



## Pharmacovigilance in Dentistry: A Study to Evaluate Knowledge, Attitude and Perception (KAP) of Reporting of Any Adverse Drug Reaction (ADR) Among Dental Students in Southern Region of Tamil Nadu

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### KEYWORDS

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### ABSTRACT:

**Background:** An unfavourable side effect brought on by taking medications is known as an adverse drug reaction (ADR). Even at the recommended dosages of medications used to treat or prevent disease, these reactions can still happen. To avoid any potentially fatal situations in a dental office, a dentist must have a thorough understanding of ADR and the medicines that cause it.

**Aim:** The purpose of this questionnaire study was to assess the level of ADR knowledge among dentistry college students.

**Materials and Methods:** In this cross-sectional question-and-answer survey, 102 dentistry students were involved. They were asked to respond to 18 questions to gauge their level of understanding of pharmacovigilance.

**Results:** The calculations were done using an MS-Excel spreadsheet and the findings were presented as a percentage of observations. It was discovered that among the 102 dental students, nearly 45.1%, did not understand what the term "pharmacovigilance" meant. 63.7% were not aware of the regulatory body for monitoring ADR's.

**Conclusions:** It was concluded that dental students had inadequate knowledge of reporting adverse drug reactions, hence it is imperative to take steps to impart to dental students the fundamentals of pharmacovigilance.

### Introduction:

The main goal of using medicine in dentistry is to promote good oral health. Dental professionals utilize a variety of drugs to treat oral health issues [1]. WHO (World Health Organisation) defines pharmacovigilance as "the science and activities relating to the detection,

assessment, understanding and prevention of adverse effects or any other medicine related problems" [2].

Despite proper drug selection and dosage, Adverse Drug Reactions (ADR's) can still occur from a variety of causes. An unnecessary hospital admission brought on by an ADR represents to the patient both an unwarranted loss of quality of life and a loss of health.



So, one of the main objectives in deciding a health policy is to prevent unnecessarily hospitalization due to ADRs [3].

In order to prevent causing needless ADRs in their patients, healthcare professionals have a duty to fully comprehend the health situation of their patients before prescribing new medications or changing dosages. Additionally, the dental healthcare team must be well prepared to handle both predictable and unforeseen ADRs that develop in the dental office setting [4]. According to the survey, barely 1% of ADR reports have been submitted in India, compared to a global average of 5% [5].

Dentist's lack of in-depth knowledge may be to blame for their lack of concern in the slow reporting of adverse medication responses [6]. It is crucial for dental personnel to understand how and where to report a negative drug reaction. Dental health care worker's active involvement in the pharmacovigilance program

might increase the reporting of adverse medication reactions in the field of dentistry [7]. This cross-sectional questionnaire-based study's objective was to assess dentistry students attitudes and levels of knowledge on reporting adverse drug reactions.

#### Materials and Methods:

This cross sectional questionnaire based study was carried out in Tirunelveli district located in southern region of Tamil Nadu. 102 dental students answered 18 predesigned questions prepared based on previous studies [8-10].

#### Results:

The results of this KAP study is shown in table 1. It was found that dentistry students had very little understanding of and awareness of pharmacovigilance. Approximately 60% of dentistry students were unaware of pharmacovigilance and 65% were unaware of the authority to whom reports on pharmacovigilance should be directed.

Table 1: Showing Questionnaire and answer with results

| S.No | KAP Questionnaire   | Response of Dental Students N=102 (%) |
|------|---|---------------------------------------|
| 1    | Male  | 23.50%                                |
|      | Female  | 76.50%                                |
| 2    | Is there enough awareness about ADR, among health care professionals?             |                                       |
|      | Yes   | 45.10%                                |
|      | No  | 11.80%                                |
|      | Maybe   | 36.30%                                |
|      | Not Sure  | 6.90%                                 |
| 3    | What is Pharmacovigilance?  |                                       |
|      | The science of ADR happening in the hospital                                      | 9.80%                                 |
|      | The science of detecting the type and incidence of ADR after the drug is marketed | 28.40%                                |
|      | The detection, assessment, understanding and prevention of adverse effects*       | 54.90%                                |
|      | The process of improving the safety of drugs                                      | 6.90%                                 |
| 4    | The aim of Pharmacovigilance is to access   |                                       |
|      | Safety*   | 81.40%                                |



|    |  |        |
|----|--|--------|
|    | Efficacy   | 12.70% |
|    | Cost   | 2%     |
|    | None of the above  | 3.90%  |
|    |  |        |
| 5  | Pharmacovigilance Includes   |        |
|    | Drug related problems  | 55.40% |
|    | Herbal products  | 4%     |
|    | Blood related problems   | 1%     |
|    | All of the above*  | 39.60% |
|    |  |        |
| 6  | Adverse drug reaction and adverse drug effect are the same                   |        |
|    | Strongly agree   | 14.70% |
|    | Agree  | 39.20% |
|    | Disagree   | 32.40% |
|    | Strongly Disagree  | 13.70% |
|    |  |        |
| 7  | In India which regulatory body is responsible for monitoring of ADRs         |        |
|    | Central drug standard controlorganisation                                    | 36.30% |
|    | Food and drug administration   | 26.50% |
|    | DCI  | 6.90%  |
|    | Pharmacy council of India  | 30.40% |
|    |  |        |
| 8  | Health care professional responsible for reporting of ADR in hospital is/are |        |
|    | Nurses   | 4.90%  |
|    | Doctors  | 13.70% |
|    | Pharmacist   | 8.80%  |
|    | All of the above*  | 72.50% |
|    |  |        |
| 9  | Which among the following factors discourage you from reporting ADR?         |        |
|    | Lack of time to report   | 11.80% |
|    | Difficult to decide whether ADR has occurred or not                          | 56.90% |
|    | A single unreported may not affect ADR database                              | 24.50% |
|    | Non remuneration for reporting   | 6.90%  |
|    |  |        |
| 10 | If you experience ADR, will you report it to health care professionals?      |        |
|    | Yes  | 66.70% |
|    | No   | 12.70% |
|    | Maybe  | 19.60% |
|    | Try to self treat  | 1%     |



