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ORIGINAL RESEARCH

Practice attitude and knowledge of pharmacovigilance in Indian undergraduate medical students - a questionnaire-based assessment

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ABSTRACT

Background: Reporting for ADRs (adverse drug reactions) forms the basic structural unit in the pharmacovigilance program. It has been reported that undergraduate medical students in India have underreported pharmacovigilance. **Aim:** The present study, using a questionnaire, aimed to assess the practice, attitude, and knowledge of pharmacovigilance in Indian undergraduate medical students. **Methods:** The present study utilized a cross-sectional questionnaire-based design and the questionnaire used in the study comprised 21 questions for evaluation of KAP (knowledge, attitude, and practice of undergraduate students concerning pharmacovigilance. **Results:** The study results showed that mean KAP scores for 2nd years, prefinal, and final-year students were 4.71, 5.61, and 4.74 respectively for knowledge, 4.24, 4.93, and 4.51 for attitude, and 1.64, 1.53, and 1.26 for practice. Also, a significant difference was seen in an intergroup comparison of mean scores in three groups for attitude and knowledge. However, a non-significant difference was seen for practice. Students showed a better attitude, but poor practice and knowledge of pharmacovigilance. **Conclusion:** The present study concludes that undergraduate Indian medical students lack adequate skill and knowledge for reporting adverse drug reactions, however, they have a positive attitude concerning the pharmacovigilance program. Integration of undergraduate curriculum with pharmacovigilance can help in the improvement of reporting and monitoring of ADRs.

Keywords: Adverse drug reporting, ADRs, medical students, pharmacovigilance, undergraduate

INTRODUCTION

Drug therapy forms a structural and functional unit for medical management. It can be advantageous, however, ADRs (adverse drug reactions) and side effects constitute its major drawbacks. By definition, 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 the modification of physiological function". ADR leads to significant mortality and morbidity with 4th to 6th leading mortality cause in the USA and 0.2-24% hospital admission globally. ADR also poses a significant impact on costs associated with oral health care.[1]

Following WHO (World Health Organization), pharmacovigilance is defined as “the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems”. For drug safety promotion, the WHO initiated the Program for International Drug Monitoring in 1961 and further promoted the pharmacovigilance program at the National level in collaboration with the Center for International Drug Monitoring, Uppsala. In India, National Pharmacovigilance started in 2004 for the detection

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and spontaneous reporting of ADR to ensure drug safety. This National program is now renamed as Pharmacovigilance Program of India which has been in function since 2010 under the Central Drug Standard Control Organization.[2]

The UMC (Uppsala Monitoring Centre) from Sweden has maintained an international ADR database from various countries where India participates actively in this program and the contribution of India has risen from 0.5% to 2% from 2012 to 2013 with India being 7th largest contributor to UMC drug safety database. However, some improvement has been reported and still major work is needed to increase spontaneous ADR reporting. Spontaneous ADR reporting from a functional unit of the pharmacovigilance program. It has been reported that there has been under reporting of pharmacovigilance in undergraduate medical students of India.[3]

Presently, ADR reporting is not considered routine professional practice by healthcare professionals. This is particularly owing to the absence of an active and vibrant ADR monitoring system and the lack of a reporting culture among healthcare professionals. Medical students play a vital role and cause a paradigm shift for successful pharmacovigilance program implementation if adequate skill and knowledge are imparted during undergraduate training career, but have no significant role presently owing to inadequate training concerning ADR reporting. Existing literature data is scarce concerning the assessment of KAP (knowledge, attitude, and practice) of pharmacovigilance in undergraduate Indian medical students.[4] Hence, the present study aimed to assess the practice, attitude, and knowledge of pharmacovigilance in Indian undergraduate medical students utilizing a questionnaire.

MATERIALS AND METHODS

The present study questionnaire-based cross-sectional study aimed to assess the practice, attitude, and knowledge of pharmacovigilance in Indian undergraduate medical students utilizing a questionnaire.The study subjects were from the Outpatient Department of the Institute. Verbal and written informed consent were taken from all the subjects before study participation.

The study included 360 undergraduate medical students from the Institute with 120 students from each batch that attended the clinical postings and were willing to participate in the present study. For the study, a KAP questionnaire was formed and designed considering the preceding studies including Palaian S et al in 2011 and Angamo MT et al in 2012.

The questionnaire utilized was resented in small groups of students. To all the participants, a modified questionnaire was given. The questionnaire comprised 21 questions where 10 questions were aimed at assessing the knowledge, 4 to test practice, and 7 to assess the attitude.

The study included 2nd year, prefinal, and final-year undergraduate medical students. The questionnaire was given to all the students after telling them about the study's purpose. The primary investigator clarified any doubt concerning the questionnaire before starting the questionnaire. Each participant was allotted 25 minutes to fill out the questionnaire. For each correct answer and positive response, a score of 1 was allotted, and 0 score for negative, unattempted, or wrong response. Maximum possible scoring was 10, 4, and 7 respectively for KAP. Mean scores of <50%, 50-69%, and 70% or higher were seen for maximum possible scores considered as good, average, and poor performance respectively.

