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Original Research Article

# Comparison of impact of undergraduate teaching program to assess the knowledge and attitude towards pharmacovigilance and adverse drug reporting among undergraduate medical students at a teaching medical institute in South India

**K. H. Hemanth Kumar*, J. K. Akshay**

Department of Pharmacology, Mysore Medical College and Research Institute, Mysuru, Karnataka, India

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***Correspondence to:**
Dr. K. H. Hemanth Kumar,
Email: 2011hemanth@gmail.com



## ABSTRACT

**Background:** Pharmacovigilance has become an important tool to ensure the safety of patient in recent years. To ensure right practice of pharmacovigilance, proper understanding is very essential and the medical colleges with the undergraduate teaching program become a vital platform to educate and train the medical students towards pharmacovigilance. This study compares the impact of teaching program of the undergraduate curriculum in assessing the knowledge and attitude of the undergraduate medical students towards pharmacovigilance.
**Methods:** The study includes 158 undergraduate medical students of second year being trained in pharmacology at Mysore Medical College. A validated and standardized questionnaire was distributed to all the students twice, once during their 3rd term (pre-sensitization) and the second time during their 5th term (post sensitization). Willingness to answer and complete the questionnaire was considered as consent.
**Results:** The pre and post sensitization questionnaires were analyzed individually. A decrease from 114 to 90 students (15.19 % decrease) willing to complete the questionnaire was seen. The mean total knowledge score was 6.37±1.90 during the pre-test as compared to 6.35±1.78 in the post test analysis. An overall increase was seen with the knowledge of ADRs and pharmacovigilance. Only 18.4% knew of the presence of an ADR monitoring center in the institute pre-test which increased to 64.4% post sensitization. 81.6% answered rightly the type of ADRs that needs to be reported as compared to the 67.3% pre-sensitization. The overall attitude towards ADR reporting was seen to be in the right direction, with 71% saying that pharmacovigilance covered adequately in the curriculum. Voluntary reporting attitude increased from 74.6% to 88%. 70% of the students feel ADR reporting as a professional obligation, while only 54% felt so pre-sensitization.
**Conclusions:** Pharmacovigilance should be included in the curriculum with more hours dedicated to teaching. Various interesting methods should be implemented to train and made aware of its importance to ensure patient safety on a global scale.

**Keywords:** Adverse drug reactions, Pharmacovigilance, PvPI, Sensitization, Undergraduate curriculum

## INTRODUCTION

Pharmacovigilance is a systematic and structural process for detecting and monitoring the adverse drug reactions (ADRs).[1] Pharmacovigilance was designed to ensure patient care and safety. It aims at getting the best outcome from treatment with medicines. ADRs are responsible for about 5% to 20% of the hospital admissions globally,

affecting the morbidity and mortality of various magnitudes in both the adult and children population.[2-5]

The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.[6]

Pharmacovigilance is still in its infant stages in India and there exists very less knowledge and right attitude towards it and ADR reporting. The pharmacovigilance program of India, just like the rest globally suffers because of lack of knowledge and right attitude towards pharmacovigilance and adverse drug reactions reporting, which can delay and detection of important ADRs and hamper patient safety.[7] Various other studies have highlighted the lack of awareness and knowledge with under reporting of ADRs by the health care professional as the major reason for the under functioning of the pharmacovigilance program of India.[8-13] Thus, it becomes essential to educate and train the younger generation towards pharmacovigilance and emphasize on the need for voluntary and frequent reporting of ADRs.[14]

The initial step towards achieving a better attitude-oriented professional is to start educating and training the students (medical and para-medical) during their undergraduate years. As future clinical practicing physicians, the students need to be educated and trained as to how to recognize, report, assess and if possible prevent adverse drug reactions.[15] Thus, the numerous medical teaching institutes with their undergraduate teaching programs become a major bridge in helping to achieve the same. Currently the medical undergraduate curriculum includes Adverse Drug Reactions as well as very little information related to pharmacovigilance.

