



Original Article

Knowledge, Attitude, and Practice of Pharmacovigilance among Undergraduate Medical and Dental students in a Tertiary Care Teaching Hospital

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ABSTRACT

Background and Aim: Young healthcare professionals are future prescribers and therefore need adequate understanding of adverse drug reactions (ADRs) and the importance of timely reporting. Early engagement in pharmacovigilance programs is necessary to improve awareness, strengthen reporting practices, and ensure patient safety. This study aimed to assess the knowledge, attitude, and practice (KAP) regarding pharmacovigilance and ADR reporting among undergraduate medical and dental students at a tertiary care teaching hospital.

Methods: The cross-sectional, questionnaire-based descriptive study was conducted among final-year medical (n=90) and dental (n=61) students. A 20-item self-administered questionnaire with open-ended and closed-ended questions was used to assess participant's KAP related to pharmacovigilance and ADR reporting.

Results: Medical students demonstrated better pharmacovigilance knowledge than dental students across all domains, including correct definition (93.3% vs 55.7%), identifying drug safety issues (90% vs 63.9%), awareness of India's Pharmacovigilance Programme (100% vs 98.4%), knowledge of regulatory frameworks and reporting tools. Most medical students recognized the importance of including ADR reporting in pharmacology practicals (87.8% vs 73.8%) and its establishment in hospitals (97.8% vs. 72.1%). While most medical students knew about ADR reporting forms (96.7% vs. 14.8%) and had seen ADR cases during clinical postings (81.1% vs. 16.4%), actual reporting rates were still low in both groups (42.2% vs. 3.3%).

Conclusion: Both medical and dental students demonstrated basic knowledge and positive attitude toward pharmacovigilance; however, ADR reporting practices were low comparatively low among dental students. These findings underscore the need for structured pharmacovigilance training programs to improve ADR reporting practices and enhance patient safety.

Keywords: Adverse drug reaction, awareness, knowledge, pharmacovigilance.

INTRODUCTION

With increasing use of new drugs, fixed-dose combinations, rapid drug development, antibiotic resistance, and over-the-counter medicines, the risk of adverse drug reactions (ADRs) has increased, resulting in significant morbidity and mortality.[1, 2] ADRs are reported to be the 4th to 6th leading cause of death in the United States.[3] Pharmacovigilance is defined as the science and activities concerned with detection, assessment, understanding and prevention of adverse reactions to medicines.[1] Understanding pharmacovigilance is particularly important for students, who will soon be responsible for independent prescribing.[4]

Underreporting of ADRs remains a global issue.[5] Undergraduate healthcare students are future prescribers and healthcare providers who will encounter ADRs during their training and practice.[5] Assessing their knowledge, attitude

and practices (KAP) toward pharmacovigilance is essential for developing targeted educational interventions.[5] Early integration of pharmacovigilance training in clinical pharmacology can improve ADR reporting rates and establish safe prescribing practices.[4, 5]

Although pharmacovigilance is included in both medical and dental curricula, practical training is often limited, particularly in the dental programs.[6] Consequently, dental students may lack awareness of the ADR reporting process and how pharmacovigilance works.[6] Most existing studies have focused on medical students and limited evidence is available on pharmacovigilance awareness among dental students.[7, 8] Therefore, this study aimed to assess the KAP of pharmacovigilance among undergraduate medical and dental students in a tertiary care teaching hospital.

METHODS

This cross-sectional, questionnaire-based descriptive study was conducted at SDM College of Medical Sciences and Hospital, a tertiary care hospital in Dharwad. Final year medical and dental students were included in the study. First-year medical students, second-year dental students, interns, and postgraduate were excluded. Ethics clearance was obtained from institutional ethics committee before the study initiation. Written informed consent was obtained from all students before their participation.

A 20-item self-administered questionnaire with open-ended and closed-ended questions was used to assess participants understanding of pharmacovigilance. The questionnaire evaluated KAP regarding pharmacovigilance, including pharmacovigilance and its importance, reporting, causality assessment, and regulatory frameworks. Each question was scored either 0 or 1, with a total possible score of 0-20.

STATISTICAL ANALYSIS

Data were compiled and entered into a Microsoft excel sheet, then analysed using SPSS version 19 and presented as descriptive statistics. The Mann–Whitney U test was used to compare KAP scores between medical and dental students. $P < 0.05$ was considered as statistically significant.

RESULTS

Of 151 participants, 90 (59.6%) were medical students. The mean of the participants was 21.8 ± 0.6 years with female predominance (68.2%) (Table 1).

