Original Article

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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

Abstract

Objectives: Spontaneous reporting of adverse drug reaction (ADR) is the backbone of pharmacovigilance program. Under reporting by prescribers is still exist. This study was done to assess the knowledge, attitude, and practice (KAP) of undergraduate students about pharmacovigilance. **Materials and Methods:** It was a questionnaire-based cross-sectional study. Study tool was a validated questionnaire containing 21 questions to evaluate KAP of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. **Results:** All data were analyzed by using Microsoft Excel sheet, Chi-square, and ANOVA. The mean score of final, prefinal, and 2nd year students is respectively (4.76, 5.63, and 4.73) for knowledge, (4.26, 4.95, and 4.53) for attitude and (1.66, 1.55, and 1.28) for the practice. There is a significant difference in mean score between three groups for knowledge and attitude, but not for practice. They have a better attitude, but poor in knowledge and practice regarding pharmacovigilance. **Conclusion:** Students lack adequate knowledge and skill of reporting ADR, but they have a positive attitude toward pharmacovigilance program. The integration of pharmacovigilance with undergraduate curriculum may help in improving ADR monitoring and reporting.

Key words: Adverse drug reporting, pharmacovigilance, undergraduate

INTRODUCTION

Drug therapy is an integral part of the medical management. It has many beneficial effects, but side-effects and adverse drug reactions (ADRs) are some of its major disadvantages. ADR is defined by World Health Organization (WHO) as "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function".[1] ADR is responsible for significant morbidity and mortality; it is fourth to sixth leading cause of death in USA.[2] Studies suggested that ADR is responsible for 0.2-24% of hospital admission.[3,4] ADR also has a significant impact on health care cost.[5] Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems".[6] To promote drug safety WHO started Program for International Drug Monitoring in 1961 and subsequent to that it promoted pharmacovigilance program at country level in collaboration with Center for International Drug Monitoring, Uppsala.[7]

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To detect and spontaneously report ADR and to ensure drug safety, National Pharmacovigilance Program was initiated in India in the year 2004.[8] It is now renamed as Pharmacovigilance Program of India and operational since July 2010 under the aegis of Central Drug Standard Control Organization.[9]

The Uppsala Monitoring Centre (UMC), Sweden maintains the international database of ADR report received from different countries. India is an active participant in this program and its contribution to UMC database has rose from 0.5% in 2012 to 2% in 2013 making it seventh largest contributor of UMC drug safety database.[10] Although it has shown some improvement, but still lot is required to be done to increase the spontaneous reporting. Spontaneous reporting of ADR by health care professionals is backbone of pharmacovigilance program, but under reporting of ADR is still prevalent and is the cause of concern. Study showed that only 6-10% of all ADR cases are reported. Health care professional has a major role in pharmacovigilance program.[11] ADR reporting does not currently appear to be considered part of routine professional practice by health care professionals. This is essentially due to the absence of a vibrant and active ADR monitoring system and also lack of a reporting culture among health care professionals.[12-14] Medical students could play a major role and bring a paradigm shift in successful implementation of pharmacovigilance program if adequate knowledge and skill are imparted to them during undergraduate training career, but at present they don't have any significant role which is due to inadequate training to them regarding ADR reporting.[15,16] Very few studies are there to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among undergraduate medical students. Hence, this study has been done to assess of KAP among medical students about same and to compare the result among different groups according to year of study.

MATERIALS AND METHODS

It was a cross-sectional questionnaire-based study carried out in a Tertiary Care Teaching Hospital and Medical College in Puducherry. One hundred and eighty undergraduate MBBS students, 60 from each batch attending clinical posting and willing to participate and gave written informed consent were included in the study. A KAP questionnaire was designed by following preceding studies.[17,18] Questionnaire was pretested in a small group of students by doing a pilot study. Modified questionnaire was given to participants. The questionnaire contains 21 questions, 10 to test knowledge, seven to test the attitude, four to test practice. Study was initiated after obtaining clearance from the Institutional Ethics Committee. The study involved 2nd year, prefinal year, and final year undergraduate medical students. The questionnaire was handed to the students after explaining the purpose of the study. Any doubts regarding questionnaire were clarified by investigator. 25 min was given for filling the questionnaire. A score of 1 was allocated for each correct answer or positive response and score 0 was allocated for wrong, unattempted answer, or negative response. Maximum possible score was 10, 7 and 4 for KAP, respectively. Mean Score of <50%, 50-69%, and 70% or above of maximum possible score were considered as poor, average, and good performance, respectively. Data were compiled, entered in Microsoft Excel sheet by using SPSS version 19 and analyzed by descriptive statistics, Chi-square and ANOVA test.

