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Original Research Article

Assessment of knowledge, attitude, and practice of pharmacovigilance amongst undergraduate students at a tertiary care teaching hospital: a questionnaire-based study

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ABSTRACT

Background: Pharmacovigilance ensures patient safety and rational medication use. Spontaneous reporting by healthcare professionals is crucial, but underreporting is a major limitation. Education and training are vital to improve Adverse Drug Reaction (ADR) reporting. Inculcating pharmacovigilance into undergraduate programs empowers medical students to report ADRs.

Methods: This prospective questionnaire-based study focused on assessing knowledge, attitude, and practice (KAP) regarding pharmacovigilance. A total of 223 medical undergraduate students of which 156 were students in 2nd year and 67 in 3rd final years who gave their consent were included in this study. Participants completed a pre-questionnaire before undergoing a training session on pharmacovigilance related to KAP. Following the training session, a post-questionnaire was given. Pre- and post-test questionnaires were compared and analysed using an appropriate statistical test.

Results: The study showed that knowledge and attitude scores among second and third-year medical students improved after the training program. Following training, the mean knowledge score for second-year students significantly increased from 5.56 to 8.6, while their mean attitude score increased from 5.9 to 7.24. Similarly, for third-final-year students, the mean knowledge score improved from 6.62 to 9.01, and the mean attitude score increased from 6.69 to 7.52. The results clearly showed that the training program had a positive impact on the knowledge and attitude of both student groups. The mean practice scores for second-year and third-final-year students were 0.76 and 1.34, respectively.

Conclusions: The study showed significant improvement in knowledge and attitude after the educational intervention, indicating a positive impact of the training program.

Keywords: Adverse drug reaction, KAP, Pharmacovigilance, Undergraduate medical students

INTRODUCTION

Drug therapy is essential in medical management, offering many benefits but also posing risks such as side effects and adverse drug reactions (ADRs). According to the World Health Organization (WHO), an ADR is “a response to a drug that is noxious, unintended, undesired and which occurs at doses normally used in humans for prophylaxis, diagnosis, therapy of disease or the modification of physiological function”.¹ ADRs are a significant health

issue, ranking among the top 10 causes of patient mortality worldwide.² ADRs are significant cause of hospitalisation worldwide.³

Pharmacovigilance is crucial for ensuring patient safety and the proper use of medicines.^{4,5} According to the WHO, pharmacovigilance is defined as “the science relating to the detection, assessment, understanding, and prevention of adverse effects, particularly long- and short-term side effects of medicines.”⁶ India contributes to the

international ADR reporting centre through the Pharmacovigilance Program of India (PVPI) which runs under authority of the Central Drug Standard Control Organization (CDSCO).⁷ Spontaneous reporting by healthcare professionals is an important part of this program while underreporting remains a significant issue.⁸ The rate of ADR reporting by India is below 1%.⁹ Education and training are the most crucial ways of improving ADR reporting.¹⁰

To improve reporting rates, it is crucial to enhance healthcare professionals' knowledge, attitude, and practice about ADR reporting and pharmacovigilance, especially undergraduate medical students who are future healthcare professionals. Medical students could significantly contribute to the successful implementation of pharmacovigilance program if they receive adequate training during their undergraduate studies. With this background, a study was planned to assess the knowledge, attitude, and practice about pharmacovigilance among undergraduate medical students at a tertiary care teaching hospital. This study aimed to assess the knowledge, attitude, and practice (KAP) about pharmacovigilance among undergraduate medical students. The objectives of this study were 1) To evaluate medical undergraduate student's knowledge, attitude, and practice about pharmacovigilance (PV); 2) To assess the effect of educational intervention among medical undergraduates regarding knowledge and attitudes about pharmacovigilance.

METHODS

This was a prospective questionnaire-based comparative study conducted in the department of pharmacology at a tertiary care teaching hospital. The permission from the Institutional Ethics Committee (IEC) of the institution was obtained before starting the study. This study conducted for 6 months.

Inclusion criteria

All second-year medical students and students in their final year (who chosen pharmacology as one of their electives) were included.

Exclusion criteria

Medical students who refused to provide their consent were excluded.

Sampling technique

Purposive sampling was used in this study.