The gathered were analyzed statistically using the chi-square test, Fisher’s exact test, Mann Whitney U test, and SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk. NY, USA) using ANOVA and student's t-test. The significance level was considered at a p-value of <0.05.

RESULTS

The present study questionnaire-based cross-sectional study aimed to assess the practice, attitude, and knowledge of pharmacovigilance in Indian undergraduate medical students utilizing a questionnaire.The present study utilized a cross-sectional questionnaire-based design and the questionnaire used in the study comprised 21 questions for evaluation of KAP (knowledge, attitude, and practice of undergraduate students concerning pharmacovigilance. For a response of study subjects to knowledge questions from the questionnaire, ADR definition was known in 61.67% (n=74), 80% (n=96), and 61.67% (n=74) students from 2nd, prefinal, and final years respectively showing the statistically significant difference with $p<0.05$. Concerning UMC location, expansion of acronym CDSCO, National Pharmacovigilance India center location,PvPI full form, commonly used casualty ADR assessment, who can report ADR, and are ADR and adverse drug events same, the results were statistically non-significant in the final, prefinal, and second-year students with $p>0.05$. For knowledge of pharmacovigilance and if reporting ADR is mandatory, significantly higher knowledge was seen for prefinal and final year students compared to second-year students with $p<0.05$ (Table 1).

On assessing the response of study subjects to attitude questions from the questionnaire, a non-significant difference was seen for the collection box at clinical departments helpful in reporting ADR, Should ADR reporting be included in pharmacology practice, ADR reporting benefits both patients and clinicians, and ADR reporting-necessary or waste a non-significant difference was seen in the final, prefinal, and second-year students with $p>0.05$. However, for ADR discussion in clinical posting to have relevance, medical students have a role in reporting ADR, and

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ADR reporting in the professional obligation part was significantly higher in the prefinal year than final and second year which was significant with p<0.05 (Table 2).

The study results showed that for the response of study subjects to practice questions from the questionnaire, a non-significant difference was seen forever visited any ADR monitoring center, ever played any role in ADR reporting from the Institute, and never seen any adverse drug reporting form by CDSCO, a non-significant significant difference was seen in final, prefinal, and second-year students with p>0.05. However, forever seen an ADR case during ward posting, the significantly higher practice was reported by final year and prefinal year students compared to second-year students with p<0.05 (Table 3).

It was seen that for comparison of mean scores in undergraduate Indian medical students, mean practice scores were comparable in second, prefinal, and final year students with p>0.05. For attitude, significantly higher mean scores were seen for prefinal-year students followed by second-year and final-year students with p<0.05. For knowledge, significantly higher mean scores were seen for pre-final year students followed by final-year and second-year students with p<0.05 (Table 4).

Table 1: Response of study subjects to knowledge questions from the questionnaire

S. No	Questions	Final year		Prefinal year		Second year		p-value
		n	%	n	%	n	%	
1.	**ADR definition**	74	61.67	96	80	74	61.67	**<0.05**
2.	**UMC location**	68	56.67	52	43.33	46	38.33	>0.05
3.	**Acronym CDSCO expansion**	34	28.33	40	33.33	38	31.67	>0.05
4.	**National Pharmacovigilance India center location**	50	41.67	66	55	68	56.67	>0.05
5.	**PvPI full form**	82	68.33	82	68.33	84	70	>0.05
6.	**Commonly used casualty ADR assessment**	46	38.33	52	43.33	34	28.33	>0.05
7.	**Pharmacovigilance**	60	50	82	68.33	44	36.67	**<0.05**
8.	**Is reporting ADR mandatory**	12	10	32	26.67	12	10	**<0.05**
9.	**Who can report ADR**	76	68.33	88	73.33	80	66.67	>0.05
10.	**Are ADR and adverse drug events the same**	96	80	90	75	88	73.33	>0.05

Table 2: Response of study subjects to attitude questions from the questionnaire

S. No	Questions	Final year		Prefinal year		Second year		p-value
		n	%	n	%	n	%	
1.	**Collection boxes at clinical departments help report ADR**	96	80	102	85	102	85	>0.05
2.	**ADR discussion in clinical posting has relevance**	12	10	46	38.33	22	18.33	**<0.05**
3.	**Medical students have a role in reporting ADR**	66	55	68	56.67	58	48.33	**>0.05**
4.	**ADR reporting is a professional obligation part**	16	13.33	46	38.33	24	20	**<0.05**
5.	**Should ADR reporting be included in pharmacology practice**	102	85	108	90	110	91.67	>0.05
6.	**ADR reporting benefits both patients and clinicians**	106	88.33	108	90	100	83.33	>0.05
7.	**ADR reporting-necessary or waste**	114	95	112	93.33	118	98.33	>0.05