This study aims at comparing and understanding the impact of the teaching program to the undergraduate medical students towards assessing the knowledge and attitude of the undergraduate medical students towards pharmacovigilance and adverse drug reactions reporting.

## METHODS

The study was conducted at Mysore Medical College and Research Institute, a Government Medical Teaching Institute in the Southern state of Karnataka, India between the months of September 2017 and July 2018.

It was a questionnaire based comparative study of the knowledge and attitude towards pharmacovigilance of second year undergraduate medical students of the same institution. The questionnaire used was designed to assess the knowledge, attitude and practice of undergraduate medical students and interns of Mysore Medical College and Krishnarajendra General Hospital. The questionnaire was standardized and validated by the faculty members of the department of Pharmacology, Mysore Medical College and Research Institute and the required necessary corrections being made to the questionnaire and taken into consideration.

The second-year undergraduate students being trained in the subject of pharmacology were subjected to the questionnaire. All students were distributed the questionnaire after taking approval from the Institutional Ethics Committee to conduct the study. Willingness to answer and complete the questionnaire was considered as informed consent. 30 minutes was given for the completion of the questionnaire after explaining the details of how to fill the questionnaires, reason for the same and the need for the study. The students were instructed clearly that this was purely for a study and would not reflect on their internal assessments individually as well as that they were not obligated and not forced to take part in the study (pre-sensitization).

The questionnaire consisted of questions pertaining to assess the knowledge and attitude towards pharmacovigilance and adverse drug reactions. 10 questions Q1-Q10 were based on knowledge while the next 10 questions, Q11-Q20 were related to attitude towards pharmacovigilance. The knowledge-based question had multiple choices with only one correct answer and the attitude-based question were based on a 5-point Likert scale design which included strongly agree, agree, neutral/ no comment, disagree and strongly disagree. The final 3 question Q21-23 were based on practice of ADR reporting.

After a period of 9 months (post sensitization), in the month of June, the same population of second year undergraduate medical students in their 5$^{th}$ term, having been educated about adverse drug reactions and pharmacovigilance were again subjected to the same questionnaire and the same methodology that was followed during the pre-sensitization was followed for the post sensitization analysis. The students weren't informed about the questionnaire filling beforehand and were subjected to the questionnaire on a day with maximal attendance. The questionnaires were analyzed individually.

### *Inclusion criteria*

Only all 23 questions answered questionnaire were considered and included.

### *Exclusion criteria*

Incomplete questionnaires were excluded from the study.

### *Statistical analysis*

For statistical analysis, SPSS version 20 software for descriptive analysis, number and percentage as well as for chi square test and to test for statistical significance were used.

## RESULTS

The standardized and validated questionnaire were distributed to all students of second year undergraduate medical course, both during the pre-sensitization as well as the post-sensitization time. All the distributed questionnaires were collected completely. A total of 114 students consented and had completely filled the questionnaire during the initial pre-sensitization period, whereas only 90 students did so during the post sensitization. The comparison of the student involvement and participation has been shown in Figure 1.