Study instrument

Data was collected using the questionnaire. The questionnaire included the student's personal information and signature, title of the study, appropriate instructions,

and 24 questions about pharmacovigilance, of which 10 were about knowledge, 8 about attitude, and 6 about practice. For all questions, correct or positive responses were given one point, while incorrect or unattempted answers were given zero points. A prequestionnaire was given to all students, and 15 minutes was allowed to complete the questionnaire. An education training session of 2 hrs on pharmacovigilance was arranged regarding KAP. This educational intervention included a theoretical PowerPoint presentation about pharmacovigilance which includes: when to report, who can report, what to report, how to report, where to report ADRs, and problems in reporting ADRs.

And the role of health-care professionals in reporting suspected ADRs, followed by what happens to reported ADRs. After this session, a post-questionnaire was given to participants. The pre-and post-test questionnaires were analysed by an appropriate statistical test.

Sample size

This study included all 2nd-year MBBS students and students in their 3rd final year who chosen pharmacology in their electives at a tertiary care teaching hospital.

Statistical analysis

The pre-questionnaire and post-questionnaire data were assessed using Microsoft Excel to compare the difference of 223 positive responses for each question and a paired t-test was applied. The statistical significance level was set at $p < 0.05$. Only questions related to knowledge were assessed using a scoring system, the maximum score being 10, and the minimum being 0. More than one answer was not acceptable.

RESULTS

Total 223 medical undergraduate students participated in our study out of which 156 students were of second year and 67 were of third final year. The mean age of students was 20.33 ± 1.19 years, 93 were male, and 130 were female.

There were 10 knowledge-based questions. Students from second year (32.05 %), and third final year (47.76%) were aware of the definition of pharmacovigilance before training and after training response increased by 80.13%, and 97.01% respectively (Table 1). Education training significantly improved the knowledge of both second-year and third-final-year MBBS students in most areas of pharmacovigilance (Figure 1). Thus, the understanding about pharmacovigilance, the role of government regulatory bodies, the location of the International Collaborating Centre for ADR monitoring, and the use of Vigiflow saw substantial improvements. However, the question about the most important purpose of pharmacovigilance showed no improvement in third final year students in comparison to second year students (Table 1).

Table 1: Response to knowledge-based questions.

Knowledge-based questions	No (%) of students responded correctly			
	Second year MBBS (n=156)		Third final year MBBS (n=67)	
	Before training	After training	Before training	After training
Pharmacovigilance is	50 (32.05)	125 (80.13)	32 (47.76)	65 (97.01)
Which is the most important purpose of pharmacovigilance?	36 (23.07)	46 (29.48)	26 (38.80)	22 (32.83)
Government regulatory body involved in drug safety issues in India.	54 (34.61)	118 (75.64)	50 (74.62)	62 (92.53)
The International Collaborating Centre for ADR monitoring is located in	72 (46.15)	151 (96.79)	30 (44.77)	67 (100)
What is Adverse drug reaction (ADR)?	121 (77.56)	150 (96.75)	66 (98.50)	65 (97.01)
The health care professionals responsible for reporting ADR in the hospital is/are?	121 (77.56)	156 (100)	51 (76.11)	67 (100)
Which of the following ADRs can be reported?	139 (89.1)	155 (99.36)	67 (100)	67 (100)
Pharmacovigilance centre at SMIMER, Surat is a__	49 (31.41)	145 (92.95)	25 (37.31)	67 (100)
Which scale is most commonly used to establish ADR causality?	96 (61.53)	143 (91.66)	35 (52.23)	56 (83.58)
Is Vigiflow a WHO online database for reporting ADR?	129 (82.69)	154 (98.71)	64 (95.52)	66 (98.50)

Table 2: Response to attitude-based questions.

Attitude-based questions	No (%) of students positively responded			
	Second year MBBS (n=156)		Third final year MBBS (n=67)	
	Before training	After training	Before training	After training
Do you think ADR reporting should be mandatory?	149 (95.51)	153 (98.08)	66 (98.5)	67 (100)
Do you think ADR reporting is a professional obligation?	79 (50.64)	119 (76.28)	41 (61.19)	49 (73.13)
Do you think an ADR monitoring centre should be there in every hospital?	121 (77.56)	148 (94.87)	54 (80.59)	64 (95.52)
Do you think Pharmacovigilance should be taught in detail during undergraduate course?	136 (87.17)	151 (96.79)	65 (97.01)	67 (100)
Do you think medical students could play a role in ADR reporting?	118 (75.64)	155 (99.35)	62 (92.54)	67 (100)
Do you think ADR monitoring and reporting will benefit patients?	134 (85.89)	153 (98.08)	64 (95.52)	67 (100)
Do you think ADR reporting reduces the cost of medical care in India?	84 (53.84)	112 (71.79)	39 (58.21)	60 (89.55)
Do you feel ADR reporting is time-consuming with no outcome?	100 (64.1)	138 (88.46)	58 (86.56)	63 (94.03)