|    |   |        |
|----|---|--------|
|    |   |        |
| 11 | Do you think reporting of ADR is necessary?   |        |
|    | Yes   | 82.40% |
|    | No  | 5.90%  |
|    | Maybe   | 11.80% |
|    | Not Necessary   | 0%     |
|    |   |        |
| 12 | Have you ever come across with ADR?   |        |
|    | Yes   | 32.40% |
|    | No  | 52.90% |
|    | Always  | 6.90%  |
|    | Rarely  | 7.80%  |
|    |   |        |
| 13 | Are you willing to make ADR reporting?  |        |
|    | yes   | 65.70% |
|    | May be  | 29.40% |
|    | Not Willing   | 3.90%  |
|    | Not Necessary   | 1%     |
|    |   |        |
| 14 | Do you think pharmacovigilance should be taught in detail to health care professionals? |        |
|    | Yes   | 77.50% |
|    | No  | 7.80%  |
|    | Maybe   | 13.70% |
|    | Not Necessary   | 1%     |
|    |   |        |
| 15 | Is Pharmacovigilance important in Dentistry?  |        |
|    | Yes   | 82.40% |
|    | No  | 3.90%  |
|    | Maybe   | 12.70% |
|    | Not sure  | 1%     |
|    |   |        |
| 16 | Is there a need to include pharmacovigilance in undergraduate curriculum?               |        |
|    | Yes compulsory  | 63.70% |
|    | Not compulsory  | 10.80% |
|    | Can be included   | 25.50% |
|    | Not needed  | 0%     |
|    |   |        |
| 17 | Which of the following scale is mostly used to establish the casualty of ADR?           |        |
|    | Hartwig scale   | 22.50% |



|    |  |        |
|----|--|--------|
|    | Naranjo algorithm*   | 41.20% |
|    | Schumock and Thornton scale  | 32.40% |
|    | Karch and lasagna scale  | 3.90%  |
|    |  |        |
| 18 | Do you feel it's important to record ADR for apt database and it's duty too? |        |
|    | Yes  | 66.70% |
|    | No   | 9.80%  |
|    | I want to but I am not aware how to  | 23.50% |
|    |  |        |
| 19 | Have you ever been trained on how to report ADR?                             |        |
|    | Yes properly   | 28.40% |
|    | Never  | 44.10% |
|    | Read a lot but don't know howto report                                       | 27.50% |

### Discussion:

For the diagnosis and treatment of numerous oral, dental, and maxillofacial disorders, dentists employ a variety of drugs. Antibiotics, antacids, non-steroidal anti-inflammatory medications, and opioid analgesics are among the medications that are frequently utilized [10]. These medications have a history of various adverse drug reactions, ranging from tinnitus and headaches to severe anaphylactic shock and teratogenic effects [11].

Therefore, documenting these unintended adverse drug reactions becomes crucial for future reference and the creation of better medications, as well as for preventing needless strain on the healthcare system and patient morbidity or death. As a result, the idea of pharmacovigilance was developed. 56.9% of the students in this study said it was difficult to determine whether or not there had been ADR. 66.7% of students said they would be willing to report adverse drug reactions (ADRs) to health officials if they were to occur, and 82.4% of students felt that it was vital to do so. This proportion is greater than that of the Kahkashan I survey [12], where 74% of respondents thought that reporting ADRs is essential.

The current studies results were in accordance with the review done by Reumerman et al [13] where it was found that although most healthcare students lack the fundamental abilities and information necessary to report ADRs, they generally had positive intentions and attitudes toward doing so. Similarly in a survey conducted by Arjun TN [14], 75.2% of medical

professionals were aware that India has a National Pharmacovigilance Program, and 97% of them believed that reporting adverse drug reactions is essential.

In this study, 82.4% dental students said that pharmacovigilance is important in dentistry and 77.5 percent of the dentistry students said that health care providers should receive comprehensive training in pharmacovigilance. 44.1 percentage of the students reported that they were never trained to report ADR events. This study unequivocally shows that dentistry students report adverse drug reactions (ADRs) at a low knowledge rate. The results aligned with the survey conducted by Gupta SK [15], which revealed a low percentage of pharmacovigilance reporting among healthcare practitioners.

### Conclusion:

The majority of dental graduates acknowledged that reporting adverse drug reactions (ADRs) is a professional duty and agreed that dentists ought to do so, but they were not aware that pharmacists play a crucial role in health care and should also report ADRs.

Therefore, it is necessary to implement standards for ADR reporting, provide ongoing training, and advise that all drug-related matters be overseen and handled by appropriate pharmacovigilance cells.

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