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Table 3: Response of study subjects to practice questions from the questionnaire

S. No	Questions	Final year		Prefinal year		Second year		p-value
		n	%	n	%	n	%	
1.	**Ever visited any ADR monitoring center**	4	3.33	18	15	12	10	>0.05
2.	**Ever played any role in ADR reporting from the Institute**	22	18.33	12	10	6	5	>0.05
3.	**Ever seen an ADR case during ward posting**	96	80	76	63.33	102	85	**<0.05**
4.	**Ever seen any adverse drug reporting form by CDSCO**	74	61.67	72	60	64	53.33	>0.05

Table 4: Comparison of mean scores in undergraduate Indian medical students

S. No	Study year	Second year (n=120)	Prefinal year (n=120)	Final year (n=120)	p-value
1.	**Practice (maximum=4)**	1.51±0.71	1.43±1.19	1.64±0.77	>0.05
2.	**Attitude (maximum=7)**	4.51±1.04	4.93±1.32	4.24±0.77	**<0.05**
3.	**Knowledge (maximum=10)**	4.71±1.72	5.61±1.77	4.74±1.55	**<0.05**

DISCUSSION

The present study utilized a cross-sectional questionnaire-based design and the questionnaire used in the study comprised 21 questions for evaluation of KAP (knowledge, attitude, and practice of undergraduate students concerning pharmacovigilance. For a response of study subjects to knowledge questions from the questionnaire, ADR definition was known in 61.67% (n=74), 80% (n=96), and 61.67% (n=74) students from 2nd, prefinal, and final years respectively showing the statistically significant difference with p<0.05. Concerning UMC location, expansion of acronym CDSCO, National Pharmacovigilance India center location,PvPI full form, commonly used casualty ADR assessment, who can report ADR, and are ADR and adverse drug events same, the results were statistically non-significant in the final, prefinal, and second-year students with p>0.05. For knowledge of pharmacovigilance and if reporting ADR is mandatory, significantly higher knowledge was seen for prefinal and final year students compared to second-year students with p<0.05. These data were comparable to the studies of Meher BR et al[5] in 2015 and Subish P et al[6] in 2010 where authors assessed similar results for knowledge in study subjects concerning pharmacovigilance in their study subjects as seen in the present study.

The study results showed that on assessing the response of study subjects to attitude questions from the questionnaire, a non-significant difference was seen for the collection box at clinical departments helpful in reporting ADR, Should ADR reporting be included in pharmacology practice, ADR reporting benefits both patients and clinicians, and ADR reporting-necessary or waste a non-significant difference was seen in the final, prefinal, and second-year students with p>0.05. However, for ADR discussion in clinical posting to have relevance, medical students have a role in reporting ADR, and ADR reporting in the professional obligation part was significantly higher in the prefinal year than final and second year which was significant with p<0.05. These results were consistent with the findings of Radhakrishnan R et al[7] in 2011 and Li Q et al[8] in 2004 where the response of study subjects to attitude questions in pharmacovigilance similar to the present study were also reported by the authors in their respective studies.

It was seen that for the response of study subjects to practice questions from the questionnaire, a non-significant difference was seen forever visited any ADR monitoring center, ever played any role in ADR reporting from the Institute, and never seen any adverse drug reporting form by CDSCO, a non-significant significant difference was seen in the final, prefinal, and second-year students with p>0.05. However, forever seen an ADR case during ward posting, the significantly higher practice was reported by final year and prefinal year students compared to second-year students with p<0.05. These findings were in agreement with the results ofChatterjee S et al[9] in 2006 and Angamo MT et al[10] in 2012 where the response of study subjects to practice questions from pharmacovigilance reported by the authors in their studies were comparable to the results of the present study.

The study results also showed that for comparison of mean scores in undergraduate Indian medical students, mean practice scores were comparable in second, prefinal, and final year students with p>0.05. For attitude, significantly higher mean scores were seen for prefinal-year students followed by second-year and final-year students with p<0.05. For knowledge, significantly higher mean scores were seen for pre-final year students followed by final-year

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and second-year students with $p<0.05$. These results were in line with the findings of Rehan HS et al[11] in 2002 and Desai CK et al[12] in 2011 where a comparison of mean scores in undergraduate Indian medical students for knowledge, attitude, and practice similar to the present study were also reported by the authors in their respective studies.

CONCLUSION

Within its limitations, the present study concludes that undergraduate Indian medical students lack adequate skill and knowledge for reporting adverse drug reactions, however, they have a positive attitude concerning the pharmacovigilance program. Integration of undergraduate curriculum with pharmacovigilance can help in the improvement of reporting and monitoring of ADRs.

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