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A prospective questionnaire based study to assess the knowledge and attitude about pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital

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Abstract

Study background: inculcating knowledge and attitude in health professionals especially young budding doctors and other health professionals is the best way to overrule the under reporting in pharmacovigilance. Objective: To assess the knowledge and attitude about pharmacovigilance in medical students in a tertiary care hospital in Tamil Nadu. Materials and methods: It is a prospective questionnaire based study. The questionnaire containing 17 questions to evaluate knowledge and attitude among MBBS students. Results: The data were entered in MS excel sheets and analyzed using appropriate statistical method. This study shows mean score of 59.6% and 57.5% in knowledge and attitude domain of the questionnaire. Conclusion: There is improvement in knowledge and attitude in our study when compared to studies conducted in previous years by others. The inclusion of pharmacovigilance chapter in the medical undergraduate curriculum has improved knowledge and attitude among medical undergraduates. Further recent addition of syllabus to develop skills in undergraduates to interpret ADR and handling Spontaneous reporting forms in the practicals will significantly improve ADR reporting in future years.

Keywords: pharmacovigilance, under reporting, knowledge, attitude

1. Introduction

WHO defines pharmacovigilance as “the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems”. ADR is responsible for 0.2-24% of hospital admission and is one of the largest cause of mortality and morbidity^[1, 2]. It has a major influence in the health care economy.

WHO started Program for International Drug Monitoring in 1961 following Thalidomide disaster and promoted pharmacovigilance program at country level in collaboration with Centre for International Drug Monitoring, at Uppsala. It is estimated that only 6-10% of adverse drug reactions (ADRs) are reported worldwide. India is a participant in this program and is the seventh largest contributor to UMC drug safety database. National Pharmacovigilance Program initiated in India in the year 2004, renamed as Pharmacovigilance Program of India is operational since July 2010 under of Central Drug Standard Control Organization through its efficient function has improved the detection and spontaneously reporting of ADR in India from 0.5% to currently 4%.

But in India spontaneous reporting is still lacking when compared to international scenario. So a lot is to be done to increase the spontaneous reporting.

Health care professionals are the backbone of pharmacovigilance program, but under reporting of ADR is still prevalent and Gross under-reporting of ADRs is a cause for concern, the reasons for which may be lack of awareness about detection, communication and monitoring of ADRs and lack of trained staff.

Healthcare professional students if trained with adequate knowledge and skill during undergraduate training career, could play a major role in successful implementation of pharmacovigilance program^[3, 4].

Few studies carried out in different countries like U.K, France, Nigeria, China, Nepal to assess the knowledge of pharmacovigilance among the medical students, shows that lack of knowledge and awareness was the reason for under reporting in these countries^[5]. Studies conducted in South India prior to 2013 show similar results^[6, 8].

Pharmacology is drug oriented and is now taught with special emphasis on Adverse Drug Effects,

in the MBBS, dental, nursing and pharmacy course. Recently, The Tamil Nadu Dr MGR Medical University also has recommended teaching of Pharmacovigilance in theory and suggested research activities based on ADR reporting.

Therefore this study was undertaken to assess the knowledge, attitude about pharmacovigilance among undergraduate medical students in our institution.

Table 1: Response to questionnaire based on knowledge about pharmacovigilance.

	Knowledge	Correct		Incorrect	
		Response	Percentage	Response	Percentage
1	all drugs may produce adverse reactions	191	81	13	19
2	Definition of pharmacovigilance	189	88	25	12
3	In India which regulatory body is responsible for monitoring ADRs	110	51	104	49
4	Who can report incidence of an ADR	160	75	54	25
5	Existence of a National Pharmacovigilance Programme in india	163	76	5	24
6	Activities involved in pharmacovigilance programme	155	72	59	28
7	A serious adverse event in India should be reported within	104	49	110	51
8	Method commonly employed to monitor ADR in post marketing surveillance	25	12	189	88
9	Use of information generated from pharmacovigilance programme	105	49	109	51
10	Scale used to analyse ADRs	92	43	122	57

2. Aim

To assess the knowledge and attitude about Pharmacovigilance among undergraduate medical students.

3. Methodology

This study was undertaken in a tertiary care teaching hospital in Tamilnadu. It is a cross section descriptive questionnaire based study done over a period of 2 months. The questionnaire was formatted attending the aspects of knowledge and attitude about Pharmacovigilance. Out of 17 questions 12 were knowledge based and 5 were attitude based. 300 paraclinical and clinical year undergraduate medical students who were willing to participate and given written informed consent, were included in this study. The questionnaire was provided to each student and time of 30 minutes was given for answering the questionnaire. The responses were fed in excel spread sheets and results were analysed statistically.

4. Results

4.1 Demographic details

A total of 300 medical undergraduates students of paraclinical and clinical years were involved in this study.

Response rate:

Out of 300 undergraduate medical students 214 responded to the questionnaire and returned the filled questionnaire.

4.2 Knowledge

81% of medical students were aware that ‘all’ drugs ‘may’ produce adverse effects. 75% of the medical knew that ADRs can be reported by doctors, nurses and also pharmacists. 88% of medical undergraduates are able to define pharmacovigilance correctly.