RESULTS

There were 10 knowledge-based questions. Among the respondents 61% of final year, 80% of prefinal year and 61.67% of 2nd year student responded correctly to the definition of ADR ($P < 0.05$). 41. 67% of final year, 55% of prefinal year, and 56.67% of 2nd year students were aware about locality of National Pharmacovigilance Center. Thirty-eight percent, 44% and 40% of final, prefinal and 2nd year students knew who can report ADR. Thirty percent of final, 41% of prefinal and 22% of 2nd year student know the definition of pharmacovigilance ($P < 0.05$). The details regarding the responses of the medical students for knowledge based questions are listed in Table 1. Mean knowledge score of prefinal year students is more than final and 2nd year student. Difference in knowledge score among three groups is statistically significant as shown in Table 4 and Figure 1.

Total number of questions to test the attitude was seven. Ninety-five percent, 88%, 91% final, prefinal, and 2nd year student, respectively felt ADR reporting is necessary. Students thought it relevant to have a discussion on pharmacovigilance in clinical posting. The details regarding the responses of the medical students for knowledge-based questions are listed in Table 2. Mean score of attitude between three groups is respectively, and difference in score among them is statistically significant as depicted in Table 4 and Figure 2.

There were four practice related questions. It was seen that only 18.13% students of final, 12.5% of prefinal and 5% students of 2nd year ever played any role in reporting ADR. About 80%, 63.3% and 85% of final, prefinal and 2nd year students, respectively updating their knowledge about new drug regularly ($P < 0.05$). The details regarding the responses of the healthcare professionals for these questions are listed in Table 3. Difference in mean practice

score among three groups is not statistically significant as shown in Table 4 and Figure 3.

DISCUSSION

Pharmacovigilance is an integral part of holistic health care. It helps in detection and prevention of ADR of medicinal products. Spontaneous reporting of ADR is vital for the success of pharmacovigialnce program. There are innumerable studies to evaluate the KAP of health care providers toward pharmacovigilance program, but a very few study have been done among the budding doctors to capture their knowledge about same.[13,14,17] This study is one of the few studies done among undergraduate medical students regarding KAP of pharmacovigilance.

In this study, most students have an average or poor score in KAP. Among them, prefinal year students have a relatively better score than final and 2nd year students. From this study, it was clear that students have inadequate knowledge about pharmacovigilance, which corroborates with the finding of Vora *et al*.[16] The aim of pharmacovigilance is to ensure patient safety and rational use of medicines. It has played a major role in detection of ADRs, but previous studies suggests that under-reporting of ADRs is one of the major problems associated with pharmacovigilance program.[19] Major reason for under reporting is lack of knowledge and skill about pharmacovigilance program, which was reflected in our study, and it corroborates with the finding of studies done previously.[20,21] It can be overcome by educational intervention program like incorporation of it in undergraduate practical, continuous medical

Table 1: Response of students to knowledge-based questions

Questions	Number (%) of students responded correctly			*P* value
	Final year	Prefinal year	Second year	
Knowledge-based questions				
Define ADR	37 (61.67)	48 (80)	37 (61.67)	<0.05
Are adverse drug event and ADR same?	48 (80)	45 (75)	44 (73.33)	>0.05
Who can report ADR?	38 (68.33)	44 (73.33)	40 (66.67)	>0.05
Is ADR reporting mandatory?	6 (10)	16 (26.67)	6 (10)	<0.05
What is pharmacovigilance?	30 (50)	41 (68.33)	22 (36.67)	<0.05
Which method is commonly used for causality assessment of ADR?	23 (38.33)	26 (43.33)	17 (28.33)	>0.05
What does PvPI stand for?	41 (68.33)	41 (68.33)	42 (70)	>0.05
Where is national pharmacovigilance center in India located?	25 (41.67)	33 (55)	34 (56.67)	>0.05
Expand the acronym CDSCO	17 (28.33)	20 (33.33)	19 (31.67)	>0.05
Where is UMC located?	34 (56.67)	26 (43.33)	23 (38.33)	>0.05

ADR=Adverse drug reaction, PvPI=Pharmacovigilance programme of India, CDSCO=Central Drugs Standard Control Organization, UMC=Uppsala Monitoring Centre

Table 2: Response of students to attitude based questions

Questions	Number (%) of students responded correctly (year)			*P* value
	Final	Prefinal	Second	
Attitude based questions				
What do you think about ADR reporting? Is it necessary or a waste of time?	57 (95)	56 (93.33)	59 (98.33)	>0.05
Do you think ADR reporting benefits both patients and doctors?	53 (88.33)	54 (90)	50 (83.33)	>0.05
Should ADR reporting be included under Pharmacology practical?	51 (85)	54 (90)	55 (91.67)	>0.05
Do you think ADR reporting is a part of professional obligation of all related to health care?	8 (13.33)	23 (38.33)	12 (20)	<0.05
Do you think medical students could play a role in ADR reporting?	33 (55)	34 (56.67)	29 (48.33)	>0.05
Do you think discussion on ADR during clinical posting has any relevance?	6 (10)	23 (38.33)	11 (18.33)	<0.05
Do you think collecting box at all clinical departments is helpful for proper reporting?	48 (80)	51 (85)	51 (85)	>0.05