While comparing the mean score of knowledge-based questions, there was a significant improvement by a difference of 3.03 ± 0.46 in second year students and 2.39 ± 0.54 in third-final year students after educational training (Table 4, 5).

There were total 8 attitude-based questions. Before training, 95.51% from second year and 83.78% from third final year thought that ADR reporting should be mandatory (Table 2). Training had a positive impact on the attitude of both second-year and third final-year MBBS students towards ADR reporting. Post-training, there was significant increase in the number of students who believed

in the importance and benefits of ADR reporting, professional obligation to report ADRs, and the role medical students could play in this process (Figure 2). Additionally, there was an increased awareness of the benefits of ADR monitoring and reporting for patients and the healthcare system.

While comparing the mean score of Attitude-based questions, there was a significant improvement by a difference of 1.35 ± 0.77 in second year students and 0.83 ± 0.46 in third-final year students after educational training (Table 4, 5).

Table 3: Response to practice-based questions.

Practice-based questions	No (%) of students positively responded	
	Second year MBBS (n=156)	Third final year MBBS (n=67)
	Before training	Before training
Have you ever seen a case of ADR during ward posting?	18 (11.53)	17 (25.37)
Have you ever filled ADR reporting form by CDSCO at clinical posting?	10 (6.41)	10 (14.92)
Have you ever played any role in ADR reporting?	8 (5.12)	2 (2.98)
Have you ever been trained on how to report ADR?	11 (7.05)	23 (34.32)
Have you ever visited any ADR monitoring centre?	13 (8.33)	3 (4.47)
Can a non-medico person report ADR to nearby health care professional?	60 (38.46)	35 (52.23)

Table 4: Comparing mean score of knowledge and attitude of second year medical students before and after training.

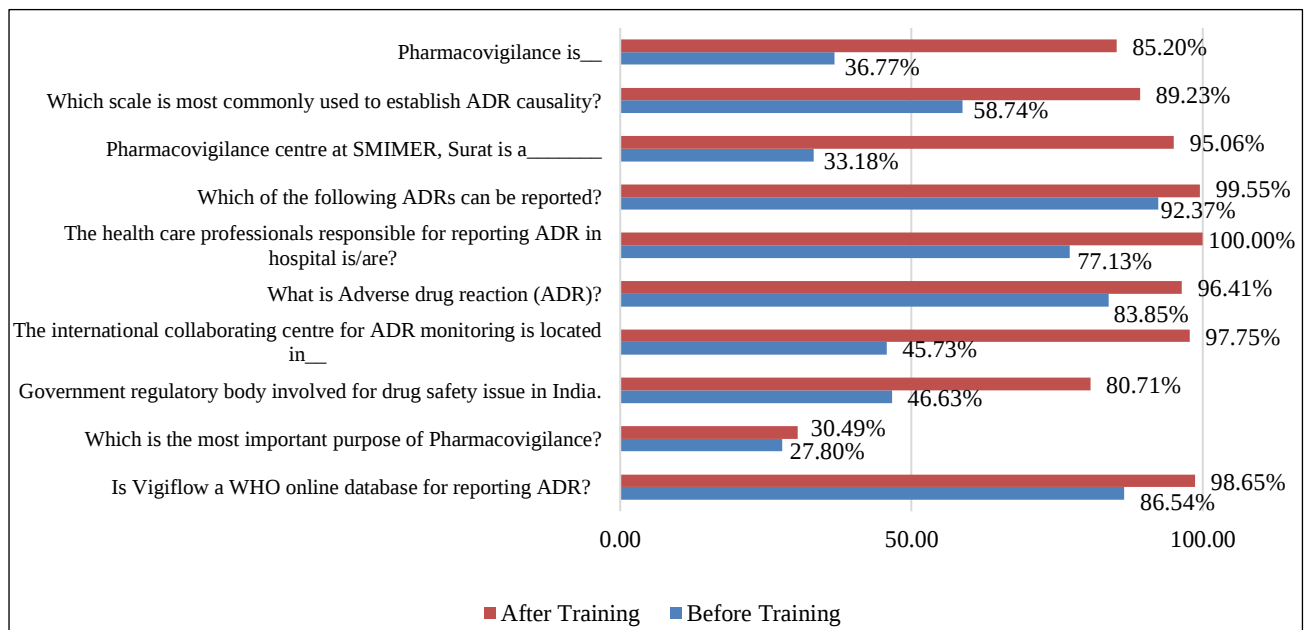
Factors	Before training	After training
Knowledge	5.56±1.49	8.59±1.03
Attitude	5.89±1.67	7.24±0.90