49% and 20% of medical students knew that serious ADRs must be reported within 14 calender days. 12% have adequate knowlege regarding the methods commonly employed to maintain ADR in post marketing surveillance period. 43 % medical students based on the questions with respect to the naranjo and WHO scales used in causality analysis have knowledge on ADR reorting process

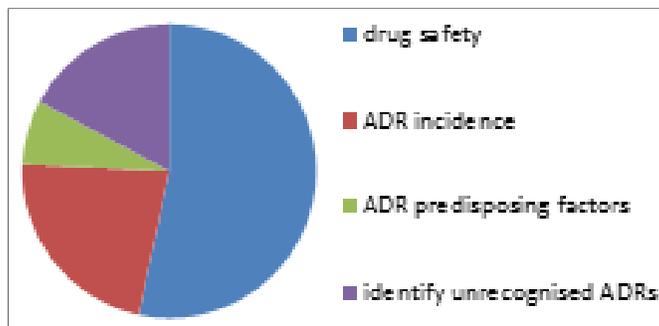


Fig 1: Knowledge on Purpose of Pharmacovigilance

Assessment of knowledge in national pharmacovigilance programme in india shows that 76% of medical students were aware of the existence of PVPI. Further, analysis of knowledge regarding the activies taking place in pharmacovigilance programme 72% of medical students were aware 0.49% medical students knew the use of information generated from PVPI. 17% of medical students were able to know the purpose of PVPI.

4.3 Attitude

43% of medical students acknowledge that creating ADR

database by reporting all Adverse drug effects is a professional obligation. 68% of medical students were willing to report any ADR they come across thereafter. 83% of medical students opine that pharmacovigilance should be taught in detail to health care students.

In response to the question regarding the factor that may discourage them from ADR reporting, 42% opted for lack of time, followed by 35% who felt a single unreported ADR may not affect the national ADR database, 13% responded for difficulty in identifying ADR and 0.5% for lack of incentive.

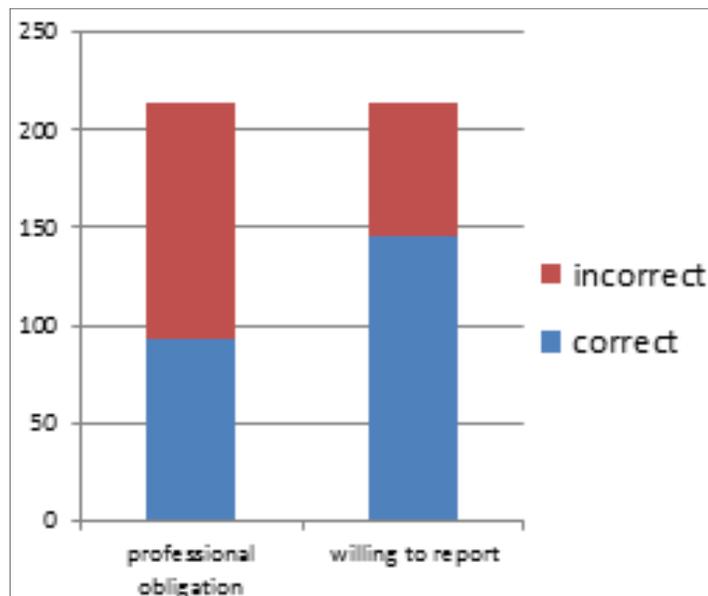


Fig 2: Attitude towards Pharmacovigilance

5. Discussion

In our study Mean score of the knowledge domain questions was 59.6% among medical students. Sufficient theoretical knowledge regarding adverse drug reactions and definition of pharmacovigilance was present. This is superior to the report of similar studies^[6, 8]

Medical students possess adequate theoretical knowledge regarding ADR reporting, who all can report ADR and where it is to be reported, but have only fair knowledge about the time period within which a serious ADR to be reported. This correlates with studies conducted among health care students in South India^[7].

On analyzing the knowledge of medical students about national pharmacovigilance programme in India, majority are aware of existence of PVPI, CDSCO, purpose and activities taking place in the PVPI, with moderate knowledge about the use of information generated from PVPI.

Medical students have only average awareness about the spontaneous reporting form of ADR and scales used in causality analysis of ADR. When compared to similar studies the knowledge possessed by the students is uniformly similar^[8].

Mean score for attitude domain questions in our study was 65% among medical students. Medical students have good attitude to report ADR and have opined that pharmacovigilance should be taught in detail to health care students. This attitude and opinion among medical students is similar when compared with other studies.

In response to the question regarding the factor that may discourage them from ADR reporting, majority opted for lack of time. Very meager students opined lack of incentive as a factor.

Because of the active implementation of pharmacovigilance programme in tertiary care hospitals and inclusion of syllabus about pharmacovigilance, ADR reporting and monitoring in the medical curriculum, knowledge and attitude has increased among the medical students. When all the medical and paramedical undergraduates are given proper and regular continuing education, awareness and participation in reporting will improve further. The same is suggested by studies conducted among dental, nursing and pharmacy students^[6, 8].

6. Conclusion

In conclusion this study shows good knowledge and attitude regarding Pharmacovigilance, ADR monitoring and reporting in this tertiary care teaching hospital. Our study shows enhanced knowledge and attitude among undergraduate medical students when compared to similar KAP studies done among undergraduate students in South India conducted before 2013. This enhancement is mainly because of the inclusion of pharmacovigilance in the syllabus of Pharmacology. The previous studies also suggested the same to improve the knowledge, attitude and practice of ADR reporting. Our university, as per MCI recommendations, has now suggested teaching methodologies to develop the ability to interpret simple aspects on adverse drug reaction monitoring using uniform Spontaneous ADR reporting form and to motivate research activities in pharmacovigilance (from current academic year 2017-18), so that the students can be trained with uniform spontaneous ADR reporting form and feedback form. This hands-on training, in addition to their enhanced knowledge and attitude, will definitely improve the practice of ADR reporting among young budding doctors in near future.

Since ADR reporting can be done by Doctors, Dentists, Nurses and Pharmacist, training can be given to the dental, nursing and pharmacy students also.

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