ADR=Adverse drug reaction

Table 3: Response of students to practice based questions

Questions	Number (%) of students responded correctly			*P* value
	Final year	Prefinal year	Second year	
Practice based questions				
Have you seen an adverse drug reporting form by CDSCO?	37 (61.67)	36 (60)	32 (53.33)	>0.05
Have you ever seen a case of ADR during your ward posting?	48 (80)	38 (63.33)	51 (85)	<0.05
Have you ever played any role in reporting ADR from your institution?	11 (18.33)	6 (10)	3 (5)	>0.05
Have you ever visited any ADR monitoring center?	2 (3.33)	9 (15)	6 (10)	>0.05

ADR = Adverse drug reaction, CDSCO = Central Drugs Standard Control Organization

Table 4: Comparison of mean score

Year of study	Final year (*n*=60)	Prefinal year (*n*=60)	Second year (*n*=60)	*P* value
Knowledge (maximum=10)	4.76±1.57*	5.63±1.79*	4.73±1.74*	*P*<0.05 *F*=4.52
Attitude (maximum=7)	4.26±0.79*	4.95±1.34*	4.53±1.06*	*P*<0.05 *F*=6.15
Practice (maximum=4)	1.66±0.79	1.45±1.21	1.53±0.73	*P*>0.05 *F*=0.77

*P<0.05 and difference in mean score of different groups are significant

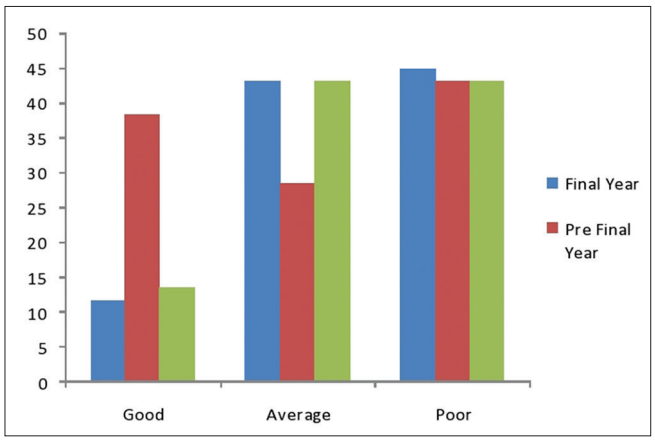

Figure 1: Knowledge score

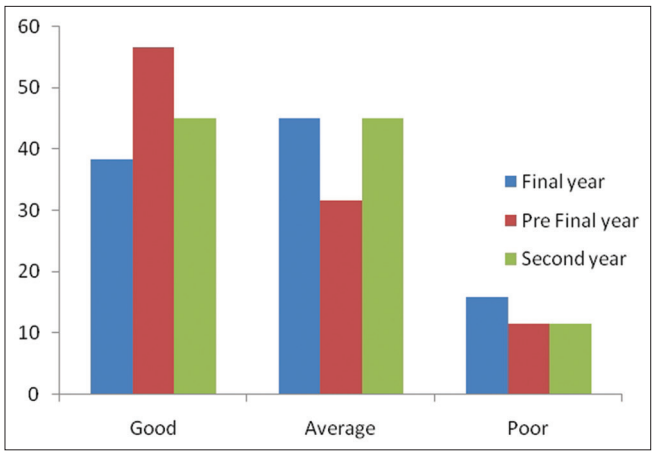

Figure 2: Attitude Score

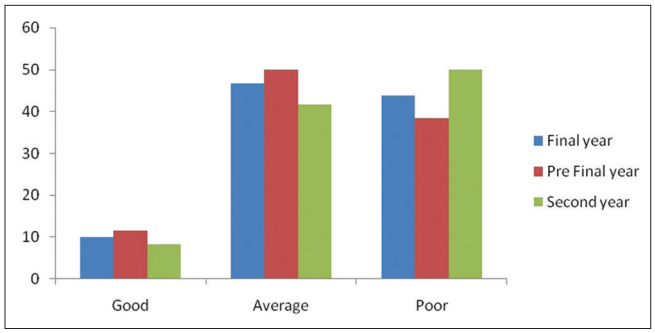

Figure 3: Practice Score

education (CME), and workshop on pharmacovigilance.[22] Students showed better attitude, but limited knowledge and poor practice toward pharmacovigilance. The findings of the study suggest a huge scope for improving the awareness and knowledge about pharmacovigilance among the students who will be the backbone of health care delivery in future. For this, there is a need for continuous educational initiatives like CME, and it should also be included in their curriculum as part of their study.

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