,14}

Table 3: Mean scores and post hoc analysis of knowledge, attitude and practice of pharmacovigilance among different batches of undergraduate medical students.

Item	Batch	Mean±SD	P value	Batches	Mean difference between batches	P value
Knowledge score	1	7.12±1.33292	0.042*	1 and 2	0.68	0.08
	2	6.44±1.35647		1 and 3	0.96	0.015*
	3	6.16±1.37477		2 and 3	0.28	0.467
	Total	6.5733±1.39665				
Attitude score	1	3.96 ±0.53852	0.266	1 and 2	-0.24	0.111
	2	4.2 ±0.40825		1 and 3	-0.08	0.592
	3	4.04 ±0.61101		2 and 3	0.16	0.286
	Total	4.066±0.52847				
Practice score	1	2.48±0.87178	< 0.001*	1 and 2	0.6	0.032*
	2	1.88 ±1.16619		1 and 3	1.72	<0.001*
	3	0.76 ± 0.83066		2 and 3	1.12	<0.001*
	Total	1.7067±1.19428				

(Batch 1 - Final Years, Batch 2 - Prefinal years, Batch 3 - Third year students).

(* --p value <0.05)

Lack of awareness regarding the existence of PvPI can serve as an important deterrent to ADR reporting. Several studies have been done so far, to assess knowledge, attitude and practice of Pharmacovigilance among students and health care professionals. Study conducted by Sivadasan et al on nursing students in a private university of Malaysia, Het B. Upadhyaya in Gujarat on postgraduate students from different clinical departments, Meher et al on three different batches of medical students and Prathiban G et al on medical students of Puducherry, reported that students had a positive attitude but were only moderately aware of Pharmacovigilance and ADR reporting.^{6,9,11,12} However, a study conducted on 250 medical and 250 dental students by Sanjay et al reported that 72% of students had good knowledge, 80% had a positive attitude but only 60% practised Pharmacovigilance.⁵

In this study, the responses from 75 Medical students were analysed. The response rate was 100% and the mean age of the study population was 22.01±1.438 years. 62.7% of the students were females. In our study, majority of the students were aware of the term Pharmacovigilance, its definition, existence of a national programme for Pharmacovigilance and the criteria to call an ADR as a serious adverse event. Most of them also knew that all ADRs irrespective of whether they were common, serious or rare have to be reported and were aware of the existence of a Pharmacovigilance committee in their institution. However, Knowledge regarding details of International ADR monitoring centre, the regulatory authority for PvPI, when to report a Serious adverse event, who all could report an ADR and whether an ADR could be reported without relating it to a drug were lacking in many students.

Final year students had better knowledge of Pharmacovigilance when compared to Pre final years and

third year students. The mean difference in knowledge score was significant between the groups with a p value of 0.042 and the maximum difference was seen between final year and third year medical students. This difference in knowledge might be because of lack of ADR reporting exercises given to third year students. The final year students could perform better as they were given ADR reporting exercises as part of their project works and practical exercises.

There was a strong positive attitude towards Pharmacovigilance in all the students and it was maximum among Pre final year students. Majority of the students agreed that it was their duty to report ADRs. All of them wanted ADR reporting to be made mandatory as part of hospital policy and wanted training on Pharmacovigilance. In 46.7% students, the Practice of Pharmacovigilance was inadequate. However, it was better among final year students and least among third year students. There was a significant difference in the Practice scores between all the groups. As the final years and Pre final year students had reported ADRs as part of their project works, they scored better than third year students in this study.

Practice of Pharmacovigilance is important for generating a national safety database of drugs. Under-reporting of ADRs have been a major cause for poor signal detection. It is difficult to practice ADR reporting without proper knowledge and attitude towards Pharmacovigilance. Hence, it is necessary to implement different educational interventions to promote Pharmacovigilance activities in the country.

CONCLUSION

This study has shown that there is good knowledge and strong positive attitude among undergraduate Medical

students towards Pharmacovigilance. However, steps must be taken to improve Practice of Pharmacovigilance. As part of their project work, students should be encouraged to collect ADRs during their clinical postings and they should be taught the correct method of ADR reporting through the prescribed forms right from their undergraduate days. Further, regular training programmes should be conducted to promote ADR reporting culture in them. Efforts should be taken to develop a curriculum that incorporates all important aspects of Pharmacovigilance in the undergraduate and internship training periods. This will help them to understand the need for prompt Pharmacovigilance activities and deliver rational and safe clinical practice in future, thereby enhancing patient safety.

ACKNOWLEDGEMENTS

Authors are thankful to Dr. Reneega Gangadhar (Professor of Pharmacology, Sree Mookambika Institute of Medical Sciences, Tamil Nadu) for her professional guidance during the study, Dr. Kumary Jayageetha (Associate professor of Statistics, Government Medical College, Thiruvananthapuram) for her expert and invaluable guidance on the statistical aspects of the study and all the Medical students who have voluntarily participated in the study.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- World Health Organization. International Drug Monitoring: the role of National centres. Report of a WHO meeting. World Health Organ Tech Rep Ser. 1972;498:1-25.
- World Health Organization. Safety of Medicines: a guide to detecting and reporting adverse drug reactions. Geneva, Switzerland; 2002:WHO/EDM/QSM/2002.2.
- Pharmacovigilance programme in India (PvPI)- Indian Scenario. Available from: http://www.ipc.gov.in/PvPI/Pv_home.html
- Protocol of National Pharmacovigilance Programme, November 2004. CDSCO, Ministry of Health and Family Welfare, Government of India. November; 2004. Available from: <http://www.cdsc.nic.in/html/Pharmacovigilance>
- Sankar P, Khanna S, Singh DK, Lakhani P, Tutu S, Dixit RK. Knowledge, attitude and practice among medical students related to pharmacovigilance. World J Pharm Sci. 2015;3(12):2461-2.
- Sivadasan S, Sellappan M. A study on the awareness and attitude towards pharmacovigilance and adverse drug reaction reporting among nursing students in a private university, Malaysia. Int J Curr Pharm Res. 2015;7(1):84-9.
- Kumari S, Saxena A, Senthilkumar P. Evaluation of knowledge, awareness and attitude practice among nurses in pharmacovigilance at tertiary care hospital in Delhi. Jour.harmo.res. Pharm. 2015;4(1):76-86.
- Gupta SK, Nayak RP, Shivarjanani 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. Perspect Clin Res. 2015; 6(1):45-52.
- Upadhyaya HB, Vora MB, Nagar JG, Patel PB. knowledge, attitude and practices towards pharmacovigilance and adverse drug reactions in postgraduate students of tertiary care hospital in Gujarat. J Adv Pharm Technol Res. 2015;6(1):29-34.
- Radhakrishnan 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(2):678-92.
- Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of south India. Perspect Clin Res. 2015;6(4):217-21.
- Parthiban G, Nileshraj G, Mangaiarkkarasi A, Meher Ali R. A Survey on Knowledge, Attitude and Awareness of Pharmacovigilance among Medical students in a teaching hospital, Puducherry. Indian Journal of Basic and Applied Medical Research; 2015;5(1):198-203.
- Bhagavathula AS, Elnour AA, Jamshed SQ, Shehab A. Health professionals knowledge, attitudes and practices about pharmacovigilance in India: a systematic review and meta-analysis. Plos one. 2016:1-15
- Hakkarainen KM, Hedna K, Petzold M, Hagg S. Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions- a meta-analysis. PLoS One. 2012;7(3):e33236.

Cite this article as: Nair MK, Douglas R. Knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a teaching hospital of South Kerala, India. Int J Basic Clin Pharmacol 2017;6:754-8.