P<0.05-Significant (paired t-test)

Table 5: Comparing mean score of knowledge and attitude of third final year medical students before and after training.

Factors	Before training	After training
Knowledge	6.62±1.25	9.01±0.71
Attitude	6.69±1.07	7.52±0.61

P<0.05-Significant (paired t-test)

**Figure 1: Comparison of knowledge-based questions of total 223 medical undergraduate students before and after training.**

Total 5 practice-based questions were asked to students. Before training, a higher percentage of third final-year students compared to second year students had practical exposure to ADR reporting (Table 3). They were more likely to have seen a case of ADR, filled out an ADR reporting form, and received training on how to report ADRs. Despite this, the involvement in ADR reporting remained low in both groups (Figure 3). Knowledge about

the non-medico persons to report ADRs was also higher among third final-year students.

The mean score of practice-based questions before training was 0.76±0.99 in second year students and 1.34±1.12 in third-final year students.

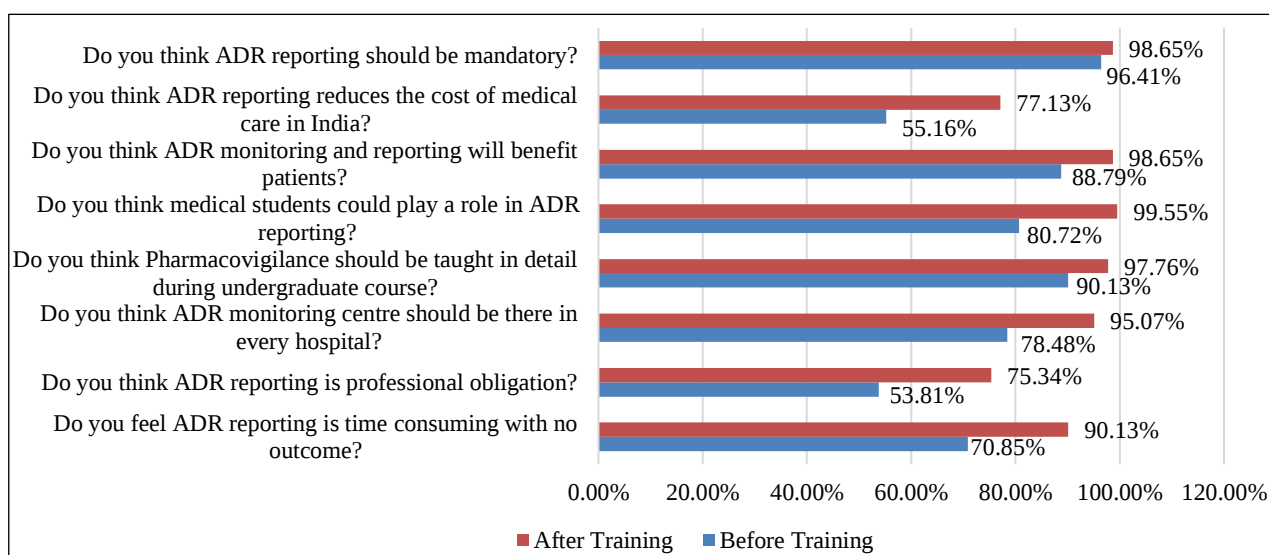


Figure 2: Comparison of attitude-based questions of total 223 medical undergraduate students before and after training.