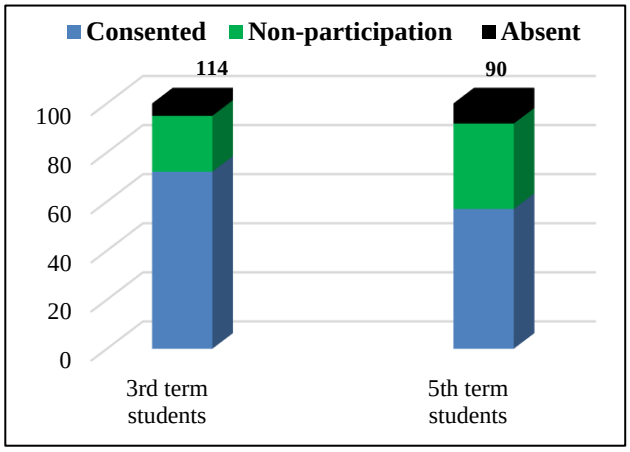


**Figure 1: Comparison of the undergraduate students participated in the study.**

The knowledge of the participants has been compared pre and post sensitization and has been depicted in Table 1. The numbers show a gradual increase in the knowledge overall, with knowing and understanding what pharmacovigilance and an ADR is from 50.9% and 47.4% during the pre-session to 72.4% and 67.3% during the post session respectively. The awareness of the presence of the Adverse Drug Monitoring Center (AMC) at our institute seem to be greatly improved from 18.4% to 64%. The understanding of types of ADRs that has to be reported and the serious ADRs shows an increase from 67.3% and 58.8%during the pre-session to 81.6% and 81.6% during the post educational session respectively (Figure 2).

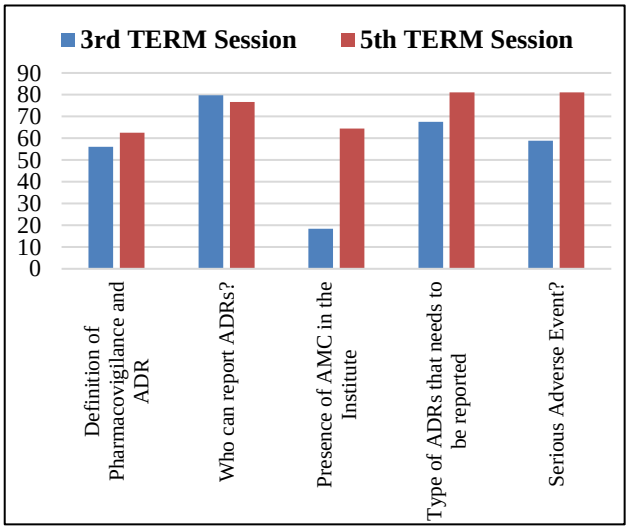


**Figure 2: Comparison of correct responses to knowledge-based question related to pharmacovigilance and adverse drug reactions.**

The overall knowledge mean scores has been depicted in Table 2 and shows no difference in numbers even with a decreased response analysis from 114 (mean total score-6.37±1.90) to 90 (mean total score-6.35±1.78) participants in the post session.

**Table 1: Comparison of knowledge of pharmacovigilance and adverse drug reactions in the medical undergraduate students during their 3rd and 5th terms in pharmacology.**

| Question | 3rd Term medical UGs N (%) | 5th Term medical UGs N (%) | Statistical significance (p-value) |
|---|---|---|---|
| What is pharmacovigilance? | 58 (50.9%) | 65 (72.2%) | 0.000 (p<0.05) |
| Definition of an ADR | 54 (47.4%) | 60 (66.7%) | 0.001 (p<0.05) |
| What is an adverse event? | 77 (67.5%) | 71 (78.9%) | |
| Who can report ADRs? | 91 (79.8%) | 69 (76.7%) | |
| Location of WHO-UMC? | 62 (54.4%) | 68 (75.6%) | 0.000 (p<0.05) |
| Presence of ADR monitoring centre in the institution? | 21 (18.4%) | 58 (64.4%) | 0.000 (p<0.05) |
| What type of ADRs should be reported? | 77 (67.5%) | 73 (81.1%) | 0.024 (p<0.05) |
| Which scale is commonly used to assess causality of an ADR? | 30 (26.3%) | 28 (31.1%) | |
| What is a serious Adverse event? | 67 (58.8%) | 73 (81.1%) | 0.000 (0<0.05) |
| Presence of an existing Pharmacovigilance Programme of India (PvPI)? | 80 (70.18%) | 73 (81.1%) | |

ADR-Adverse Drug Reactions, WHO-UMC-World Health Organization-Uppsala Monitoring Centre

**Table 2: Total knowledge and mean scores of second year medical undergraduate students.**

| Year | No. of participants (N) | Mean | Standard deviation | Minimum score | Maximum score |
|---|---|---|---|---|---|
| 3rd Term (pre-session group) | 114 | 6.3684 | 1.90139 | 2.00 | 10.00 |
| 5th Term (post-session group) | 90 | 6.3469 | 1.78252 | 3.00 | 10.00 |