Table 1. Demographic data of the participants

| Variable | Number of participants (%) |
|----------------------------------|----------------------------|
| Age (years), Mean \pm SD | 21.8 \pm 0.6 |
| Gender | |
| Female | 103 (68.2%) |
| Male | 48(31.8%) |
| Current academic position | |
| Final-year medicine | 90 (59.6%) |
| Final-year dental | 61 (40.39%) |

Medical students have better pharmacovigilance knowledge across all domains than dental students. More medical students correctly defined pharmacovigilance (93.3% vs. 55.7%) identified drug safety issue (90% vs. 63.9%) and knew 14-day ADR reporting timeline (77.8% vs. 19.7%). Also, 67.8% of medical students correctly identified Sweden as the WHO international ADR monitoring centre (vs. 37.7% of dental students). All medical students recognized India's Pharmacovigilance Programme (100% vs. 98.4%). Most medical students recognized CDSCO as the regulatory body for ADR monitoring (98.9% vs. 77%), the Naranjo algorithm for ADR causality assessment (82.2% vs. 37.7%), and Ghaziabad as the pharmacovigilance centre (83.3% vs. 27.9%), JIPMER Pondicherry (85.6% vs. 29.5%) as a regional centre, and VigiFlow as the WHO online reporting database (73.3% vs. 23%). More medical students correctly identified phase-4 clinical trials as the stage for detecting rare ADRs (76.7% vs. 44.3%) and their responsibility for ADR reporting (60% vs. 54.1%) (Table 2).

Table 2. Knowledge regarding pharmacovigilance and adverse drug reactions between medical and dental students

| Variables | Final year dental (n=61) | Final year medicine (n=90) |
|--------------------------------------------------------------------------|--------------------------|----------------------------|
| Define pharmacovigilance? | | |
| The science of monitoring ADR's happening in a hospital | 6 (9.8%) | 0 |
| The process of improving the safety of Drugs | 4 (6.6%) | 2 (2.2%) |
| The detection, assessment, understanding & prevention of adverse effects | 34 (55.7%) | 84 (93.3%) |

| | | |
|------------------------------------------------------------------------------------------|------------|------------|
| The science detecting the type & incidence of ADR after drug is marketed | 17 (27.9%) | 4 (4.4%) |
| The important purpose of pharmacovigilance is | | |
| To identify safety of drugs | 39 (63.9%) | 81 (90%) |
| To calculate incidence of ADR's | 6 (9.8%) | 5 (5.6%) |
| To identify predisposing factors to ADR | 1 (1.6%) | 1 (1.1%) |
| To identify unrecognized ADRs | 15 (24.6%) | 3 (3.3%) |
| A serious adverse event in India should be reported to the regulatory body within | | |
| One day | 18 (29.5%) | 4 (4.4%) |
| Seven calendar days | 28 (45.9%) | 13 (14.4%) |
| Fourteen calendar days | 12 (19.7%) | 70 (77.8%) |
| Fifteen calendar days | 3 (4.9%) | 3 (3.3%) |
| The international centre for adverse drug reaction monitoring is in? | | |
| Unites States of America | 31 (50.8%) | 23 (25.6%) |
| Australia | 3 (4.9%) | 2 (2.2%) |
| France | 4 (6.6%) | 4 (4.4%) |
| Sweden | 23 (37.7%) | 61 (67.8%) |
| What does PvPI stand for? | | |
| National Pharmacovigilance programme | 0 | 0 |
| Pharmaceutical program me of India | 1 (1.6%) | 0 |
| Pharmacovigilance Programme of India | 60 (98.4%) | 90 (100%) |
| American Pharmaceutical Association | 0 | 0 |
| In India, which regulatory body is responsible for monitoring of ADR's? | | |
| Central Drugs Standard Control Organization | 47 (77%) | 89 (98.9%) |
| Indian Institute of sciences | 2 (3.3%) | 0 |
| Pharmacy Council of India | 8 (13.1%) | 0 |
| Medical Council of India | 4 (6.6%) | 1 (1.1%) |
| Which of the following scales is most used to establish the causality of an ADR? | | |
| Hartwig scale | 7 (11.5%) | 5 (5.6%) |
| Naranjo algorithm | 23 (37.7%) | 74 (82.2%) |
| Schumock and Thornton scale | 20 (32.8%) | 5 (5.6%) |
| Karch & Lasagna scale | 7 (11.5%) | 5 (5.6%) |
| Where is National Pharmacovigilance Centre in India located? | | |
| Ghaziabad | 17 (27.9%) | 75 (83.3%) |
| Mumbai | 12 (19.7%) | 1 (1.1%) |
| New Delhi | 28 (45.9%) | 11 (12.2%) |
| Kolkata | 4 (6.6%) | 3 (3.3%) |
| One among these is a regional pharmacovigilance centre. | | |
| SDM medical college & hospital | 26 (42.6%) | 3 (3.3%) |
| JIPMER, Pondicherry | 18 (29.5%) | 77 (85.6%) |
| JSS Medical College & Hospital, Mysore | 6 (9.8%) | 7 (7.8%) |
| CMC, Vellore | 11 (18%) | 3 (3.3%) |
| Which one of the following is the 'WHO online database' for reporting ADRs? | | |
| ADR advisory committee | 19 (31.1%) | 6 (6.7%) |
| Medsafe | 16 (26.2%) | 10 (11.1%) |
| Vigiflow | 14 (23%) | 66 (73.3%) |
| Med watch | 12 (19.7%) | 8 (8.9%) |
| Rare ADRs can be identified in the following phase of a clinical trial | | |
| During phase-1 clinical trials | 4 (6.6%) | 7 (7.8%) |
| During phase-2 clinical trials | 20 (32.8%) | 5 (5.6%) |
| During phase-3 clinical trials | 10 (16.4%) | 9 (10%) |
| During phase-4 clinical trials | 27 (44.3%) | 69 (76.7%) |
| The healthcare professionals responsible for reporting ADR in a hospital is/are | | |
| Doctor | 18 (29.5%) | 31 (34.4%) |
| Pharmacist | 6 (9.8%) | 1 (1.1%) |
| Nurses | 4 (6.6%) | 4 (4.4%) |
| All the above | 33 (54.1%) | 54 (60%) |