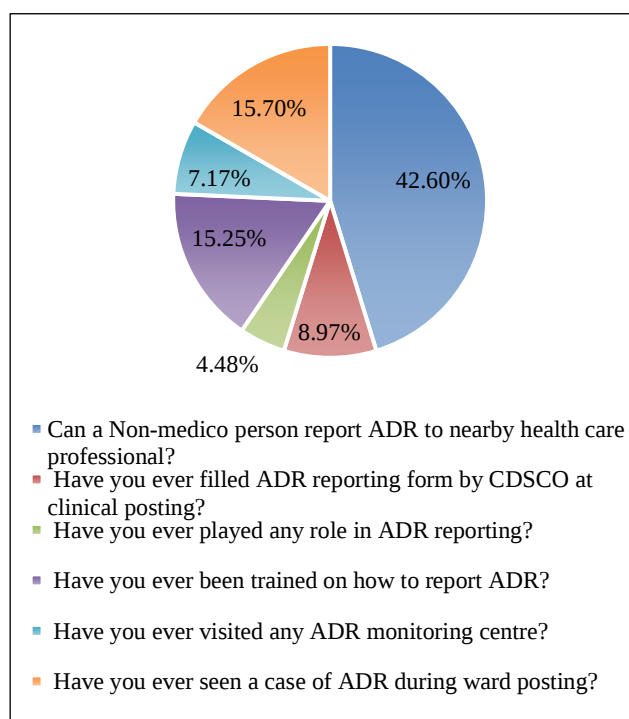


Figure 3: Positive response to practice-based question of total 223 medical undergraduate students before training.

DISCUSSION

This study aimed to evaluate knowledge, attitude, and practice of pharmacovigilance in our undergraduate medical students of second and third final year. Out of 223 students, 36.77% have knowledge about pharmacovigilance, and 83.85% have knowledge about ADR before training. Moreover, 86.54% of participants were aware about Vigiflow (WHO online database) for reporting ADR.

Regarding knowledge of the international centre for ADR reporting, 45.73% of participants had good knowledge in our study. Whereas, 24% in Parthiban et al, 50% in Dhananjay et al and 80% of participants in Umashankar et al showed good knowledge about ADR reporting centre.¹¹⁻¹³

Kaliker et al showed that 3.64% of participants before training were aware about who can report ADR and it increased to 81.77% after educational intervention, whereas in our study 77.13% before intervention and 100% after intervention had a good knowledge about who can report ADR.¹⁴

In study done by Tabassum et al 85% of students were aware about the purpose of pharmacovigilance is to assess "Safety."¹⁵ Whereas in our study only 27.80% of students were aware about the purpose of pharmacovigilance. Most participants in our study chose the option that the purpose of pharmacovigilance is to detect the incidence of ADRs.

More than 86% of participants were aware about Vigiflow (WHO online database) for reporting ADR whereas Tabassum et al result showed that 16.4% of students were aware of WHO online database.¹⁵

In our study, second-year students (5.56 ± 1.49) and third-final year students (6.62 ± 1.25) exhibited higher pre-training knowledge mean scores compared to Acharya et al (4.12 ± 1.56 and 6.06 ± 1.75), which was further increased after training.¹⁶

Regarding attitude, in a study done by Kulmi et al, more than 40% of MBBS students think that ADR reporting is compulsory whereas in our study 96.41% of students have a positive attitude toward ADR reporting and they opined that it should be mandatory. Similarly, study done by

Acharya et al showed the positive attitude of 91-92% of students and in Shankar et al study result was 80%.¹⁶⁻¹⁸

In this study, more than 90% of students before training and 97.76% after training thought that pharmacovigilance should be taught in detail during undergraduate course whereas in study done by Gedam et al results were 48% before training and 88% of participants after training were of similar opinion.¹⁹

On assessing practice, it was found that only 15.17% of them had witnessed an ADR in their clinical postings and 4.48% of the participants had ever played a role in reporting ADR. Many studies reported poor practice in ADR reporting and similar results were found in our study.^{13,20} Educational interventions improved awareness of KAP of healthcare professionals toward practice of Pharmacovigilance.²¹

CONCLUSION

The training given in different sessions has improved undergraduate medical students' knowledge and attitude. After training there was marked improvement in knowledge related questions like definition of Pharmacovigilance, the Government regulatory body involved in drug safety issues in India, and The International Collaborating Centre for ADR monitoring. The awareness among medical students about their crucial role in ADR reporting and ADR reporting benefits both doctors and patients. This awareness can significantly improve ADR reporting rates.

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

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