**Table 3: Comparison of attitude of 3rd and 5th term undergraduate students towards pharmacovigilance and adverse drug reactions.**

| Question | Agree | | Disagree | | Neutral/ no comment | |
|---|---|---|---|---|---|---|
| | 3rd Term | 5th Term | 3rd Term | 5th Term | 3rd Term | 5th Term |
| ADR reporting is necessary | 106 (93%) | 89 (98.9%) | 7 (6.1%) | 1 (1.1%) | 1 | 0 |
| Is ADR reporting a professional obligation? | 62 (54.4%) | 63 (70.0%) | 37 (32.4%) | 18 (20.0%) | 15 | 9 |
| Is it necessary to confirm that the ADR is related to a particular drug before reporting? | 87 (76.3%) | 79 (87.7%) | 13 (11%) | 6 (7.1%) | 14 | 5 |
| ADR reporting should be voluntary | 85 (74.6%) | 78 (86.8%) | 21 (18.4%) | 10 (11.2%) | 8 | 2 |
| ADR reporting must be made compulsory | 92 (80.7%) | 73 (80.6%) | 12 (10.6%) | 5 (6.1%) | 10 | 12 |
| Only serious and unexpected reactions be reported | 72 (63.1%) | 32 (35.7%) | 37 (32.5%) | 51 (57.2%) | 5 | 7 |
| Pharmacovigilance should be taught to all health care professionals | 106 (93%) | 85 (94.9%) | 2 (1.8%) | 2 (2.2%) | 6 | 3 |
| Pharmacovigilance is well covered in the undergraduate curriculum | 19 (16.6%) | 63 (70.4%) | 82 (72.0%) | 16 (17.3%) | 13 | 11 |
| ADR can be better learnt during internship/clinical postings | 87 (76.3%) | 70 (77.5%) | 14 (12.3%) | 13 (14.2%) | 13 | 7 |
| ADR reporting will ensure patient safety | 104 (91.3%) | 85 (94.9%) | 4 (3.5%) | 3 (3.1%) | 6 | 2 |

Table 3 shows the comparison of the attitude of the undergraduate students during the pre and post sensitization sessions. Analysis clearly shows the improvement in the attitude and is directed in the right direction towards ADR monitoring. 54.4% of the students believed that ADR reporting is a professional obligation which increased to 70.4% ($p < 0.05$). 28.1% during the pre-session stated that the topic of pharmacovigilance and ADRs were well covered in the curriculum, which increased to 70.4% during the post session ($p < 0.01$). More than 90% of the students believe that ADR reporting will ensure patient safety. 74.6% responded that ADR reporting should be made voluntary during the pre-session as compared to 88% during the post session (Figure 2).

The analysis of the overall attitude shows that it is definitely being inclined and headed in the right direction after the educational and teaching sessions during the undergraduate teaching program, shows the impact a good educational sensitizing platform can have on the undergraduate students. 26.3% of the students in the pre-session said that they had witnessed or detected an ADR, but none had reported an ADR as only 28.9% were aware of the ADR reporting form. The post session analysis showed that 4 students had reported an ADR (includes filled and reported ADR form or even discussed about reporting and monitoring with residents/faculty) with 37.8% witnessing or able to detect an ADR and 76.5% saying that they were aware and had seen an ADR form.

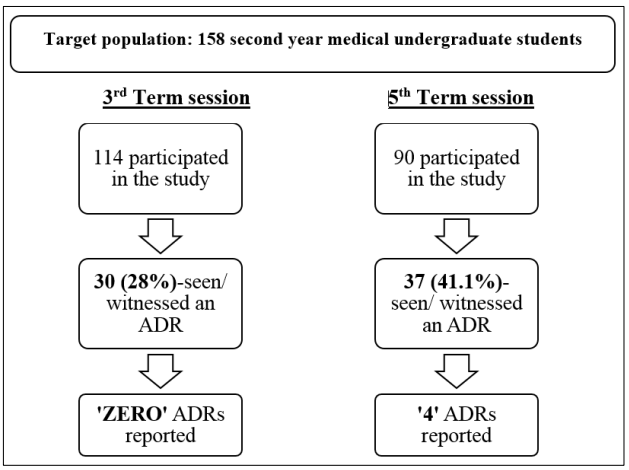


**Figure 3: Comparison of practical application of pharmacovigilance among 3rd and 5th term undergraduate student (pre-session versus post session).**

Figure 3 shows a comparative descriptive flowchart of the knowledge of ADR reporting being applied in practice in both the pre-session group and the post educational and sensitization session group.