ADR, adverse drug reaction; PvPI, Pharmacovigilance Programme of India

Most medical students strongly agreed that ADR reporting should be included in pharmacology practicals (87.8% vs 73.8%) and supported establishing ADR monitoring in hospital (97.8% vs. 72.1%). All dental students and 97.8% of medical students understood the critical role of ADR reporting (Table 3)

Table 3. Attitude regarding pharmacovigilance and adverse drug reactions between medical and dental students

| Variables | Final year dental (n=61) | Final year medicine (n=90) |
|-----------------------------------------------------------------------------------------------|--------------------------|----------------------------|
| Should ADR reporting be included under pharmacology practical? | | |
| Yes | 45 (73.8%) | 79 (87.8%) |
| No | 7 (11.5%) | 0 |
| Don't know | 3 (4.9%) | 2 (2.2%) |
| Perhaps | 6 (9.8%) | 9 (10%) |
| Do you think reporting is a professional obligation for you? | | |
| Yes | 40 (65.6%) | 83 (92.2%) |
| No | 12 (19.7%) | 6 (6.7%) |
| Don't know | 6 (9.8%) | 1 (1.1%) |
| Perhaps | 3 (4.9%) | 0 |
| What is your opinion about establishing ADR monitoring centre in every hospital? | | |
| Should be in every hospital | 44 (72.1%) | 88 (97.8%) |
| Not necessary in every hospital | 7 (11.5%) | 1 (1.1%) |
| One in a city is sufficient | 6 (9.8%) | 1 (1.1%) |
| Depends on number of bed size in the hospitals | 4 (6.6%) | 0 |
| Do you think reporting of ADR is necessary? | | |
| Yes | 61 (100%) | 88 (97.8%) |
| No | 0 | 1 (1.1%) |
| Don't know | 0 | 0 |
| Perhaps | 0 | 1 (1.1%) |
| Do you think pharmacovigilance should be taught in detail to healthcare professionals? | | |
| Yes | 58 (95.1%) | 87 (96.7%) |
| No | 3 (4.9%) | 3 (3.3%) |

ADR, adverse drug reaction

Most medical students had observed ADRs during their ward postings (81.1% vs. 16.4%) and had observed adverse drug reporting forms issued by CDSCO (96.7% vs. 14.8%). However, only 42.2% had reported ADR within the institution (vs. 3.3%) (Table 4).

Table 4. Practice of pharmacovigilance and adverse drug reaction between medical and dental students

| Variables | Final year dental (n=61) | Final year medicine (n=90) |
|------------------------------------------------------------------------------|--------------------------|----------------------------|
| Have you ever seen a case of ADR during your ward posting? | | |
| Yes | 10 (16.4%) | 73 (81.1%) |
| No | 51 (83.6%) | 17 (18.9%) |
| Have you seen an adverse drug reporting form by CDSCO? | | |
| Yes | 9 (14.8%) | 87 (96.7%) |
| No | 52 (85.2%) | 3 (3.3%) |
| Have you ever played any role in reporting ADR from your institution? | | |
| Yes | 2 (3.3%) | 38 (42.2%) |
| No | 59 (96.7%) | 52 (57.8%) |

ADR, adverse drug reaction; CDSCO, Central Drugs Standard Control Organisation

Final-year medical students had significantly higher knowledge ($p < 0.001$), attitude ($p < 0.05$), and practice scores ($p < 0.001$) than final year dental students (Table 5).