## DISCUSSION

This is a questionnaire-based study conducted to assess the impact of a good teaching platform in the undergraduate curriculum of the second-year medical students at a teaching institute towards knowledge, attitude and understanding of pharmacovigilance and adverse drug reactions, with the possible application of it in practice.

Many previous studies have concluded stating that the lack of underreporting of ADRs is mainly due to lack of awareness and knowledge of pharmacovigilance.[8-13] Numerous studies have targeted the medical undergraduate students to assess their knowledge, attitude and practice, including our previous study which concluded that a better, interesting methods were required to be incorporated in teaching and training the students.[14,16,17]

So, this study, one of its kind was taken up to assess the impact of the existing teaching program of the undergraduate students towards the knowledge and attitude related to pharmacovigilance practice. The currently available methods under the medical undergraduate curriculum include a few hours of theory classes on Adverse Drug Reactions and nothing else. So, authors decided to add a few more teaching hours dedicated to pharmacovigilance and ADR reporting, as well as practical classes including group tasks related to ADRs.

The current study shows a decrease in voluntary participating students during the 5$^{th}$ term, 114 to 90, a 15.19% decrease which might indicate that the overall attitude towards pharmacovigilance towards a negative direction. The overall knowledge of the students had definitely improved during the 5$^{th}$ term post-session as well as individually, the understanding of the concept of pharmacovigilance is seen to be better in the 5$^{th}$ term, as suggested by the results (Table 1, 2, 3). The results are in accordance with a similar KAP based study among pharmacy students which concluded saying that the knowledge towards pharmacovigilance and ADR was better during the post-interventional session.[15]

The results from the study also suggest the right direction of the attitude towards pharmacovigilance and ADR reporting, with about 90% agreeing the need for pharmacovigilance and 70.4% as compared to 54.4% agreeing that it is a professional obligation.[18] 86.6% during the post session in the 5$^{th}$ term agreed that the ADRs should be reported voluntarily as compared to 74.6% in the pre-session.[19-21]

With respect to the teaching program in the undergraduate curriculum, 70.4% agree that the topic of pharmacovigilance is well covered as compared to a mere 16.6% during the 3$^{rd}$ term session.

The additional practical sessions seem to motivate the students in actively taking part in ADR reporting and pharmacovigilance as depicted by the study results, with 4 students of the 90 having reported an ADR and 2 students presenting a poster at a CME and undergraduate conference conducted recently, showcasing that pharmacovigilance is not just a professional obligation and ensuring patient safely but also can provide opportunities, exposure and experience for the students to grow in their academic profession.[22]

## CONCLUSION

The addition of a few extra hours dedicated towards the practical aspects of ADR reporting definitely seem to have a positive effect with improved, increase in knowledge and a positive attitude towards the right direction to apply of pharmacovigilance in clinical practice ensuring patient safety.

Pharmacovigilance with more teaching hours dedicated to it and various, different interesting methods need to be implemented during the medical undergraduate teaching sessions/program for a better understanding of the students and creating a better awareness to develop positive attitude towards pharmacovigilance and adverse drug reactions reporting, so that the practice is initiated much earlier and continued to during their clinical practice.

The need for pharmacovigilance to ensure patient safety with the use of drugs on a global level has been established. It becomes very important that every health professional right from the undergraduate training days are made aware of its importance and sensitized to practice adverse drug reactions reporting voluntarily, thereby minimizing the adverse drug events or any other drug related events.

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