Table 5. Distribution of subjects based on KAP score over Current academic position

| Variable | Final year dental (n=61) | Final year medicine (n=90) | p-value |
|-----------------|--------------------------|----------------------------|---------|
| Knowledge score | 5.72 ± 2.00 | 9.9 ± 2.24 | <0.001* |
| Attitude score | 4.15 ± 0.833 | 4.64 ± 0.754 | <0.05* |
| Practice score | 0.34 ± 0.655 | 2.23 ± 0.750 | <0.001* |

*indicates statistical significance

DISCUSSION

Our study showed that while both groups had basic knowledge of pharmacovigilance, dental students lack thorough knowledge compared with medical students. Although most students recognized the importance of pharmacovigilance, dental students had limited awareness of ADR reporting process and regulatory framework. While attitudes toward pharmacovigilance was encouraging, structured training is necessary to translate awareness into practice.

In our study, medical students' KAP scores were significantly higher than those of dental students, reflecting difference in curriculum and clinical exposure. These results are expected, as medical students are exposed to patients from the second year and receive adequate exposure to pharmacology and clinical pharmacology training, making them better at assessing ADRs. Dental students, in contrast, begin patient exposure from the third year. However, the Kumar et al study found no significant difference in KAP scores between medical and dental students, reflects difference in curriculum and teaching methodologies in different institutions.[9]

Our study demonstrated that above three-quarters of medical students possess better pharmacovigilance's knowledge compared with dental students across all domains. In contrast, the Kumar et al. study, found that both medical and dental students were familiar with pharmacovigilance (70.5% vs 75.8%), its definition (80% vs 86.4%), and adverse drug effects (70% vs 76.4%).[9] Similarly, Nisa et al. study showed that 83.1% of healthcare professionals had strong pharmacovigilance knowledge.[10] In contrast to our findings, Kumar et al. reported that very few medical and dental students (3.5%) were aware of the Naranjo causality assessment scale.[9] Another study reported that 24.3% of dental students were aware of Naranjo scale.[11]

Both groups in our study recognized the importance of ADR reporting in pharmacology practical for pharmacovigilance education in hospitals and showed highly positive attitude. These findings align closely with Kumar et al., who reported that 79% medical and 70.9% of dental students supported ADR reporting and over 88% of students in both groups agreed that pharmacovigilance should be taught in greater detail.[9] Similarly, the Prasad et al. study found that 85.29% of medical students supported detailed pharmacovigilance education to healthcare professionals.[12]

Although positive attitude, very few dental students in our study had seen or used ADR reporting forms or had reported such incidents during their ward postings, demonstrating a significant knowledge-practice gap. Similarly, in the Kumar et al. study, only 9.5% of medical and 1.1% of dental students had seen an ADR reporting form, and only 5% of medical students had ever reported an ADR.[9] Other questionnaire-based studies among dentists and dental students have also demonstrated inadequate knowledge and poor practice toward ADR reporting.[13, 14] Prasad et al also mentioned a gap between the ADR experienced (36.4 %), and ADR reported (5.88%) by medical students and only 64.71% students have ever seen the ADR reporting form.[12] Previous studies suggest that contributing factors include insufficient training and educational interventions in pharmacovigilance, limited understanding of the ADR reporting process, inadequate experience in identifying ADRs, unavailability of reporting formats, uncertainty in deciding whether ADR has occurred, lack of time for ADR reporting, and the perception that single unreported case may not affect ADR database.[5, 15]

This study has few potential limitations. As our study was conducted at a single tertiary care teaching hospital, the findings may not be generalizable to healthcare professionals at different institutions or in other regions. The study did not investigate factors contributing to ADR underreporting. However, this study enhanced our understanding that pharmacovigilance is a shared responsibility among healthcare professionals. It also highlights the importance of early sensitization among healthcare students to build a strong culture of patient safety. By including both medical and dental undergraduates, this study evaluated students' awareness and practices to identify gaps and suggest educational interventions to strengthen ADR reporting at the grassroots level in a tertiary care teaching hospital.

Overall, the study demonstrates that both medical and dental students could successfully implement pharmacovigilance program if adequate training is provided during their undergraduate education. This study also supports the goals of PvPI by identifying training needs to strengthen ADR reporting at the grassroots level. Therefore, future studies should provide training to all the students for at least six months on use of ADR reporting system and spontaneous reporting in the hospital.[16]

CONCLUSION

Our study demonstrates that both medical and dental students have basic knowledge and positive attitudes toward pharmacovigilance; however, practical ADR reporting rates were comparatively low, particularly among dental students. Therefore, implementing effective pharmacovigilance training programs can improve ADR reporting rates, thereby enhancing patient safety and healthcare outcomes. In addition to training, establishing ADR monitoring centers, regular workshops, and implementing periodic awareness programs within the undergraduate curriculum further strengthen pharmacovigilance practices.

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